

New York State Pharmacy Immunization Regulations

§63.9 Immunizations and emergency treatment of anaphylaxis pursuant to patient specific and non-patient specific orders and protocols.

- a. Applicability. This section shall apply only to the extent that the applicable provisions in Education Law sections 6527, 6801, 6802, 6828 and 6909, authorizing certified pharmacists to administer certain immunization agents and medications for the emergency treatment of anaphylaxis, have not expired or been repealed.
- 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, 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.
 - 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 immunizing agents to prevent influenza or pneumococcal disease to patients 18 years of age or older.
 3. Requirements for a certificate to administer immunizations. No licensed pharmacist shall administer immunizing agents without a certificate of administration issued by the Department. For purposes of this section, a certified pharmacist shall mean a licensed pharmacist who is issued a certificate of administration pursuant to this paragraph. To meet the requirements for a certificate of administration, the licensed pharmacist shall submit an application with the fee specified in section 6828 of the Education Law and present satisfactory evidence of completion of the requirements set forth in one of the following subparagraphs:
 - i. 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:
 - a. techniques for screening patients and for obtaining informed consents;
 - b. techniques in the administration of immunizing agents, including the injection of a harmless, non-medicinal saline solution into voluntary recipients;

- c. indications, precautions and contraindications in the use of immunizing agents;
 - d. handling of emergencies, including the use of medications required for emergency treatment of anaphylaxis;
 - e. cardio-pulmonary resuscitation techniques; and
 - f. recordkeeping and reporting of immunizations and information; or
 - ii. Training course associated with Doctor of Pharmacy Degree.
 - a. Graduation with a Doctor of Pharmacy degree from a professional program of study in pharmacy that is registered by the Department pursuant to Part 52 of this Chapter, or is accredited by an acceptable accrediting agency as defined in section 63.1(a) of this Part, or is determined by the Department to be the equivalent of such a registered or accredited program; and
 - b. completion of training in the administration of immunization agents satisfactory to the Department, including instruction in the areas identified in subparagraph (i) of this paragraph, received as part of his/her pharmacy degree program, provided that such training was completed within the three years immediately preceding application for a certificate of administration; or
 - iii. Certificate of administration issued by another jurisdiction.
 - a. Possession of a current certificate of administration issued by another jurisdiction, authorizing the pharmacist to administer immunization agents based on the pharmacist's completion of training or coursework in the administration of immunizing agents as described in subparagraph (i) of this paragraph, or its equivalent as determined by the Department; and
 - b. continuous practice in the administration of immunizing agents since the pharmacist received such training or completion of a retraining program in the administration of immunization agents, acceptable to the Commissioner and the Commissioner of Health, provided that such retraining incorporates the areas identified in subparagraph (i) of this paragraph.
- 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. prior to administering an immunization agent, a certified pharmacist shall ensure that each potential recipient is assessed for contraindications that would preclude immunization(s);
 - ii. a certified pharmacist shall be responsible for having emergency anaphylaxis treatment agents, related syringes and needles available at the location at which immunizations will be administered;
 - iii. a certified pharmacist shall inform each recipient of potential side effects and adverse reactions, orally and in writing, prior to immunization;
 - iv. a certified pharmacist shall not administer immunizations unless the recipient is adequately informed as prescribed in this paragraph and the recipient consents to the immunization; except for recipients incapable of consenting to the administration of an immunization, in which case, before an immunization may be administered, either a person legally responsible for the recipient shall have given prior written consent to the immunization after having been informed in writing of potential side effects and adverse reactions, or a person legally responsible for the

- recipient is in attendance during the immunization and consents to the immunization after having been informed of potential side effects and adverse reactions;
- v. 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. a certified pharmacist shall provide a copy of the appropriate vaccine information statement to the recipient, or other person legally responsible when the patient is incapable of consenting to immunization administering, before administering the immunization;
 - vii. 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. 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. 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. 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 to the New York City Department of Health and Mental Hygiene, in a manner required by the Commissioner of Health. 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. 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.
5. Order and protocol.
- i. The certified pharmacist shall maintain or ensure the maintenance of a copy of the patient specific order or the non-patient specific order and protocol prescribed by a licensed physician or a certified nurse practitioner which authorizes the certified pharmacist to administer immunization agents in accordance with the requirements of this section. Each patient specific and non-patient specific order shall contain the information

prescribed in subparagraph (ii) of this paragraph and for non-patient specific orders, the order shall also incorporate a protocol that meets the requirements of subparagraph (iii) of this paragraph. Such order and any protocol accompanying such order shall be considered a record of the patient. A certified pharmacist shall maintain a record of each patient in either:

