ii. A written report is filed with the Federal Drug Enforcement Administration upon discovery of the theft or diversion or any significant loss of controlled substances, consistent with Federal requirements. A copy of such report shall be filed with the Office of Drug Control, consistent with State requirements and with the Board;

3. There is a secure area for receiving packages known to contain prescription legend drugs and devices and controlled substances. No prescription drug shall be accepted during the hours the pharmacy or pharmacy department is closed unless adequate security for the storage of such shipments has been provided; and

4. If a drop-off device is utilized for prescriptions, it is of a one-way, irretrievable and secure design.

(c) In addition to the requirements set forth in (b) above, the holder of a pharmacy department permit and the pharmacist-in-charge of the pharmacy department shall also ensure that:

1. The pharmacy department is constructed so as to enable the closing off and securing of the department from the main store area. The department shall be separated from the main store area by a secured barrier or partition extending from the floor or fixed counter to the ceiling of either the department or main store and attached thereto;

2. All medications requiring supervision of a pharmacist, including dispensed medication, remain within the confines of the department when the pharmacist is not in the pharmacy department;

3. The pharmacy department has a published telephone number different from that of the establishment in which the department is located. No extensions of this phone shall be located outside the department; and

4. The telephone number of the pharmacist-in-charge is available in the office of the manager of the establishment.

(d) The holder of a pharmacy or pharmacy department permit shall comply with any law and/or ordinance of the municipality in which the pharmacy or pharmacy department is located requiring the placement of a security key box on the exterior of the pharmacy or the premises in which the pharmacy department is located for purposes of permitting emergency access to the premises.

Amended by R.1994 d.351, effective July 18, 1994.
See: 26 N.J.R. 1596(a), 26 N.J.R. 2905(b).
Amended by R.1999 d.214, effective July 19, 1999.
See: 31 N.J.R. 1151(a), 31 N.J.R. 1932(a).
In (b), substituted references to registered pharmacists-in-charge for references to pharmacists-in-charge in 2 and 8.
Recodified from N.J.A.C. 13:39-4.15 and amended by R.2005 d.25, effective January 18, 2005.
See: 36 N.J.R. 3345(a), 37 N.J.R. 295(a).
Rewrote the section. Former N.J.A.C. 13:39-4.14, Contract pharmaceutical services, recodified to N.J.A.C. 13:39-9.4.
Repeal and New Rule, R.2009 d.247, effective August 3, 2009.
See: 41 N.J.R. 371(a), 41 N.J.R. 2969(b).
Section was "Permitting of pharmacy department".
Recodified from N.J.A.C. 13:39-4.14 and amended by R.2010 d.090, effective June 21, 2010.
See: 42 N.J.R. 132(a), 42 N.J.R. 1221(a).
In the introductory paragraph of (a), deleted "registered" preceding "pharmacist(s)"; in (a)3, the introductory paragraph of (b), (b)1, (b)2, the introductory paragraph of (c) and (c)4, deleted "registered" preceding "pharmacist-in-charge" throughout; in (a)3, substituted "or" for "and/or" preceding "the pharmacy permit"; and in (b)1, deleted "of the permitted premises or the pharmacy department" preceding "shall be responsible".
Former N.J.A.C. 13:39-4.15, Permits; specialized permits, recodified to N.J.A.C. 13:39-4.16.

13:39-4.16 Permits; specialized permits

(a) The Board may issue a special permit, wherein the type of service is of a limited nature. The permit so issued, being based on special conditions of use imposed by the Board, may necessitate the waiver of certain rule requirements.

(b) Specialized permits shall pertain to pharmacies providing specific services as may be necessary and proper to efficiently meet a limited public need for pharmaceutical services. An applicant for any specialized pharmacy permit shall provide the Board with an application and a policy and procedure manual which sets forth a detailed description of the type of specialized pharmacy services to be provided within the pharmacy practice. The policy and procedure manual shall also contain detailed provisions which ensure the protection of the public welfare as determined by the Board.

Recodified from N.J.A.C. 13:39-4.16 by R.2005 d.25, effective January 18, 2005.
See: 36 N.J.R. 3345(a), 37 N.J.R. 295(a).
Former N.J.A.C. 13:39-4.15, Retail permit; prescription department or pharmacy department, recodified to N.J.A.C. 13:39-4.14.
Recodified from N.J.A.C. 13:39-4.15 by R.2010 d.090, effective June 21, 2010.
See: 42 N.J.R. 132(a), 42 N.J.R. 1221(a).
Former N.J.A.C. 13:39-4.16, Steering prohibited, recodified to N.J.A.C. 13:39-4.17.

