

1 of 1 DOCUMENT

NEW JERSEY REGISTER
Copyright © 2009 by the New Jersey Office of Administrative Law

VOLUME 41, ISSUE 2

ISSUE DATE: JANUARY 20, 2009

RULE PROPOSALS

**LAW AND PUBLIC SAFETY
DIVISION OF CONSUMER AFFAIRS
BOARD OF PHARMACY**

41 N.J.R. 371(a)

Proposed 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*

Proposed New Rules: *N.J.A.C. 13:39-2.1, 2.5, 2.6, 2.7, 2A.1 and 2A.3*

Proposed 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*

Proposed 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*

Proposed Repeals and New Rules: *N.J.A.C. 13:39-2.7 and 4.14*

[Click here to view Interested Persons Statement](#)

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

Authorized By: Joanne Boyer, Executive Director, Board of Pharmacy.

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

Calendar Reference: See Summary below for explanation of exception to calendar requirement.

Proposal Number: PRN 2009-35.

Submit comments by March 21, 2009 to:

Joanne Boyer, Executive Director

Board of Pharmacy

P.O. Box 45013

Newark, N.J. 07101

The agency proposal follows:

Summary

The New Jersey Board of Pharmacy (the Board) is proposing various amendments to the existing rules in Subchapter 2, as well as several new rules in order to clarify requirements applicable to individuals applying for licensure as pharmacists in the State. The Board is also proposing various amendments at this time to the rules governing pharmacy practice contained in Subchapters 4, 5, 6 and 7.

Initially, the Board notes that it is proposing amendments to its fee schedule at *N.J.A.C. 13:39-1.3(a)1* to include a fee of \$ 225.00 for reinstatement from an administrative suspension. The fee schedule currently provides that this fee will be determined by future rulemaking. The \$ 225.00 proposed fee is consistent with the reinstatement fee imposed by the Board for reinstatement from disciplinary suspensions and is also consistent with the reinstatement fees charged by other professional boards within the Division of Consumer Affairs for the return to active practice following a license suspension. In addition, the Board is proposing amendments to the fee schedule at *N.J.A.C. 13:39-1.3(a)5* to reflect the new fees the Board will charge in connection with the registration of pharmacy interns. The proposed amendments provide for a \$ 50.00 application fee, a \$ 70.00 registration fee and a \$ 70.00 registration renewal fee. These fees are necessary to offset the anticipated costs the Board will incur in processing these applications and in regulating these individuals. The requirements for pharmacy intern registration are discussed below.

The Board notes that many of the existing rules are being recodified in order to better organize the rules and make them easier for applicants for licensure and licensees to follow and understand. Currently, Subchapter 2 contains rules applicable to applicants for initial licensure, as well as requirements imposed upon licensed pharmacists. The Board is proposing that these requirements be separated into two distinct subchapters; Subchapter 2, for which the heading is amended to "Requirements for Initial Licensure," will contain those rules applicable only to applicants for initial licensure; and proposed new Subchapter 3, Registered Pharmacist Requirements, will contain requirements applicable to pharmacists licensed by the Board. The Board notes that existing Subchapter 3, which contains rules applicable to licensure by reciprocity, is being recodified with amendments as new Subchapter 2A, and is discussed below.

Proposed new rule *N.J.A.C. 13:39-2.1* sets forth requirements with which applicants for initial licensure as pharmacists in the State must comply. Many of these requirements are currently outlined in various rules throughout current Subchapter 2. The proposed new rule continues to require an applicant to be at least 18 years of age; to submit a completed application, including a photo and an application fee; to be of good moral character; and to undergo a criminal history background check. All applicants must have graduated with either a Bachelor of Science degree in pharmacy, with a minimum five-year course of study, or with a Doctor of Pharmacy. The pharmacy degree must have been obtained from a pharmacy school accredited by, or deemed equivalent to accredited programs by, the American Council of Pharmaceutical Education (ACPE). As part of the application, the applicant must submit an official transcript from the pharmacy school.

Proposed new rule *N.J.A.C. 13:39-2.1* continues to require an applicant to have passed the North American Pharmacist Licensure Examination (NAPLEX) and the Multistate Jurisprudence Pharmacy Examination (MJPE). The new rule, however, clarifies that the applicant may not take the NAPLEX and the MJPE until submitting an official

transcript to the Board and receiving authorization from the National Association of Boards of Pharmacy (NABP) to sit for the examination. The Board notes that the proposed new rule discontinues the practice of allowing an applicant who has completed all requirements for graduation but who has not graduated yet to take the NAPLEX and MJPE. The Board has chosen to eliminate this option for applicants under the new rule because applicants who avail themselves of this option are precluded from transferring their examination scores to any other jurisdiction. Consistent with standards endorsed by the National Association of Boards of Pharmacy (NABP), every state, other than New Jersey, currently prohibits applicants for licensure to sit for the NAPLEX and MJPE prior to the applicant's actual date of graduation. Other jurisdictions, therefore, will not recognize NAPLEX and MJPE results of applicants who have taken the examinations prior to graduation based on approval granted by the Board.

