

CHAPTER 39

STATE BOARD OF PHARMACY

Authority

N.J.S.A. 45:1-15.1 and 45:14-1 et seq.

Source and Effective Date

R.2005 d.25, effective December 10, 2004
See: 36 N.J.R. 3345(a), 37 N.J.R. 295(a).

Chapter Expiration Date

Chapter 39, State Board of Pharmacy, expires on December 10, 2009.

Chapter Historical Note

Chapter 39, State Board of Pharmacy, was adopted and became effective prior to September 1, 1969.

Chapter 39, State Board of Pharmacy, was repealed and adopted as new rules by R.1989 d.314, effective June 19, 1989. See: 20 N.J.R. 1648(a), 21 N.J.R. 1712(a).

Pursuant to Executive Order No. 66(1978), Chapter 39, State Board of Pharmacy, was readopted as R.1994 d.351, effective June 16, 1994. See: 26 N.J.R. 1596(a), 26 N.J.R. 2905(b), 26 N.J.R. 3878(a).

Pursuant to Executive Order No. 66(1978), Chapter 39, State Board of Pharmacy, was readopted as R.1999 d.214, effective June 16, 1999. See: 31 N.J.R. 1151(a), 31 N.J.R. 1932(a).

Subchapter 10, Automated Medication Systems, was adopted as R.2000 d.28, effective January 18, 2000. See: 31 N.J.R. 2293(b), 32 N.J.R. 317(a).

Subchapter 3A, Continuing Education, was adopted as R.2003 d.130, effective March 17, 2003. See: 34 N.J.R. 1089(a), 35 N.J.R. 1433(a).

Chapter 39, State Board of Pharmacy, was readopted as R.2005 d.25, effective December 10, 2004. See: Source and Effective Date. See, also, section annotations.

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- (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 C.F.R. §§ 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.

13:39-4.19 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 out-of-State pharmacy is licensed, permitted or registered; 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 through 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 registered 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).

SUBCHAPTER 5. RETAIL FACILITY REQUIREMENTS

13:39-5.1 Purpose and scope

The rules in this subchapter shall apply to all retail pharmacies and retail pharmacy departments in the State. For purposes of this subchapter, "pharmacy" means a retail pharmacy or a retail pharmacy department.

New Rule, 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. 13:39-5.1, Imprinted prescription blanks, repealed.

Case Notes

Out-of-state applicant could not be deemed an institutional pharmacy because: (1) the applicant's Wisconsin license stated only that it was a "pharmacy" and did not further describe the licensee as either retail or institutional; (2) the Justice Department registration recognized petitioner as a retail pharmacy; (3) an "institutional pharmacy" under New Jersey regulations must be within a healthcare facility or system licensed as such by the Board; and (4) the New Jersey regulations also state that the term "pharmacy" standing alone indicates a retail pharmacy. Because the applicant was not deemed an institutional pharmacy, its authorization as a Medicaid provider was not proscribed under N.J.A.C. 10:51-2.2(b)1. *Phoenix Pharmacy, Inc. v. DMAHS*, OAL Dkt. No. HMA 03266-07, 2007 N.J. AGEN LEXIS 489, Initial Decision (July 6, 2007).

13:39-5.2 Pharmacy access and egress

Pharmacies shall maintain entrances which are easily and safely accessible to the general public. Access to and egress from the pharmacy shall not be such that the public must

traverse or traffic through any area in which prescriptions are prepared.

Recodified from N.J.A.C. 13:39-7.1 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. 13:39-5.2, Lack of directions on original prescription, recodified to N.J.A.C. 13:39-7.2.

13:39-5.3 Pharmacy signs

(a) Pharmacies shall post a sign on the exterior of the building or a sign which is otherwise visible from a public roadway, conspicuously identifying the existence of a pharmacy on the premises, unless prohibited by lease agreement or municipal ordinance. In such case, a copy of the lease or ordinance shall be furnished to the Board.