Search
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RULE ADOPTIONS

LAW AND PUBLIC SAFETY

DIVISION OF CONSUMER AFFAIRS

BOARD OF PHARMACY

Adopted Amendments: N.J.A.C. 13:39-1.3, 2.1, 2.5, 3.3, 4.1, 4.5, 4.8, 5.3, 5.8, 5.12, 6.2, 6.4, 7.1 and 7.9
Adopted New Rules: N.J.A.C. 13:39-2.1, 2.5, 2.6, 2.7, 2A.1 and 2A.3
Adopted Recodifications and Amendments: N.J.A.C. 13:39-2.10 through 2.20 as 3.1 through 3.11 and 3.3 as 2A.2
Adopted Repeals: N.J.A.C. 13:39-2.2, 2.3, 2.4, 2.8, 2.9, 3.1, 3.2, 3.4, 3.5 and 8
Adopted Repeals and New Rules: N.J.A.C. 13:39-2.7 and 4.14

Fee Schedule; Requirements for Initial Licensure as a Pharmacist; Licensure Examination Scores; Proof of Character; Criminal History Background Check; Alleged Violations of Pharmacy Law; Internship and Externship Practical Experience Requirements; Pharmacy Intern Registration Requirements; Requirements for Reciprocal Licensure; Multistate Jurisprudence Pharmacy Examination; Authorization to Practice; Display of License; Replacement License; Change of Name; Change of Address of Record; Service of Process; Verification of Licensure; Reproduction of License Prohibited; Biennial License Renewal; Administrative Suspension; Reinstatement from Administrative and Disciplinary License Suspensions; Inactive Licensure; Steering Prohibited; Responsibilities of Pharmacists; New Pharmacies; Pharmacy Departments; Eligibility and Application; Change of Ownership; Asset Acquisition; Discontinued Pharmacies; Security of Pharmacies and Pharmacy Departments; Pharmacy Signs; Minimum Equipment and Facilities; Restriction on Storage of Prescription Legend Drugs and Controlled Dangerous Substances; Registered Pharmacist-in-Charge; Meal or Restroom Breaks; Valid Prescriptions; Out-of-State Prescriptions; Filing and Storage of Controlled Substance Prescriptions

Proposed: January 20, 2009 at 41 N.J.R. 371(a).

Adopted: April 22, 2009 by the Board of Pharmacy, Edward G. McGinley, R.Ph, President.

Filed: July 9, 2009 as R.2009 d.247, **with technical changes** not requiring additional public notice and comment (see N.J.A.C. 1:30-6.3).

Authority: N.J.S.A. 45:14-47 and 45:14-48.

Effective Date: August 3, 2009.

Expiration Date: December 10, 2009.

Federal Standards Statement

A Federal standards analysis is not required because the adopted amendments and new rules are governed by N.J.S.A. 45:14-40 et seq., and are not subject to any Federal requirements or standards. Although the rules in N.J.A.C. 13:39 are not subject to any mandated Federal requirements or standards, the Board has required licensees and permit holders, in adopted new rule N.J.A.C. 13:39-4.14, to comply with the Federal requirements set forth in 21 CFR 1301.74(c) when reporting a significant loss of prescription legend drugs and devices and controlled substances.

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

SUBCHAPTER 1. GENERAL PROVISIONS

13:39-1.3 Fee schedule

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

1. For pharmacists as follows:

i.-iii. (No change.)

iv. Application for reinstatement

(1) (No change.)

(2) Administrative suspension 225.00

[page=2971] v.-xiii. (No change.)

2.-4. (No change.)

5. For pharmacy interns as follows:

i. Application for registration 50.00

ii. Initial registration fee 70.00

iii. Registration renewal (One time only) 70.00

SUBCHAPTER 2. REQUIREMENTS FOR INITIAL LICENSURE

13:39-2.1 Requirements for initial licensure as a pharmacist

(a) An applicant for initial licensure as a pharmacist in New Jersey shall satisfy the following requirements:

1. The applicant shall be at least 18 years of age and shall submit a completed application for initial licensure, which shall include a passport size photo of the applicant and the application fee set forth in N.J.A.C. 13:39-1.3;

