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RULE ADOPTION
LAW AND PUBLIC SAFETY
DIVISION OF CONSUMER AFFAIRS
BOARD OF PHARMACY
BOARD OF PHARMACY RULES

Proposed Readoption with Amendments: N.J.A.C. 13:39

Adopted Repeals: N.J.A.C. 13:39-3.8, 3.9, 3.10, 3.12, 3.13, 3.15, 3.16, 3.17, 4.13, 5.1, 6.4, 6.6, 8.6, 8.7, 9.8, 9.13, 9.22 and 11.4

Adopted New Rules: N.J.A.C. 13:39-2.6, 2.16 through 2.20, 3.2 through 3.6, 5.1, 6.1, 6.4, 7.4, 7.8, 7.9, 9.1 and 9.26

Proposed: July 19, 2004 at 36 N.J.R. 3345(a).

Adopted: November 10, 2004 by the Board of Pharmacy, Pamela Allen, R.Ph., President.

Filed: December 10, 2004 as R.2005 d.25, with substantive and technical changes not requiring additional public notice and comment (see N.J.A.C. 1:30- 6.3).

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

Effective Dates: December 10, 2004, Readoption;
January 18, 2005, Amendments.

Expiration Date: December 10, 2009.

Summary of Changes Upon Adoption:

Upon adoption, the Board has elected to amend the definition of "pharmacy technician" at N.J.A.C. 13:39-1.2 to make it clear that cashiers, stocking and clerical help are not encompassed in the term "pharmacy technician."

The Board is revising N.J.A.C. 13:39-3A.1 upon adoption to clarify a misconception raised by the use of the phrase "New Jersey pharmacy law" in the regulation. The Board intended the rule to encompass all pharmacy law that is applicable to the practice of pharmacy in New Jersey, including Federal law, not just the laws of the State of New Jersey.

The Board is revising N.J.A.C. 13:39-4.10 to extend the time period of an emergency closure of a pharmacy for which notification to the Board is required from 24 hours to 48 hours.

The Board is amending N.J.A.C. 13:39-6.4 upon adoption to make it clear that the patient related services referenced in paragraph (a)2 are not the only services that can be performed by pharmacy staff while the pharmacist is on his or her meal break.

The Board is revising the definition of "health care facility" in N.J.A.C. 13:39-9.2 by replacing "place" with "facility or institution." The Board is also revising the definition of "Pharmacy and Therapeutics Committee" so as to make it clear that the membership of pharmacists in the committee is not limited to the pharmacy staff of the facility, but that outside pharmacists, such as consultant pharmacists, are also encompassed.

The Board is amending N.J.A.C. 13:39-9.6 by removing the reference to N.J.A.C. 8:43G-23 from subsections (a) and (b) so that all health care facilities, not only hospitals, are to comply with the regulations of the DHSS, as well as those of the Board. Subsection (b) is also being amended to make it clear that the pharmacist-in-charge being referred to is from the provider pharmacy of the facility.

The Board is amending the heading of N.J.A.C. 13:39-9.8 upon adoption to make it clear that the rule addressed pharmaceutical services provided in the facility and does not address pharmaceutical care. In addition, the Board is revising N.J.A.C. 13:39-9.8(a) and (c) to make it clear that the pharmacist- in-charge referred to in the rule is the pharmacist-in-charge of the provider pharmacy.

The Board is revising N.J.A.C. 13:39-9.16 upon adoption so that where permitted by DHSS rules, the director of pharmaceutical services can develop the necessary policies and procedures for patients to use their own medication in the facility.

The Board is amending N.J.A.C. 13:39-9.18 to permit health care facilities to dispose of unused medication consistent with DHSS rules.

The Board is revising N.J.A.C. 13:39-9.19 upon adoption to eliminate any confusion that may exist as to what records of pharmaceutical services are being referenced in the rule, but making it clear that the records of pharmaceutical services referred to are those of the provider pharmacy.

The Board is amending N.J.A.C. 13:39-9.23(a) to permit facilities, where provided for in DHSS rules, to have a director of pharmaceutical services, who is not a registered pharmacist-in-charge, responsible for all the medications in the facility. The Board is also amending N.J.A.C. 13:39-9.23(b) to bring the rule into conformance with DHSS rules, which provide that the director of pharmaceutical services can establish the system for dispensing drugs in the institution, as the Board did not intend the regulation to conflict with rules of the DHSS. In addition, N.J.A.C. 13:39-9.23(b) is also being revised so that inspections in hospitals can be conducted in the manner provided for in DHSS rules.

The Board is revising N.J.A.C. 13:39-11.10(a)5 to require only "active" ingredients to be listed on prescription labels.

The Board is amending N.J.A.C. 13:39-11.11 by providing examples of the types of documentation it would find as acceptable substantiation for extending the "use by" date for a sterile preparation.

Federal Standards Statement

A Federal standards analysis is not required because the rules readopted with amendments and the adopted new rules are governed by N.J.S.A. 45:14-1 et seq. and are not subject to any Federal standards or requirements. Although the rules in N.J.A.C. 13:39 are not subject to any mandatory Federal requirements or standards, where deemed appropriate, the Board has incorporated Federal standards. Specifically, the Board notes that the requirements for facsimile and electronic transmission of prescriptions for controlled substances set forth at N.J.A.C. 13:39-7.10, 7.11 and 9.27 are consistent with the Federal Drug Enforcement Administration standards articulated at 21 C.F.R. § § 1306.11 and 1306.21.

Full text of the readoption can be found in the New Jersey Administrative Code at N.J.A.C. 13:39.

Full text of the adopted amendments and new rules follows :

SUBCHAPTER 1. GENERAL PROVISIONS

<< NJ ADC 13:39-1.1 >>

13:39-1.1 Purpose and scope

(a) (No change.)

(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.

<< NJ ADC 13:39-1.2 >>

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

... "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.

... "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. 13:39-6.6. For purposes of this definition, interns <<-and->><<+,+>> externs<<+, cashiers, stocking and clerical help+>> are not pharmacy technicians.

...

<< NJ ADC 13:39-1.3 >>

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.-vii. (No change.)
- viii. Inactive license renewal (To be determined by future rulemaking)
- ix. (No change.)
- x. Replacement of initial wall license 40.00.
- xi.-xiii. (No change.)

2. For pharmacies as follows:

- i. Pharmacy permits
 - (1) (No change.)
 - (2) Annual permit renewal 175.00.
 - (3) Change of ownership/name 275.00.
 - (4) (No change.)
- ii. Replacement of annual permit 25.00.
- iii. (No change in text.)
- iv. Verification of permit 25.00.

