

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Chapter 39, State Board of Pharmacy, was repealed and adopted as new rules by R.1989 d.314, effective June 19, 1989.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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SUBCHAPTER 1. GENERAL PROVISIONS

13:39-1.1 Purpose and scope

(a) This chapter is promulgated by the New Jersey State Board of Pharmacy. The rules contained in this chapter implement the provisions of the Pharmacy Act, N.J.S.A. 45:14-1 et seq. and regulate the practice of pharmacy within the State of New Jersey.

(b) This chapter shall apply to all registered pharmacies, pharmacists, pharmacist applicants, interns, externs, pharmacy technicians and anyone within the jurisdiction of the Board of Pharmacy.

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.2005 d.25, effective January 18, 2005.
 See: 36 N.J.R. 3345(a), 37 N.J.R. 295(a).

In (b), substituted "pharmacy technicians" for "supportive personnel" preceding "and anyone within the jurisdiction".

Case Notes

Violations of N.J.A.C. 13:39-8.14(b)2, 10 and 13 found as controlled substances records were improperly kept, misbranded drugs were in pharmacy and drugs were improperly stored, respectively; penalties (also cited as N.J.A.C. 13:39-8.12). *New Jersey State Bd. of Pharmacy v. Yanuzzi*, 4 N.J.A.R. 489 (1981).

13:39-1.2 Definitions

The following words and terms when used in this chapter shall have the following meanings, unless the context clearly indicates otherwise.

"Address of record" means an address designated by a licensee or registrant. "Address of record" may be a licensee's or registrant's home, business or mailing address, but shall not be a post office box unless the licensee or registrant also provides another address which includes a street, city, state and zip code.

"Authorized prescriber" means a licensed practitioner who is authorized by law to write prescriptions and/or medication orders.

"Board" means the New Jersey State Board of Pharmacy.

"Compounding" means the act of preparing pharmaceutical components into medications, pursuant to an authorized prescriber's prescription or medication order, including, but not limited to prescription compounding, and intravenous admixture preparation.

"Device" means an instrument, apparatus, implement, machine, contrivance, implant, in vitro reagent or other similar or related article, including any component part or accessory, which is required under Federal or State law to be prescribed by an authorized prescriber and dispensed by a pharmacist, in the usual scope of pharmacy practice.

"Dispense or dispensing" means the procedure entailing the interpretation of an authorized prescriber's prescription order for a drug or device, and pursuant to that order, the proper selection, measuring, labeling, and packing in a proper container. The act of dispensing shall include all necessary consultation by the pharmacist.

"Drug or medicine" means:

- Articles recognized in the official United States Pharmacopoeia/National Formulary, official Homeopathic Pharmacopoeia of the United States, or any official supplement to any of them;
- Articles intended for use in the diagnosis, cure, mitigation, treatment or prevention of disease in human beings or animals;
- Articles (other than food) intended to affect the structure of any function of the body of human beings or animals; and
- Articles intended for use as components of any article specified in 1, 2 or 3 above, but not including devices or their components, parts or accessories.

"Immediate personal supervision" means that the registered pharmacist is physically present in the compounding/dispensing area when interns, externs and pharmacy technicians are performing delegated duties, and the pharmacist conducts any necessary in-process checks and the final check in preparation and compounding of medications, including the checking of each ingredient used, the quantity of each ingredient whether weighed, measured or counted, and the finished label.

"Legend drug or device" means any drug or device that:

- Bears, at a minimum, the symbol "Rx only" or words of similar import; and/or
- Requires a prescription or order by an authorized prescriber.

"Licensed practitioner" means a duly licensed physician, dentist, optometrist, veterinarian, certified nurse midwife, nurse practitioner/clinical nurse specialist or physician assistant, or other health care practitioner licensed or approved to write prescriptions intended for the treatment or prevention of disease, as set forth in N.J.S.A. 45:14-14.

“Pharmaceutical services” means all services provided by a registered pharmacist. These services shall be concerned with, but not limited to: interpreting the prescription or medication order; selecting, preparing, compounding, packaging, labelling, distributing and dispensing prescribed drugs; the proper and safe storage of drugs; the monitoring of drug therapy; the reporting and recording of adverse drug reactions and the provision of appropriate drug information; teaching and counselling on the proper and safe use of drugs and medications.

“Pharmacy technician” means an individual employed by a pharmacy whose responsibilities do not require professional judgment in the preparation and distribution of medications and who works under the immediate personal supervision of a pharmacist in compliance with N.J.A.C. 13:39-6.15. For purposes of this definition, interns, externs, cashiers, stocking and clerical help are not pharmacy technicians.

“Prescription” means any order for drugs and related items as defined in N.J.S.A. 45:14-14.

“Professional judgment” means judiciousness and discretion based upon thorough knowledge and sound application of the specialized body of knowledge peculiar to the practice of pharmacy, and an understanding of the relationship of this knowledge and its application to the well-being of the patient and to the judgment of the prescriber.

“Registered pharmacist” or “pharmacist” means a person whose license is in good standing for the current license renewal period.

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).

Inserted “Address of record”; in “Legend drug or device”, rewrote 1; rewrote “Licensed practitioner”; and in “Registered pharmacist” or “pharmacist”, substituted a reference to licenses for a reference to certificates, and substituted a reference to the current license renewal period for a reference to the current registration period.

Amended by R.2005 d.25, effective January 18, 2005.
See: 36 N.J.R. 3345(a), 37 N.J.R. 295(a).

Rewrote “Address of record”, added “Immediate personal supervision” and “Pharmacy technician”, deleted “Direct supervision” and “Supportive personnel”.

Amended by R.2007 d.283, effective September 4, 2007.
See: 38 N.J.R. 3137(a), 39 N.J.R. 3774(b).

In definition “Address of record”, inserted “or registrant” twice and inserted “or registrant’s”; and in definition “Pharmacy technician”, updated the N.J.A.C. reference.

13:39-1.3 Fee schedule

(a) The following fees shall be charged by the Board:

1. For pharmacists as follows:

i. Application for licensure	125.00.
ii. Verification of licensure	25.00.
iii. Application for reciprocity	125.00.

iv. Application for reinstatement	
(1) Disciplinary suspension	225.00.
(2) Administrative suspension	(To be determined by future rulemaking)
v. Initial licensure fee	
(1) If paid during the first year of a biennial renewal period	140.00.
(2) If paid during the second year of a biennial renewal period	70.00.
vi. Biennial license renewal	140.00.
vii. Replacement biennial license	25.00.
viii. Inactive license renewal	(To be determined by future rulemaking)
ix. Late renewal fee	100.00.
x. Replacement of initial wall license	40.00.
xi. Continuing education review fee	10.00.
xii. Continuing education program or course: sponsor review fee	50.00.
xiii. Yearly fee for distribution of minutes and agenda	60.00.

2. For in-State pharmacies as follows:

i. Pharmacy permits	
(1) Application for permit	275.00.
(2) Annual permit renewal	175.00.
(3) Change of ownership/name	275.00.
(4) Change of location	275.00.
ii. Replacement of annual permit	25.00.
iii. Late renewal fee	100.00.
iv. Verification of permit	25.00.

3. For pharmacy technicians as follows:

i. Application for registration\$50.00;
ii. Initial registration fee:	
(1) If paid during the first year of a biennial renewal period\$70.00;
(2) If paid during the second year of a biennial renewal period\$35.00;
iii. Biennial registration renewal\$70.00;
iv. Replacement biennial registration\$25.00;
v. Late renewal fee\$25.00;
vi. Verification of registration\$25.00; and
vii. Reinstatement fee:	
(1) Disciplinary suspension\$125.00;
(2) Administrative suspension(To be determined by future rulemaking).

4. For out-of-State pharmacies as follows:

i. Pharmacy permits	
(1) Application for permit 175.00
(2) Annual permit renewal 175.00
(3) Change of ownership/name 175.00
(4) Change of location 175.00
ii. Replacement of annual permit 25.00
iii. Late renewal fee 100.00
iv. Verification of permit 25.00

Amended by R.1993 d.414, effective August 16, 1993.

See: 25 N.J.R. 1666(a), 25 N.J.R. 3839(a).

Amended by R.1999 d.214, effective July 19, 1999.

See: 31 N.J.R. 1151(a), 31 N.J.R. 1932(a).

In (a)1, rewrote ii, substituted a reference to licensure fees for a reference to registration fees in the introductory paragraph of v, substituted a reference to license renewal for a reference to registration in vi, substituted a reference to biennial licenses for a reference to registration certificates in vii, and substituted a reference to licenses for a reference to certificates in x.

Amended by R.2003 d.130, effective March 17, 2003.

See: 34 N.J.R. 1089(a), 35 N.J.R. 1433(a).

In (a)xii, added "or course" and substituted "sponsor" for "provider".

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.

Amended by R.2007 d.283, effective September 4, 2007.

See: 38 N.J.R. 3137(a), 39 N.J.R. 3774(b).

Added (a)3.

Amended by R.2007 d.351, effective November 19, 2007.

See: 38 N.J.R. 4630(a), 39 N.J.R. 4935(a).

In (a)2, inserted "in-State"; and added (a)4.

13:39-1.4 Payment of penalties

(a) Any penalties levied by the Board shall be paid within 10 calendar days of the finalization of a penalty letter or final order of the Board unless otherwise prescribed by statute or terms of a final order.

(b) Failure to comply with this rule may result in action by the Board according to the provisions of N.J.S.A. 45:1-24.

Amended by R.2005 d.25, effective January 18, 2005.

See: 36 N.J.R. 3345(a), 37 N.J.R. 295(a).

13:39-1.5 Opportunity to be heard

(a) Any time the Board seeks to impose a disciplinary sanction upon a licensee, the licensee may request an opportunity to be heard by the Board.

(b) When demonstrated facts are in dispute, a hearing shall be conducted pursuant to the Administrative Procedure Act, N.J.S.A. 52:14B-1 et seq., and the Uniform Administrative Procedure Rules, N.J.A.C. 1:1.

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.

13:39-1.6 Waiver

(a) The rules in this chapter may be relaxed by the Board upon a showing of undue hardship, economic or otherwise, on an applicant; that the waiver of the rule would not unduly burden any affected parties; and that the waiver is consistent with the underlying purposes of the Pharmacy Practice Act, N.J.S.A. 45:14-40 et seq. and the implementing rules of this chapter.

(b) Waiver requests shall be submitted to the Board in writing and shall include the following:

1. The specific rule(s) or part(s) of the rule(s) for which the waiver is requested;

2. The reasons for requesting the waiver, including a statement detailing the hardship that would result to the applicant if the waiver is not approved; and

3. Documentation which supports the applicant's request for the waiver, if applicable.

(c) Absent a request for a waiver, the Board may waive the rules in this chapter if full compliance with the rules, or parts of the rules, would endanger the health, safety and welfare of the general public.

New Rule, R.2007 d.351, effective November 19, 2007.

See: 38 N.J.R. 4630(a), 39 N.J.R. 4935(a).

SUBCHAPTER 2. LICENSURE REQUIREMENTS

13:39-2.1 Examinations; score

(a) The examination for licensure by the Board shall be the North American Pharmacist Licensure Examination (NAPLEX). An applicant shall attain a passing score of not less than 75. If an applicant fails the examination, he or she shall be required to repeat the examination.

(b) A licensee shall maintain all documentation concerning the completion of continuing education requirements for a period of five years from the completion of the credit hours and shall submit such documentation to the Board upon request. Such documentation shall consist of:

1. For programs offered by American Council of Pharmaceutical Education approved providers, a certificate of completion from the course or program;
2. For programs and courses approved by the Board, the sponsors' written verification of attendance;
3. For teaching or research appointments in an academic setting, a statement from the chairperson of the department verifying completion of the assignment;
4. For research appointments in an industrial setting, a statement from the project coordinator verifying completion of the assignment;
5. For participation as a preceptor in an externship program, a certificate from the college of pharmacy;
6. For participation as a preceptor in an internship program, a certificate from the Board; and
7. For publications in a peer-reviewed professional journal, submission of the published article.

(c) The Board shall audit licensees on a random basis at the end of each biennial period to determine compliance with continuing education requirements.

13:39-3A.5 Waiver of continuing education requirements

(a) The Board may waive continuing education requirements on an individual basis for reasons of military service, hardship, illness or disability.

(b) A licensee seeking a waiver of continuing education requirements shall apply to the Board in writing and set forth with specificity the reasons for requesting the waiver. The licensee shall also provide the Board with such additional information as the Board may request in support of the application for waiver.

(c) A waiver of continuing education requirements granted pursuant to this section shall be effective only for the biennial period in which such waiver is granted. If the condition(s) which necessitated the waiver continues into the next biennial period, a licensee shall apply to the Board for a renewal of such waiver for the new biennial period.

13:39-3A.6 Responsibilities of continuing education sponsors

(a) A continuing education sponsor shall receive prior Board approval for a program or course if the sponsor provides, in writing on a form provided by the Board, infor-

mation which demonstrates that the program or course meets the following requirements:

1. The program or course is offered in a subject matter relevant to the practice of pharmacy;
2. The program or course is at least one contact hour in length; and
3. The program or course is conducted by a qualified instructor or discussion leader who submits a curriculum vitae and who is:
 - i. A pharmacist with a B.S. in Pharmacy or a Pharm.D. with at least five years of experience;
 - ii. A pharmacist with a B.S. in Pharmacy or a Pharm.D. with expertise in the program or course subject area;
 - iii. A pharmacist with a B.S. in Pharmacy or a Pharm.D. who is certified by a nationally recognized board or association; or
 - iv. A licensed health care professional who demonstrates special expertise in the lecture subject area.

(b) A continuing education sponsor may request approval for a program or course conducted by an individual who possesses expertise in a subject area relevant to the practice of pharmacy, provided that the program or course to be conducted by that individual satisfies the requirements of (a)1 and 2 above.

(c) Applications for pre-approval of continuing education programs or courses shall be submitted by the continuing education sponsor on a form provided by the Board at least 45 days prior to the date the program or course is to be offered. Incomplete applications shall be returned to the sponsor.

(d) The Board shall approve only such continuing education programs and courses as are available and advertised on a reasonable nondiscriminatory basis to all persons licensed to practice pharmacy in the State. The Board shall maintain a list of all approved programs and courses at the Board office and shall furnish the list to licensees upon request.

(e) A continuing education sponsor shall not make substantive changes to an approved program or course, such as a change in program or course content or instructor, without prior Board approval.

(f) The continuing education sponsor shall monitor attendance at, or ensure completion of, each approved program or course and furnish to each enrollee a verification of attendance which shall include at least the following information:

1. The title, date and location of the program or course offering;
2. The name of the program or course presenter;

3. The name and certificate number of the program or course presented;

4. The number of continuing education credits awarded; and

5. The name, address, telephone number and signature of the sponsor, or if the sponsor is an association or organization, the signature of an officer or responsible party of the association or organization.