13:39-4.17 Steering prohibited

It shall be unlawful for a pharmacy permit holder to enter into an arrangement with a practitioner for the purpose of directing or diverting patients to or from a specified pharmacy for the filling of prescriptions or restraining in any way a patient's freedom of choice to select a pharmacy.

Recodified from N.J.A.C. 13:39-4.17 and amended by R.2005 d.25, effective January 18, 2005.
See: 36 N.J.R. 3345(a), 37 N.J.R. 295(a).
Rewrote the section. Former N.J.A.C. 13:39-4.16, Permits; specialized permits, recodified to N.J.A.C. 13:39-4.15.
Recodified from N.J.A.C. 13:39-4.16 and amended by R.2010 d.090, effective June 21, 2010.
See: 42 N.J.R. 132(a), 42 N.J.R. 1221(a).
Substituted "practitioner" for "health care practitioner who is licensed to issue prescriptions" and inserted "for the filing of prescriptions".
Former N.J.A.C. 13:39-4.17, Responsibilities of permit holders, recodified to N.J.A.C. 13:39-4.18.

Case Notes

Division of Medical Assistance and Health Services did not present any cogent reason for denying an out-of-state pharmacy's application for Medicaid provider authorization where the applicant's 24-hour emer-

gency response arrangement with a New Jersey-based pharmacy resolved any question about emergency services, as that arrangement did not constitute prohibited steering as defined in the regulations, and the Division admitted that out-of-state mail order services had been authorized. Thus, the Division's decision denying the out-of-state provider's application was arbitrary, capricious, and unreasonable as well as otherwise not in accordance with law. Phoenix Pharmacy, Inc. v. DMAHS, OAL Dkt. No. HMA 03266-07, 2007 N.J. AGEN LEXIS 489, Initial Decision (July 6, 2007).

13:39-4.18 Responsibilities of permit holders

(a) All permit holders shall be responsible for compliance with all the rules, regulations and laws governing the practice of pharmacy.

(b) Any permit holder may be held liable for violations of the New Jersey Pharmacy Practice Act, N.J.S.A. 45:14-40 et seq., and the rules in this chapter and may be subject to disciplinary action.

Recodified from N.J.A.C. 13:39-4.18 and amended by R.2005 d.25, effective January 18, 2005.
See: 36 N.J.R. 3345(a), 37 N.J.R. 295(a).
Rewrote the section. Former N.J.A.C. 13:39-4.17, Steering prohibited, recodified to N.J.A.C. 13:39-4.16.
Recodified from N.J.A.C. 13:39-4.17 and amended by R.2010 d.090, effective June 21, 2010.
See: 42 N.J.R. 132(a), 42 N.J.R. 1221(a).
In (b), inserted "New Jersey" and "Practice" and substituted "40" for "1". Former N.J.A.C. 13:39-4.18, Procedures for centralized prescription handling, recodified to N.J.A.C. 13:39-4.19.

13:39-4.19 Procedures for centralized prescription handling

(a) The four component functions of handling a prescription are intake, processing, fulfillment and dispensing.

(b) Central prescription handling entails two or more licensed pharmacies sharing responsibility for performing the four component functions of handling a prescription. For purposes of this section, the term "prescription" shall include medication orders when a healthcare facility is involved in any of the component functions of central prescription handling.

(c) The following pharmacies may engage in central prescription handling: an intake or originating pharmacy; a central processing pharmacy; a central fill pharmacy; and a dispensing pharmacy. The four component functions of handling a prescription shall be performed by the following pharmacies:

1. An intake or originating pharmacy, which is a pharmacy that received the patient's or prescribing practitioner's request to fill or refill a prescription. A central processing pharmacy or a central fill pharmacy, as delineated in (c)2 and 3 below, may be considered the intake or originating pharmacy if the prescription was transmitted by the prescribing practitioner directly to the centralized pharmacy as provided in N.J.A.C. 13:39-7.10 and 7.11 or if the patient requested the refill from that pharmacy;

2. A central processing pharmacy, which is a pharmacy that engages in prescription review by performing functions that may include, but are not limited to, data entry, prospective drug review, refill authorizations, interventions, patient counseling, claims submission, claims resolution and adjudication;

3. A central fill pharmacy, which is a pharmacy engaging in central prescription handling by filling and/or refilling prescriptions, which includes the preparation and packaging of the medication; and

4. A dispensing pharmacy, which is a pharmacy that receives the processed prescription and/or the filled or refilled prescription for dispensing to the patient or to the patient's authorized representative and that offers patient counseling regarding the dispensed medication.