<< NJ ADC 13:39-1.4 >>

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.

<< NJ ADC 13:39-1.5 >>

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.

SUBCHAPTER 2. LICENSURE REQUIREMENTS

<< NJ ADC 13:39-2.1 >>

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) 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).

<< NJ ADC 13:39-2.2 >>

13:39-2.2 Education requirements

- (a) (No change.)
- (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.

<< NJ ADC 13:39-2.3 >>

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.

<< NJ ADC 13:39-2.4 >>

13:39-2.4 (No change in text.)

<< NJ ADC 13:39-2.5 >>

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. (No change in text.)

Recodify existing 5.-7. as 3.-5. (No change in text.)

<< NJ ADC 13:39-2.6 >>

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.

<< NJ ADC 13:39-2.7 >>

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.

<< NJ ADC 13:39-2.8 >>

13:39-2.8 (No change in text.)

<< NJ ADC 13:39-2.9 >>

13:39-2.9 Applicants educated in a foreign country

(a)-(c) (No change.)

(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.

<< NJ ADC 13:39-2.10 >>

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.

<< NJ ADC 13:39-2.11 >>

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.

<< NJ ADC 13:39-2.12 >>

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.

<< NJ ADC 13:39-2.13 >>

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.

<< NJ ADC 13:39-2.14 >>

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.

<< NJ ADC 13:39-2.15 >>

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.

<< NJ ADC 13:39-2.16 >>

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.

<< NJ ADC 13:39-2.17 >>

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).

<< NJ ADC 13:39-2.18 >>

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.

<< NJ ADC 13:39-2.19 >>

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.

<< NJ ADC 13:39-2.20 >>

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.

SUBCHAPTER 3. LICENSURE BY RECIPROCITY

<< NJ ADC 13:39-3.1 >>

13:39-3.1 Limitation of reciprocal licensure

- (a) (No change.)
- (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) (No change in text.)

<< NJ ADC 13:39-3.2 >>

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.

<< NJ ADC 13:39-3.3 >>

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.

<< NJ ADC 13:39-3.4 >>

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.

<< NJ ADC 13:39-3.5 >>

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.

<< NJ ADC 13:39-3.6 >>

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.

<< NJ ADC 13:39-3.7 >>

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) (No change.)

SUBCHAPTER 3A. CONTINUING EDUCATION

<< NJ ADC 13:39-3A.1 >>

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 <<-New Jersey->> pharmacy law <<+applicable to the practice of pharmacy in New Jersey+>>.

(b) (No change.)

SUBCHAPTER 4. PHARMACY PERMIT REQUIREMENTS

<< NJ ADC 13:39-4.1 >>

13:39-4.1 New pharmacies; eligibility and application

(a)-(b) (No change.)

(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) (No change.)

(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) (No change.)

(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) (No change.)

Recodify existing N.J.A.C. 13:39-4.1 and 4.2 as 4.2 and 4.3 (No change in text.)

<< NJ ADC 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.

<< NJ ADC 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.

<< NJ ADC 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.

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.

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.

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.-3. (No change.)

13:39-4.10 Business hours; unauthorized closing

(a) (No change.)

(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 <<-24->> <<+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 <<- 24->> <<+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.

<< NJ ADC 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.

<< NJ ADC 13:39-4.12 >>

13:39-4.12 Change of name

(a) (No change.)

(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.

<< NJ ADC 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.

<< NJ ADC 13:39-4.14 >>

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. (No change in text.)

<< NJ ADC 13:39-4.15 >>

13:39-4.15 (No change in text.)

<< NJ ADC 13:39-4.16 >>

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.

<< NJ ADC 13:39-4.17 >>

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.

<< NJ ADC 13:39-5.10 >>

<< NJ ADC 13:39-4.18 >>

13:39-~~5.10~~ <<+4.18+>> (No change in text.)

(Agency Note: N.J.A.C. 13:39-5.10 is recodified upon adoption as N.J.A.C. 13:39-4.18)

SUBCHAPTER 5. RETAIL FACILITY REQUIREMENTS

<< NJ ADC 13:39-5.1 >>

13:39-5.1 Purpose and scope

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

<< NJ ADC 13:39-5.2 >>

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.

<< NJ ADC 13:39-5.3 >>

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.

<< NJ ADC 13:39-5.4 >>

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.

<< NJ ADC 13:39-5.5 >>

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.

<< NJ ADC 13:39-5.6 >>

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.

<< NJ ADC 13:39-5.7 >>

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.

<< NJ ADC 13:39-5.8 >>

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.-3. (No change.)

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;

Recodify existing 8.-16. as 7.-15. (No change in text.)

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.

Recodify existing N.J.A.C. 13:39-7.8 and 7.9 as 5.9 and 5.10 (No change in text.)

<< NJ ADC 13:39-5.11 >>

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.

<< NJ ADC 13:39-5.12 >>

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.

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

<< NJ ADC 13:39-6.1 >>

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.

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) (No change in text.)
- (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.

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.

<< NJ ADC 13:39-6.4 >>

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->> <<-The<<+ receipt of new written prescriptions->>+>> and

<<-ii.<<+ ->>for the<<- ->>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."

<< NJ ADC 13:39-6.5 >>

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.

<< NJ ADC 13:39-6.6 >>

13:39-6.6 Pharmacy technicians

(a) Pharmacy technicians may assist the registered pharmacist in performing the following tasks:

1. Retrieval of prescription files, patient files and profiles and other such records pertaining to the practice of pharmacy;

2. Data entry;

3. Label preparation; and

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 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. 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 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) Except as provided in (e) below, a pharmacist shall not supervise more than two pharmacy technicians at any given time. Those personnel who do computer processing of prescriptions are to be included in the 1 to 2 ratio.

(e) A pharmacy that wishes to employ 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 technician;
2. Ensure and document that each pharmacy technician passes the National Pharmacy Technician Certification Examination and fulfills the requirements to maintain this status, or completes a program which includes a testing component and which has been approved by the Board as satisfying the criteria set forth in (f) below;
3. Ensure that each pharmacy technician is knowledgeable in the established job descriptions, task protocols, and policies and procedures in the pharmacy setting in which the technician is to perform his or her 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 each pharmacy technician receives in-service training before the pharmacy technician assumes his or her responsibilities and maintain documentation thereof;
6. Require and maintain on site a signed patient confidentiality statement from each technician;
7. Provide immediate personal supervision as defined in N.J.A.C. 13:39- 1.2; and
8. Provide the Board, upon request, with a copy of the established job descriptions, task protocols, and policies and procedures for all pharmacy technician duties.