(g) The continuing education sponsor shall submit the fee set forth at N.J.A.C. 13:39-1.3(a)lxii for each submission of program or course offerings.

(h) The continuing education sponsor shall maintain a list of all attendees who completed each approved program or course for a period of five years from the date the program or course was offered.

13:39-3A.7 Monitoring of continuing education programs or courses

A Board member or a Board representative may monitor an approved program or course without prior notification to the continuing education sponsor.

SUBCHAPTER 4. PHARMACY PERMIT REQUIREMENTS

13:39-4.1 New pharmacies; eligibility and application

(a) A permit application shall be submitted to the Board by every person or corporation desiring to operate a new pharmacy. Such application shall be made on a form furnished by the Board.

(b) The permit application shall indicate the exact intended location and plan or physical arrangement of the proposed pharmacy area and shall indicate any premises contiguous to but not necessarily a part of the pharmacy.

(c) The permit application shall bear the exact trade name, if any; the corporate names, if any; the name and addresses of the owners and operators, if a sole proprietorship, partnership, limited liability partnership or limited liability company; the names and addresses of all officers and stockholders and the names and addresses of all principals duly licensed to write prescriptions if the pharmacy is not a publicly traded corporation; and the names and addresses of the officers, if a publicly traded corporation.

(d) The permit application shall include the name of the registered pharmacist-in-charge who shall be a registered pharmacist in good standing in the State of New Jersey.

(e) No person, business entity or equity holder of the business entity shall be eligible for a new permit or a renewal thereof who is not of high moral character or against whom

there is pending any indictment or any alleged violation of local, State or Federal law pertaining to the practice of pharmacy or the dispensing of controlled dangerous substances or any drug under N.J.S.A. 24:21-2.

(f) A person submitting an application may be interviewed by the Board to review his or her qualifications and eligibility.

(g) Before a permit may be issued to an applicant, the Board shall inspect and approve the premises, fixtures and equipment of the new pharmacy to ensure compliance with this subchapter and all relevant statutes, regulations and ordinances.

(h) Upon approval of the permit application, the Board shall issue a permit number that will allow the applicant to place prescription legend drugs in stock.

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 (d), substituted a reference to registered pharmacists-in-charge for a reference to pharmacists-in-charge; inserted a new (g); and recodified former (g) as (h).

Recodified from N.J.A.C. 13:39-4.7 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. 13:39-4.1, Issuance of permits, recodified to N.J.A.C. 13:39-4.2.

13:39-4.2 Issuance of permits; permit renewals

(a) All permits shall be issued by the Board in the name of the pharmacy or other licensed establishment for the operation of which the permit is issued.

(b) A permit holder shall submit to the Board, on an annual basis, within 30 days after the permit expiration, a renewal application and the renewal fee set forth in N.J.A.C. 13:39-1.3(a)2. A permit holder that fails to submit the renewal application within 30 days after the permit expiration shall submit the late renewal fee set forth in N.J.A.C. 13:39-1.3(a)2 in addition to the renewal fee. A permit holder that continues to engage in the practice of pharmacy with an expired permit 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.

(c) The Board shall send a notice of renewal to each permit holder, at least 60 days prior to the expiration of the permit. If the notice to renew is not sent 60 days prior to the expiration date, no monetary penalty or fines shall apply to the permit holder for any unauthorized practice during the period following the permit expiration, not to exceed the number of days short of 60 before the renewal was issued.

Recodified from N.J.A.C. 13:39-4.1 and amended by R.2005 d.25, effective January 18, 2005.

See: 36 N.J.R. 3345(a), 37 N.J.R. 295(a).

Former N.J.A.C. 13:39-4.2, Display of permits, recodified to N.J.A.C. 13:39-4.3.

Amended by R.2007 d.351, effective November 19, 2007.
See: 38 N.J.R. 4630(a), 39 N.J.R. 4935(a).

Section was "Issuance of permits". Inserted designation (a); and added (b) and (c).

13:39-4.3 Display of permits

A permit issued by the Board for the operation of a pharmacy or other licensed establishment shall be conspicuously displayed.

Recodified from N.J.A.C. 13:39-4.2 and amended 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. 13:39-4.3, Death of owner or partner, recodified to N.J.A.C. 13:39-4.4.

13:39-4.4 Death of owner or partner

In the case of death of an individual owner or a partner, the permit issued to the deceased owner or to the partnership is terminated and shall be returned to the Board pursuant to N.J.A.C. 13:39-4.8. If the operation of the pharmacy is to be continued, the estate or heirs of the deceased partner and/or the remaining partners shall comply with the requirements set forth at N.J.A.C. 13:39-4.5.

(b) The applicant shall also pass the Multistate Jurisprudence Pharmacy Examination (MJPE). A passing score of not less than 75 shall be attained. If an applicant fails the examination, he or she shall be required to repeat the examination.

(c) If the applicant should fail either the NAPLEX or the MJPE three times, the Board may direct the applicant to take remedial courses at an accredited school or college of pharmacy prior to retaking the failed examination(s).

Recodified from N.J.A.C. 13:39-2.10 and amended by R.1999 d.214, effective July 19, 1999.

See: 31 N.J.R. 1151(a), 31 N.J.R. 1932(a).

Rewrote the section. Former N.J.A.C. 13:39-2.1, Education requirements, recodified to N.J.A.C. 13:39-2.2.

Amended by R.2005 d.25, effective January 18, 2005.

See: 36 N.J.R. 3345(a), 37 N.J.R. 295(a).

In (c), substituted "failed" for "field" at the end.

13:39-2.2 Education requirements

(a) An applicant for the NAPLEX and MJPE examinations shall have been duly granted or have fully completed all the requirements for graduation of a minimum five-year pharmacy course leading to a degree of Bachelor of Science in pharmacy or Doctor of Pharmacy given in a school or college of pharmacy accredited by the American Council of Pharmaceutical Education (ACPE).

(b) Before being admitted to the NAPLEX AND MJPE examinations, either a transcript of the applicant's record or a certificate by the registrar of the school or college of pharmacy attended must be supplied stating that the applicant has either graduated or has completed all of the requirements for graduation. If the transcript or certificate does not state that the applicant has graduated or has completed all the graduation requirements, the Board may require other forms of proof to be supplied by the applicant.

Amended by R.1994 d.351, effective July 18, 1994.

See: 26 N.J.R. 1596(a), 26 N.J.R. 2905(b).

Recodified from N.J.A.C. 13:39-2.1 and amended by R.1999 d.214, effective July 19, 1999.

See: 31 N.J.R. 1151(a), 31 N.J.R. 1932(a).

In (a), substituted a reference to NAPLEX and MJPE examinations for a reference to written examinations. Former N.J.A.C. 13:39-2.2, Application to be filed, recodified to N.J.A.C. 13:39-2.3.

Amended by R.2005 d.25, effective January 18, 2005.

See: 36 N.J.R. 3345(a), 37 N.J.R. 295(a).

In (b), inserted "NAPLEX AND MJPE" preceding "examinations".

13:39-2.3 Application for examinations

An applicant for the NAPLEX and MJPE examinations shall file an application for such examinations at least 30 days prior to the date of the respective examination unless the 30-day requirement is waived by the Board because of extenuating circumstances. The application fee set forth in N.J.A.C. 13:39-1.3 shall also be submitted.

Amended by R.1990 d.551, effective November 19, 1990.

See: 22 N.J.R. 2395(b), 22 N.J.R. 3499(b).

Changed filing deadline from 60 to 30 days.

Recodified from N.J.A.C. 13:39-2.2 and amended by R.1999 d.214, effective July 19, 1999.

See: 31 N.J.R. 1151(a), 31 N.J.R. 1932(a).

Substituted a reference to NAPLEX and MJPE examinations for a reference to written examinations. Former N.J.A.C. 13:39-2.3, Birth certificate, repealed.

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.

13:39-2.4 Age requirement

An applicant who is not of legal age, that is, the age of majority in the State of New Jersey, but who has otherwise met the application requirements, with the exception of the internship requirement, may be admitted to the NAPLEX and MJPE examinations; however, the applicant shall not be eligible for licensure until attaining legal age.

Recodified from N.J.A.C. 13:39-2.6 and amended by R.1999 d.214, effective July 19, 1999.

See: 31 N.J.R. 1151(a), 31 N.J.R. 1932(a).

Substituted a reference to NAPLEX and MJPE examinations for a reference to written examinations. Former N.J.A.C. 13:39-2.7, Proof of character, recodified to N.J.A.C. 13:39-2.8.

Recodified from N.J.A.C. 13:39-2.7 by R.2005 d.25, effective January 18, 2005.

See: 36 N.J.R. 3345(a), 37 N.J.R. 295(a).

13:39-2.5 Proof of character

(a) An applicant for the NAPLEX and MJPE examinations shall submit, in advance, an application containing evidence of good moral character which is an ongoing requirement for licensure, and evidence that he or she:

1. Is not presently engaged in drug or alcohol use that is likely to impair the ability to practice pharmacy with reasonable skill and safety. For purposes of this section, the term "presently" means at this time or any time within the previous 365 days;
2. Has not been convicted of violating any law of this State or any other state of the United States relating to controlled dangerous substances or other habit-forming drugs;
3. Has not been convicted of violating any law relating to the practice of pharmacy;
4. Has not been convicted of a crime involving moral turpitude; and
5. Has not had his or her license or, if a permit holder, his or her permit, suspended or revoked in the last five years as a result of any administrative or disciplinary proceedings in this or any other jurisdiction which proved the applicant to be in violation of any laws, rules or regulations pertaining to the practice of pharmacy, and that the applicant is not currently under suspension or revocation.

Amended by R.1994 d.351, effective July 18, 1994.

See: 26 N.J.R. 1596(a), 26 N.J.R. 2905(b).

Recodified from N.J.A.C. 13:39-2.7 and amended by R.1999 d.214, effective July 19, 1999.

See: 31 N.J.R. 1151(a), 31 N.J.R. 1932(a).

In (a), substituted a reference to NAPLEX and MJPE examinations for a reference to written examinations in the introductory paragraph. Former N.J.A.C. 13:39-2.8, Proof of identity of applicant, recodified to N.J.A.C. 13:39-2.9.

Recodified from N.J.A.C. 13:39-2.8 and amended by R.2005 d.25, effective January 18, 2005.

See: 36 N.J.R. 3345(a), 37 N.J.R. 295(a).

13:39-2.6 Criminal history background check

An applicant for initial licensure as a pharmacist in the State shall submit his or her name, address and fingerprints for purposes of a criminal history background check to be conducted by the State of New Jersey pursuant to N.J.S.A. 45:1-28 et seq., P.L. 2002, c. 104, to determine whether criminal history record information exists which may be considered by the Board in determining whether the applicant shall be licensed in the State.

New Rule, R.2005 d.25, effective January 18, 2005.
See: 36 N.J.R. 3345(a), 37 N.J.R. 295(a).

13:39-2.7 Proof of identity of applicant

An applicant for the NAPLEX and MJPE examinations shall submit to the Board 30 days in advance of the date of the examinations a passport photograph mounted on a document to be supplied by the Board requesting certain identification information.

Amended by R.1990 d.551, effective November 19, 1990.

See: 22 N.J.R. 2395(b), 22 N.J.R. 3499(b).

Submission deadline changed from 60 to 30 days in advance.

Recodified from N.J.A.C. 13:39-2.8 and amended by R.1999 d.214, effective July 19, 1999.

See: 31 N.J.R. 1151(a), 31 N.J.R. 1932(a).

Substituted a reference to NAPLEX and MJPE examinations for a reference to written examinations, and substituted a reference to passport photographs for a reference to bust photographs. Former N.J.A.C. 13:39-2.9, Alleged violations of the Pharmacy Act, recodified to N.J.A.C. 13:39-2.10.

Recodified from N.J.A.C. 13:39-2.9 and amended by R.2005 d.25, effective January 18, 2005.

See: 36 N.J.R. 3345(a), 37 N.J.R. 295(a).

Deleted "written" following "in advance of the date". Former N.J.A.C. 13:39-2.7, Age requirement, recodified to N.J.A.C. 13:39-2.4.

13:39-2.8 Alleged violations of the Pharmacy Act

If an applicant for any Board examination is being investigated for any alleged violation of the Pharmacy Act, N.J.S.A. 45:14-1 et seq., the Board in its discretion may deny the applicant the opportunity to take the examination.

Recodified from N.J.A.C. 13:39-2.9 and amended by R.1999 d.214, effective July 19, 1999.

See: 31 N.J.R. 1151(a), 31 N.J.R. 1932(a).

Substituted "being investigated for" for "involved in" following "examination is". Former N.J.A.C. 13:39-2.10, Written examinations; grades, recodified to N.J.A.C. 13:39-2.1.

Recodified from N.J.A.C. 13:39-2.10 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. 13:39-2.8, Proof of character, recodified to N.J.A.C. 13:39-2.5.

13:39-2.9 Applicants educated in a foreign country

(a) Any pharmacist applicant with a degree from a country where the primary language is other than English, prior to being granted initial licensure as a professional pharmacist in this State, shall submit to the Board evidence that he or she has been certified within two years of applying for licensure in the State by the Foreign Pharmacy Graduate Examination Committee (FPGEC) of the National Association of Boards of Pharmacy.

(b) Any pharmacist applicant with a degree from a country other than the United States, where the primary language is English, prior to being granted initial licensure as a professional pharmacist in this State, shall submit to the Board evidence that he or she has successfully completed the Foreign Pharmacy Graduate Equivalency Examination (FPGEE).

(c) A request for waiver of the FPGEC certificate shall delineate good cause for the waiver request. The Board may, after due consideration and within its own discretion,

waive the TOEFL examination and the Test of Spoken English (TSE) examination components of the FPGEC certification process.

(d) Notwithstanding (a) through (c) above, the provisions of this section shall not apply to any pharmacist applicant who has graduated from a pharmacy school which has been accredited by the American Council of Pharmaceutical Education (ACPE), or has graduated from a pharmacy school that has been accredited by a program that has been deemed ACPE-equivalent by ACPE.

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).

Rewrote the section.

Recodified from N.J.A.C. 13:39-3.11 and amended by R.2005 d.25, effective January 18, 2005.

See: 36 N.J.R. 3345(a), 37 N.J.R. 295(a).

Added (d). Former N.J.A.C. 13:39-2.9, Proof of identity of applicant, recodified to N.J.A.C. 13:39-2.7.

