

AMENDMENT TO THE REGULATIONS OF THE COMMISSIONER OF EDUCATION

Pursuant to sections 207, 6504, 6507, 6527, 6801, 6802, 6806, 6902 and 6909 of the Education Law and Chapter 359 of the Laws of 2018.

1. Subdivision (d) of section 63.4 of the Regulations of the Commissioner of Education is added, as follows:

(d) Requirements for a certificate to administer immunizations. No pharmacy intern shall administer immunizing agents without a certificate of administration issued by the department. For purposes of this section, a certified pharmacy intern shall mean a limited permit holder who is issued a certificate of administration pursuant to this subdivision. To meet the requirements for a certificate of administration, the pharmacy intern shall submit an application, on a form prescribed by the department. Each application shall contain an attestation by the dean or other appropriate official of the registered program that the applicant has completed the required training as specified in section 6806 of the Education Law and present satisfactory evidence of completion of the requirements set forth in one of the following subparagraphs:

(1) Training course. Completion of a training course in the administration of immunizations acceptable to the Commissioner and the Commissioner of Health, within the three years immediately preceding application for a certificate of administration. Such course shall include, but not be limited to, instruction in:

- (i) techniques for screening patients and for obtaining informed consent;
- (ii) techniques in the administration of immunizing agents, including the injection of a harmless, non-medicinal saline solution into voluntary recipients;

(iii) indications, precautions and contraindications in the use of immunizing agents;

(iv) handling of emergencies including needlestick injuries and anaphylaxis, including the use of medications required for emergency treatment of anaphylaxis;

(v) cardio-pulmonary resuscitation techniques; and

(vi) recordkeeping and reporting of immunizations and information; or

(2) A pharmacy intern that has completed a training course associated with Doctor of Pharmacy degree pursuant to the requirements in section 63.9(b)(3)(ii).

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

(b) Immunizations

(1) ...

(2) ...

(3) ...

(4) With the exception of a certified pharmacy intern, a certified pharmacist shall not delegate the administration of immunizations to another person. For purposes of this section, a certified pharmacy intern shall mean a pharmacy intern who is certified to administer immunization as specified in section 6806 of the Education Law and has completed the requirements set forth in subdivision (d) of section 63.4 of this Part. Such a certified pharmacy intern may only administer immunizations under the immediate personal supervision of the certified pharmacist.

~~[(4)]~~ (5) 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) a certified pharmacist shall not allow a certified pharmacy intern to administer immunizations unless the recipient, or the person legally responsible for the recipient when the patient is incapable of consenting to the immunization, is informed that the pharmacy intern will be administering the immunization and the recipient, or the person legally responsible for the recipient when the patient is incapable of consenting to the immunization, consents to administration of the immunization by the certified pharmacy intern. If the recipient, or the person legally responsible for the recipient when the patient is incapable of consenting to the immunization, does not consent to administration by the certified pharmacy intern, then the option to receive the immunization from a certified pharmacist shall be provided.

~~[(v)]~~ (vi) a certified pharmacist shall provide written instructions to the recipient regarding the appropriate course of action in the event of contraindications or adverse reactions, which statements are required to be developed by a competent entity knowledgeable about the adverse reactions of the immunization agent which shall be

administered, such as the Centers for Disease Control of the U.S. Department of Health and Human Services, which issues vaccine information statements;

[(vi)] (vii) 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);

(b) education materials on influenza vaccines for children as determined by the commissioner and the commissioner of the department of health.

[(vii)] (viii) 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)] (ix) 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;

[(ix)] (x) 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;

[(x)] (xi) 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;

[(xi)] (xii) 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

[(xii)] (xiii) 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;

[(xiii)] (xiv) 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

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

(a) 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.