(f) 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 on-going 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.

(g) 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.

(h) On yearly pharmacy permit renewal applications, the pharmacy shall list the name and address of all pharmacy technicians which it currently employs.

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

SUBCHAPTER 7. DRUG DISPENSING AND PRESCRIPTION RECORDS

<< NJ ADC 13:39-7.1 >>

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.

<< NJ ADC 13:39-7.2 >>

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.

<< NJ ADC 13:39-7.3 >>

13:39-7.3 (No change in text.)

<< NJ ADC 13:39-7.4 >>

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.

<< NJ ADC 13:39-7.5 >>

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 participating 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.

<< NJ ADC 13:39-7.6 >>

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.

<< NJ ADC 13:39-7.7 >>

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.

<< NJ ADC 13:39-7.8 >>

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

<< NJ ADC 13:39-7.9 >>

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.

<< NJ ADC 13:39-7.10 >>

13:39-7.10 (No change in text.)

<< NJ ADC 13:39-7.11 >>

13:39-7.11 Electronically transmitted prescriptions

(a)-(j) (No change.)

(k) Two or more permit holders may establish a common electronic filing system to maintain required dispensing information.

(l) Nothing in this section shall be construed to preclude the electronic transfer of information between pharmacies for purposes of transferring prescriptions pursuant to N.J.A.C. 13:39-7.8.

<< NJ ADC 13:39-7.12 >>

13:39-7.12 Labeling

(a) (No change.)

(b) In addition to the requirements set forth in (a) above, the dispensed container for any product shall bear all auxiliary labeling as recommended by the manufacturer.

(c) When, in the judgment of the pharmacist, directions to the patient or cautionary messages are necessary, either for

clarification or to ensure proper administration, storage or use of the medication, the pharmacist may add such directions or cautionary messages to those indicated by the prescriber on the original prescription.

<< NJ ADC 13:39-7.13 >>

13:39-7.13 Professional judgment in dispensing drugs

The pharmacist shall have the right to refuse to fill a prescription if, in his or her professional judgment, the prescription is outside the scope of practice of the prescriber; or if the pharmacist has sufficient reason to question the validity of the prescription; or to protect the health and welfare of the patient.

<< NJ ADC 13:39-7.14 >>

13:39-7.14 Advertising and sale of prescription drugs

(a)-(d) (No change.)

(e) Upon request by any consumer, the pharmacist shall give usual and customary price information for a non-third party paying customer over the telephone and shall stipulate the effective period of the price quotation.

(f) All advertisements shall be predominantly informational and shall not be misleading, confusing or false. Any advertisement demeaning the quality of professional services rendered by another licensee or permittee shall be prohibited.

<< NJ ADC 13:39-7.15 >>

13:39-7.15 (No change in text.)

<< NJ ADC 13:39-7.16 >>

13:39-7.16 Return of prescription medication

(a) Prescription medication correctly dispensed to a patient may be accepted for return by the pharmacist but shall not be placed in stock for reuse or resale, except as provided in N.J.A.C. 13:39-9.18(a)2.

(b) Prescription medication incorrectly dispensed to a patient shall be accepted for return by the pharmacist and shall not be placed back in stock for reuse or resale.

(c) Prescription medication which has been prepared for a patient, but which has not been dispensed to the patient, may be placed back in stock for reuse or resale provided that:

1. In the professional judgment of the pharmacist, the prescription medication is eligible for re-dispensing. Eligible medications are those medications that are able to be consumed by a patient within the original time frame established for the medication's stability and expiration. Products that have a limited shelf life and/or that have not been stored consistent with manufacturers' storage requirements may not be re-dispensed;

2. The prescription medication shall not be placed in manufacturers' stock containers of different lot numbers and/or with different expiration dates;

3. Manufacturers' stock containers shall not be over-filled;

4. In those circumstances in which prescription medications cannot be properly returned to the original manufacturers' stock containers, the medication shall be held in the pharmacy in the labeled container in which it has been repackaged;

5. If the manufacturer or the FDA orders a recall of a drug product, the pharmacist shall assume products held in

labeled containers without lot numbers are included in the recall and proceed accordingly; and

6. Medications held for re-dispensing shall be used as soon as possible. Such medications, lacking original lot numbers and expiration dates, shall not be dispensed to patients beyond six months from the date the medications were originally prepared for dispensing. Re-dispensed medications shall be marked with the same use by date as the medication which was originally prepared for dispensing.

<< NJ ADC 13:39-7.17 >>

13:39-7.17 (No change in text.)

<< NJ ADC 13:39-7.18 >>

13:39-7.18 Outdated drugs or drugs marked "sample"

No outdated, misbranded, deteriorated, improperly stored or adulterated drugs, or any drugs marked "sample" or with any like designation or meaning shall be dispensed or placed or maintained in active stock for use or sale.

<< NJ ADC 13:39-7.19 >>

13:39-7.19 Patient profile record system

(a) (No change.)

(b) The following information shall be recorded in the PPRS:

1.-7. (No change.)

8. Pharmacist's comments relevant to the patient's drug therapy.

(c)-(d) (No change.)

(e) Upon receipt of a new or refill prescription, a pharmacist shall examine the patient's profile record either in a manual or electronic data processing system before dispensing the medication, to determine the possibility of a potentially significant drug interaction, reaction or misutilization of the prescription. Upon determining a potentially significant drug interaction, reaction or misutilization, the pharmacist shall take the appropriate action to avoid or minimize the problem, which shall, if necessary, include consultation with the patient and/or the prescriber.

1.-2. (No change.)

3. A pharmacist shall not be required to counsel a patient or caregiver when the patient or caregiver refuses such consultation. The absence of any record of a failure to accept the pharmacist's offer to counsel shall be presumed to signify that the offer was accepted and that the counseling was provided.

4.-9. (No change.)

(f) A patient profile record shall be maintained for a period of not less than five years from the date of the last entry in the profile record. In using an electronic data processing system, the system shall have the capability of producing retrievable and readable documents of all original and refilled prescription data for a period of not less than five years, including the number of refills authorized by the prescriber. 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.

(g)-(j) (No change.)

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.

... "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.

...

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. (No change.)

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) (No change.)