13:39-2.10 Authorization to practice; display of license

(a) An applicant who has successfully satisfied all Board requirements for licensure and has been approved by the Board to be licensed shall receive an authorization signed by the Executive Director of the Board granting the applicant the right to practice pharmacy in the State of New Jersey until such time as an initial license may be issued. The licensee shall maintain such authorization on his or her person at all times while engaging in the practice of pharmacy until the initial license is issued.

(b) Upon issuance of a license, the initial wall license and current biennial renewal license shall be conspicuously displayed in the registered pharmacist's principal place of employment.

(c) A registered pharmacist who is employed by more than one licensed pharmacy in the State shall maintain the wallet-sized license issued by the Board on his or her person when he or she is working at a location where his or her wall license and current biennial renewal license are not on display.

Amended by R.1999 d.214, effective July 19, 1999.

See: 31 N.J.R. 1151(a), 31 N.J.R. 1932(a).

Substituted a reference to the Executive Director for a reference to the Secretary, and substituted a reference to initial licenses for a reference to original certificates of registration.

Recodified from N.J.A.C. 13:39-3.1 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. 13:39-2.10, Alleged violations of the Pharmacy Act, recodified to N.J.A.C. 13:39-2.8.

13:39-2.11 Replacement license

A replacement initial license or renewal license shall be issued by the Board upon payment of a fee as prescribed in N.J.A.C. 13:39-1.3 and upon submission of proof of the applicant's identity and reasonable proof of the loss or destruction of the initial license or renewal license, or upon return of the damaged initial license or renewal license to the Board.

Amended by R.1999 d.214, effective July 19, 1999.

See: 31 N.J.R. 1151(a), 31 N.J.R. 1932(a).

Substituted references to licenses for references to certificates of registration throughout.

Recodified from N.J.A.C. 13:39-3.2 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.

13:39-2.12 Change of name

If a registered pharmacist legally changes the name under which he or she engages in the practice of pharmacy, the pharmacist shall notify the Board within 30 days of such change. The registered pharmacist shall submit original proof of the change of name or a certified copy of the court order or marriage certificate which shall be retained by the Board. When a replacement license is issued, the initial license shall be returned for cancellation and the pharmacist shall remit the required fee as prescribed in N.J.A.C. 13:39-1.3.

Amended by R.1999 d.214, effective July 19, 1999.

See: 31 N.J.R. 1151(a), 31 N.J.R. 1932(a).

Substituted references to licenses for references to certificates in the last sentence.

Recodified from N.J.A.C. 13:39-3.3 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.

13:39-2.13 Change of address of record; service of process

(a) A registered pharmacist shall notify the Board in writing of any change in his or her address of record within 30 days.

(b) Failure to notify the Board of any change in a registered pharmacist's address of record pursuant to (a) above may result in disciplinary action in accordance with N.J.S.A. 45:1-21(h) and N.J.A.C. 13:45C-1.3, and the imposition of penalties set forth in N.J.S.A. 45:1-25.

(c) Service of any administrative complaint or other Board-initiated process at a registered pharmacist's address of record shall be deemed adequate notice for the purposes of N.J.A.C. 1:1-7.1 and the commencement of any disciplinary proceedings.

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).

Substituted a reference to addresses of record for a reference to home addresses.

Recodified from N.J.A.C. 13:39-3.4 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.

13:39-2.14 Verification of licensure

A verification that the license of a registered pharmacist is in good standing shall be supplied by the Board upon written request and upon payment of the fee set forth in N.J.A.C. 13:39-1.3.

Amended by R.1999 d.214, effective July 19, 1999.

See: 31 N.J.R. 1151(a), 31 N.J.R. 1932(a).

Rewrote the section.

Recodified from N.J.A.C. 13:39-3.5 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.

13:39-2.15 Reproduction of initial license prohibited

The initial wall license, biennial license or wallet-sized license issued by the Board to any pharmacist shall not be reprinted, photographed, photostated, duplicated or reproduced by any other means either in whole or in part, except as provided in N.J.A.C. 13:39-2.11.

Amended by R.1999 d.214, effective July 19, 1999.

See: 31 N.J.R. 1151(a), 31 N.J.R. 1932(a).

Rewrote the section.

Recodified from N.J.A.C. 13:39-3.6 and amended by R.2005 d.25, effective January 18, 2005.

See: 36 N.J.R. 3345(a), 37 N.J.R. 295(a).

Substituted "initial" for "original" preceding "wall license" and amended the N.J.A.C. reference.

13:39-2.16 Biennial license renewal; administrative suspension

(a) A pharmacist shall renew his or her license for a period of two years from the last expiration date. The pharmacist shall submit a renewal application to the Board, along with the renewal fee set forth in N.J.A.C. 13:39-1.3, prior to the date of license expiration. A pharmacist who submits a renewal application within 30 days following the date of license expiration shall submit the renewal fee, as well as the late fee set forth in N.J.A.C. 13:39-1.3. A pharmacist who fails to submit a renewal application within 30 days of license expiration shall have his or her license suspended without a hearing. Such suspension shall be deemed an administrative suspension.

(b) A pharmacist who continues to engage in the practice of pharmacy with a suspended license 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.

(c) The Board shall send a notice of renewal to each pharmacist at least 60 days prior to the expiration of the license. If the notice to renew is not sent at least 60 days prior to the expiration date, no monetary penalties or fines shall be imposed upon the pharmacist for failure to renew.

New Rule, R.2005 d.25, effective January 18, 2005.

See: 36 N.J.R. 3345(a), 37 N.J.R. 295(a).

13:39-2.17 Reinstatement from administrative and disciplinary license suspensions

(a) A pharmacist who has had his or her license administratively suspended pursuant to N.J.A.C. 13:39-2.16 may apply to the Board for reinstatement within five years following the date of license expiration. A pharmacist applying for reinstatement shall submit:

1. A renewal application, including an affidavit of employment listing each job held during the period of license suspension, including the names, addresses, and telephone numbers of each employer;
2. All past due renewal fees set forth in N.J.A.C. 13:39-1.3;
3. A reinstatement fee set forth in N.J.A.C. 13:39-1.3;
4. Any outstanding penalties imposed by the Board; and

5. Evidence of having completed all delinquent continuing education credits consistent with the requirements of N.J.A.C. 13:39-3A to a maximum of five years or 75 credits.

(b) If the license has been administratively suspended for a period of more than five years, a pharmacist applying for reinstatement shall satisfy all requirements in (a)1 through 4 above and shall pass the MJPE and the NAPLEX.

(c) A pharmacist who has had his or her license suspended pursuant to disciplinary action taken by the Board may apply to the Board for reinstatement of his or her license at the conclusion of the suspension period. A pharmacist applying for reinstatement from a disciplinary suspension shall submit:

1. A reinstatement application, including an affidavit of employment listing each job held during the period of license suspension, including the names, addresses, and telephone numbers of each employer;
2. A reinstatement fee set forth in N.J.A.C. 13:39-1.3;
3. The applicable renewal fee(s) set forth in N.J.A.C. 13:39-1.3; and
4. Evidence of having met all conditions imposed by the Board pursuant to the disciplinary and/or reinstatement order(s).

New Rule, R.2005 d.25, effective January 18, 2005.
See: 36 N.J.R. 3345(a), 37 N.J.R. 295(a).

13:39-2.18 Inactive licensure

(a) A pharmacist may, upon application to the Board, choose inactive status. A pharmacist electing inactive status shall not engage in the practice of pharmacy in New Jersey for the entire biennial registration period. A licensee on inactive status may resume the practice of pharmacy in New Jersey upon application to the Board consistent with the following requirements:

1. If a licensee was practicing pharmacy in another state where he or she is licensed, and practiced for at least 1,000 hours within the two years immediately prior to the date of application for return to active status, the licensee shall remit payment of the renewal fee for the current biennial registration period set forth in N.J.A.C. 13:39-1.3;
2. If a licensee was practicing pharmacy in another state where he or she is licensed, but practiced for less than 1,000 hours within the two years immediately prior to the date of application for return to active status, the licensee shall submit evidence of having completed 30 credits of continuing education, consistent with the requirements set forth in N.J.A.C. 13:39-3A.1, within the two years immediately prior to the date of application. The licensee shall also remit the renewal fee for the current biennial registration period set forth in N.J.A.C. 13:39-1.3; and
3. If a licensee has not practiced pharmacy in another state during the inactive period, the licensee shall submit evidence of having completed 15 credits of continuing education per year, consistent with the requirements set forth in N.J.A.C. 13:39-3A to a maximum of 75 credits. At least 30 credits shall have been completed within the

two years immediately prior to the date of application to return to active status. The licensee shall also remit the renewal fee for the current biennial registration period set forth in N.J.A.C. 13:39-1.3.

New Rule, R.2005 d.25, effective January 18, 2005.
See: 36 N.J.R. 3345(a), 37 N.J.R. 295(a).

13:39-2.19 Steering prohibited

It shall be unlawful for a pharmacist to enter into an arrangement with a health care practitioner who is licensed to issue prescriptions for the purpose of directing or diverting patients to or from a specified pharmacy or restraining in any way a patient's freedom of choice to select a pharmacy.

New Rule, R.2005 d.25, effective January 18, 2005.
See: 36 N.J.R. 3345(a), 37 N.J.R. 295(a).

13:39-2.20 Responsibilities of pharmacists

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

(b) Any pharmacist found to have violated the Pharmacy Act, N.J.S.A. 45:14-1 et seq., and the rules in this chapter, shall be subject to disciplinary action.

New Rule, R.2005 d.25, effective January 18, 2005.
See: 36 N.J.R. 3345(a), 37 N.J.R. 295(a).

SUBCHAPTER 3. LICENSURE BY RECIPROCITY

13:39-3.1 Limitation of reciprocal licensure

(a) Reciprocal licensure of out-of-State pharmacists shall be limited to those pharmacists who have been duly licensed in mutually reciprocating states.

(b) An applicant for reciprocal licensure shall submit an application to the Board demonstrating satisfaction of the requirements set forth in N.J.A.C. 13:39-3.2.

(c) Applicants who have graduated from pharmacy schools which have not been accredited by the American Council on Pharmaceutical Education but who have been licensed by the District of Columbia, a reciprocating state or a United States territory shall be eligible for transfer of licensure if the Board is satisfied that the licensing procedures applicable to graduates of non-accredited schools in a state of licensure are equivalent to the Board's standards for licensure at the time initial licensure was obtained.

Amended by R.1999 d.214, effective July 19, 1999.
See: 31 N.J.R. 1151(a), 31 N.J.R. 1932(a).

In (a), substituted a reference to licensure for a reference to registration; and rewrote (b).
Recodified from N.J.A.C. 13:39-3.7 and amended by R.2005 d.25, effective January 18, 2005.
See: 36 N.J.R. 3345(a), 37 N.J.R. 295(a).

Added a new (b); recodified former (b) as (c). Former N.J.A.C. 13:39-3.1, License, recodified to N.J.A.C. 13:39-2.10.

13:39-3.2 Requirements for reciprocal licensure of pharmacist currently licensed in another jurisdiction

(a) In order for a pharmacist currently licensed in another jurisdiction to obtain a license by reciprocity in this State, an applicant shall submit a completed application and the licensure fee set forth in N.J.A.C. 13:39-1.3. The completed application shall include evidence that:

1. The applicant has attained the age of 18;
2. The applicant is of good moral character and satisfies the requirements of N.J.A.C. 13:39-3.3;
3. The applicant has engaged in the practice of pharmacy for a period of at least 1,000 hours within the last two years or has met the internship requirements set forth at N.J.A.C. 13:39-8, within the one-year period immediately preceding the date of application;
4. The applicant obtained initial licensure by examination and that the license is in good standing;
5. Any other license granted to the applicant by any other state has not been suspended, revoked or otherwise restricted for any reason except the failure to renew or for the failure to obtain the required continuing education credits in any state where the applicant is currently licensed but not engaged in the practice of pharmacy; and
6. The applicant has graduated and received a professional degree from a college or school of pharmacy that has been accredited by the American Council of Pharmaceutical Education (ACPE), or has graduated from a pharmacy school that has been accredited by a program that has been deemed ACPE-equivalent by ACPE.

(b) In addition to the requirements set forth in (a) above, an applicant for licensure by reciprocity shall also satisfy all licensure transfer requirements imposed by the National Association of Boards of Pharmacy.

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. 13:39-3.2, Duplicate license, recodified to N.J.A.C. 13:39-2.11.

13:39-3.3 Proof of character

(a) An applicant for licensure by reciprocity shall submit, as part of his or her licensure application, evidence that he or she:

1. Is not presently engaged in drug or alcohol use that is likely to impair the ability to practice pharmacy with reasonable skill and safety. For purposes of this section, the term "presently" means at this time or any time within the previous 365 days;
2. Has not been convicted of violating any law of this State or any other state of the United States relating to controlled dangerous substances or other habit-forming drugs;
3. Has not been convicted of violating any law relating to the practice of pharmacy;
4. Has not been convicted of a crime involving moral turpitude; and
5. Has not had his or her license suspended or revoked in the last five years as a result of any disciplinary

proceedings in this or any other jurisdiction which proved the applicant to be in violation of any laws, rules or regulations pertaining to the practice of pharmacy, and that the applicant is not currently under such suspension or revocation.

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. 13:39-3.3, Change of name, recodified to N.J.A.C. 13:39-2.12.

13:39-3.4 Proof of identity of applicant

An applicant for licensure by reciprocity shall submit a passport photograph mounted on a document to be supplied by the Board requesting certain identification information.

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. 13:39-3.4, Change of address of record, recodified to N.J.A.C. 13:39-2.13.

13:39-3.5 Alleged violations of the Pharmacy Act

If an applicant for licensure by reciprocity is being investigated for any alleged violation of the Pharmacy Act, N.J.S.A. 45:14-1 et seq., the Board in its discretion may deny the applicant a license to engage in the practice of pharmacy in this State.

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. 13:39-3.5, Certification of records, recodified to N.J.A.C. 13:39-2.14.

13:39-3.6 Criminal history background check

An applicant for licensure by reciprocity in the State shall submit his or her name, address and fingerprints for purposes of a criminal history background check to be conducted by the State of New Jersey pursuant to N.J.S.A. 45:1-28 et seq., P.L. 2002, c.104, to determine whether criminal history record information exists which may be considered by the Board in determining whether the applicant shall be licensed in the State.

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. 13:39-3.6, Reproduction of original license prohibited, recodified to N.J.A.C. 13:39-2.15.

13:39-3.7 Multistate Jurisprudence Pharmacy Examination

(a) An applicant for reciprocal licensure shall pass the Multistate Jurisprudence Pharmacy Examination. A passing score of not less than 75 shall be attained. If an applicant fails the examination, he or she shall be required to repeat the examination.

