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RULE ADOPTIONS
LAW AND PUBLIC SAFETY
DIVISION OF CONSUMER AFFAIRS
STATE BOARD OF MEDICAL EXAMINERS
BOARD OF PHARMACY

Jointly Adopted New Rules: N.J.A.C. 13:35-6.26 and 13:39-4.20

Procedures for Physician Ordered or Government-Sponsored Immunizations Performed by Pharmacists

Proposed: March 3, 2008 at 40 N.J.R. 1072(a).

Adopted: December 3, 2008 by the State Board of Medical Examiners, Paul C. Mendelowitz, M.D., President and December [page=1494] 10, 2008 by the Board of Pharmacy, Edward G. McGinley, R.Ph, President.

Filed: March 3, 2009 as R.2009 d.104, **with substantive and technical changes** not requiring additional public notice and comment (see N.J.A.C. 1:30-6.3).

Authority: N.J.S.A. 45:14-48a(5) and 45:14-63.

Effective Date: April 6, 2009.

Expiration Dates: March 17, 2010, N.J.A.C. 13:35;

December 10, 2009, N.J.A.C. 13:39.

Federal Standards Statement

A Federal Standards analysis is not required because adopted new rules N.J.A.C. 13:35-6.26 and 13:39-4.20 are governed by N.J.S.A. 45:14-48a(5) and 45:14-63 of the Pharmacy Practice Act. The adopted new rules are not subject to any Federal requirements or standards.

Full text of the adopted new rules follows (additions to proposal indicated in boldface with asterisks ***thus***; deletions from proposal indicated in brackets with asterisks ***[thus]***):

13:35-6.26 Procedures for physician ordered immunizations performed by licensed pharmacists

(a) A New Jersey licensed physician may participate in an immunization program with a licensed pharmacist pursuant to N.J.S.A. 45:14-63 of the Pharmacy Practice Act, provided that the pharmacist is authorized to engage in such activities by the Board of Pharmacy pursuant to N.J.A.C. 13:39-4.20, and provided the pharmacist administers vaccines and related emergency medications, which shall be limited to diphenhydramine and epinephrine, pursuant to:

1. A prescription for the vaccine, related emergency medications, and pharmacist administration of the vaccine that is patient specific; and/or

2. A physician's standing order for the vaccine, related emergency medications above, and administration instructions that are not patient specific.

(b) A physician shall supervise a licensed pharmacist who is participating in an immunization program implemented pursuant to the physician's standing order. Supervision by the delegating physician shall be deemed adequate if the delegating physician:

1. Is responsible for formulating or approving a standing order, which shall include compliance with Centers for Disease Control and Prevention (CDC) guidelines for vaccine administrations, set forth in Appendix D of "Epidemiology and Prevention of Vaccine-Preventable Diseases (The Pink Book: Course Textbook)," updated 10th

edition, February 2007. The CDC vaccine administration guidelines are incorporated herein by reference, as amended and supplemented, and can be found at the CDC website, www.cdc.gov, specifically, <http://www.cdc.gov/vaccines/pub/pinkbook/downloads/appendices/appdx-full-d.pdf>. The standing order shall also include compliance with the American Heart Association (AHA) Guidelines for Cardiopulmonary Resuscitation and Emergency Cardiovascular Care (2005)*[, including the use of automated external defibrillators (AED)]*. The AHA Guidelines for Cardiopulmonary Resuscitation and Emergency Cardiovascular Care (2005) are incorporated herein by reference, as amended and supplemented, and can be found at the AHA website, www.americanheart.org, specifically, http://circ.ahajournals.org/content/vol112/24_suppl/. The order shall also include procedures which shall be followed for the reporting of adverse events. The delegating physician shall annually review the order and the services provided to patients under the order;

2. Is geographically located to be easily accessible to the pharmacy practice site and, if applicable, to the immunization location.
3. Is available through direct telecommunication for consultation, assistance, and direction; and
4. Receives annual status reports on the immunization program as administered by the pharmacist.

13:39-4.20 Procedures for physician ordered or government sponsored immunizations performed by pharmacists

(a) The provisions of this section set forth the requirements for licensed pharmacists authorized to administer vaccines and related emergency medications, which shall be limited to diphenhydramine and epinephrine, to eligible patients who are 18 years of age and older, consistent with the requirements of N.J.S.A. 45:14-63, under the following circumstances:

1. Pursuant to a prescription by a New Jersey licensed physician for a vaccine, related emergency medications, and pharmacist administration of the vaccine that is patient specific;
2. In immunization programs implemented pursuant to a New Jersey licensed physician's standing order for the vaccine, related emergency medications, and administration instructions that are not patient specific; and/or
3. In immunization programs sponsored by government agencies that are not patient specific.