(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) (No change in text.)

13:39-8.4 Internship and externship practical experience

(a) (No change.)

(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) (No change.)

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

SUBCHAPTER 9. PHARMACEUTICAL SERVICES FOR HEALTH CARE FACILITIES

<< NJ ADC 13:39-9.1 >>

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 outpatient use shall comply with all retail pharmacy requirements of this chapter.

<< NJ ADC 13:39-9.2 >>

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.

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

... "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 <<-pharmacy staff->> <<+pharmacists+>> and which acts to review and promote rational drug therapy and utilization in the facility.

... "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. (No change.)
2. Strength and/or quantity and/or volume, where appropriate;
3. (No change.)
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.

<< NJ ADC 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.

(b) (No change.)

<< NJ ADC 13:39-9.4 >>

13:39-9.4 Contract pharmaceutical services; institutional permit required

An institutional permit is required for any area within an institution serviced by an outside vendor that performs on-site pharmaceutical services as defined in N.J.A.C. 13:39-1.2.

<< NJ ADC 13:39-9.6 >>

13:39-9.5 (No change in text.)

13:39-9.6 Pharmacy and Therapeutics Committee; applicability; polices and procedures

(a) In all health care facilities providing pharmaceutical services to patients, an active standing committee of the institution entitled the Pharmacy and Therapeutics Committee or other appropriate name shall be established if required pursuant to Department of Health and Senior Services rules <<-set forth at N.J.A.C. 8:43G-23->>. A Pharmacy and Therapeutics Committee shall be multidisciplinary and include a pharmacist.

(b) In all health care facilities providing pharmaceutical services to patients that are not required to maintain a Pharmacy and Therapeutics Committee pursuant to Department of Health and Senior Services rules <<-set forth at N.J.A.C. 8:43G-23->>, the pharmacist-in-charge <<+of the provider pharmacy+>>, in cooperation with the health care facility, shall create policies and procedures as needed to provide pharmaceutical services to the health care facility. The written policies and procedures shall be available to the Board.

<< NJ ADC 13:39-9.7 >>

13:39-9.7 Institutional pharmacy staff

The institutional pharmacy shall be staffed by sufficient, competent personnel in keeping with the size, scope and complexity of the pharmaceutical services provided consistent with the requirements of N.J.A.C. 13:39-6.2(f)1.

<< NJ ADC 13:39-9.8 >>

13:39-9.8 Control of health care <<-facility pharmacy->> <<+ pharmaceutical+>> services; responsibilities of the registered pharmacist-in-charge <<+of the provider pharmacy+>>

(a) The pharmaceutical services of the health care facility shall be the responsibility of and under the control, supervision, and direction of the registered pharmacist-in-charge <<+of the provider pharmacy+>>.

(b) If a health care facility does not have an institutional pharmacy on its premises or chooses to utilize the services of a pharmacy outside the health care system, it may enter into an agreement with a retail pharmacy licensed by the Board. The registered pharmacist-in-charge of the retail pharmacy shall direct, control, supervise and be responsible for the pharmaceutical services provided to the facility.

(c) The registered pharmacist-in-charge <<+of the provider pharmacy+>>, with the cooperation of the Pharmacy and Therapeutics Committee, shall develop written policies and procedures as needed to provide pharmaceutical services to the facility. The written policies and procedures shall be available to the Board.

<< NJ ADC 13:39-9.9 >>

13:39-9.9 (No change in text.)

<< NJ ADC 13:39-9.10 >>

13:39-9.10 Pharmaceuticals; drug supply; investigational drugs; controlled dangerous substances

(a) The pharmacist-in-charge shall be responsible for determining the specifications for drugs and pharmaceutical preparations used in the treatment of patients of the facility as to quality, quantity and source of supply. An authorized purchasing agent and/or materials manager and/or pharmacy buyer of the facility may perform the actual procurement. In such a case, the purchase shall be supervised by the pharmacist-in-charge or his or her designee, who shall be a pharmacist.

(b) (No change.)

(c) The institutional pharmacy shall have an adequate inventory of drugs and biologicals to assure timely initiation of routine, and disaster drug therapy. Limited quantities of drugs shall be placed under controlled conditions in locations within the facility to assure immediate access by authorized licensed health care personnel for use in an emergency situation. Written policies and procedures for the maintenance, content, control and accountability of drugs supplied and located throughout the facility shall be developed by the registered pharmacist-in-charge and approved by the Pharmacy and Therapeutics Committee.

(d) 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 these drugs shall not be construed to be a violation of N.J.A.C. 13:39-7.5(a). A facility participating in experimental research involving residents must be in compliance with Federal Department of Health and Human Services regulations, 45 C.F.R. Part 46, Protection of Human Subjects of Research, which is incorporated by reference herein, as amended and supplemented.

(e) Investigational drugs shall be properly labeled and stored in the pharmacy until dispensed. Essential information on the investigational drug shall be maintained in the pharmacy. The investigational drug may be administered only after basic chemical, pharmaceutical and pharmacological information has been made available to all concerned and all the requirements of the Food and Drug Administration and the facility are satisfied.

(f) Controlled dangerous substances shall be purchased, received, stored, dispensed, administered, recorded and controlled in accordance with State and Federal laws and regulations. Written policies and procedures concerning control, use and accountability of controlled drugs shall be developed by the registered pharmacist-in-charge.

<< NJ ADC 13:39-9.11 >>

13:39-9.11 Drug disbursement; written orders; outpatient prescriptions

(a) The pharmacist shall review the prescriber's original order, a direct copy thereof, or a facsimile before any initial dose of medication is dispensed, except as provided for in N.J.A.C. 13:39-9.13.

(b) (No change.)

(c) The Pharmacy and Therapeutics Committee shall develop a list of unapproved or unacceptable abbreviations and symbols which shall not be used in the facility. Orders involving symbols or abbreviations shall only be dispensed consistent with this list.

(d) When appropriate, the pharmacist shall make necessary entries into the patient medical record relative to drug use in accordance with health care facility policies <<+and, where applicable, pursuant to regulations of the Department of Health and Senior Services and/or Centers for Medicare and Medicaid Services+>>.

<< NJ ADC 13:39-9.12 >>

13:39-9.12 Drug disbursement; oral orders

(a) The provisions of this section shall be implemented in accordance with the policy and protocols of the Pharmacy and Therapeutics Committee.

(b) A pharmacist shall receive oral orders only from an authorized prescriber. Such orders shall be immediately recorded and signed by the person receiving the order on the medication order sheet or into the electronic data processing system.