(d) Two or more of the pharmacies delineated in (c) above may engage in central prescription handling provided:

1. Any or all of the pharmacies participating in central prescription handling have a contractual agreement to provide such services or have the same owner;

2. Prior to engaging in central prescription handling, all pharmacies that are parties to the central prescription handling obtain Board approval. If a participating pharmacy is located outside the State of New Jersey, the pharmacy shall have registered with the Board pursuant to N.J.A.C. 13:39-4.19. The pharmacies shall make a single application to the Board, delineating the scope of practice of each pharmacy and the specific rules in this chapter with which each pharmacy shall comply;

3. An audit trail is maintained that records and documents the unique and secure user identifier(s) of the pharmacist(s), pharmacy technician(s), intern(s) or extern(s) and the component function(s) performed by each, at the time the functions are performed, for each step of prescription handling that is required to be performed by a pharmacist, pharmacy technician, intern or extern pursuant to the requirements of this chapter. All steps performed by a pharmacy technician, intern or extern shall be documented in the audit trail. All entries to the audit trail made by a pharmacy technician, intern or extern shall be reviewed and approved by the pharmacist. When more than one pharmacist is involved in the component functions of prescription handling, the unique and secure user identifier(s) of the pharmacist(s) responsible for the accuracy and appropriateness of each component function(s) shall be recorded in the audit trail. The audit trail and prescription information shall be maintained or stored in original hard copy form or in any other media that facilitates the reproduction of the original hard copy and shall be maintained for not less than five years from the date the prescription is filled or refilled. The oldest four 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 off-site facilities used to store such records shall be secure. Patient records shall be kept confidential, but shall be made available to persons authorized to inspect them under State and Federal statutes and regulations;

4. The dispensed prescription for any product bears a permanently affixed label with at least the following information:

i. The brand name, or if a generic, the brand name and the name of the generic in the following form, with the generic name and brand name inserted as appropriate:

"--------- Generic for ---------";

ii. The strength of medication, where applicable;

iii. The quantity dispensed;

iv. The date upon which prescription medication is dispensed;

v. A CDS cautionary label, where applicable and when permitted by law;

vi. The patient name;

vii. The practitioner name;

viii. The prescription number;

ix. Directions for use;

x. The phrase "use by" followed by the product's use by date, if dispensed in any packaging other than the manufacturer's original packaging. For purposes of this paragraph, "use by date" means the earlier of one year from the date of dispensing or the expiration date on the manufacturer's container;

xi. All auxiliary labeling as recommended by the manufacturer and/or as deemed appropriate in the professional judgment of the dispensing pharmacist; and

xii. The name, address and telephone number of any or all of the following:

(1) The intake pharmacy;

(2) The central processing pharmacy;

(3) The central fill pharmacy; and/or

(4) The dispensing pharmacy;

5. The patient name, the brand or generic name of the medication, and the directions for use appear in larger type, in a different color type, or in bolded type, in comparison to the other information required to appear on the label of the dispensed container pursuant to (d)4 above;

6. The patient is provided with written information, either on the prescription label or with the prescription container, that indicates which pharmacy to contact if the patient has any questions about the prescription or the medication. The written information provided to the patient shall be in bold print, easily read, and shall include the hours a pharmacist is available and a telephone number where a pharmacist may be reached. The telephone service shall be available at no cost to the pharmacy's primary patient population;

7. All pharmacies that are to engage in central prescription handling maintain a common policies and procedures manual which designates who shall be responsible for each of the component functions of handling the prescription and for ensuring compliance with the Board rules set forth in this chapter. The policies and procedures manual shall also include maintenance of the audit trail required by (d)3 above. The policies and procedures manual shall be made available to the Board upon request;

8. All pharmacies that are to engage in central prescription handling share a common electronic file; and

9. All pharmacies that are to engage in central prescription handling are responsible for ensuring that the prescription has been properly filled.