2. The applicant shall have graduated with either a degree of Bachelor of Science in pharmacy with a minimum five-year course of study, or with a Doctor of Pharmacy, from a school or college of pharmacy accredited by the American Council of Pharmaceutical Education (ACPE) or deemed ACPE-equivalent by ACPE;

i. The applicant shall submit an official transcript from the registrar of the school or college of pharmacy substantiating that the applicant has graduated;

ii. An applicant who has received a pharmacy degree from a school or college of pharmacy located in a foreign country that has not been accredited by ACPE or has not been deemed ACPE-equivalent by ACPE, shall satisfy the requirements of (b) below;

3. The applicant shall have passed the North American Pharmacist Licensure Examination (NAPLEX) and the Multistate Jurisprudence Pharmacy Examination (MJPE), consistent with the requirements of N.J.A.C. 13:39-2.2. The applicant shall take the NAPLEX and the MJPE only after providing the Board with an official transcript and receiving authorization to test from the National Association of Boards of Pharmacy (NABP). An applicant who has already taken the NAPLEX and has had his or her scores transferred to New Jersey within five years of having passed

the examination consistent with N.J.A.C. 13:39-2.2, shall take the MJPE only after providing the Board with an official transcript and receiving authorization to test from NABP allowing the applicant to be admitted to the MJPE examination;

4. If the applicant is applying for initial licensure more than two years following his or her graduation from pharmacy school, the applicant shall complete *[1,420]* ***1,440*** hours of practical experience in a Board-approved internship. The applicant shall register with the Board as an intern and shall satisfy all internship requirements set forth in N.J.A.C. 13:39-2.6 within the two***-***year period immediately preceding the date of application; and

5. The applicant shall have satisfied the good moral character and criminal history background check requirements set forth in N.J.A.C. 13:39-2.3 and 2.4.

(b) An applicant for initial licensure as a pharmacist in New Jersey who has graduated from a school or college of pharmacy in a foreign country that has not been accredited by ACPE or has not been deemed ACPE-equivalent by ACPE, shall satisfy the following requirements:

1. The applicant shall be at least 18 years of age and shall submit a completed application for initial licensure, which shall include a passport size photo of the applicant and the application fee set forth in N.J.A.C. 13:39-1.3;

2. The applicant shall have graduated with either a degree of Bachelor of Science in pharmacy with a minimum five-year course of study or with a Doctor of Pharmacy;

3. The applicant shall have a valid certification from the Foreign Pharmacy Graduate Examination Committee (FPGEC) of NABP;

4. The applicant shall complete *[1,420]* ***1,440*** hours of practical experience in a Board-approved internship. The applicant shall register with the Board as an intern and shall satisfy all internship requirements set forth in N.J.A.C. 13:39-2.6 within the two-year period immediately preceding the date of application. The internship shall not commence before the applicant has been certified by FPGEC;

5. The applicant shall have passed the NAPLEX and the MJPE, consistent with the requirements of N.J.A.C. 13:39-2.2. The applicant shall take the NAPLEX and the MJPE only after providing the Board with an official transcript and receiving authorization to test from NABP. An applicant who has already taken the NAPLEX and has had his or her scores transferred to New Jersey within five years of having passed the examination consistent with N.J.A.C. 13:39-2.2, shall take the MJPE only after providing the Board with an official transcript and receiving authorization to test from NABP allowing the applicant to be admitted to the MJPE examination. An applicant shall not be eligible to take the referenced examination until the completion of his or her internship; and

6. The applicant shall have satisfied the good moral character and criminal history background check requirements set forth in N.J.A.C. 13:39-2.3 and 2.4.

13:39-2.2 Licensure examination scores

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

(b) An applicant for initial licensure shall attain a passing score of not less than 75 on the Multistate Jurisprudence Pharmacy Examination (MJPE). If an applicant fails the MJPE, he or she shall be required to repeat the examination.

(c) If an applicant fails 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).

(d) NAPLEX and MJPE results shall be valid only for a period of five years from the date that an applicant receives a passing score on the respective examination.

13:39-2.3 Proof of character

(a) An applicant for initial licensure shall submit evidence of good moral character, which shall be an ongoing requirement for licensure. In determining whether the applicant shall be licensed in the State, the Board shall consider evidence, which demonstrates that the applicant:

1.-2. (No change.)