The proposed new rule also provides that if an applicant is applying for licensure more than two years following his or her graduation from [page=372] pharmacy school, the applicant must complete 1,420 hours of practical experience in a Board-approved internship. The Board notes that the 1,420 hours of practical experience proposed to be required for the internship period is consistent with ACPE accreditation guidelines. The applicant must register with the Board as an intern, consistent with the newly established internship registration requirements, which are discussed below. Because the requirements currently outlined in existing rules *N.J.A.C. 13:39-2.2, 2.3, 2.4 and 2.7*, are proposed to be included in new rule *N.J.A.C. 13:39-2.1*, the Board is proposing that *N.J.A.C. 13:39-2.2, 2.3, 2.4 and 2.7* be repealed.

The Board notes that proposed new rule *N.J.A.C. 13:39-2.1* also sets forth requirements for initial licensure for applicants trained in a foreign country. Specifically, the rule provides that 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, must have graduated with a Bachelor of Science degree in pharmacy, with a minimum five-year course of study, or with a Doctor of Pharmacy; must hold a valid certification from the Foreign Pharmacy Graduate Examination Committee (FPGEC); and must have completed 1,420 hours of practical experience in a Board-approved internship. The internship may not commence before the applicant has been certified by FPGEC. The applicant must also have passed the NAPLEX and the MJPE after the completion of his or her internship. In light of the requirements set forth in proposed new rule *N.J.A.C. 13:39-2.1*, the Board is proposing that existing rule *N.J.A.C. 13:39-2.9*, concerning requirements for applicants educated in a foreign country, be repealed.

Existing rule *N.J.A.C. 13:39-2.1*, which concerns examination scores, is proposed to be recodified as *N.J.A.C. 13:39-2.2*, with amendments to clarify that the provisions of the rule pertain to applicants for initial licensure. The Board is also proposing a new subsection to the rule, which provides that NAPLEX and MJPE results will only be valid for five years from the date that the applicant receives a passing score on the respective examination, in order to ensure that examination results used by an applicant to qualify for licensure are not dated and are reflective of current competency. Existing rule *N.J.A.C. 13:39-2.5*, concerning proof of character, is proposed to be recodified as *N.J.A.C. 13:39-2.3*, with amendments. The Board is proposing to amend the rule, which provides, in part, that the Board may consider evidence that the applicant has not had his or her pharmacy license or permit in another jurisdiction suspended or revoked in the last five years, to eliminate the five-year limitation. The proposed amendment will enable the Board to consider a pharmacy license or permit suspension from another jurisdiction in its license application deliberations, regardless of the amount of time that has passed.

Existing rule *N.J.A.C. 13:39-2.6*, concerning criminal history background check requirements for applicants for initial licensure, is proposed to be recodified as *N.J.A.C. 13:39-2.4*, without change. The Board is also proposing a new rule at *N.J.A.C. 13:39-2.5*, providing that any violation of *N.J.S.A. 45:1-21* or any law related to the practice of pharmacy by an applicant for initial licensure may result in the Board's refusal to issue a license. In light of this proposed new rule, the Board is proposing the repeal of existing rule *N.J.A.C. 13:39-2.8*, which provides that alleged violations of New Jersey pharmacy law may result in the Board's refusal to permit an applicant for licensure to take the required licensing examinations.

The Board is proposing a new rule at *N.J.A.C. 13:39-2.6* concerning internship and externship practical experience requirements. Currently, the Board's internship and externship requirements are set forth in Subchapter 8. The Board

believes that the recodification of these requirements as part of Subchapter 2, Requirements for Initial Licensure, is appropriate because the internship and externship requirements must be satisfied by persons applying for initial licensure as pharmacists in the State. The Board, therefore, is proposing to repeal all of the existing rules in Subchapter 8 and to reorganize, amend and recodify those requirements in proposed new rule *N.J.A.C. 13:39-2.6*. The Board is proposing that Subchapter 8 be reserved.