(c)-(d) (No change.)

(e) The pharmacist may release to the patient at discharge any remaining medication in a multiple dose container (for example, inhalers, multiple dose injectable medications such as insulin, topical preparation, drops, ointments, and topical irrigation solutions), provided that the pharmacist:

1. (No change.)

2. Counsels the patient prior to discharge from the hospital or medical facility pursuant to N.J.A.C. 13:39-7.19; and

3. (No change.)

Recodify existing N.J.A.C. 13:39-9.9 and 9.10 as 9.13 and 9.14 (No change in text.)

<< NJ ADC 13:39-9.15 >>

13:39-9.15 Drug labeling

Labeling of medications, other than intravenous solutions, shall be in conformance with written policies and procedures controlling the drug distribution system in use within the facility and in accord with current acceptable standards of pharmaceutical practice.

<< NJ ADC 13:39-9.16 >>

13:39-9.16 Use of patient's own medication

(a) No drugs shall be administered to a patient except those provided through the pharmacy or as provided by written policies and procedures developed by the registered pharmacist-in-charge <<+or, where applicable, the director of pharmaceutical services+>> and approved by the Pharmacy and Therapeutics Committee.

(b) (No change.)

<< NJ ADC 13:39-9.17 >>

13:39-9.17 Drug-dispensing devices

(a) (No change.)

(b) Packaging and labeling of medication for drug-dispensing devices, when done in the facility, shall be performed under the immediate personal supervision of a pharmacist in the employ of or under contract to the facility.

(c) Stocking of the drug-dispensing devices with prepackaged medications shall be performed by or under the supervision of a pharmacist.

(d) The cleanliness of the drug dispensing devices shall be maintained by a pharmacist or by a person under the

supervision of a pharmacist.

(e) Controlled substances and other medications to which, in the professional judgment of the registered pharmacist-in-charge, access should be limited, shall be secured within the drug dispensing device to limit access to single medications only and shall be checked and documented by the pharmacist or his or her designee who shall be a licensed professional, every 24 hours. Other than a pharmacist, only authorized registered nurses, licensed practical nurses, physicians, authorized prescribers or designated pharmacy technicians, interns and externs shall have access to the medication in each drug-dispensing device. The activity regarding all medication, including the identity of the person accessing the medication, shall be recorded and available to the pharmacist.

(f)-(g) (No change.)

<< NJ ADC 13:39-9.18 >>

13:39-9.18 Disposal of unused medications

(a) Written policies and procedures governing unused medications shall be established and implemented by the registered pharmacist-in-charge and shall comply with the following requirements:

1. All medications where the drug source, lot or control number, or expiration or use by date are missing, shall be sent to the pharmacy for final disposition, or shall be disposed of by the health care facility according to its written protocol.

2.-3. (No change.)

4. The record of disposal of unused or nonadministered dispensed controlled dangerous substances expended or wasted either by accident or intent shall be signed and cosigned and witnessed by a licensed nurse, physician or pharmacist<<+, or where allowed by Department of Health and Senior Services rules an administrator of the health care facility,+>> and disposed of by the health care facility according to its written protocol and consistent with all local, State and Federal laws and regulations.

<< NJ ADC 13:39-9.19 >>

13:39-9.19 Records and reports

(a) Records of the pharmaceutical services of the <<+provider pharmacy for the+>> facility shall be the responsibility of the registered pharmacist-in-charge. Adequate storage for pharmacy records shall be provided. Records not currently in use need not be stored in the pharmacy, but the storage facilities shall be secure, and the records shall be readily retrievable by the pharmacy staff and authorized inspectors. These records shall be made available to persons authorized to inspect them under State and Federal statutes and regulations. Patient records shall be kept confidential.

(b) The pharmacy shall maintain a patient profile record for each patient receiving drug therapy in accordance with N.J.A.C. 13:39-7.19 and as follows:

1. (No change.)

2. All notations made on the inpatients' profile records by pharmacy technicians, interns and externs shall be verified and countersigned, either manually or electronically, by the supervising pharmacist.

3. The inpatient profile record shall be filed and stored for five years following patient discharge. 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 immediately retrievable and readable.

(c)-(e) (No change.)

(f) The registered pharmacist-in-charge shall be responsible for maintaining a system by which all reported adverse

drug reactions are recorded and reviewed by the Pharmacy and Therapeutics Committee, where applicable, and are submitted to all appropriate State and local agencies consistent with State and local laws and regulations.

<< NJ ADC 13:39-9.20 >>

13:39-9.20 Drug information and education

(a) The registered pharmacist-in-charge shall be responsible for maintaining drug standards, references and sources of drug information current and adequate to meet the needs of the pharmacists, physicians, nurses, other health care personnel, and patients of the facility. Reference texts shall include, but not be limited to, those required by the Board under N.J.A.C. 13:39-5.8.

(b)-(c) (No change.)

<< NJ ADC 13:39-9.21 >>

13:39-9.21 After hours access to the institutional pharmacy

(a)-(e) (No change.)

(f) All records in (d) above shall be kept by the pharmacy for five years. 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 immediately retrievable and readable.

<< NJ ADC 13:39-9.22 >>

13:39-9.22 Pharmacy facilities; space

(a) (No change.)

(b) The facilities shall include, but are not limited to, those requirements provided in N.J.A.C. 13:39-5.4 through 5.8.

(c) (No change.)

<< NJ ADC 13:39-9.23 >>

13:39-9.23 Storage and security

(a) Provisions shall be made for adequate safe storage of drugs wherever they are stored in the health care facility.

1.-2. (No change.)

3. The registered pharmacist-in-charge <<+or, where provided for in Department of Health and Senior Services rules, the director of pharmaceutical services+>> shall be responsible for all the medications in the facility, that is, the drugs in the pharmacy area, drugs in transit, and the drugs in the patient care areas.

4. The drugs throughout the facility shall be maintained under adequate storage conditions including proper lighting, ventilation and temperature control as required by the drug manufacturer.