3. Has not been convicted of violating any law relating to the practice of pharmacy consistent with N.J.S.A. 45:1-21(f);

4. (No change.)

5. Has not had his or her license or, if a permit holder, his or her permit, suspended or revoked as a result of any administrative or disciplinary proceedings in this or any other jurisdiction which proved the applicant to be in violation of any laws, rules or regulations pertaining to the practice of pharmacy, and that the applicant is not currently under suspension or revocation.

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

13:39-2.5 Refusal to license

The Board may refuse to issue a license to any applicant who has violated any law related to the practice of pharmacy or for any of the reasons set forth in N.J.S.A. 45:1-21 et seq.

13:39-2.6 Internship and externship practical experience requirements

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

"Extern preceptor" means an individual approved by an American Council of Pharmaceutical Education (ACPE) approved school or college of pharmacy, at which a pharmacy extern is enrolled, who assumes the responsibility to supervise and provide instructional training to a pharmacy extern.

"Intern preceptor" means a pharmacist registered in this State who assumes the responsibility to supervise and provide instructional training to a pharmacy intern as set forth in (f) below.

["Extern preceptor" means an individual approved by an American Council of Pharmaceutical Education (ACPE) approved school or college of pharmacy, at which a pharmacy extern is enrolled, who assumes the responsibility to supervise and provide instructional training to a pharmacy extern.]

"Pharmacy extern" means any person who is in the fifth or sixth college year, or the third or fourth professional year, at an ACPE-approved school or college of pharmacy who is assigned to a pharmacy training site for the purpose of acquiring practical experience under the supervision of the school or college at which he or she is enrolled.

[page=2972]"Pharmacy intern" means a person who is employed in an approved pharmacy training site for the purpose of acquiring practical experience and who has first registered for such purposes with the Board pursuant to N.J.S.A. 45:14-48b(2), and who has:

1. Graduated from an ACPE-approved school or college of pharmacy who is making an application for initial licensure as a pharmacist more than two years following the date of graduation;

2. Graduated from a school or college of pharmacy in a foreign country that has not been accredited by ACPE or that has not been deemed ACPE-equivalent by ACPE; or

3. Applied to the Board for reciprocal licensure and has not been engaged in the practice of pharmacy for at least 1,500 hours within the two-year period immediately preceding the date of application.

"Pharmacy internship or externship" means the program in which practical experience is acquired by a pharmacy intern or extern.

"Pharmacy training site" means a site that is licensed by the Board where drugs are dispensed or pharmaceutical care is provided by a licensed pharmacist and that has a satisfactory record of observance of Federal, State and municipal law and ordinances governing the activities in which it is or has been engaged.

(b) The *[1,420]* ***1,440*** hours of practical experience required for the successful completion of a pharmacy internship shall be obtained consistent with the following:

1. The *[1,420]* ***1,440*** hours of practical experience shall be completed in no less than 34 weeks and no more than 104 weeks, under the supervision of an intern preceptor. Each week of practical experience shall consist of no less than 15 hours and no more than 45 hours of actual service per week;

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

3. No credit shall be given for hours served as a pharmacy intern prior to the applicant's registration with the Board and approval of the intern preceptor by the Board.

(c) A pharmacist who wishes to be an intern preceptor shall apply to the Board and shall furnish evidence that he or she:

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

2. Has not been convicted of a crime or offense relating adversely to the practice of pharmacy consistent with N.J.S.A. 45:1-21(f) or a crime of 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.

(d) The Board shall approve an intern preceptor selected by each pharmacy intern prior to the beginning of the internship. An intern preceptor shall not supervise the training of more than one pharmacy intern at a time.

(e) The intern 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.

(f) The intern preceptor shall be responsible for supervising the activities of the pharmacy intern and providing the pharmacy intern with experience and knowledge related to the preceptor's area of practice.

13:39-2.7 Pharmacy intern registration requirements

(a) No person shall be employed as a pharmacy intern until he or she has been registered with the Board pursuant to this section and his or her preceptor has been approved by the Board pursuant to N.J.A.C. 13:39-2.6(c).