(e) A prescription for a controlled substance may be filled or refilled by pharmacies engaging in central prescription handling when permitted by law, consistent with Federal requirements set forth at 21 CFR 1300 et seq.

New Rule, R.2004 d.380, effective October 4, 2004.
See: 36 N.J.R. 11(a), 36 N.J.R. 4480(a).
Recodified from N.J.A.C. 13:39-5.10 by R.2005 d.25, effective January 18, 2005.
See: 36 N.J.R. 3345(a), 37 N.J.R. 295(a).
Former N.J.A.C. 13:39-4.18, Responsibilities of pharmacists and permit holders, recodified to N.J.A.C. 13:39-4.17.
Amended by R.2007 d.351, effective November 19, 2007.
See: 38 N.J.R. 4630(a), 39 N.J.R. 4935(a).
In (d)2, inserted the second sentence.
Amended by R.2009 d.305, effective October 5, 2009.
See: 40 N.J.R. 5170(a), 41 N.J.R. 3840(a).
In (b), inserted the second sentence; in (c)1, substituted "13:39-7.10 and 7.11" for "13:39-5.8A and 5.8B"; in (c)4, inserted "and which offers patient counseling regarding the dispensed medication"; in the introductory paragraph of (d), inserted "of the"; and rewrote (d)3.
Recodified from N.J.A.C. 13:39-4.18 and amended by R.2010 d.090, effective June 21, 2010.
See: 42 N.J.R. 132(a), 42 N.J.R. 1221(a).
In (c)1, (c)2, (c)3 and (c)4, deleted "licensed" preceding the second occurrence of "pharmacy"; in (c)3, inserted a comma following "prescriptions"; in (c)4, substituted the second occurrence of "that" for "which"; in the introductory paragraph of (d), deleted "licensed" preceding "pharmacies"; rewrote (d)4i; in (d)4vii, substituted "practitioner" for "prescriber"; and in (c), substituted "CFR" for "C.F.R. §§". Former N.J.A.C. 13:39-4.19, Out-of-State pharmacy registration, recodified to N.J.A.C. 13:39-4.20.

13:39-4.20 Out-of-State pharmacy registration

(a) Any pharmacy located in a state other than New Jersey (hereinafter "out-of-State pharmacy") that ships, mails, distributes or delivers in any manner, legend drugs or devices or controlled dangerous substances pursuant to a prescription into the State, or which participates in a central prescription

handling arrangement pursuant to N.J.A.C. 13:39-4.18, shall be registered with the Board pursuant to this section.

(b) It shall be unlawful for any out-of-State pharmacy not registered with the Board pursuant to this section to ship, mail, distribute or deliver in any manner, legend drugs or devices or controlled dangerous substances pursuant to a prescription into the State of New Jersey. Such conduct shall be deemed a violation of N.J.S.A. 45:14-73 and this section.

(c) An out-of-State pharmacy seeking to register with the Board shall submit a completed application for registration to the Board, which shall include the following:

1. The name under which the pharmacy is to be operated, the type of practice in which the pharmacy will be engaging, the weekly hours of operation for the pharmacy, and a copy of the prescription label to be used by the pharmacy;

2. The location, names and titles of all principal corporate officers, if the applicant is a corporation, or the location, names and titles of any individuals in whom ownership is or will be vested, if the applicant is not a corporation;

3. The name of the pharmacist-in-charge and his or her license number in the state in which the pharmacy is located, and his or her weekly hours of employment;

4. A dated copy of the most recent inspection report resulting from an inspection of the out-of-State pharmacy conducted by the regulatory or licensing agency in the state in which the pharmacy is located;

5. A letter of good standing from the state licensing authority in the state in which the licensed, permitted or registered out-of-State pharmacy is located; and

6. The application fee specified in N.J.A.C. 13:39-1.3(a)4.

(d) An out-of-State pharmacy registered with the Board shall maintain, at all times, a valid unexpired license, permit, or registration to conduct the pharmacy in compliance with the laws and regulations of the state in which it is located. The pharmacy shall notify the Board immediately upon the permanent closing of the pharmacy or upon the commencement of any action by the licensing authority in the state in which it is located concerning its license, permit or registration to conduct the pharmacy. Suspension or revocation of a pharmacy's license, permit or registration in the state in which it is located shall result in the immediate commencement of proceedings by the Board to suspend or revoke the out-of-State pharmacy's registration in New Jersey.