(b) If the applicant for reciprocal licensure fails the examination three times, the Board may direct the applicant to take remedial courses at an accredited school or college of pharmacy prior to retaking the law examination.

Amended by R.1999 d.214, effective July 19, 1999.

See: 31 N.J.R. 1151(a), 31 N.J.R. 1932(a).

Rewrote the section.

Recodified from N.J.A.C. 13:39-3.14 and amended by R.2005 d.25, effective January 18, 2005.

See: 36 N.J.R. 3345(a), 37 N.J.R. 295(a).

In (a), substituted "score" for "grade" and "shall" for "will". Former N.J.A.C. 13:39-3.7, Limitation of reciprocal licensure, recodified to N.J.A.C. 13:39-3.1.

SUBCHAPTER 3A. CONTINUING EDUCATION

13:39-3A.1 Continuing education credit hour requirements

(a) Each applicant for biennial license renewal shall complete a minimum of 30 credits of continuing education during the preceding biennial period, except that the Board shall not require completion of continuing education credits for an applicant's initial license renewal. At least 10 of the continuing education credits shall be obtained through didactic instruction. For purposes of this paragraph, "didactic instruction" means in-person instruction and may include telephonic or electronic instruction that is interactive, but shall not include videotaped instruction. For the biennial renewal period commencing May 2005 and thereafter, at least three continuing education credits shall be obtained in pharmacy law applicable to the practice of pharmacy in New Jersey.

(b) Ten credits of continuing education may be carried over into a succeeding biennial period only if such credits were earned during the last six months of the preceding biennial period and were not previously reported.

Amended by R.2005 d.25, effective January 18, 2005.

See: 36 N.J.R. 3345(a), 37 N.J.R. 295(a).

In (a), added the fourth sentence.

13:39-3A.2 Criteria for continuing education credit

(a) A licensee may obtain continuing education credit from the following categories:

1. Programs or courses offered by American Council of Pharmaceutical Education approved providers;
2. Programs and courses that have received prior Board approval pursuant to N.J.A.C. 13:39-3A.6;
3. Graduate course work relevant to the practice of pharmacy, taken at an accredited college or university, beyond that required for professional licensure;
4. Participation in teaching and/or research appointments;
5. Participation as a preceptor in externship programs;
6. Participation as a preceptor in internship programs; and
7. Publication of an article related to the practice of pharmacy in a peer-reviewed professional journal.

13:39-3A.3 Continuing education credit hour calculations

(a) Credit for continuing education shall be granted as follows for each biennial license period:

1. Attendance at approved programs or courses shall be granted one credit for each hour of attendance. Credit

shall not be granted for programs or courses which are less than one contact hour in duration, which is defined as 50 minutes of actual attendance in a program or course of study. One half credit shall be granted for each 30 minute segment of a program or course that is more than one contact hour in duration. Completion of an entire program or course is required in order to receive any continuing education credit for the program or course.

2. Successful completion of graduate course work related to the practice of pharmacy at an accredited college or university beyond that which is required for professional licensure shall be granted three continuing education credits for each course credit awarded.

3. Teaching and research appointments related to the practice of pharmacy shall be granted three continuing education credits for each new program or course taught or subject matter researched by a licensee, to a maximum of six credits. "New," in this paragraph, means a program, course or subject matter which the licensee has never taught or researched before in any educational or practice setting. A licensee who is employed as a teacher and/or as a researcher on a full-time basis shall not be eligible to obtain continuing education credit for such activities.

4. Participation as a preceptor in an externship program, upon prior approval by a college of pharmacy, shall be granted three continuing education credits per student to a maximum of six credits.

5. Participation as a preceptor in an internship program shall be granted three continuing education credits per 160 hours of work performed by the intern(s) and supervised by the licensee, to a maximum of six credits.

6. Publication of an article related to the practice of pharmacy in a peer-reviewed professional journal shall be granted three continuing education credits per article to a maximum of six credits.

(b) The Board shall not grant credit for, or approve as a component of a continuing education program, participation in the routine business portion of any meeting of a pharmaceutical organization or any presentation that is offered to sell a product or promote a business enterprise.

13:39-3A.4 Continuing education credit hour reporting procedure

(a) A licensee shall specify on his or her application for biennial license renewal the number of continuing education credits completed. Falsification of any information contained in the renewal application may result in an appearance before the Board and the assessment of penalties and/or license suspension pursuant to N.J.S.A. 45:1-21 et seq.

(b) A licensee shall maintain all documentation concerning the completion of continuing education requirements for a period of five years from the completion of the credit hours and shall submit such documentation to the Board upon request. Such documentation shall consist of:

1. For programs offered by American Council of Pharmaceutical Education approved providers, a certificate of completion from the course or program;
2. For programs and courses approved by the Board, the sponsors' written verification of attendance;
3. For teaching or research appointments in an academic setting, a statement from the chairperson of the department verifying completion of the assignment;
4. For research appointments in an industrial setting, a statement from the project coordinator verifying completion of the assignment;
5. For participation as a preceptor in an externship program, a certificate from the college of pharmacy;
6. For participation as a preceptor in an internship program, a certificate from the Board; and
7. For publications in a peer-reviewed professional journal, submission of the published article.

(c) The Board shall audit licensees on a random basis at the end of each biennial period to determine compliance with continuing education requirements.

13:39-3A.5 Waiver of continuing education requirements

(a) The Board may waive continuing education requirements on an individual basis for reasons of military service, hardship, illness or disability.

(b) A licensee seeking a waiver of continuing education requirements shall apply to the Board in writing and set forth with specificity the reasons for requesting the waiver. The licensee shall also provide the Board with such additional information as the Board may request in support of the application for waiver.

(c) A waiver of continuing education requirements granted pursuant to this section shall be effective only for the biennial period in which such waiver is granted. If the condition(s) which necessitated the waiver continues into the next biennial period, a licensee shall apply to the Board for a renewal of such waiver for the new biennial period.

13:39-3A.6 Responsibilities of continuing education sponsors

(a) A continuing education sponsor shall receive prior Board approval for a program or course if the sponsor provides, in writing on a form provided by the Board, information which demonstrates that the program or course meets the following requirements:

1. The program or course is offered in a subject matter relevant to the practice of pharmacy;
2. The program or course is at least one contact hour in length; and
3. The program or course is conducted by a qualified instructor or discussion leader who submits a curriculum vitae and who is:
 - i. A pharmacist with a B.S. in Pharmacy or a Pharm.D. with at least five years of experience;
 - ii. A pharmacist with a B.S. in Pharmacy or a Pharm.D. with expertise in the program or course subject area;
 - iii. A pharmacist with a B.S. in Pharmacy or a Pharm.D. who is certified by a nationally recognized board or association; or
 - iv. A licensed health care professional who demonstrates special expertise in the lecture subject area.

(b) A continuing education sponsor may request approval for a program or course conducted by an individual who possesses expertise in a subject area relevant to the practice of pharmacy, provided that the program or course to be conducted by that individual satisfies the requirements of (a)1 and 2 above.

(c) Applications for pre-approval of continuing education programs or courses shall be submitted by the continuing education sponsor on a form provided by the Board at least 45 days prior to the date the program or course is to be offered. Incomplete applications shall be returned to the sponsor.

(d) The Board shall approve only such continuing education programs and courses as are available and advertised on a reasonable nondiscriminatory basis to all persons licensed to practice pharmacy in the State. The Board shall maintain a list of all approved programs and courses at the Board office and shall furnish the list to licensees upon request.

(e) A continuing education sponsor shall not make substantive changes to an approved program or course, such as a change in program or course content or instructor, without prior Board approval.

(f) The continuing education sponsor shall monitor attendance at, or ensure completion of, each approved program or course and furnish to each enrollee a verification of attendance which shall include at least the following information:

1. The title, date and location of the program or course offering;
2. The name of the program or course presenter;

3. The name and certificate number of the program or course presented;

4. The number of continuing education credits awarded; and

5. The name, address, telephone number and signature of the sponsor, or if the sponsor is an association or organization, the signature of an officer or responsible party of the association or organization.

(g) The continuing education sponsor shall submit the fee set forth at N.J.A.C. 13:39-1.3(a)1xii for each submission of program or course offerings.

(h) The continuing education sponsor shall maintain a list of all attendees who completed each approved program or course for a period of five years from the date the program or course was offered.

13:39-3A.7 Monitoring of continuing education programs or courses

A Board member or a Board representative may monitor an approved program or course without prior notification to the continuing education sponsor.

SUBCHAPTER 4. PHARMACY PERMIT REQUIREMENTS

13:39-4.1 New pharmacies; eligibility and application

(a) A permit application shall be submitted to the Board by every person or corporation desiring to operate a new pharmacy. Such application shall be made on a form furnished by the Board.

(b) The permit application shall indicate the exact intended location and plan or physical arrangement of the proposed pharmacy area and shall indicate any premises contiguous to but not necessarily a part of the pharmacy.

(c) The permit application shall bear the exact trade name, if any; the corporate names, if any; the name and addresses of the owners and operators, if a sole proprietorship, partnership, limited liability partnership or limited liability company; the names and addresses of all officers and stockholders and the names and addresses of all principals duly licensed to write prescriptions if the pharmacy is not a publicly traded corporation; and the names and addresses of the officers, if a publicly traded corporation.

(d) The permit application shall include the name of the registered pharmacist-in-charge who shall be a registered pharmacist in good standing in the State of New Jersey.

(e) No person, business entity or equity holder of the business entity shall be eligible for a new permit or a renewal thereof who is not of high moral character or against whom there is pending any indictment or any alleged violation of local, State or Federal law pertaining to the practice of pharmacy or the dispensing of controlled dangerous substances or any drug under N.J.S.A. 24:21-2.

(f) A person submitting an application may be interviewed by the Board to review his or her qualifications and eligibility.

(g) Before a permit may be issued to an applicant, the Board shall inspect and approve the premises, fixtures and equipment of the new pharmacy to ensure compliance with this subchapter and all relevant statutes, regulations and ordinances.

(h) Upon approval of the permit application, the Board shall issue a permit number that will allow the applicant to place prescription legend drugs in stock.

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 (d), substituted a reference to registered pharmacists-in-charge for a reference to pharmacists-in-charge; inserted a new (g); and recodified former (g) as (h).

Recodified from N.J.A.C. 13:39-4.7 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. 13:39-4.1, Issuance of permits, recodified to N.J.A.C. 13:39-4.2.

13:39-4.2 Issuance of permits

All permits shall be issued by the Board in the name of the pharmacy or other licensed establishment for the operation of which the permit is issued.

Recodified from N.J.A.C. 13:39-4.1 and amended by R.2005 d.25, effective January 18, 2005.

See: 36 N.J.R. 3345(a), 37 N.J.R. 295(a).

Former N.J.A.C. 13:39-4.2, Display of permits, recodified to N.J.A.C. 13:39-4.3.

13:39-4.3 Display of permits

A permit issued by the Board for the operation of a pharmacy or other licensed establishment shall be conspicuously displayed.

Recodified from N.J.A.C. 13:39-4.2 and amended 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. 13:39-4.3, Death of owner or partner, recodified to N.J.A.C. 13:39-4.4.

13:39-4.4 Death of owner or partner

In the case of death of an individual owner or a partner, the permit issued to the deceased owner or to the partnership is terminated and shall be returned to the Board pursuant to N.J.A.C. 13:39-4.8. If the operation of the pharmacy is to be continued, the estate or heirs of the deceased partner and/or the remaining partners shall comply with the requirements set forth at N.J.A.C. 13:39-4.5.

Amended by R.1999 d.214, effective July 19, 1999.

See: 31 N.J.R. 1151(a), 31 N.J.R. 1932(a).

Substituted "is terminated and shall be returned to the Board pursuant to N.J.A.C. 13:39-4.8" for "becomes null and void" at the end of the first sentence.

Recodified from N.J.A.C. 13:39-4.3 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 second sentence. Former N.J.A.C. 13:39-4.4, Change of ownership, recodified to N.J.A.C. 13:39-4.5.

13:39-4.5 Change of ownership

(a) Whenever there is any change in ownership of the business entity holding a permit to operate a pharmacy, the new ownership of such entity shall apply for a new permit on a form prescribed and furnished by the Board and pay a fee pursuant to N.J.A.C. 13:39-1.3. The new owner(s) of such entity shall not operate a pharmacy under an existing permit for more than 60 days following a change in ownership. Before a permit may be issued to the new owner(s) of the business entity, the Board shall inspect and approve the fixtures, equipment and inventory of the pharmacy to ensure compliance with this subchapter and all relevant statutes, regulations and ordinances, and shall require evidence of the transfer of ownership and an inventory of controlled substances being transferred to the new owner(s).

(b) Upon a change in ownership pursuant to (a) above, the new ownership of such entity shall ensure that the prescription and profile records of the previous pharmacy are maintained pursuant to N.J.A.C. 13:39-7.6 and 7.19 after the date of acquisition.

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).

Rewrote the section.

Recodified from N.J.A.C. 13:39-4.4 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. 13:39-4.5, Change of corporate officers or stockholders of public companies, recodified to N.J.A.C. 13:39-4.6.

13:39-4.6 Change of corporate officers or stockholders of a publicly traded corporation

If there is 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, the corporation shall file an affidavit with the Board within 30 days indicating the changes that have taken place and any other information requested by the Board.

Recodified from N.J.A.C. 13:39-4.5 and amended by R.2005 d.25, effective January 18, 2005.

See: 36 N.J.R. 3345(a), 37 N.J.R. 295(a).

Inserted "of a publicly traded corporation" preceding ", the corporation shall file". Former N.J.A.C. 13:39-4.6, Change of location; remodeling of premises, recodified to N.J.A.C. 13:39-4.7.

13:39-4.7 Change of location; remodeling of premises

(a) Whenever a pharmacy or licensed establishment changes location, the pharmacy or licensed establishment shall apply for a new permit on a form prescribed and furnished by the Board. The pharmacy or licensed establishment shall pay a fee for the new permit pursuant to N.J.A.C. 13:39-1.3. The permit holder shall not operate a pharmacy under an existing permit for more than 60 days following a change of location. Before a permit may be issued to the permit holder for the new location, the Board shall inspect and approve the premises, fixtures, equipment and inventory of the new location to ensure compliance with this subchapter and all relevant statutes, regulations and ordinances.

(b) Prior to the remodeling of a pharmacy, pharmacy department or licensed establishment, where such remodeling entails a physical change of location or size of the prescription area within the premises or a change of the physical specifications of the licensed premises, it shall be necessary to notify the Board at least 30 days in advance on a form prescribed by the Board. The permit holder shall not operate a pharmacy under an existing permit for more than 60 days following the remodeling of a pharmacy. Within 60 days of the remodeling, the Board shall inspect and approve the premises, fixtures, equipment and inventory of the remodeled pharmacy to ensure compliance with this subchapter and all relevant statutes, regulations and ordinances.