(b) An applicant for registration as a pharmacy intern shall submit a written application, on a form supplied by the Board, and shall submit:

1. 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 that may disqualify the applicant from being registered as a pharmacy intern by the Board;

2. A passport size photo of the applicant;

3. Evidence of good moral character, which shall be an ongoing requirement for registration. In determining whether the applicant shall be registered, the Board shall consider evidence, which demonstrates that the applicant:

i. Is not presently engaged in drug or alcohol use that is likely to impair the ability to practice as a pharmacy intern with reasonable skill and safety. For purposes of this section, the term "presently" means at the time of application or any time within the previous 365 days;

ii. Has not been convicted of violating any law of this State or any other state of the United States relating to controlled dangerous substances or other habit-forming drugs;

iii. Has not been convicted of violating any law relating to the practice of pharmacy consistent with N.J.S.A. 45:1-21(f) or a crime of moral turpitude; and

iv. Has not had his or her authority to engage in the activity regulated by the Board suspended or revoked as a result of any administrative or disciplinary proceedings in this or any other jurisdiction that determined the applicant to be in violation of any laws, rules or regulations pertaining to the practice of pharmacy and that the applicant is not currently under suspension or revocation; and

4. The application fee and registration fee set forth at N.J.A.C. 13:39-1.3.

(c) A person who has been educated in a foreign country in a college or school of pharmacy that has not been approved by the American Council of Pharmaceutical Education (ACPE) or that has not been deemed ACPE-equivalent by ACPE, shall be certified by the Foreign Pharmacy Graduate Examination Committee (FPGEC) of the National Association of Boards of Pharmacy prior to applying to the Board for registration as a pharmacy intern.

(d) A pharmacy intern registration obtained pursuant to this section shall be valid for a period of two years from the date of issuance. Upon application to the Board, an intern registration may be renewed one time only, on an individual basis, for reasons of military service, hardship, illness or disability.

(e) A change in an intern preceptor shall require prior Board approval, consistent with the requirements of N.J.A.C. 13:39-2.6(d). The new intern preceptor shall be responsible for making application to the Board for approval.

(f) The intern preceptor and the pharmacy intern shall notify the Board in writing within 10 days of a change in the pharmacy training site and/or the termination or resignation of the intern.

(g) In addition to the notification requirements of (f) above, a pharmacy intern shall notify the Board in writing within 10 days of any change in his or her name or address of record, as defined in N.J.A.C. 13:39-1.2.

SUBCHAPTER 2A. REQUIREMENTS FOR RECIPROCAL LICENSURE

13:39-2A.1 Requirements for reciprocal licensure

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

(b) A pharmacist currently licensed in a mutually reciprocating jurisdiction shall satisfy the following requirements in order to obtain a license by reciprocity in New Jersey:

1. The applicant shall be at least 18 years of age and shall submit a completed application for reciprocity, including a passport size photo of the applicant and the application fee set forth in N.J.A.C. 13:39-1.3. The application shall substantiate that the applicant:

i. Has obtained his or her initial licensure by examination and that the initial license is in good standing; and

ii. Has not had any other license granted to the applicant by any other state suspended, revoked or otherwise restricted for any reason except for 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 is not engaged in the practice of pharmacy;

[page=2973] 2. The applicant shall have graduated with either a degree of Bachelor of Science in pharmacy with a minimum five-year course of study, or a Doctor of Pharmacy degree, from a college or school of pharmacy that has been accredited by the American Council of Pharmaceutical Education (ACPE), or that has been deemed ACPE-equivalent by ACPE.

i. An applicant who has received a pharmacy degree from a school or college of pharmacy located in a foreign country that has not been accredited by ACPE or that has not been deemed ACPE-equivalent by ACPE, who wishes to obtain a license by reciprocity in this State shall satisfy the requirement of (c) below;

3. The applicant shall have engaged in the practice of pharmacy for a period of at least 1,500 hours within the two-year period immediately preceding the date of application; or shall have registered with the Board as an intern and shall have satisfied all internship requirements set forth in N.J.A.C. 13:39-2.6 within the two-year period immediately preceding the date of application;

4. The applicant shall have passed the Multistate Jurisprudence Pharmacy Examination (MJPE), consistent with N.J.A.C. 13:39-2A.5. The applicant shall take the MJPE only after submitting all required documentation to the Board and receiving authorization to test from the National Association of Boards of Pharmacy (NABP); and

5. The applicant shall have satisfied the good moral character and criminal history background check requirements set forth in N.J.A.C. 13:39-2A.2 and 2A.4.