(b) The pharmacist-in-charge <<+or, where provided for in Department of Health and Senior Services rules, the director of pharmaceutical services+>> shall establish a system of control for all drugs dispensed for use in the drug therapy of patients of the facility. Inspections shall be conducted of all medication areas located in the facility or any other service area of the facility at least once every two months to check for expiration or use by dates, misbranding, physical integrity, security and accountability of all drugs dispensed for use. These inspections shall be fully documented. Written inspection reports shall be prepared and signed by the inspecting pharmacist <<-or->><<+, except for hospitals, where they can also be prepared and signed+>> by the pharmacy technician, intern or extern and

co-signed by his or her supervising pharmacist. The pharmacist-in-charge shall be responsible for ensuring that, prior to performing any inspections pursuant to this subsection, pharmacy technicians, interns and externs are trained and can successfully demonstrate competency. Procedures for the review of these reports shall be developed and instituted by the pharmacist-in-charge and can be incorporated into the overall quality assurance program of the <<- hospital->> <<+health care facility+>>.

(c) Procedures shall be established to assure the immediate and efficient removal of all outdated and recalled drugs from patient care areas and from the active stock of the pharmacy. The registered pharmacist-in-charge shall develop written policies and procedures governing the removal from the facility of outdated or recalled drugs.

<< NJ ADC 13:39-9.24 >>

13:39-9.24 (No change in text.)

<< NJ ADC 13:39-9.25 >>

13:39-9.25 Institutional decentralized pharmacies

(a) An institutional decentralized pharmacy or a "satellite pharmacy", means an area within a health care system that has been issued an institutional permit and is in a location other than the original permitted location, where the preparation or dispensing or compounding of medications is performed.

(b) Medication shall not be dispensed from a decentralized pharmacy without a pharmacist present, except that, when the decentralized pharmacy is closed, a licensed nurse may dispense medication in accordance with the written policies and procedures of the institution.

(c) Institutions operating decentralized pharmacies shall notify the Board, in writing, of the existence of, and the discontinuation of, each decentralized pharmacy location.

(d) Institutional decentralized pharmacies shall be subject to normal Board inspections.

(e) Inspections of all medications in a decentralized institutional pharmacy shall be performed consistent with the requirements of N.J.A.C. 13:39-9.23.

(f) Institutional decentralized pharmacies shall comply with all requirements in this subchapter applicable to the pharmaceutical services provided by the decentralized pharmacy, as determined by the registered pharmacist-in-charge.

<< NJ ADC 13:39-9.26 >>

13:39-9.26 Valid medication orders; out-of-State medication orders

(a) Only medication orders issued by an authorized prescriber licensed to write medication orders in the United States or any territory of the United States shall be considered valid medication orders and such medication orders shall be filled pursuant to New Jersey law.

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

<< NJ ADC 13:39-9.27 >>

13:39-9.27 Prescriptions and medication orders transmitted by technological devices in an institution

(a) (No change.)

(b) A registered pharmacist filling prescriptions under an institutional permit for employees of the institution and their dependents and for eligible outpatients may accept for dispensing prescriptions for all substances other than Schedule II

controlled dangerous substances which have been transmitted by technological device, under the following conditions only:

1. Before releasing to other than an inpatient of a health care facility, as defined in N.J.A.C. 13:39-9.2, any prescription medication for a controlled dangerous substance listed in Schedules III, IV or V, the pharmacist shall obtain and file the original signed prescription.

2. (No change.)

(c) A registered pharmacist who is authorized to fill inpatient medication orders, as defined in N.J.A.C. 13:39-9.2, in an institutional pharmacy may accept all inpatient medication orders, including orders for Schedule II substances, which have been transmitted by technological device. Medication orders for narcotic Schedule II controlled substances written for long-term care facility residents or hospice patients or for direct administration to patients by parenteral, intravenous, intramuscular, subcutaneous or intraspinal infusion, which are transmitted by facsimile, shall serve as the original written medication orders, in accordance with the provisions of 21 C.F.R. 1306.11(d), (e), (f) and (g).

(d)-(g) (No change.)

SUBCHAPTER 10. AUTOMATED MEDICATION SYSTEMS

<< NJ ADC 13:39-10.3 >>

13:39-10.3 Authority to use automated medication system

(a) (No change.)

(b) The registered pharmacist in charge or the registered pharmacist under contract with a healthcare facility responsible for the dispensing of medications shall be responsible for the following:

1. (No change.)

2. Ensuring that medications in the automated medication system are inspected, at least monthly, for expiration or use by date, misbranding and physical integrity, and ensuring that the automated medication system is inspected, at least monthly, for security and accountability;

3.-5. (No change.)

<< NJ ADC 13:39-10.5 >>

13:39-10.5 Personnel training requirements

The registered pharmacist in charge shall be responsible for ensuring that, prior to performing any services in connection with an automated medication system, all licensed practitioners and pharmacy technicians, interns and externs are trained in the pharmacy's standard operating procedures with regard to automated medication systems as set forth in the written policies and procedures of operation maintained pursuant to N.J.A.C. 13:39-10.4.

SUBCHAPTER 11. COMPOUNDING IN RETAIL AND INSTITUTIONAL PHARMACIES FOR STERILE AND/OR NON-STERILE PREPARATIONS

<< NJ ADC 13:39-11.1 >>

13:39-11.1 Purpose and scope

This subchapter shall apply to all retail and institutional pharmacies which compound and dispense sterile and/or non-sterile preparations.

13:39-11.2 Definitions

The following words and terms, when used in this subchapter, shall have the following meanings:

"ISO class 5 air quality conditions" means conditions in which the air particle count is no greater than a total of 3,520 particles of 0.5 micrometers and larger per cubic meter of air (100 particles per cubic foot).

"ISO class 6 air quality conditions" means conditions in which the air particle count is no greater than a total of 35,200 particles of 0.5 micrometers and larger per cubic meter of air (1,000 particles per cubic foot).

"ISO class 7 air quality conditions" means conditions in which the air particle count is no greater than a total of 352,000 particles of 0.5 micrometers and larger per cubic meter of air (10,000 particles per cubic foot).

...

13:39-11.3 Sterile and non-sterile preparation services; environment

(a) A sterile preparation service is one specializing in the compounding and dispensing of sterile preparations upon receipt of a valid prescription or medication order. Such compounding shall take place in the confines of a controlled environment as required by N.J.A.C. 13:39-11.16; or when circumstances permit as set forth in N.J.A.C. 13:39-11.11(c), in a laminar hood, as provided by N.J.A.C. 13:39-11.22, or in a glove box, as provided by N.J.A.C. 13:39-11.23.

(b) Compounding of non-sterile preparations shall take place in a compounding environment designated specifically for that purpose.

13:39-11.4 General requirement for compounded sterile preparations; pre-approval

An applicant or permitholder who wishes to compound sterile preparations shall notify the Board at least 60 days prior to commencement and shall receive approval from the Board before commencing compounding of sterile preparations.