Amended by R.1999 d.214, effective July 19, 1999.

See: 31 N.J.R. 1151(a), 31 N.J.R. 1932(a).

Rewrote (a); and in (b), added the second and third sentences.

Recodified from N.J.A.C. 13:39-4.6 and amended 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. 13:39-4.7, New pharmacies; eligibility and application, recodified to N.J.A.C. 13:39-4.1.

13:39-4.8 Discontinued pharmacies

(a) Whenever a pharmacy is terminated by suspension, retirement or death of the owner, sale or other cause including insolvency, the permit holder shall remove all drug signs from both the inside and outside of the discontinued pharmacy and shall notify the Board of the location of prescription records. The permit holder shall return the permit to the Board for cancellation within 30 days of the closing. Prescription records and other information may be requested by the Board as outlined in N.J.A.C. 13:39-7.6.

(b) Whenever a pharmacy is to be discontinued, the permit holder shall immediately notify by telephone the State Board of Pharmacy, the Office of Drug Control and the Drug Enforcement Administration of the proposed closing at least 15 days beforehand, followed by a letter in writing to those agencies. All medication (both prescription legend and controlled drugs) shall remain on the licensed pharmacy premises with all licenses and registrations in effect until such medications are disposed of in the manner prescribed by the above agencies.

Amended by R.1999 d.214, effective July 19, 1999.

See: 31 N.J.R. 1151(a), 31 N.J.R. 1932(a).

In (a), changed N.J.A.C. reference.

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.

13:39-4.9 Availability of records upon termination of business

(a) When a pharmacy ceases operation as the result of a suspension, retirement or death of the owner, sale or other cause including insolvency, the licensee, or the one responsible for supervising the disposition of the practice, shall make every effort to notify patrons of their right to retrieve currently valid prescriptions and the location of the prescriptions and profile records for a six-month period following notice, using all of the following methods:

1. Notification in writing to the Board;
2. Publication, once weekly for two successive weeks in a newspaper whose circulation encompasses the major area of the licensee's former practice, of a notice advising patrons of the right to retrieve their prescriptions and the location of the prescriptions for a six-month period following publication; and
3. A sign placed in the pharmacy location informing the patrons of the right to retrieve their prescriptions and the location of the prescriptions.

Recodified from N.J.A.C. 13:39-5.7 and amended 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. 13:39-4.9, Business hours, recodified to N.J.A.C. 13:39-4.10.

13:39-4.10 Business hours; unauthorized closing

(a) All pharmacies shall be kept open for the transaction of business at least 40 hours per week and at least five days per week.

(b) If any permanent changes are made in the opening or closing hours of a pharmacy or other Board-licensed establishment, the Board office shall be notified in writing of these changes within 30 days.

(c) A notice shall be conspicuously displayed on the exterior of any pharmacy or other Board-licensed establishment indicating any temporary changes in the opening or closing hours of the pharmacy or establishment, or indicating a temporary closing of the pharmacy or establishment whenever such changes occur.

(d) Any temporary closing of a pharmacy or other Board-licensed establishment for more than 48 hours shall be reported to and approved by the Board. Notification to the Board shall include contingency plans for accessing patient records. Any temporary closing of more than 48 hours without prior Board approval shall result in the pharmacy being deemed a discontinued pharmacy requiring compliance with the requirements of N.J.A.C. 13:39-4.8.

Amended by R.1994 d.351, effective July 18, 1994.

See: 26 N.J.R. 1596(a), 26 N.J.R. 2905(b).

Recodified from N.J.A.C. 13:39-4.9 and amended by R.2005 d.25, effective January 18, 2005.

See: 36 N.J.R. 3345(a), 37 N.J.R. 295(a).

In (b), inserted "permanent" following "If any"; added (c) and (d). Former N.J.A.C. 13:39-4.10, Duplicate permit, recodified to N.J.A.C. 13:39-4.11.

13:39-4.11 Replacement permit

A replacement permit may be issued by the Board upon payment of a fee pursuant to N.J.A.C. 13:39-1.3 and submission of an affidavit describing the loss or destruction of the permit originally issued, or upon return of the damaged permit.

Recodified from N.J.A.C. 13:39-4.10 and amended by R.2005 d.25, effective January 18, 2005.

See: 36 N.J.R. 3345(a), 37 N.J.R. 295(a).

Substituted "replacement" for "duplicate". Former N.J.A.C. 13:39-4.11, Change of name, recodified to N.J.A.C. 13:39-4.12.

13:39-4.12 Change of name

(a) A change in the name of a pharmacy or other Board-licensed establishment shall be made upon the submission to the Board for approval of the new name and of prescription labels bearing the new name.

(b) The Board shall issue an amended permit bearing the new name upon return of the permit bearing the previous name to the Board for cancellation and payment of the permit fee as prescribed in N.J.A.C. 13:39-1.3.

Recodified from N.J.A.C. 13:39-4.11 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 (h). Former N.J.A.C. 13:39-4.12, Reproduction of permits, recodified to N.J.A.C. 13:39-4.13.

13:39-4.13 Reproduction of permits

(a) Any permit issued by the Board for the operation of a pharmacy or other board-licensed establishment may only be photocopied for State agencies and other business entities with whom the permit holder does pharmacy related business.

(b) Any reproduction of a pharmacy permit by a permit holder for any unlawful purpose shall subject a permit holder to disciplinary action pursuant to N.J.S.A. 45:1-21.

Recodified from N.J.A.C. 13:39-4.12 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. 13:39-4.13, Certification of records, repealed.

13:39-4.14 Permitting of pharmacy department

(a) If the area for which a pharmacy permit is sought is less than the total store area of the enterprise, the area subject to permit shall be known as the "Pharmacy Department."

(b) The holder of a permit to operate a pharmacy department and the registered pharmacist-in-charge of the department shall comply with all requirements in this chapter and shall also be subject to the following additional requirements:

1. The pharmacy department shall be 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. Any entrance to the pharmacy department shall be capable of being locked and connected to a security device or other Board approved security system.

2. The registered pharmacist on duty shall be responsible for keeping the pharmacy department secure and locked and the alarm system turned on at all times when he or she is not present within the department, except as provided in N.J.A.C. 13:39-6.4, and shall be responsible for the security of the keys to the department.

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

4. The hours that the department is open and the name of the registered pharmacist-in-charge shall be posted in plain view at the entrance to the department and at the public entrance to the enterprise containing the department.

5. When the enterprise in which the department is located maintains different store hours from the pharmacy department, all advertising, announcements, signs or statements indicating store hours and the presence of the pharmacy department shall clearly and distinctly indicate the hours that the department is open.

6. The pharmacy department shall have 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.

7. The telephone number of the registered pharmacist-in-charge shall be available in the office of the manager of the establishment.

8. There shall be provided a secure area for the receiving of prescription drugs from suppliers. No prescription drug shall be accepted from any supplier during the hours the pharmacy department is closed unless adequate security for the storage of department shipments has been provided.

9. If a drop-off device is utilized for prescriptions it shall be of a one-way, irretrievable design.

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.

13:39-4.15 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.

13:39-4.16 Steering prohibited

It shall be unlawful for a pharmacy permit holder to enter into an arrangement with a health care practitioner who is licensed to issue prescriptions for the purpose of directing or diverting patients to or from a specified pharmacy 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.

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 emergency 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).

13:39-4.17 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 Pharmacy Act, N.J.S.A. 45:14-1 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.

13:39-4.18 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.

(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 licensed 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. 13:39-5.8A and 5.8B or if the patient requested the refill from that pharmacy;

2. A central processing pharmacy, which is a licensed 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 licensed 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 licensed 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.

(d) Two or more licensed 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 name(s) or other personal identifier(s) of the pharmacist(s) or pharmacy technician(s) and the component function(s) performed by each, at the time the functions are performed, for each step of prescription handling. The audit trail 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;

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

- i. The brand name or generic name, and if generic, the name of the manufacturer;
- 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 prescriber 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;

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.

(b) Pharmacies shall post the name of the registered pharmacist-in-charge on the entrance to the pharmacy in such a way as to be visible to the public.

Recodified from N.J.A.C. 13:39-7.2 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 (a); added (b). Former N.J.A.C. 13:39-5.3, Authorization for renewal of prescriptions, recodified to N.J.A.C. 13:39-7.3.

13:39-5.4 Spatial requirement of pharmacy prescription area

(a) For pharmacies in operation prior to July 1, 1963, the space devoted to the prescription area and laboratory shall not be less than 10 percent of the main floor area of the pharmacy, and in no instance shall it be less than 50 square feet. If the main floor area of such pharmacy exceeds 1,200 square feet, the 10 percent requirement does not apply and the minimum requirement for the prescription area shall not be less than 120 square feet.

(b) For all other pharmacies including pharmacies subject to the provisions of (a) above which are moving to a new location, the prescription area must occupy exclusively a minimum of 150 square feet.

Recodified from N.J.A.C. 13:39-7.3 and amended by R.2005 d.25, effective January 18, 2005.

See: 36 N.J.R. 3345(a), 37 N.J.R. 295(a).

In (a), deleted "or drugstore" following "floor area of the pharmacy"; in (b), deleted "retail" preceding "pharmacies". Former N.J.A.C. 13:39-5.4, Approval of FDA necessary, recodified to N.J.A.C. 13:39-7.5.

13:39-5.5 Prescription counter

Pharmacies shall contain a prescription counter or counters on which to work, and the free working space shall not be less than 18 inches in width and not less than 12 total feet in length. This minimum working surface shall be kept clear at all times for the processing and/or compounding of prescriptions.

Amended by R.1999 d.214, effective July 19, 1999.

See: 31 N.J.R. 1151(a), 31 N.J.R. 1932(a).

Inserted "or counters" following "counter", and substituted "total" for "continuous" following "12".

Recodified from N.J.A.C. 13:39-7.4 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. 13:39-5.5, Copies of prescriptions; transfers, recodified to N.J.A.C. 13:39-7.7.

13:39-5.6 Prescription area sink

An adequate sink with hot and cold running water shall be provided in the prescription area, easily accessible to the prescription counter.

Amended by R.1999 d.214, effective July 19, 1999.

See: 31 N.J.R. 1151(a), 31 N.J.R. 1932(a).

Substituted a reference to anterooms for a reference to rooms.

Recodified from N.J.A.C. 13:39-7.5 and amended by R.2005 d.25, effective January 18, 2005.

See: 36 N.J.R. 3345(a), 37 N.J.R. 295(a).

Deleted "of retail and institutional pharmacies;" preceding "easily accessible" in the first sentence, deleted the second sentence. Former N.J.A.C. 13:39-5.6, Record of pharmacist filling prescription, recodified to N.J.A.C. 13:39-7.6.

13:39-5.7 Storage and adequate stock

There shall be sufficient shelf, drawer or cabinet space within the prescription area for proper storage of prescription drugs and chemicals and the minimum equipment required pursuant to N.J.A.C. 13:39-5.8.

Recodified from N.J.A.C. 13:39-7.6 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. 13:39-5.7 Availability of records upon termination of business, recodified to N.J.A.C. 13:39-4.9.

13:39-5.8 Minimum equipment and facilities

(a) The following minimum equipment and facilities shall be required to be in every prescription area, and this equipment shall be stored so as to be readily accessible and shall be kept in a clean condition:

1. An up-to-date, comprehensive pharmaceutical reference text(s) and suitable current reference texts encompassing the general practice of pharmacy, drug interactions, drug product composition and patient counseling. Unabridged computerized versions of these reference texts shall be acceptable;
2. Over the counter Schedule V Record Book, if Schedule V medication is sold without a prescription;
3. Permanent prescription filing device and patient profile record system;
4. Securely locked, substantially constructed storage place for Schedule II controlled substances if not dispersed;
5. Class A prescription balance with a complete set of metric weights or equivalent electronic weighing device;
6. Volumetric devices capable of measuring 0.3 ml to 500 ml;
7. A glass mortar and pestle;
8. Glass funnels;
9. Stirring rods;
10. A steel spatula and a spatula of rubber or composition;
11. Ointment tile or parchment paper;
12. Refrigerator, as required by United States Pharmacopoeia Standards, to be used only for the storage of pharmaceuticals;
13. Suitable counting trays or approved counting device;
14. Labels;
15. Auxiliary labels, including poison labels;

16. Suppository mold;

17. Two Drug Utilization Review Council Placards and the current Drug Utilization Review Council Formulary; and

18. Assorted stock of prescription containers and child safety closures or caps.

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.196 effective June 21, 1999.

See: 30 N.J.R. 4113(a), 31 N.J.R. 253(a), 31 N.J.R. 1618(a).

In (a), added a reference to equivalent electronic weighing devices at the end of 5, and rewrote 15.

Amended by R.1999 d.214. effective July 19, 1999.

See: 31 N.J.R. 1151(a), 31 N.J.R. 1932(a).

In (a), rewrote 1, 2 and 13.

Recodified from N.J.A.C. 13:39-7.7 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. 13:39-5.8 Prescriptions and medication orders transmitted by technological devices in an institution, recodified to N.J.A.C. 13:39-9.27.

13:39-5.9 Cleanliness, orderliness and sanitation

The entire prescription area shall at all times be kept in a clean, orderly and sanitary condition.

Recodified from N.J.A.C. 13:39-7.8 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. 13:39-5.9, Labeling, recodified to N.J.A.C. 13:39-7.12.

13:39-5.10 Television in prescription area prohibited

No commercial television, other than for security measures, pharmacy training or patient counseling, may be operated in a prescription area or in any location outside of a prescription area such that its operation may be viewed from the prescription area.

Amended by R.1999 d.214. effective July 19, 1999.

See: 31 N.J.R. 1151(a), 31 N.J.R. 1932(a).

Inserted references to pharmacy training and patient counseling.

Recodified from N.J.A.C. 13:39-7.9 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. 13:39-5.10, Procedures for Centralized Prescription Handling, recodified to N.J.A.C. 13:39-4.18.

13:39-5.11 Prescription balances, scales, weights and automatic counting devices

All pharmacies shall have all balances, scales, weights and automatic counting devices inspected every 12 months by the Department of Weights and Measures of the municipality or county in which the pharmacy or other Board-licensed establishment is located, and such balances, scales, weights and automatic counting devices shall be properly sealed by the applicable authority.

Amended by R.1994 d.351, effective July 18, 1994.
 See: 26 N.J.R. 1596(a), 26 N.J.R. 2905(b).
 Recodified from N.J.A.C. 13:39-7.11 and amended by R.2005 d.25,
 effective January 18, 2005.
 See: 36 N.J.R. 3345(a), 37 N.J.R. 295(a).