(c) A pharmacist currently licensed in a mutually reciprocating jurisdiction who received a pharmacy degree from a school or college of pharmacy located in a foreign country that has not been accredited by ACPE or that has not been deemed ACPE-equivalent by ACPE, who wishes to obtain a license by reciprocity in this State shall satisfy the following requirements:

1. The applicant shall be at least 18 years of age and shall submit a completed application for reciprocity, including a passport size photo of the applicant and the application fee set forth in N.J.A.C. 13:39-1.3. The application shall substantiate that the applicant:

i. Has obtained his or her initial licensure by examination and that the initial license is in good standing; and

ii. Has not had any other license granted to the applicant by any other state suspended, revoked or otherwise restricted for any reason except for 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 is not engaged in the practice of pharmacy;

2. The applicant shall have a valid certification from the Foreign Pharmacy Graduate Examination Committee (FPGEC) of NABP;

3. The applicant shall have graduated with either a degree of Bachelor of Science in pharmacy with a minimum five-year course of study or a Doctor of Pharmacy degree;

4. The applicant shall have engaged in the practice of pharmacy for a period of at least 1,500 hours within the two-year period immediately preceding the date of application.

i. An applicant who has engaged in the practice of pharmacy for less than 1,500 hours, shall register with the Board as an intern and shall satisfy all internship requirements set forth in N.J.A.C. 13:39-2.6 within the two-year period immediately preceding the date of application;

5. The applicant shall have passed the Multistate Jurisprudence Pharmacy Examination (MJPE), consistent with N.J.A.C. 13:39-2A.5. The applicant shall take the MJPE only after submitting all required documentation to the Board and receiving authorization to test from NABP; and

6. The applicant shall have satisfied the good moral character and criminal history background check requirements set forth in N.J.A.C. 13:39-2A.2 and 2A.4.

(d) In addition to the requirements set forth in (a) and (b) above, an applicant for licensure by reciprocity shall meet all licensure transfer criteria utilized by NABP.

13:39-2A.2 Proof of character

(a) An applicant for licensure by reciprocity shall submit, as part of his or her licensure application, evidence of good moral character, which shall be an ongoing requirement for licensure. In determining whether the applicant shall be licensed in the State, the Board shall consider evidence, which demonstrates that the applicant:

1.-2. (No change.)

3. Has not been convicted of violating any law relating to the practice of pharmacy consistent with N.J.S.A. 45:1-21(f);

4. (No change.)

5. Has not had his or her license suspended or revoked 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.

13:39-2A.3 Refusal to license

The Board may refuse to issue a license to any applicant for licensure by reciprocity that has violated any law relating to the practice of pharmacy or for any of the reasons set forth in N.J.S.A. 45:1-21 et seq.

Recodify existing N.J.A.C. 13:39-3.6 and 3.7 as 2A.4 and 2A.5 (No change in text.)

SUBCHAPTER 3. REGISTERED PHARMACIST REQUIREMENTS

13:39-3.1 Authorization to practice; display of license

(a) (No change.)

(b) Upon issuance of a license, the 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 current biennial renewal license is not on display.

Recodify existing N.J.A.C. 13:39-2.11 through 2.14 as 3.2 through 3.5 (No change in text.)

13:39-3.6 Reproduction of license prohibited

The 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. 13:39-3.2.

13:39-3.7 (No change in text.)

13:39-3.8 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. 13:39-3.7 may apply to the Board for reinstatement within five years following the date of license expiration. A pharmacist applying for reinstatement shall submit:

1.-5. (No change.)

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

Recodify existing N.J.A.C. 13:39-2.18 and 2.19 as 3.9 and 3.10 (No change in text.)

13:39-3.11 Responsibilities of pharmacists

(a) (No change.)

(b) Any pharmacist found to have violated the New Jersey Pharmacy Practice Act, N.J.S.A. 45:14-40 et seq., or the rules in this chapter, shall be subject to disciplinary action.