13:39-11.5 Pharmacist in charge and permitholders' responsibilities

(a) The pharmacist-in-charge shall supervise all sterile and/or non-sterile compounding. For purposes of supervising sterile compounding, the pharmacist-in-charge shall be trained in aseptic manipulation skills.

(b) The pharmacist in charge shall have the responsibility, in that section of the pharmacy where sterile and/or non-sterile preparations are compounded, for, at a minimum, the following:

1. Compounding of all preparations within the pharmacy or pharmacy satellite, including compounding of individual medication orders or prescriptions, the formulation of products in response to special drug needs and batch compounding;
2. Storage of all materials pertinent to the compounding of preparations, including drugs, chemicals and biologicals, and the establishment of specifications for procurement of the materials in accordance with State and Federal laws and regulations;
3. Ensuring that all packaging and labeling of all drugs compounded with the pharmacy are performed under the

immediate personal supervision of a pharmacist;

4. Recording all transactions of the pharmacy as may be applicable to State, Federal and local laws and rules, as may be necessary to maintain accurate control over, and accountability for, all pharmaceutical materials;

5. Ensuring that preparation and compounding of sterile preparations is performed only by licensed pharmacists who have been trained in aseptic manipulation skills, or by pharmacy technicians, interns or externs who have been trained in aseptic manipulation skills working under the immediate personal supervision of a licensed pharmacist trained in aseptic manipulation skills;

6. Ensuring that preparation and compounding of non-sterile preparations is performed only by licensed pharmacists or by pharmacy technicians, intern or externs working under the immediate personal supervision of a licensed pharmacist; and

7. Establishing procedures for maintaining the integrity and manufacturer's control identity of packaged material. The packaging records shall be initialed by the supervising pharmacist.

<< NJ ADC 13:39-11.6 >>

13:39-11.6 Pharmacy technicians, interns and externs; required supervision

(a) Dispensing pharmacists shall provide immediate personal supervision to pharmacy technicians, interns or externs who are performing delegated sterile and non-sterile preparation compounding. The ratio of dispensing pharmacists to pharmacy technicians shall not exceed 1:2 at any given time unless all of the requirements of N.J.A.C. 13:39-6.6(d) and (e) are met.

1. (No change in text.)

(b) The dispensing pharmacist may delegate to pharmacy technicians, interns or externs only the following tasks: recording of the prescription, selection of the drugs, container and diluent, typing of labels and compounding of preparations. The dispensing pharmacist shall ensure that each task has been performed correctly in the dispensing process.

<< NJ ADC 13:39-11.7 >>

13:39-11.7 Training requirements for compounding sterile preparations

(a) The pharmacist in charge and all personnel involved in compounding sterile preparations shall have practical or academic training in sterile preparation compounding, clean room technology, laminar flow technology, and quality assurance techniques. Such training shall be documented for each person before that individual begins to compound sterile preparations and annually thereafter. That documentation shall be maintained by the permitholder for five years and made available to the Board upon request.

(b) The pharmacist in charge shall be responsible for ensuring that, prior to compounding sterile preparations, all personnel are trained and can successfully demonstrate:

1. Comprehensive knowledge of the pharmacy's standard operating procedures with regard to compounding sterile preparations as set forth in the policy and procedure manual required to be maintained pursuant to N.J.A.C. 13:39-11.13;

2.-3. (No change.)

(c) At least annually, the pharmacist in charge shall be responsible for testing the aseptic technique of all personnel involved in compounding sterile preparations by means of a test batch of culture media, media fill or the equivalent. Test results shall be maintained for five years, and shall be made available for the Board's inspection upon request.

Individuals who fail to demonstrate acceptable aseptic technique shall be prohibited from engaging in sterile preparation compounding until demonstrating acceptable technique by means of a test batch of culture media, media fill or the equivalent.

<< NJ ADC 13:39-11.8 >>

13:39-11.8 Batch preparation

Pharmacists and pharmacy technicians, interns and externs may compound sterile and non-sterile preparations consistent with the provisions of N.J.A.C. 13:39-11.6 in a quantity that is supported by prior valid prescription or medication orders before receiving a valid written prescription or medication order, provided the pharmacist can document a history of valid prescriptions subsequently received shortly thereafter or medication orders that have been generated solely within an established professional prescriber-patient-pharmacist relationship, and provided they maintain the prescription on file for all such products dispensed at the pharmacy as required by state law. The pharmacist shall document the batch preparation process in accordance with N.J.A.C. 13:39-11.9(d).

<< NJ ADC 13:39-11.9 >>

13:39-11.9 Documentation

(a) Consistent with the provisions of N.J.A.C. 13:39-11.5, the dispensing pharmacist shall ensure that compounded preparations have been properly prepared, labeled, controlled, stored, dispensed and distributed in accordance with the provisions of this subchapter.

(b) The pharmacist in charge shall be responsible for ensuring that policies and procedures exist so that all aspects of the dispensing process set out in (d) below are documented and that the pharmacist responsible for each preparation can be identified.

(c) The dispensing pharmacist shall assure that appropriate documentation is maintained to track completion of each of the steps of the compounding process set out in (d) below.

(d) Compounding steps which shall be documented are as follows:

1. Receipt of prescription or medication order;
2. Recording of prescription or medication order in the patient record profile system, pursuant to N.J.A.C. 13:39-11.15;
3. (No change.)
4. Verification that all pharmacy sterile preparation compounding is performed within a ISO class 5 laminar air flow hood or ISO class 5 clean room and that proper aseptic procedures are being used at all times to prevent bacterial contamination of this product;
5. Verification that ingredients comply with the prescription or medication order;
6. Verification that the prescription or medication order label complies with the requirements of N.J.A.C. 13:39-11.10; and
7. Verification that the prescription or medication order is complete and ready to be dispensed, including any necessary ancillary supplies.

(e) The completed documentation shall be maintained for not less than five years from the date of the last entry in the record. 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 shall be immediately retrievable and readable within 24 hours.

<< NJ ADC 13:39-11.10 >>

13:39-11.10 Information required to appear on prescription label

(a) The dispensed container for any compounded preparation shall bear a permanently affixed label with at least the following information:

1. The date and, for sterile preparations, the time prepared;
- 2.-4. (No change.)
5. The name and quantity of all <<+active+>> ingredients;
6. The name or identifying code of the pharmacist who checked or prepared the compounded preparation;
7. (No change in text.)
8. The use by date and, for sterile preparations, the use by time (If no time is stated, it is presumed to be 11:59 P.M. of the stated use by date).