13:39-5.12 Restriction on storage of prescription legend drugs and controlled dangerous substances

Prescription legend drugs, devices and controlled dangerous substances shall not be stored in the pharmacy in such a manner that they can be accessible to the public.

Recodified from N.J.A.C. 13:39-6.5 and amended by R.2005 d.25, effective January 18, 2005.

See: 36 N.J.R. 3345(a), 37 N.J.R. 295(a).

Substituted "stored" for "displayed" following "shall not be" and substituted "pharmacy" for "licensed establishment" preceding "in such a manner".

SUBCHAPTER 6. REGISTERED PHARMACIST-IN-CHARGE; PHARMACY PERSONNEL

13:39-6.1 Purpose and scope

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

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. 13:39-6.1, Professional judgment in dispensing drugs, recodified to N.J.A.C. 13:39-7.13.

13:39-6.2 Registered pharmacist-in-charge

(a) Every pharmacy shall name a pharmacist licensed and in good standing in New Jersey as the registered pharmacist-in-charge of the pharmacy. No pharmacy shall operate without a registered pharmacist-in-charge for longer than 30 days.

(b) Whenever the registered pharmacist-in-charge is absent from the pharmacy for more than 30 days, the registered pharmacist-in-charge and the permit holder shall notify the Board of the name of the registered pharmacist who shall act as the interim registered pharmacist-in-charge.

(c) A registered pharmacist shall not assume the responsibilities of a registered pharmacist-in-charge of more than one pharmacy or pharmacy department simultaneously.

(d) Whenever there is a change of a registered pharmacist-in-charge of a pharmacy or other Board-licensed establishment, an inventory of all controlled dangerous substances as defined in N.J.A.C. 8:65-10.1 through 10.5 shall be performed consistent with the requirements of N.J.A.C. 8:65-5.4 and 5.5.

(e) Whenever a registered pharmacist assumes or terminates the duties as a registered pharmacist-in-charge of a

pharmacy or other Board-licensed establishment, the registered pharmacist-in-charge and the permit holder shall so advise the Board in writing within 30 days by completing a form provided by the Board.

(f) A registered pharmacist-in-charge shall be a full-time employee, employed for a minimum of 35 hours per week and shall be physically present in the pharmacy or pharmacy department for that amount of time necessary to supervise and ensure that:

1. Adequate staffing is present to fulfill the needs of the pharmacy or pharmacy department;

2. Accurate records of all prescription medication received and dispensed are maintained;

3. Policies are in place regarding accurate dispensing and labeling of prescriptions and that such policies are followed;

4. Security of the prescription area and its contents are maintained at all times, including the restriction of persons unauthorized by the pharmacist on duty from being present in the prescription area while the pharmacist is temporarily absent but within the premises and the reporting of any thefts and/or diversions of controlled substances are reported upon discovery to the Office of Drug Control and the Drug Enforcement Administration pursuant to Federal and State requirements, consistent with the requirements of N.J.A.C. 8:65-2.5(d);

5. Only pharmacists and interns or externs under immediate personal supervision provide professional consultation with patients and physicians;

6. Only pharmacists, interns or externs accept telephone prescriptions and only pharmacists, interns or externs, or pharmacy technicians consistent with the requirements of N.J.A.C. 13:39-6.6(b), accept renewal authorizations;

7. No misbranded, deteriorated, adulterated, improperly stored or outdated drugs or any drugs marked "sample" or with any like designation or meaning are dispensed or present in the active stock in the pharmacy;

8. The prescription area is maintained in an orderly and sanitary manner; and

9. The pharmacy and all pharmacy personnel comply with all Federal and State statutes, rules and regulations governing the practice of pharmacy.

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 (c), through (e), substituted references to registered pharmacist-in-charge for references to pharmacist-in-charge.

Amended by R.2004 d.380, effective October 4, 2004.

See: 36 N.J.R. 11(a), 36 N.J.R. 4480(a).

In (e), deleted existing 8, recodified former 9 to 14 as 8 to 13.

Recodified from N.J.A.C. 13:39-3.18 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. 13:39-6.2, Prescription prepared, compounded or dispensed by pharmacy externs or interns, recodified to N.J.A.C. 13:39-6.5.

13:39-6.3 Identification tag

All personnel working in the pharmacy shall wear an identification tag which shall include at least the person's first name and job title. The identification tag of any employee in training shall reflect the status of the employee as a trainee.

Repealed by R.1994 d.351, effective July 18, 1994.

See: 26 N.J.R. 1596(a), 26 N.J.R. 2905(b).

Section was "Sale of controlled dangerous substances and prescription legend drugs by other than a registered pharmacist in a Board-licensed establishment".

New Rule, R.1998 d.166, effective April 6, 1998.

See: 29 N.J.R. 5051(a), 30 N.J.R. 1297(b).

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.

Amended by R.2007 d.283, effective September 4, 2007.

See: 38 N.J.R. 3137(a), 39 N.J.R. 3774(b).

Inserted the final sentence.

13:39-6.4 Meal breaks

(a) A sole pharmacist on duty may take a 30-minute meal break while working in a pharmacy consistent with the following requirements:

1. The pharmacist shall remain in the pharmacy or, in the case of a pharmacy department, in the pharmacy department building, and shall be accessible for emergencies or for counseling, if requested;
2. The pharmacy shall remain open during the meal break for patient related services, which include, but are not limited to, the following:
 - i. The receipt of new written prescriptions; and
 - ii. The dispensing of prescription medications which have been checked by the pharmacist; and
3. A sign shall be posted in the pharmacy stating "Pharmacist on meal break, but available for emergencies and counseling."

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. 13:39-6.4, Direct supervision of dispensing and compounding, repealed.

13:39-6.5 Prescription prepared or compounded by pharmacy externs, interns or pharmacy technicians

A pharmacy intern, extern or technician may prepare or compound prescriptions only under the immediate personal supervision of a registered pharmacist of this State. The registered pharmacist shall be personally responsible for the accuracy and appropriateness of the filled prescription.

Recodified from N.J.A.C. 13:39-6.2 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. 13:39-6.5 Restriction on display of prescription legend drugs and, recodified to N.J.A.C. 13:39-5.12.

13:39-6.6 Pharmacy technician registration and pharmacy technician applicants

(a) A person wishing to be registered with the Board as a pharmacy technician shall:

1. Be 18 years of age or older;
2. Possess a high school diploma or its equivalent;
3. Submit a certification attesting to the fact that he or she is proficient in written and spoken English;
4. Apply to the Board for registration and submit the application fee set forth in N.J.A.C. 13:39-1.3;
5. Submit his or her name, address and fingerprints for purposes of a criminal history background check pursuant to N.J.S.A. 45:1-28 et seq., (P.L. 2002, c. 104) to determine whether criminal history record information exists which may disqualify the applicant from being registered by the Board; and
6. Submit, as part of the application for registration, evidence of good moral character which is an ongoing requirement for registration, and evidence that he or she:
 - i. Is not presently engaged in drug or alcohol use that is likely to impair the ability to practice as a pharmacy technician with reasonable skill and safety. For purposes of this section, the term "presently" means at the time of application or any time within the previous 365 days;
 - ii. Has not been convicted of violating any law of this State or any other state of the United States relating to controlled dangerous substances or other habit-forming drugs;
 - iii. Has not been convicted of violating any law relating to the practice of pharmacy;
 - iv. Has not been convicted of a crime involving moral turpitude; and
 - v. Has not had his or her authority to engage in the activity regulated by the Board suspended or revoked as a result of any administrative or disciplinary proceedings in this or any other jurisdiction which determined the applicant to be in violation of any laws, rules or regulations pertaining to the practice of pharmacy, and that the applicant is not currently under suspension or revocation.

(b) By March 2, 2008, a pharmacy shall only employ a person registered with the Board as a pharmacy technician pursuant to (a) above, or a pharmacy technician applicant, consistent with (c) below, to perform pharmacy technician functions.

4. The counting, weighing, measuring, pouring and compounding of prescription medication or stock legend drugs and controlled substances, including the filling of an automated medication system.

(b) Pharmacy technicians and pharmacy technician applicants may accept authorization from a patient for a prescription refill, or from a physician or his or her agent for a prescription renewal, provided that the prescription remains unchanged. The pharmacy technician or pharmacy technician applicant shall identify himself or herself as a pharmacy technician when accepting authorization from a physician or his or her agent. For purposes of this section, "prescription refill" means the dispensing of medications pursuant to a prescriber's authorization provided on the original prescription. For purposes of this section, "prescription renewal" means the dispensing of medications pursuant to a practitioner's authorization to fill an existing prescription that has no refills remaining.

(c) Pharmacy technicians and pharmacy technician applicants shall not:

1. Receive new verbal prescriptions;
2. Interpret a prescription or medication order for therapeutic acceptability and appropriateness;
3. Verify dosage and directions;
4. Engage in prospective drug review;
5. Provide patient counseling;
6. Monitor prescription usage;
7. Override computer alerts without first notifying the pharmacist;
8. Transfer prescriptions from one pharmacy to another pharmacy; or
9. Violate patient confidentiality.

(d) A pharmacy shall require all pharmacy technicians and pharmacy technician applicants employed by the pharmacy to sign a patient confidentiality statement. Such statements shall be maintained on-site by the pharmacy.

(e) Except as provided in (f) below, a pharmacist shall not supervise more than two pharmacy technicians at any given time. The pharmacist shall provide immediate personal supervision, as defined in N.J.A.C. 13:39-1.2, of all pharmacy technicians he or she supervises. Those personnel who do computer processing of prescriptions are to be included in the 1 to 2 ratio. A registered pharmacy technician or a pharmacy technician applicant who is receiving in-service training, which shall not exceed 210 days, shall be excluded from the 1 to 2 ratio during such training. A pharmacist shall not supervise more than two persons receiving in-service training at the same time.

(f) A pharmacy that employs a registered pharmacist to pharmacy technician ratio greater than 1:2 shall:

1. Establish written job descriptions, task protocols, and policies and procedures that pertain to the duties performed by the pharmacy technicians;
 2. Ensure and document that all pharmacy technicians who are working when the ratio exceeds 1:2 have:
 - i. Passed the Pharmacy Technician Certification Board's Pharmacy Technician Certification Examination and have fulfilled the requirements to maintain this status;
 - ii. Passed a Board-approved certification program and have fulfilled the requirements to maintain this status; or
 - iii. Completed a program which includes a testing component which has been approved by the Board as satisfying the criteria set forth in (g) below. Completion of a program with a Board-approved testing component shall qualify the pharmacy technician to work only for the specific pharmacy and/or corporation for which the pharmacy technician was employed when the training was obtained. If the pharmacy technician becomes employed by another pharmacy and/or corporation, the pharmacy technician shall be required to complete the new employer's training program;
 3. Ensure that all pharmacy technicians are knowledgeable in the established job descriptions, task protocols, and policies and procedures in the pharmacy setting in which the technicians are to perform their duties;
 4. Ensure that the duties assigned to any pharmacy technician do not exceed the established job descriptions, task protocols, and policies and procedures, nor involve any of the prohibited tasks in (c) above;
 5. Ensure that all pharmacy technicians receive in-service training before the pharmacy technicians assume their responsibilities and maintain documentation thereof. A registered pharmacy technician or a pharmacy technician applicant who is receiving in-service training, which shall not exceed 210 days, shall be excluded from the 1 to 2 ratio during such training. A pharmacist shall not supervise more than two persons receiving in-service training at the same time;
 6. Provide immediate personal supervision as defined in N.J.A.C. 13:39-1.2; and
 7. Provide the Board, upon request, with a copy of the established job descriptions, task protocols, and policies and procedures for all pharmacy technician duties.
- (g) If the pharmacist to pharmacy technician ratio exceeds 1:2, the pharmacy shall maintain a policy and procedure manual with regard to pharmacy technicians which shall include the following:

1. Supervision by a pharmacist;
 2. Confidentiality safeguards of patient information;
 3. Minimum qualifications;
 4. Documentation of in-service education and/or ongoing training and demonstration of competency, specific to practice site and job function;
 5. General duties and responsibilities of pharmacy technicians;
 6. Retrieval of prescription files, patient files, patient profile information and other records pertaining to the practice of pharmacy;
 7. All functions related to prescription processing;
 8. All functions related to prescription legend drug and controlled substance ordering and inventory control;
 9. Prescription refill and renewal authorization;
 10. Procedures dealing with documentation and records required for controlled drug substance and prescription legend drugs;
 11. Procedures dealing with medication errors, including classification of medication errors;
 12. Pharmacy technician functions related to automated systems;
 13. Functions that may not be performed by pharmacy technicians, including at a minimum those functions listed in (c) above; and
 14. A form signed by the pharmacy technician which verifies that the manual has been reviewed by the technician.
- (h) The pharmacist in charge shall review at least every two years and, if necessary, amend the policy and procedure manual. Documentation of the review shall be made available to the Board upon request.

(i) When pharmacy technicians and pharmacy technician applicants are engaged in any permitted activities, the registered pharmacist(s) shall be responsible for all the activities of the pharmacy technicians and the pharmacy technician applicants.

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.1997 d.502, effective December 1, 1997.

See: 28 N.J.R. 5048(a), 29 N.J.R. 5072(a).

Added (d) through (f).

Amended by R.1999 d.214, effective July 19, 1999.

See: 31 N.J.R. 1151(a), 31 N.J.R. 1932(a).

In (f), substituted a reference to supervising registered pharmacists for a reference to a registered pharmacists-in-charge.

Recodified from N.J.A.C. 13:39-6.7 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. 13:39-6.6, Foreign prescriptions, repealed.

Recodified from N.J.A.C. 13:39-6.6 and amended by R.2007 d.283, effective September 4, 2007.

See: 38 N.J.R. 3137(a), 39 N.J.R. 3774(b).

Section was "Pharmacy technicians". Rewrote the introductory paragraph of (a); in (b), inserted "and pharmacy technician applicants" and inserted the second sentence; in the introductory paragraph of (c), inserted "and pharmacy technician applicants"; added new (d); recodified former (d) through (g) as (e) through (h); rewrote (e) and (f); deleted former (h); and in (i), inserted "and pharmacy technician applicants" and "and the pharmacy technician applicants".

SUBCHAPTER 7. DRUG DISPENSING AND PRESCRIPTION RECORDS

13:39-7.1 Valid prescriptions; out-of-State prescriptions

(a) A pharmacist shall only fill a written prescription issued in New Jersey if the prescription is on a New Jersey Uniform Prescription Blank pursuant to N.J.S.A. 45:14-14.4 and N.J.A.C. 13:45A-27, except as provided in N.J.A.C. 13:39-7.10 and 7.11.