SUBCHAPTER 4. PHARMACY PERMIT REQUIREMENTS

13:39-4.1 New pharmacies; pharmacy departments; eligibility and application

(a) A permit application shall be submitted to the Board by every individual or business entity desiring to operate a new pharmacy. Such application shall be made on a form furnished by the Board. If the area for which a pharmacy permit is sought is less than the total area of the premises, the area subject to permit shall be known as the "pharmacy department."

(b) The permit application shall indicate the exact intended location and plan or physical arrangement of the proposed pharmacy or pharmacy department area, including any drive-thru area, and shall indicate any [page=2974] area contiguous or adjacent to but not necessarily a part of the proposed permitted area, and any area where drugs will be stored and/or dispensed.

(c)-(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 or pharmacy department to ensure compliance with this subchapter and all relevant statutes, regulations and ordinances.

(h) (No change.)

13:39-4.5 Change of ownership; asset acquisition

(a) (No change.)

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

(c) Upon the sale, transfer or acquisition of the business assets of a pharmacy, the person or entity acquiring such assets shall take custodial ownership of the pharmacy's previous five years of prescription and profile records and shall ensure that the prescription and profile records are maintained pursuant to N.J.A.C. 13:39-7.6 and 7.19 after the date of acquisition.

13:39-4.8 Discontinued pharmacies

(a) Whenever a pharmacy is to be discontinued and closed for any reason, including suspension or retirement of the permit holder, sale or insolvency, the permit holder shall immediately send written notification of the anticipated closing to the State Board of Pharmacy, the Office of Drug Control and the Drug Enforcement Administration at least 15 days prior to the anticipated closing date. Whenever a pharmacy is to be discontinued and closed as a result of an unanticipated occurrence, such as the death of the permit holder, the permit holder's representative shall send written notification to the Board, the Office of Drug Control and the Drug Enforcement Administration, as soon as possible prior to the actual closing date. All medications, including prescription legend and controlled drugs, should be transferred to the holder of a current pharmacy permit; a wholesaler; a reverse distributor; and/or a manufacturer. All medications not properly transferred 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 Board, the Office of Drug Control and/or the Drug Enforcement Administration.

(b) Within 30 days of closing a pharmacy pursuant to (a) above, the permit holder or his or her representative shall remove all drug signs from both the inside and outside of the discontinued pharmacy and shall notify the Board in writing of the location of the previous five years of prescription and patient profile records, consistent with the requirements of N.J.A.C. 13:39-7.6 and 7.19. The permit holder or his or her representative 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 and 7.19.

13:39-4.14 Security of pharmacies and pharmacy departments

(a) The registered pharmacist(s) on duty in all pharmacies, including pharmacy departments, shall be responsible for:

1. Keeping the pharmacy or pharmacy department closed and the security system turned on at all times when he or she is not present within the permitted premises in the case of a pharmacy, or, in the case of a pharmacy department, when he or she is not present within the department, except as provided in N.J.A.C. 13:39-6.4;

i. In the case of a pharmacy or pharmacy department that has been issued an institutional permit, pharmacy technicians may remain within the permitted premises when the pharmacy or pharmacy department is closed and secured, if the pharmacist determines, based on his or her professional judgment, that the security of prescription legend drugs, devices and controlled substances will be maintained in the pharmacist's absence;

2. Ensuring that the security of the prescription dispensing 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 dispensing area; and

3. Reporting all thefts or diversions of prescription legend drugs and devices and controlled substances, and any significant loss of prescription legend drugs and devices and controlled substances, to the registered pharmacist-in-charge and/or the pharmacy permit holder upon discovery. When determining whether a loss of prescription legend drugs or devices or controlled substances is significant, the following factors shall be considered, consistent with 21 CFR 1301.74(c):

i. The actual quantity of prescription legend drugs, devices or controlled substances missing in relation to the type of business;

ii. The specific prescription legend drug, device or controlled substance missing;

iii. Whether the loss of the prescription legend drug, device or controlled substance can be associated with access to those drugs, devices or controlled substances by specific individuals, or whether the loss can be attributed to unique activities that may take place involving the drugs, devices or controlled substances;

iv. A pattern of losses over a specific time period, whether the losses appear to be random and the results of efforts taken to resolve the losses;

v. If known, whether the specific prescription legend drugs, devices or controlled substances are likely candidates for theft or diversion; and

vi. Local trends and other indicators of the theft or diversion potential of the missing prescription legend drug, device or controlled substance.