- a. a patient medication profile that is prepared and retained in conformity with section 63.6(b)(7) of this Part, if one is required; or
 - b. in instances where a patient medication profile is not required, on a separate form that is retained by the pharmacist who has administered the immunization, in a retrievable format available to the Department and the patient. Such record shall be maintained in accordance with section 29.2(a)(3) of this Title.
- ii. All patient specific orders and non-patient specific orders authorizing a certified pharmacist to administer immunizations to certain patients, shall contain, but need not be limited to, the following information:
- a. the specific immunization agents that the pharmacist is permitted to administer including the indications, dose and route of administration for the vaccine; and
 - b. the name, license number, and signature of the licensed physician or nurse practitioner who has issued the order.
- iii. Non-patient specific orders shall incorporate a protocol that meets the requirements of subparagraph (iv) of this paragraph and shall also contain:
- a. authorization for one or more named pharmacists, or pharmacists who are not individually named but are identified as employed or under contract with an entity that it legally authorized to employ or contract with pharmacists to provide pharmaceutical services, to administer specified immunization agents to a defined group of individuals, for a prescribed period of time;
 - b. the name(s) and license number(s) of the of the certified pharmacist(s) authorized to administer the immunization agent(s) pursuant to the order or, for non-patient specific orders that do not identify the pharmacist(s) by name, the name of the entity that is legally authorized to employ or contract with licensed pharmacists to provide pharmaceutical services with whom licensed pharmacists who are not individually named are employed or under contract to administer the prescribed immunization agent(s) pursuant to the order;
 - c. in instances where the certified pharmacists are not individually named in the order, but are identified as employed or under contract with an entity that is legally authorized to employ or contract with certified pharmacists to provide pharmaceutical services, a statement limiting the certified pharmacists to administering immunizations only in the course of such employment or pursuant to such contract; and
 - d. the period of time that the order is effective, including the beginning and ending dates.
- iv. The protocol, incorporated into the non-patient specific order shall include, but need not be limited to, the standards, procedures and reporting requirements set forth in paragraph (4) of this subdivision.
- c. Anaphylaxis treatment agents.

1. Pursuant to sections 6801 and 6802 of the Education Law, each pharmacist who is issued a certificate of administration pursuant to this section shall be authorized to administer medications for the emergency treatment of anaphylaxis to patients 18 years of age or older.
2. Standards, procedures and reporting requirements for the administration of anaphylaxis treatment agents. Each certified pharmacist shall comply with the following requirements when administering medications for the emergency treatment of anaphylaxis under this section:
 - i. each certified pharmacist shall ensure that a record of all persons to whom such pharmacist has administered an anaphylaxis treatment agent, including but not limited to: the recipient's name, date, address of administration, administering pharmacist, anaphylaxis treatment agent, manufacturer, and lot number, is recorded and maintained in either a patient medication profile, if one is required, that is prepared and retained in conformity with section 63.6(b)(7) of this Part; or, in the event that a patient medication profile is not required, on a separate form retained by the pharmacist who administered the anaphylaxis treatment agent and shall be maintained in accordance with section 29.2(a)(3) of this Title;
 - ii. each certified pharmacist shall contact the local emergency medical services system following the administration of the anaphylaxis treatment agent, or shall ensure that equivalent follow-up care is provided through other arrangements; and
 - iii. certified pharmacists shall report to the local emergency medical system or other provider of equivalent follow-up care information concerning the administration of the anaphylaxis treatment agent, including but not limited to: the name of the agent, when it was administered, the dosage, strength, and route of administration. Certified pharmacists shall also report such information to the patient's primary health care practitioner if one exists, unless the patient is unable to communicate the identity of his or her primary health care practitioner.
3. Non-patient specific order and protocol.
 - i. The certified pharmacist shall either maintain or ensure the maintenance of a copy of the non-patient specific order and protocol prescribed by a licensed physician or a certified nurse practitioner that authorizes such pharmacist to administer medications for the emergency treatment of anaphylaxis to adults, in accordance with the requirements of paragraph (1) of this subdivision. The order prescribed in subparagraph (ii) of this paragraph shall incorporate a protocol that meets the requirements of subparagraph (iii) of this paragraph. Such order and protocol shall be considered a record of the patient who receives the anaphylaxis treatment agent and maintained as a record for the patient who receives the anaphylaxis treatment agent. A record of each patient shall be maintained in either:
 - a. a patient medication profile that is prepared and retained in conformity with section 63.6(b)(7) of this Part, if one exists; or
 - b. in instances where a patient medication profile does not exist, on a separate form that is retained by the pharmacist who has administered the immunization, in a retrievable format available to the Department and the patient. Such record shall be maintained in accordance with section 29.2(a)(3) of this Title.
 - ii. The non-patient specific order shall authorize one or more named certified pharmacists, or certified pharmacists who are not individually named but