(b) In order to administer vaccines and related emergency medications pursuant to this section, a licensed pharmacist shall be pre-approved by the Board to perform such functions. In order to obtain such prior Board approval, a pharmacist shall submit documentation to the Board which establishes that he or she has satisfied the following education and training requirements:

1. Completion of an academic and practical curriculum that includes instruction in Centers for Disease Control and Prevention (CDC) guidelines for vaccine administrations, set forth in Appendix D of "Epidemiology and Prevention of Vaccine-Preventable Diseases (The Pink Book: Course Textbook)," updated 10th edition, February 2007. The CDC vaccine administration guidelines are incorporated herein by reference, as amended and supplemented, and can be found at the CDC website, www.cdc.gov, specifically, <http://www.cdc.gov/vaccines/pubs/pinkbook/downloads/appendices/appdx-full-d.pdf>. The instruction shall be offered by a provider accredited by the Accreditation Council for Pharmacy Education (ACPE). The curriculum shall include the following subjects:

- i. The Occupational Exposure to Bloodborne Pathogens standard of the Occupational Health and Safety Administration (OSHA), set forth at 29 C.F.R. §1910.1030, and the New Jersey Public Employees Occupational Safety and Health (PEOSH) Act, set forth at N.J.S.A. 34:6A-25 et seq., incorporated herein by reference;
- ii. CDC Guideline for Infection Control in Health Care Personnel (1998). The CDC Guideline for Infection Control in Health Care Personnel (1998) are incorporated herein by reference, as amended and supplemented, and can be found at the CDC website, www.cdc.gov, specifically, <http://www.cdc.gov/ncidod/dhqp/pdf/guidelines/InfectControl98.pdf>;

- iii. Basic immunology;
- iv. Communicable or vaccine preventable disease epidemiology;
- v. Vaccine characteristics, contraindications, monitoring, proper storage and proper handling;
- vi. Informed consent;
- vii. Pre- and post-vaccine assessment and counseling;
- viii. Immunization record management;

[page=1499] ix. Immunization schedules established pursuant to "General Recommendations on Immunization" of the CDC Advisory Committee on Immunization Practices (ACIP) (December 1, 2006), incorporated herein by reference, as amended and supplemented. The ACIP recommendations can be found at the CDC website, www.cdc.gov, specifically, <http://www.cdc.gov/mmwr/preview/mmwrhtml/rr5515a1.htm>;

- x. Injection techniques;
- xi. Emergency responses to adverse events;
- xii. Medical waste disposal; and
- xiii. Reporting adverse events;

2. Current certification in the American Heart Association Basic Life Support (BLS) protocol*,* *[or]* the Red Cross Adult Cardiac Pulmonary Resuscitation (CPR) protocol for health care providers*[*];]* ***or in a course that complies with guidelines created by the International Liaison Committee on Resuscitation (ILCOR). The ILCOR guidelines, 2005 International Consensus on Cardiopulmonary Resuscitation (CPR) and Emergency Cardiovascular Care (ECC) Science with Treatment Recommendations, are incorporated herein by reference, as amended and supplemented, and can be found at the American Heart Association website,** <http://americanheart.org/presenter.jhtml?identifier=3022512>, specifically, http://circ.ahajournals.org/content/vol112/22_suppl/; **and***

[3. Current certification in the use of a heart defibrillator; and]

[4.] ***3.*** At least two hours of continuing education in immunizations, consistent with the requirements of N.J.A.C. 13:39-3A.1, in each biennial renewal period.

(c) Documentation which establishes that a licensed pharmacist has satisfied the education and training requirements of (b) above shall be maintained at the pharmacy practice site. If the immunization program is to take place somewhere other than the pharmacy practice site, the documentation shall be maintained in the licensed pharmacist's possession at the immunization location. Such documentation shall be made available for inspection by the Board.

(d) Board approval granted pursuant to this section shall be renewed on a biennial basis. A pharmacist seeking such renewal shall submit documentation which establishes that he or she has satisfied the requirements of (b)2 *[through 4]* ***and 3*** above.

(e) A physician's standing order shall specify the procedures that shall be followed for the reporting of adverse events. The licensed pharmacist shall maintain and adhere to a manual of policies and procedures for dealing with acute adverse events. The policies and procedures manual shall require, at a minimum, that the pharmacist immediately notify emergency medical personnel and obtain assistance for the patient when an adverse event requiring the administration of emergency medications occurs. The policies and procedures manual shall be reviewed annually by the licensed pharmacist and such review shall be documented.

(f) Physicians' standing orders shall be maintained in either hard copy or electronic form as provided in ***[(m)]* *(I)***

below, and shall be available for inspection by the Board at the pharmacy practice site and, if applicable, at the immunization location.