(b) The holder of a pharmacy or pharmacy department permit and the registered pharmacist-in-charge of the pharmacy or pharmacy department shall ensure that:

1. All entrances to the pharmacy or pharmacy department are capable of being locked and are connected to a monitored security system that transmits an audible, visual or electronic signal warning of intrusion. The security system shall be equipped with a back-up mechanism to ensure notification or continued operation if the security system is tampered with or is disabled. Only the registered pharmacist-in-charge of the permitted premises or the pharmacy department shall be responsible for the security of the keys and the security system access code to the pharmacy or pharmacy department;

2. If a theft or diversion of prescription legend drugs or devices or controlled substances, or a significant loss of prescription legend drugs or devices or controlled substances, as delineated in (a) above, is reported to the registered pharmacist-in-charge, the registered pharmacist-in-charge shall notify the holder of the pharmacy or pharmacy department permit of such report. The registered pharmacist-in-charge and the holder of the pharmacy or pharmacy department permit shall ensure that:

i. A written report is filed with the Board upon discovery of the theft or diversion or the significant loss of prescription legend drugs or devices; and

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

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

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

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

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

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

3. The pharmacy department has a published telephone number different from that of the establishment in which the department is [page=2975] located. No extensions of this phone shall be located outside the department; and

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

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

SUBCHAPTER 5. RETAIL FACILITY REQUIREMENTS

13:39-5.3 Pharmacy signs

(a) (No change.)

(b) Pharmacies shall post the hours that the pharmacy is open and the name of the registered pharmacist-in-charge in plain view at all consumer entrances and consumer access points to the pharmacy, including drive-thru windows and drop-off boxes.

(c) In the case of a pharmacy department, 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 all consumer entrances and consumer access points to the premises, including drive-thru windows and drop-off boxes. When the premises in which the pharmacy department is located maintains different hours of operation from the pharmacy department, all advertising, announcements, signs and statements indicating hours of operation and the presence of the pharmacy department shall clearly and distinctly indicate the hours that the pharmacy department is open.

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. Storage place of substantial construction, which is capable of being securely locked when the pharmacist is not present in the prescription dispensing area, for Schedule II controlled substances, if not dispersed;

5.-18 (No change.)

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

(a) Prescription legend drugs, devices and controlled dangerous substances shall not be stored in the pharmacy or pharmacy department in such a manner as to be accessible to the public.

(b) Prescription legend drugs, devices and controlled dangerous substances shall only be stored in areas of the premises that are part of the permitted pharmacy or pharmacy department.

13:39-6.2 Registered pharmacist-in-charge

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

(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.-3. (No change.)

4. Security of the prescription area and its contents are maintained at all times consistent with the requirements set forth in N.J.A.C. 13:39-4.14;

5.-9. (No change.)

13:39-6.4 Meal or restroom breaks

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

1. (No change.)

2. The pharmacy shall remain open during the restroom or meal breaks, provided a pharmacy employee remains present in the pharmacy, for patient related services, which include, but are not limited to, the following:

i.-ii. (No change.)

3. A sign shall be posted in the prescription dispensing area stating "Pharmacist on break, but available for emergencies and counseling."

SUBCHAPTER 7. DRUG DISPENSING AND PRESCRIPTION RECORDS

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

(a) A pharmacist shall only fill a prescription issued by a practitioner licensed to write prescriptions in New Jersey and practicing 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 fill a prescription issued by a prescriber licensed to write prescriptions in another state, territory or possession of the United States, including prescriptions issued at facilities within or outside of New Jersey that are regulated by the United States Department of Veterans Affairs and/or the Department of Defense. Such prescriptions shall be filled pursuant to New Jersey law. Such prescriptions shall not be required to be issued on a New Jersey Uniform Prescription Blank.

(c) (No change.)

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

(a) (No change.)

(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 prescription file for non-controlled substances. If a pharmacy employs an electronic recordkeeping system for prescriptions which permits identification by prescription number and retrieval of original documents by the prescriber's name, patient's name, drug dispensed and date filled, then the requirement to mark the hard copy prescription with a red "C" shall be waived.

SUBCHAPTER 8. (RESERVED)