are identified as employed or under contract with an entity that is legally authorized to employ or contract with pharmacists to provide pharmaceutical services, to administer specified anaphylaxis treatment agents in specified circumstances for a prescribed period of time. In instances in which the certified pharmacists are not individually named in the order, but are identified as employed or under contract with an entity that is legally authorized to employ or contract with certified pharmacists to provide pharmaceutical services, such pharmacists shall not be authorized by such order to administer anaphylaxis treatment agents outside of such employment or contract. The order shall contain but shall not be limited to the following information:

- a. the specific anaphylaxis treatment agents that the certified pharmacists are permitted to administer;
 - b. the period of time that the order is effective, including the beginning and end dates;
 - c. the name and license number of the certified pharmacist(s) authorized to administer the anaphylaxis treatment agent(s) pursuant to the order; or the name of the entity that is legally authorized to employ or contract with certified pharmacists to provide pharmaceutical services with whom certified pharmacists who are not individually named are employed or under contract to administer the prescribed anaphylaxis treatment agent(s) pursuant to the order;
 - d. in instances in which the certified pharmacists are not individually named in the order, but are identified as employed or under contract with an entity that is legally authorized to employ or contract with certified pharmacists to provide pharmaceutical services, the order shall contain a statement limiting the certified pharmacists to administering anaphylaxis treatment agents only in the course of such employment or pursuant to such contract; and
 - e. the name, license number, and signature of the licensed physician or certified nurse practitioner who has issued the order.
- iii. The protocol, incorporated into the order prescribed in subparagraph (ii) of this paragraph, shall include, but need not be limited to, the requirements set forth in paragraph (2) of this subdivision.

Collaborative Prescribing Protocol Template

Collaborative Agreement for Immunizations Between , Pharm.D. and, MD

I, _____ MD/ARNP/DO licensed in the State of New York, do hereby authorize _____, R.Ph./PharmD to prescribe and administer the vaccines listed in the protocol to adults in accordance with the laws (RCW 18.64.011) and regulations (WAC 246-863-100) of the State of New York.

In exercising this authority the pharmacists shall comply with the recommendations of the Advisory Committee on Immunization Practices (ACIP).

The pharmacist will document all vaccines administered as required by statute, and on each patient's personal immunization record.

As the authorizing prescriber, I will, on a quarterly basis, review the activities of the pharmacists administering vaccines.

This authorization will be in effect for two years, unless rescinded earlier in writing by either party. Any significant changes in the protocol must be agreed upon by the participants and a new protocol issued.

Date _____

Prescriber Signature _____ License# _____

Pharmacist Signature _____ License# _____

If there are multiple pharmacists collaborating on this agreement, they must sign below :

Pharmacist Signature _____ License# _____

Pharmacist Signature _____ License# _____

Pharmacist Signature _____ License# _____

Pharmacist Signature _____ License# _____

Protocol for Administration of Vaccines

Training and Procedures:

Current CDC- approved certification of immunization training; current CPR card, OSHA Air Borne Pathogens Training and registration with the NYS Board of Pharmacy will be required to participate in this Collaborative Agreement Protocol.

Each patient shall be screened for contraindications – If the pharmacist encounters a patient from whom one of the contraindications or precautions is present, the prescriber must be contacted prior to administration of the vaccine, or the patient must be referred back to the prescriber without the vaccine having been administered.

Emergency procedures for adverse reactions: An emergency kit containing a blood pressure cuff and stethoscope, tourniquet and 2 epi-pens will be available to the pharmacist for all immunizations/immunization clinics.

Vaccines to be administered:

Influenza, Pneumococcal and epinephrine only to adults 18 years of age and older.

Patient Evaluation:

The *Immunization Patient Informed Consent Form* will be utilized in conjunction with professional judgment and current ACIP Vaccination guidelines to make decisions concerning prescribing and administration of vaccine.

Documentation:

The *Immunization Patient Informed Consent Form* will be utilized to record necessary information regarding the vaccine administered and necessary patient information, and be kept on file at the pharmacy as required by state law. This document will be utilized in conjunction with professional judgment to make decisions concerning prescribing and administration of vaccine.

If the patient has a regular health care provider in the community, the pharmacist must provide the immunization record information to that provider. Otherwise, the pharmacy personnel will provide documentation on the administration of vaccines to primary health providers in the community upon request and consent of the patient.

At least monthly, the pharmacist shall transmit immunization data to the New York State Department of Health in a manner prescribe through rules and regulations.