(b) A pharmacist shall only fill a prescription issued by an authorized prescriber licensed to write prescriptions in the United States or any territory of the United States. Such prescriptions orders shall be filled pursuant to New Jersey law.

(c) Prescriptions, other than those listed in (a) and (b) above, shall not be filled by a pharmacy in New Jersey.

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. 13:39-7.1, Retail pharmacy access and egress, recodified to N.J.A.C. 13:39-5.2.

13:39-7.2 Lack of directions on original prescription

If the prescriber fails to include on the original prescription directions to the patient for use of the medication, the registered pharmacist shall make a documented attempt to contact the prescriber to obtain such directions. In cases where the prescriber cannot be contacted, the registered pharmacist shall indicate on the label the words "use as directed" or "as ordered by the physician" or similar words to the same effect.

Amended by R.1999 d.214, effective July 19, 1999.

See: 31 N.J.R. 1151(a), 31 N.J.R. 1932(a).

Rewrote (a).

Recodified from N.J.A.C. 13:39-5.2 and amended by R.2005 d.25, effective January 18, 2005.

See: 36 N.J.R. 3345(a), 37 N.J.R. 295(a).

Undesignated (a) and deleted (b). Former N.J.A.C. 13:39-7.2, Retail pharmacy signs, recodified to N.J.A.C. 13:39-5.3.

13:39-7.3 Authorization for renewal of prescriptions

(a) A prescription for medication or devices which pursuant to State or Federal law may be sold, dispensed or furnished only upon prescription, shall not be renewed without specific authorization of the prescriber, and the prescription may not be refilled after one year from the date of original prescription.

1. Prescriptions marked "PRN" or other letters or words meaning refill as needed shall not be renewed beyond one year past the date of original prescription.

(b) When the renewals listed on the original prescription have been depleted, no additional renewals may be added to the original prescription. For additional dispensing, a new prescription must be authorized by the prescriber as provided in N.J.S.A. 45:14-14, which must be reduced to writing by the pharmacist and entered into either a manual or into the electronic data processing system as a new prescription. A new prescription shall be generated and the original prescription shall remain in the prescription file in chronological order.

Amended by R.1994 d.351, effective July 18, 1994.

See: 26 N.J.R. 1596(a), 26 N.J.R. 2905(b).

Recodified from N.J.A.C. 13:39-5.3 and amended 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. 13:39-7.3, Spatial requirement of a retail pharmacy prescription area, recodified to N.J.A.C. 13:39-5.4.

13:39-7.4 Emergency dispensing

(a) In the absence of a current, valid prescription, a pharmacist may dispense an emergency supply (no more than a 72-hour quantity) of a chronic maintenance drug (except controlled dangerous substances) or device if, in his or her professional judgment, refusal would endanger the health or welfare of the patient, provided the following conditions are satisfied:

1. The pharmacist first ascertains to the best of his or her ability, by direct communication with the patient or caregiver, that such a medication or device was prescribed for that patient by order of a licensed practitioner; and

2. The pharmacist documents the communication and requires the patient or caregiver to provide suitable identification and sign a statement attesting to the need before dispensing.

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. 13:39-7.4, Prescription counter, recodified to N.J.A.C. 13:39-5.5.

13:39-7.5 Approval of FDA necessary

(a) No drug or medicine other than a compounded prescription order shall be sold or dispensed in any pharmacy within the State of New Jersey until such drug or medicine has received New Drug Application (NDA), Abbreviated New Drug Application (ANDA), Investigational New Drug Application (INDA) or other Federal Food and Drug Administration approval, where required.

(b) The storage and dispensing of all Investigational New Drugs shall be a pharmaceutical service provided in cooperation with, and in support of the principal investigator. Under these parameters the dispensing of such drugs shall not be construed to be a violation of (a) above. A pharmacy partici-

pating in experimental research shall comply with Federal Department of Health and Human Services regulations, 45 C.F.R. Part 46, Protection of Human Subjects of Research; incorporated by reference herein, as amended and supplemented.

Recodified from N.J.A.C. 13:39-5.4 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 (a) and added (b). Former N.J.A.C. 13:39-7.5, Prescription area sink, recodified to N.J.A.C. 13:39-5.6.

13:39-7.6 Record of pharmacist filling prescription

(a) A registered pharmacist who fills or compounds a prescription or who supervises the filling or compounding of a prescription by an intern, extern, or pharmacy technician shall place his or her signature or readily identifiable initials or other personal identifier on the original prescription or in the electronic data processing system.

(b) A registered pharmacist who refills a prescription shall place his or her signature or readily identifiable initials or other personal identifier on the reverse side of the original prescription or in the electronic data processing system. Each time a prescription is refilled, the date of the refill and the amount dispensed shall also be recorded on the original prescription or in the electronic data processing system.

(c) Initials and/or access code number(s) of the pharmacist responsible for the filled prescription shall be entered into the system each time a prescription is filled or refilled. Computer programs which automatically generate a pharmacist's initials without requiring a direct entry by the pharmacist responsible for the filled prescription at the time of dispensing are prohibited.

(d) Appropriate documentation identifying handwritten initials with the handwritten signature and printed name of the pharmacist shall be maintained by the pharmacy for a period of six years after the last date of employment.

(e) All prescription records, including original and refilled prescription data, and the number of refills authorized by the prescriber shall be maintained 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 a record information shall be immediately retrievable and readable.

Amended by R.1991 d.355, effective July 15, 1991.

See: 22 N.J.R. 1866(b), 23 N.J.R. 2161(a).

Added new (d) through (f).

Redesignated existing (d)-(g) as (g)-(j).

Amended by R.1994 d.351, effective July 18, 1994.

See: 26 N.J.R. 1596(a), 26 N.J.R. 2905(b).

Recodified from N.J.A.C. 13:39-5.6 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. 13:39-7.6, Storage and adequate stock, recodified to N.J.A.C. 13:39-5.7.

13:39-7.7 Copies of prescriptions

(a) A pharmacy shall immediately comply with the patient's request for copies of prescriptions. Copies of prescriptions issued directly to the patient shall state in letters at least equal in size to those describing the medication dispensed, the underlined statement: "COPY—FOR INFORMATION ONLY."

(b) Presentation of a labeled prescription container or a prescription marked "COPY—FOR INFORMATION ONLY" shall be for information purposes only and shall have no legal status as a valid prescription order. The pharmacist in receipt of such copy or labeled prescription container shall contact the prescribing practitioner for a new prescription or the last dispensing pharmacy to transfer the prescription pursuant to N.J.A.C. 13:39-7.8.

Amended by R.1997 d.502, effective December 1, 1997.

See: 28 N.J.R. 5048(a), 29 N.J.R. 5072(a).

In (c), added "or electronic transfer"; and in (d), added the second sentence.

Amended by R.1999 d.214, effective July 19, 1999.

See: 31 N.J.R. 1151(a), 31 N.J.R. 1932(a).

In (a), added the last sentence; and added (e).

Recodified from N.J.A.C. 13:39-5.5 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. 13:39-7.7. Minimum equipment and facilities, recodified to N.J.A.C. 13:39-5.8.

13:39-7.8 Transfer of prescriptions between pharmacies

(a) When a patient, the patient's caregiver, or a pharmacy acting on behalf of a patient or caregiver requests the transfer of a valid prescription between pharmacies, a pharmacy shall immediately comply with the patient's request.

(b) Except as provided in (c) and (d) below, a prescription may be transferred between pharmacies, consistent with this section, for one year from the date the prescription was written, provided refills of the prescription are available.

(c) A prescription for a Schedule II controlled substances may not be transferred.

(d) A prescription for a Schedule III, IV or V controlled substance may be transferred between pharmacies, consistent with this section, one time only, pursuant to N.J.A.C. 8:65-7.14(h) and 7.18(d).

(e) A prescription may be transferred electronically by pharmacists between pharmacies for the purpose of refill dispensing consistent with the requirements in N.J.A.C. 13:39-7.11.

(f) A prescription may be transferred by telephone between pharmacies for the purpose of refill dispensing provided that:

1. The sending pharmacy invalidates the prescription on file as of the date the prescription is transferred and

records on the back of the invalidated prescription order or in the electronic system the following:

i. That the prescription has been transferred and the date of transfer;

ii. The name of the pharmacy to which the prescription was transferred;

iii. The name or personal identifier of the pharmacist, intern or extern to whom the prescription was transferred; and

iv. The initials or personal identifier of the pharmacist, intern, or extern issuing the transferred prescription order;

2. The receiving pharmacy, upon receiving such prescription directly from another pharmacy, records the following:

i. The name, address and original prescription number of the pharmacy from which the prescription was transferred;

ii. The name or personal identifier of the sending pharmacist, intern or extern ;

iii. All information constituting a prescription order, as well as the following:

(1) Date of issuance of original prescription;

(2) Date of original dispensing;

(3) Original number of refills authorized on original prescription;

(4) Complete refill record from original prescription;

(5) Number of valid refills remaining; and

3. The pharmacist, intern, extern, or technician at the receiving pharmacy informs the patient or caregiver that the original prescription has been cancelled at the sending pharmacy.

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. 13:39-7.8, Cleanliness, orderliness and sanitation, recodified to N.J.A.C. 13:39-5.9.

Amended by R.2007 d.283, effective September 4, 2007.

See: 38 N.J.R. 3137(a), 39 N.J.R. 3774(b).

In (f)3, deleted "receiving" preceding "pharmacist" and inserted "at the receiving pharmacy".

13:39-7.9 Filing and storage of controlled substance prescriptions

(a) Prescriptions for all controlled substances listed in Schedule II shall be maintained in a separate prescription file.

(b) Prescriptions for all controlled substances listed in Schedules III, IV and V shall be maintained in a separate prescription file for such controlled substances only or in such form that they are readily retrievable from other prescription

records of the pharmacy. Prescriptions will be deemed readily retrievable if, at the time they are initially filed, the face of the prescription is stamped in red ink in the lower right corner with the letter "C" no less than one-inch high and filed either in the prescription file for controlled substances listed in schedule II or in the usual consecutively numbered prescription file for non-controlled substances.

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. 13:39-7.9, Television in prescription area prohibited, recodified to N.J.A.C. 13:39-5.10.

13:39-7.10 Prescriptions transmitted by facsimile

(a) A pharmacist may accept for dispensing a facsimile prescription, consistent with the requirements of this section. For purposes of this section, "facsimile prescription" means a prescription which is transmitted by a device which sends an exact image to the receiver.

(b) A pharmacist shall not fill a facsimile prescription transmitted by anyone other than a practitioner authorized to prescribe medications pursuant to N.J.S.A. 45:14-14, or the prescribing practitioner's authorized agent.

(c) The facsimile machine used to receive prescriptions shall be located within the pharmacy prescription area.

(d) A facsimile prescription shall contain all information required to be included on a written prescription pursuant to New Jersey State Board of Medical Examiners rule N.J.A.C. 13:35-7.2(d), except that an NJPB shall not be required for the prescription.

(e) The facsimile transmission of the prescription shall contain the following:

1. The identification number of the facsimile machine which is used to transmit the prescription;
2. The date and time of the prescription transmission;
3. The name, address, telephone number and facsimile number of the pharmacy; and
4. If an authorized agent transmits the facsimile prescription, the full name and title of the transmitting agent.

(f) A pharmacist shall seek verbal verification of a facsimile prescription from the prescribing practitioner whenever the pharmacist has reason to question the authenticity, accuracy or appropriateness of the prescription. A pharmacist may accept verbal verification regarding the authenticity or legibility of a facsimile prescription from a prescribing practitioner's authorized agent. A pharmacist shall not fill a facsimile prescription where there is a question regarding authenticity, accuracy or appropriateness if such verification is not provided.

(g) A pharmacist shall retain a printed copy of a facsimile prescription, or an electronic reproduction of the facsimile prescription that is readily retrievable and printable, for a minimum of five years pursuant to N.J.S.A. 45:14-15. The printed copy shall be of non-fading legibility.

(h) A pharmacist may fill a prescription for a Schedule II controlled substance transmitted by facsimile provided that the original signed prescription is presented to the pharmacist prior to the dispensing of the controlled substance, except as provided in (h)1, 2 and 3 below.

1. A prescription for a Schedule II narcotic substance prescribed for pain management to be compounded for the direct administration to a patient by parenteral, intravenous, intramuscular, subcutaneous or intraspinal infusion may be transmitted by the practitioner or the practitioner's agent to the dispensing pharmacy by facsimile. The facsimile shall serve as the original written prescription and shall be maintained pursuant to the requirements of (g) above.

2. A prescription for a Schedule II substance prescribed for pain management for a resident of a long-term care facility may be transmitted by the practitioner or the practitioner's agent to the dispensing pharmacy by facsimile. The facsimile shall serve as the original written prescription and shall be maintained pursuant to the requirements of (g) above.

3. A prescription for a Schedule II narcotic substance prescribed for pain management for a patient receiving services from a hospice certified by Medicare under Title XVIII or licensed by the State may be transmitted by the practitioner or the practitioner's agent to the dispensing pharmacy by facsimile. The practitioner or the practitioner's agent shall note on the facsimile prescription that the patient is a hospice patient. The facsimile shall serve as the original written prescription and shall be maintained pursuant to the requirements of (g) above.

(i) A pharmacist may fill a prescription for a Schedule III, IV or V controlled substance transmitted by facsimile consistent with the requirements of this section. The facsimile prescription shall serve as the original written prescription.

(j) A pharmacist shall not enter into any agreement with a prescribing practitioner that requires that facsimile prescriptions be transmitted to a particular pharmacy or in any way denies a patient the right to have his or her prescription transmitted by facsimile to a pharmacy of the patient's choice.

New Rule, R.2003 d.373, effective September 15, 2003.

See: 34 N.J.R. 3064(a), 35 N.J.R. 4290(a).

Administrative correction.

See: 35 N.J.R. 4724(a).

Recodified from N.J.A.C. 13:39-5.8A by R.2005 d.25, effective January 18, 2005.

See: 36 N.J.R. 3345(a), 37 N.J.R. 295(a).

(g) If the pharmacy uses an electronic data processing system, an auxiliary recordkeeping system shall be established when the electronic data processing system is inoperative for any reason. When the electronic data processing system is restored to operation, the patient profile information and number of refills authorized during the time the electronic system was inoperative shall be entered into the electronic data processing system within 72 hours.

(h) If an electronic data processing system is used, the system shall provide adequate safeguards against manipulation and alteration of records and to protect confidentiality of the information contained in the data bank.

(i) The holder of the pharmacy permit shall make arrangements with the supplier of data processing services or materials to ensure that the pharmacy will continue to have adequate and complete prescription and dispensing records if the relationship with such supplier terminates for any reason.

(j) Failure to comply with this section shall subject the pharmacist to disciplinary sanctions.