(e) An out-of-State pharmacy registered with the Board shall submit on an annual basis, prior to the expiration of the registration, a renewal application which shall contain the information set forth in (c)1 through 5 above, and the renewal fee set forth in N.J.A.C. 13:39-1.3(a)4. A registered out-of-State pharmacy that fails to submit the renewal application within 30 days after the registration expiration shall submit the late renewal fee set forth in N.J.A.C. 13:39-1.3(a)4 in addition to the renewal fee. An out-of-State pharmacy that continues to ship, mail, distribute or deliver legend drugs or devices or controlled dangerous substances into the State, or continues to participate in a central prescription handling arrangement pursuant to N.J.A.C. 13:39-4.18, with an expired registration shall be deemed to be engaging in the unauthorized practice of pharmacy and shall be subject to the penalties set forth in N.J.S.A. 45:1-25 et seq.

(f) An out-of-State pharmacy registered with the Board shall submit the information set forth in (c)1 though 5 above and the fee set forth in N.J.A.C. 13:39-1.3(a)4, if applicable, within 30 days of the following:

1. Any change in ownership of the individual equity holder(s) or business entity holding the license, permit or registration to operate the pharmacy;

2. A change of registered agents or officers or a change of stock ownership involving 10 percent or more of the outstanding stock of a publicly traded corporation holding the license, permit or registration to operate the pharmacy;

3. A change in the location of the licensed, permitted or registered pharmacy;

4. A change in the name of the licensed, permitted or registered pharmacy; or

5. A change in the pharmacist-in-charge.

(g) An out-of-State pharmacy may obtain a replacement registration upon payment of the fee specified in N.J.A.C. 13:39-1.3(a)4 and upon submission of an affidavit describing the loss or destruction of the registration originally issued, or upon return of the damaged permit.

(h) An out-of-State pharmacy registered with the Board shall:

1. Inform the Board, upon request, of the results of any inspections or investigations conducted by the regulatory or licensing agency of the state in which the pharmacy is licensed, permitted or registered or by a Federal agency, including the filing of any action against the pharmacy by the agency;

2. Inform the Board, upon request, of any directions to, and requests for information from, the pharmacy issued by the regulatory or licensing agency of the state in which the pharmacy is licensed, permitted or registered or by a Federal agency; and

3. Comply with directions concerning compliance with this section and any requests for information issued by the Board.

(i) An out-of-State pharmacy registered with the Board shall maintain its record of prescriptions for patients in the

State of New Jersey for a period of not less than five years. The oldest four years of record information shall be maintained in such a manner so as to be retrievable and readable within two weeks. The most recent one year of record information shall be retrievable and readable within one business day.

(j) An out-of-State pharmacy registered with the Board shall, during its regular hours of operation, but not less than five days per week, and for a minimum of 40 hours per week, provide a toll-free telephone service to facilitate communication between patients in the State of New Jersey and a pharmacist who has access to the patients' records. This toll-free number shall be disclosed on a label affixed to each container of drugs dispensed to patients in the State of New Jersey or the out-of-State pharmacy shall meet the requirements set forth in N.J.A.C. 13:39-4.18(d)6.

(k) The Board may forward a complaint against any out-of-State pharmacy registered with the Board for alleged violations of any New Jersey or Federal law or regulation, or any information concerning alleged violations of New Jersey or Federal law by the pharmacy, to the regulatory or licensing agency in the state in which the pharmacy is located, or the Board may institute disciplinary proceedings in New Jersey pursuant to N.J.S.A. 45:1-21 et seq., to resolve the complaint or alleged violation.

New Rule, R.2007 d.351, effective November 19, 2007.
See: 38 N.J.R. 4630(a), 39 N.J.R. 4935(a).
Recodified from N.J.A.C. 13:39-4.19 and amended by R.2010 d.090, effective June 21, 2010.
See: 42 N.J.R. 132(a), 42 N.J.R. 1221(a).
In the introductory paragraph of (c), inserted a comma following the second occurence of "Board"; in (c)5, inserted "licensed, permitted or registered" and substituted "located" for "licensed, permitted or registered"; and in (f)5, deleted "registered" preceding "pharmacist-in-charge". Former N.J.A.C. 13:39-4.20, Procedures for physician ordered or government sponsored immunizations performed by pharmacists, recodified to N.J.A.C. 13:39-4.21.

13:39-4.21 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;

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

(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 (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 (*l*) below.

(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.

(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 (*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);