(g) A defibrillator, which shall be maintained in good working order, shall be available during the administration of vaccines, unless the vaccine administration is being done at an emergency government sponsored event. A physician's standing order shall specify that a licensed pharmacist's use of a defibrillator shall be consistent with American Heart Association guidelines for cardiopulmonary resuscitation and emergency cardiovascular care. The AHA guidelines for Cardiopulmonary Resuscitation and Emergency Cardiovascular Care (2005), including use of automated external defibrillators (AED), are incorporated herein by reference, as amended and supplemented, and can be found at the AHA website, www.americanheart.org, specifically, http://circ.ahajournals.org/content/vol112/24_suppl/.

(h) *(g)* Before administration of a vaccine, the licensed pharmacist shall:

1. Screen the patient using CDC established criteria for each specific vaccine to be administered;
2. Counsel the patient and/or the patient's representative about contraindications, proper care of the injection site, and instructions to contact a physician or emergency care facility in the event of any adverse reaction;
3. Inform the patient and/or the patient's representative in writing, in specific and readily understood terms, about the risks and benefits of the vaccine and provide the patient with a vaccine information sheet published by the CDC; and
4. Obtain a signed informed consent form, which complies with the requirements of *(i)* *(h)* below, from the patient or the patient's representative which shall be maintained at the pharmacy practice site. If the immunization program is to take place somewhere other than the pharmacy practice site, the signed informed consent forms shall be maintained in the licensed pharmacist's possession at the immunization location. The signed informed consent forms shall be maintained in either hard copy or electronic form as provided in *(m)* *(l)* below.

(i) *(h)* The informed consent form provided by a licensed pharmacist to a patient shall contain a check-off box which authorizes the pharmacist to send copies of the patient's vaccine documentation to the patient's primary care provider, and another check-off box which prohibits the pharmacist from sending copies of the patient's vaccine documentation to the patient's primary care provider. The informed consent form shall specify that a patient's failure to select one of the two check-off boxes shall result in the patient's vaccine documentation being sent to the patient's primary care provider, if identified.

(j) *(i)* The licensed pharmacist shall document all immunizations he or she performs and such documentation shall be maintained at the pharmacy practice site. If the immunization program is to take place somewhere other than the pharmacy practice site, the documentation shall be maintained in the licensed pharmacist's possession at the immunization location, and then transferred to the pharmacy practice site. Such documentation shall be retained in either hard copy or electronic form, consistent with *(m)* *(l)* below, and shall be made available for inspection by the Board. Such documentation shall include:

1. The patient's name, address, telephone number, date of birth, allergies and gender;
2. The vaccine administered, the manufacturer, expiration date, lot number, site of administration, and dose administered;
3. The date of original order and the date of administration(s);
4. The name and address of the delegating physician, and the name and address of the licensed pharmacist administering the dose, and the immunization location, if different from the pharmacy practice site; and
5. The name and address of the patient's primary care provider, if provided.

(k) *(j)* The licensed pharmacist shall document in detail and immediately report all clinically significant adverse events to the delegating physician, and to the primary care provider, if identified and if authorized on the informed

consent form consistent with **[(i)]** **(h)** above. The licensed pharmacist shall, within 72 hours, report such events to the appropriate government reporting system.

[(l)] **(k)** The licensed pharmacist shall provide a copy of all patient related documentation and a copy of the signed informed consent form to each patient receiving an immunization, or to the patient's representative, to the patient's primary care provider, if provided and if authorized on the informed consent form consistent with **[(i)]** **(h)** above, and if applicable, to the appropriate government reporting system.

[(m)] **(l)** All documentation and records required to be maintained by this section shall be maintained in either hard copy or electronic form for a period of not less than seven years **from the date of most recent entry** and shall be supplied to any physician or health care provider upon receipt of a signed patient release of health information form. All records shall be made available to persons authorized to inspect them under State and Federal statutes and regulations. The oldest six years of information shall be maintained in such a manner so as to be retrievable and readable within two weeks. The most recent one year of information shall be retrievable and readable within one business day. Records not currently in use need not be stored in the pharmacy, but the storage facilities shall be secure. Patient records shall be kept confidential.

[(n)] **(m)** In the case of immunization programs implemented pursuant to a physician's standing order, a licensed pharmacist shall be supervised by the delegating physician. Supervision by the delegating physician shall be deemed adequate if the delegating physician:

[page=1500] 1. Is responsible for formulating or approving a standing order, periodically reviewing the order and the services provided to patients under the order;

2. Is geographically located to be easily accessible to the pharmacy practice site and, if applicable, to the immunization location.

3. Is available through direct telecommunication for consultation, assistance, and direction; and

4. Receives annual status reports on the immunization program as administered by the pharmacist

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