Amended by R.1993 d.307, effective June 21, 1993.
See: 24 N.J.R. 266(a), 25 N.J.R. 2697(a).
Amended by R.1994 d.351, effective July 18, 1994.
See: 26 N.J.R. 1596(a), 26 N.J.R. 2905(b).
Recodified from N.J.A.C. 13:39-7.14 and amended by R.2005 d.25, effective January 18, 2005.
See: 36 N.J.R. 3345(a), 37 N.J.R. 295(a).

Case Notes

Board of Pharmacy adopted the Initial Decision (2006 N.J. AGEN LEXIS 1077) that a pharmacist engaged in dishonesty, fraud, deception, or misrepresentation, gross negligence, and violated N.J.A.C. 13:39-7.19(b) by accepting bundled prescriptions delivered by a sales representative, filling those prescriptions without question, and dispensing medications in bulk to an unknown end user; the patient's telephone number and gender must be listed in the patient profile system. In re Suspension or Revocation of License of Sorr, OAL Dkt. No. BDS 10231-05, 2007 N.J. AGEN LEXIS 884, Final Decision (June 18, 2007).

SUBCHAPTER 8. PHARMACY TRAINING SITES

13:39-8.1 Definitions

The following words and terms, when used in this subchapter, shall have the following meanings, unless the context clearly indicates otherwise.

“Certified preceptor” means a pharmacist registered in this State who assumes the responsibility to supervise and tutor a pharmacy intern as outlined in N.J.A.C. 13:39-8.2.

“Faculty preceptor” means a member of the faculty at an American Council of Pharmaceutical Education approved school or college of pharmacy, at which a pharmacy extern is enrolled, who assumes the responsibility to supervise and tutor a pharmacy extern as outlined in N.J.A.C. 13:39-8.2.

“Pharmacy extern” means any person who is in the fifth or sixth college year (or third or fourth professional year) at an American Council of Pharmaceutical Education approved school or college of pharmacy who is assigned to a training site for the purpose of acquiring accredited practical experience under the supervision of the school or college at which he or she is enrolled.

“Pharmacy intern” means any person who has graduated from an American Council of Pharmaceutical Education approved school or college of pharmacy, or if a foreign pharmacy graduate, any person who has satisfied the requirements of N.J.A.C. 13:39-2.9, who is employed in an approved training pharmacy for the purpose of acquiring accredited practical experience and who has first registered for said purposes with the Board.

“Pharmacy internship or externship” shall mean the program of acquiring practical experience by a pharmacy intern or extern respectively.

“Pharmacy training site” means a site which satisfies the requirements of N.J.A.C. 13:39-8.3.

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).

Deleted “Approved training site”; inserted “Faculty preceptor”; rewrote “Pharmacy intern” and “Pharmacy extern”; and added “Pharmacy training site”.
Amended by R.2005 d.25, effective January 18, 2005.
See: 36 N.J.R. 3345(a), 37 N.J.R. 295(a).

In “Certified preceptor”, deleted “or extern” following “pharmacy intern”; in “Pharmacy intern”, amended the N.J.A.C. reference.

13:39-8.2 Preceptor application procedures; responsibilities

(a) A registered pharmacist who wishes to be a certified preceptor shall apply to the Board and shall furnish evidence that he or she:

1. Has been registered and employed as a pharmacist in the area of practice in which he or she is to be engaged as a preceptor, on a full-time basis for at least two years in the State of New Jersey; and

2. Has not been convicted of a crime or offense relating adversely to the practice of pharmacy or involving moral turpitude, and has not been the subject of disciplinary action taken by a professional board resulting in the suspension, revocation or surrender of a license or the placement of significant limitations on such license.

(b) The Board shall approve a certified preceptor selected by each pharmacy intern, prior to the beginning of the internship. At no time may one certified preceptor supervise the training of more than one pharmacy intern.

(c) The certified preceptor in a pharmacy training site shall provide the Board with a detailed written report outlining the progress, aptitude and readiness to practice of any pharmacy

intern under his or her supervision at the conclusion of the internship.

(d) The certified preceptor or faculty preceptor is charged with the responsibility for the following:

1. Supervising the activities of the pharmacy intern or extern and ensuring that the intern or extern will keep abreast of developments in pharmacy by reading current professional literature and journals and by attending seminars and meetings of professional and scientific organizations; and
2. Providing the pharmacy intern or extern with experience and knowledge related to the preceptor's area of practice.

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).

Rewrote the section.

Amended by R.2005 d.25, effective January 18, 2005.

See: 36 N.J.R. 3345(a), 37 N.J.R. 295(a).

In (a), rewrote 2; rewrote (c); deleted former (d); recodified existing (e) as (d).

13:39-8.3 Pharmacy training site requirements

(a) To serve as a training site for interns, a pharmacy shall meet the following requirements:

1. Have a satisfactory record of observance of Federal, state and municipal laws and ordinances governing the activity in which it is or has been engaged.
2. Have a total number of prescriptions or medication orders filled annually, including renewals, of at least 20,000, with no more than one pharmacy intern or extern in training for each 20,000 prescriptions filled in the pharmacy.
3. Establish and maintain as part of the service it renders, a medication recordkeeping system for its patients that is approved by the Board.
4. Have available a reference library for use by the pharmacy intern.

(b) Notwithstanding the provisions of (a) above, a pharmacy which does not dispense medications but which serves as a pharmacy training site shall not be required to satisfy the requirements of (a)2 and 3 above.

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 (a), rewrote the introductory paragraph and 4; and added (b).

13:39-8.4 Internship and externship practical experience

(a) The minimum accredited internship and externship practical experience requirement shall be the equivalent of 1,000 hours as follows:

1. One thousand hours for completion of a structured internship conducted after graduation from an accredited college of pharmacy and consisting of no less than 24 weeks supervised by a certified preceptor. Each week of practical experience shall consist of no less than 20 hours and no more than 45 hours of actual service per week. If the intern is a foreign pharmacy graduate, he or she must have met all of the requirements of the National Association of Board of Pharmacy Foreign Pharmacy Graduate Examination Commission.

2. The certified preceptor and the pharmacy intern shall keep accurate records of the time spent by the pharmacy intern for credit toward the requirements of (a)1 above. The Board shall provide appropriate forms to be submitted to the Board for approval of postgraduate practical experience.

3. No credit shall be given for hours served as an intern prior to the Board's receipt of the written application.

(b) In lieu of the requirements set forth in (a)1 above, an applicant may obtain up to 1,000 hours practical experience by completion of a structured, college-credited externship and clinical pharmacy clerkship program of an American Council of Pharmaceutical Education accredited college of pharmacy.

(c) In cases of a structured, college-credited externship and clinical pharmacy clerkship program, where less than 1,000 hours are accepted and approved by the Board, the balance of hours to make a total of 1,000 shall be gained through completion of a structured internship, conducted after graduation from an American Council of Pharmaceutical Education accredited college of pharmacy and supervised by a certified preceptor with each week of practical experience consisting of no less than 20 hours and no more than 45 hours of actual service per week.

(d) A college of pharmacy externship program shall provide that no less than 75 percent of the hours credited toward the practical experience requirement of the Board be gained in settings in which there is direct involvement with consumers or patients, registered pharmacists, and other licensed health care practitioners such as physicians, dentists and nurses under the supervision of a certified or faculty preceptor. Not more than 45 hours of experience shall be acquired per week.

(e) Credit for college externships or other experience programs shall not be allowed for experience gained prior to the fifth college year (or third professional year) in the college of pharmacy program.

(f) The pharmacy college shall certify that the requirements of (b) above have been met.

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.1998 d.167, effective April 6, 1998.
See: 29 N.J.R. 4740(b), 30 N.J.R. 1298(a).

In (d), deleted language regarding practical experience hours in an approved training pharmacy.

Amended by R.1999 d.214, effective July 19, 1999.
See: 31 N.J.R. 1151(a), 31 N.J.R. 1932(a).

In (a)2, substituted a reference to certified preceptors for a reference to preceptors; in (c), substituted "20 hours" for "35 hours" following "less than"; and in (d), inserted a reference to faculty preceptors in the first sentence, and substituted "40 hours" for "45 hours" in the last sentence.

Amended by R.2005 d.25, effective January 18, 2005.
See: 36 N.J.R. 3345(a), 37 N.J.R. 295(a).

In (b); inserted "American Council of Pharmaceutical Education" preceding "accredited college of pharmacy" and deleted the last sentence; in (c), inserted "American Council of Pharmaceutical Education" preceding "accredited college of pharmacy"; in (d), deleted "Board-approved" preceding "college of pharmacy externship program" and deleted "Board-accredited" following "Not more than 45 hours of"; in (f), deleted the last sentence.

13:39-8.5 Change in intern status

(a) A pharmacy intern applying for registration as a pharmacist in the State of New Jersey shall notify the Board within 10 days of any change in:

1. Beginning of a term of internship;
2. Termination of an internship;
3. Number of hours of employment;
4. Scheduled hours of employment;
5. Certified preceptor; and/or
6. Employing pharmacy.

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 (a)5, substituted a reference to certified preceptors for a reference to preceptors.

13:39-8.6 Reserved

Amended by R.1999 d.214, effective July 19, 1999.
See: 31 N.J.R. 1151(a), 31 N.J.R. 1932(a).

In (a)4, substituted a reference to certified preceptors for a reference to preceptors; deleted a former (c); and recodified former (d) as (c), and deleted a former first sentence.

Repealed by R.2005 d.25, effective January 18, 2005.
See: 36 N.J.R. 3345(a), 37 N.J.R. 295(a).

Section was "Committee on Pharmacy Internship and Externship".

13:39-8.7 Reserved

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.1998 d.167, effective April 6, 1998.
See: 29 N.J.R. 4740(b), 30 N.J.R. 1298(a).

In (a)2iii, substituted "Three examples" for "One example".

Amended by R.1999 d.214, effective July 19, 1999.
See: 31 N.J.R. 1151(a), 31 N.J.R. 1932(a).

In (a)2, inserted a reference to medication orders in i, substituted a reference to certified preceptors for a reference to preceptors in iv, and added v through ix.

Repealed by R.2005 d.25, effective January 18, 2005.
See: 36 N.J.R. 3345(a), 37 N.J.R. 295(a).
Section was "Pharmacist intern log".

SUBCHAPTER 9. PHARMACEUTICAL SERVICES FOR HEALTH CARE FACILITIES

13:39-9.1 Purpose and scope

(a) The rules in this subchapter shall apply to all retail pharmacies which contract to provide pharmaceutical services for healthcare facilities and to all institutional pharmacies which provide pharmaceutical services for their own health care system.

(b) An institutional pharmacy filling prescriptions for out-patient use shall comply with all retail pharmacy requirements of this chapter.

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. 13:39-9.1, Definitions, recodified to N.J.A.C. 13:39-9.2.

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).

13:39-9.2 Definitions

The following words and terms, as used in this subchapter, shall have the following meanings, unless the context clearly indicates otherwise.

"Drug administration" means a procedure in which a prescribed drug is given to a patient by an authorized person in accordance with all laws and rules governing such procedures.

"Formulary" means a continually revised compilation of pharmaceuticals available in the pharmacy for use in the facility developed by the Pharmacy and Therapeutics Committee.

"Health care facility" means a facility or institution licensed by the Department of Health and Senior Services pursuant to N.J.S.A. 26:2H-1 et seq.

"Health care system" means one or more health care facilities which are owned or controlled by the same legal entity.

“Institutional pharmacy” means the area in a health care facility or a health care system licensed by the Board as a pharmacy that maintains an institutional permit. “Institutional pharmacy” includes any areas of the health care facility or the health care system where pharmaceuticals are stored, compounded or dispensed.

“Medication order” means a written request for medication originated by an authorized prescriber and intended for patient use in the health care facility, and not for use of the institution’s employees or their dependents or outpatients of the facility’s clinics. A valid medication order contains the date ordered, the patient’s name and location within the facility, the name, dose, route, and frequency of administration of the medication, and any additional instructions. Computer-generated medication orders within an institutional setting, utilizing the prescriber’s electronic signature or password will meet legal requirements for a prescriber’s original handwritten signature on medication orders. Computerized signatures or passwords will be accepted provided that the facility has adequate safeguards which assure the confidentiality of each electronic signature or password and which prohibit their improper or unauthorized use.

“Pharmacy and Therapeutics Committee” means the active standing committee of the institution or health care facility which is the organizational line of communication and liaison between the medical service and pharmacists and which acts to review and promote rational drug therapy and utilization in the facility.

“Unit dose drug distribution system” means a system of dispensing drugs to be administered to patients of the facility whereby the medications are delivered daily (or more frequently) by the pharmacy to the patient care units in amounts equal to a 24-hour supply or less and are prepared, whenever possible, in single unit use packaging.

“Unit use packaging” means a single unit use medication provided in sealed packaging which contains the following information for each unit in the package:

1. Product name;
2. Strength and/or quantity and/or volume, where appropriate;
3. Lot number;
4. Use by date;
5. Manufacturer or repackager; and
6. If there is more than one product in the single unit, a physical description of each medication in the single unit.

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.1998 d.167, effective April 6, 1998.

See: 29 N.J.R. 4740(b), 30 N.J.R. 1298(a).

Amended N.J.A.C. reference in “Pharmacy and Therapeutics Committee” definition.

Amended by R.1999 d.214, effective July 19, 1999.

See: 31 N.J.R. 1151(a), 31 N.J.R. 1932(a).

Deleted “Authorized prescriber” and “Direct supervision”; in “Health care facility”, substituted a reference to patients and residents for a reference to the sick and injured; in “Unit dose drug distribution system”, deleted a reference to biologicals; and added “Unit use packaging”.

Amended by R.2000 d.457, effective November 20, 2000.

See: 31 N.J.R. 3044(a), 32 N.J.R. 4123(a).

Inserted “Health care system”; in “Institutional pharmacy”, inserted references to health care systems throughout, substituted “any” for “other” following “includes”, and deleted “manufactured,” following “stored;”.

Recodified from N.J.A.C. 13:39-9.1 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 “Health care facility”; in “Pharmacy and Therapeutics Committee”, substituted “medical service and pharmacists” for “medical and pharmacy staff” and deleted the last sentence; rewrote “Unit use packaging”. Former N.J.A.C. 13:39-9.2, Licensure of institutional pharmacies, recodified to N.J.A.C. 13:39-9.3.

13:39-9.3 Licensure of institutional pharmacies

(a) Any institutional pharmacy as defined under N.J.A.C. 13:39-9.2 shall be registered with and possess an institutional permit issued by the Board. The permit shall be conspicuously displayed in the facility’s pharmacy. The institutional pharmacy is subject to and shall be conducted in accordance with all existing State and Federal rules and regulations.