Recodify existing 11.-13. as 9.-11. (No change in text.)

<< NJ ADC 13:39-11.11 >>

13:39-11.11 Use by date of sterile preparation

(a) The use by date of a sterile compounded preparation shall be 24 hours or as otherwise stated by the manufacturer or current literature at the time of preparation, but shall not exceed 30 days after preparation.

(b) Any use by date that extends beyond 24 hours or the manufacturer's expiration date shall be substantiated by documentation satisfactory to the Board. <<+Satisfactory documentation shall include, but not be limited to:+>>

<<+1. Manufacturer's criteria on extending beyond use dates;+>>

<<+2. Appropriate literature; and+>>

<<+3. Direct testing.+>>

(c) In an institutional pharmacy, any sterile compounded preparation which is prepared under the pharmacy's control in a ISO class 5 laminar air flow hood which is not in a clean room and which meets the requirements of N.J.A.C. 13:39-11.22, shall be labeled to indicate that administration to a patient shall be initiated and completed within 28 hours of the beginning of the preparation time. If such a compounded preparation is prepared by closed-system aseptic transfer of a single, sterile, nonpyrogenic, finished medication obtained from licensed manufacturers into sterile final containers (for example, syringes, minibags, portable infusion-device cassettes), then the compounded preparation shall be labeled to indicate that administration to a patient shall be completed within the time recommended by the manufacturer but not exceeding 30 days after preparation. A closed system aseptic transfer is one which does not permit exposure of the pharmaceutical components to the environment, and shall be prepared in a ISO class 5 laminar air flow hood.

<< NJ ADC 13:39-11.12 >>

13:39-11.12 Handling, packaging and delivery

(a) The pharmacy shall be responsible for the proper handling and packaging of compounded preparations for delivery from the pharmacy to the patient in order to assure and maintain integrity, efficacy, stability, and, where applicable,

sterility, of these preparations. The pharmacist in charge shall ensure that:

1.-3. (No change.)

<< NJ ADC 13:39-11.13 >>

13:39-11.13 Policy and procedure manual for compounded sterile preparations

(a) The pharmacist in charge shall maintain a policy and procedure manual which shall set forth in detail the licensee's standard operating procedures with regard to compounded sterile preparations.

(b) The policy and procedure manual shall include policies and procedures governing the following:

1. (No change.)

2. Security measures ensuring that the premises where compounded sterile drugs are present are secured, so as to prevent access by unauthorized personnel;

3.-4. (No change.)

5. Reference materials as set out in N.J.A.C. 13:39-5.8 and 11.24;

6. (No change.)

7. Patient recordkeeping as set forth in N.J.A.C. 13:39-11.15;

8. (No change.)

9. A quality assurance program as set forth in N.J.A.C. 13:39-11.14;

10.-11. (No change.)

12. Documentation as set forth in N.J.A.C. 13:39-11.9;

13.-18. (No change.)

(c) The pharmacist in charge shall review at least every two years and, if necessary, amend the policy and procedure manual as needed. Documentation of the review shall be made available to the Board upon request.

<< NJ ADC 13:39-11.14 >>

13:39-11.14 Quality assurance program for compounded sterile preparations

(a) This section shall apply both to commercially available sterile drug products that are dispensed to patients without compounding or other manipulation, and to sterile preparations which, prior to dispensing, have been in any way repackaged, reconstituted, diluted, admixed, blended, or otherwise manipulated (collectively referred to as "compounded").

(b) The dispensing pharmacist shall ensure that the compounded sterile preparation retains its quality attributes within acceptable limits through a written quality assurance program. The quality assurance program shall require at least that:

1. A reasonable effort shall be made by the dispensing pharmacist to assure that compounded sterile preparations shall be kept under appropriate controlled conditions at the location of use by providing adequate labeling and verbal or written instructions regarding proper storage and administration as set forth by the product manufacturer, with each compounded sterile preparation dispensed;

2. The quality assurance program encompasses all phases of sterile compounding, including preparation, distribution, storage, administration, and directions for use for each type of product dispensed;
3. (No change.)
4. Air and surface sampling for microbial organisms in ISO class 5 laminar air flow hoods and ISO class 6 clean rooms is done twice annually and at any time when microbial contamination is suspected pursuant to United States Pharmacopoeia/National Formulary guidelines;
5. Laminar air flow hoods shall be certified every six months, and every time they are moved, by an independent certification company;
6. The ISO class 6 clean room and ISO class 7 anteroom shall be certified every six months by an independent certification company; and
7. All unused drugs and materials used in the compounding of sterile preparations, including antineoplastic agents, are disposed of properly in accordance with accepted professional standards and applicable laws, including the Medical Waste Act (N.J.S.A. 13:1E-48.1 et seq., P.L. 1989, c.34).

<< NJ ADC 13:39-11.15 >>

13:39-11.15 Patient profile records for compounded sterile preparations

(a) The pharmacist in charge shall ensure that a patient profile record is maintained and monitored for each patient. The patient profile record shall include, but is not limited to, the following:

1. Available medical information consistent with N.J.A.C. 13:39-7.19; and
2. (No change.)

(b)-(c) (No change.)

<< NJ ADC 13:39-11.16 >>

13:39-11.16 Controlled environment for compounded sterile preparations: use, access, location; temperature

(a) The pharmacy shall have a designated area for sterile preparation compounding, known as the "controlled environment," consisting of a clean room and an anteroom unless the pharmacy meets the requirements of N.J.A.C. 13:39-11.22 or 11.23.

(b) A controlled environment shall be:

1. (No change.)
2. Used only for the compounding of sterile preparations, or such other tasks that require a controlled environment;
- 3.-4. (No change.)

<< NJ ADC 13:39-11.17 >>

13:39-11.17 Controlled environment for compounded sterile preparations: construction

(a)-(j) (No change.)

<< NJ ADC 13:39-11.18 >>

13:39-11.18 Controlled environment for compounded sterile preparations: stocking, maintenance and supplies

(a)-(d) (No change.)

(e) The controlled environment area shall contain the following supplies:

1.-5. (No change.)

6. Any and all supplies necessary for the aseptic compounding of sterile preparations.

<< NJ ADC 13:39-11.19 >>

13:39-11.19 Controlled environment for compounded sterile preparations: clean room

(a)-(