Proposed new rule *N.J.A.C. 13:39-2.6* sets forth definitions for relevant terms used throughout the new rule. The new rule continues to define "pharmacy extern" as any person in the fifth or sixth year of college, or third or fourth professional year, at an ACPE approved school of pharmacy who is assigned to a pharmacy training site in order to acquire practical experience under the supervision of the school of pharmacy. The Board is amending the existing definition of "pharmacy intern" to clarify that an intern means a person who is employed at an approved pharmacy training site for the purpose of acquiring practical experience. In order to be considered a pharmacy intern, an individual must fall into one of three categories recognized in the new rule. The individual must be: (1) a graduate of an ACPE approved school or college of pharmacy who is making an application for initial licensure as a pharmacist more than two years following his or her graduation; (2) a graduate 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; or (3) an applicant for reciprocal licensure who has not been engaged in the practice of pharmacy for at least 1,500 hours within the two-year period immediately preceding his or her application to the Board. The 1,500 hours of practical experience must 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 must consist of no less than 15 hours and no more than 45 hours of training per week. The intern preceptor and the pharmacy intern are required to keep accurate records of the intern's time. These records must be submitted to the Board for approval.

Proposed new rule *N.J.A.C. 13:39-2.6* also provides that a pharmacy intern must register with the Board, consistent with the new registration scheme being proposed by the Board in new rule *N.J.A.C. 13:39-2.7*, which is discussed below. *N.J.A.C. 13:39-2.6* provides that an intern will not be given credit for any hours he or she works as an intern prior to the intern's registration with the Board, or prior to the Board's approval of his or her preceptor. Under proposed new rule *N.J.A.C. 13:39-2.6*, a pharmacist who wishes to be an intern preceptor must apply to the Board. The preceptor must submit evidence that he or she is currently licensed and has been employed as a pharmacist in the area of practice in which he will be working as a preceptor, on a full-time basis for at least two years prior to the date of application. The proposed new rule requires the preceptor to provide the Board with a detailed written report on the intern's progress. The proposed new rule continues the limitation in effect under the existing requirements of Subchapter 8 that an intern preceptor may not supervise the training of more than one pharmacy intern at a time.

As noted above, the Board is proposing a new rule at *N.J.A.C. 13:39-2.7* to require the registration of all persons serving as pharmacy interns throughout the State. The proposed new rule provides that no person shall be employed as a pharmacy intern until he or she has been registered with the Board. An applicant for registration as a pharmacy intern must submit a written application detailing relevant information, including evidence of good moral character. Pharmacy intern applicants must undergo a criminal history background check conducted by the New Jersey State Police. Applicants will also be required to submit an application fee of \$ 50.00, and a registration fee of \$ 70.00. The registration will be valid for two years and will be renewable one time only. The registration renewal cost will be \$ 70.00. *N.J.A.C. 13:39-2.7* also provides that a person who has been educated in a foreign country at a school of pharmacy that has not been approved by ACPE, must be certified by FPGEC prior to applying to the Board for registration as a pharmacy intern. Once registered, an intern and his or her preceptor will be responsible for notifying the Board of any changes to the intern's status. Specifically, the new rule requires notification to the Board within 10 days of a change in the pharmacy training site, the termination or resignation of the intern, or any change in the intern's name or address of record. A change in intern preceptor will require the new preceptor to make application to the Board for approval.

As noted above, the Board is proposing that existing Subchapter 3, concerning licensure by reciprocity, be recodified as Subchapter 2A. The Board is proposing to retitle the subchapter "Requirements for Reciprocal Licensure."

The Board is proposing a new rule at N.J.A.C. 13:39-2A.1, which sets forth requirements for obtaining a reciprocal license in New Jersey. Because many of the requirements set forth in the new rule are currently contained in existing rules *N.J.A.C. 13:39-3.1, 3.2, 3.4 and 3.5*, the Board is proposing that those rules be repealed at this time. Proposed new rule N.J.A.C. 13:39-2A.1 limits reciprocal licensure of out-of-State [page=373] pharmacists to those pharmacists who have been duly licensed in mutually reciprocating states and who satisfy the requirements of the rule. An applicant for reciprocal licensure must be at least 18 years of age and must submit a completed application for reciprocity, including the existing fee referenced in the Board's fee schedule.

Under proposed new rule N.J.A.C. 13:39-2A.1, an applicant for reciprocal licensure must have obtained his or her initial pharmacy license through examination and that license must be in good standing. The applicant must also have graduated with either a Bachelor of Science degree in pharmacy with a minimum five-year course of study, or a Doctor of Pharmacy degree, from an ACPE approved school of pharmacy. The applicant must have engaged in the practice of pharmacy for at least 1,500 hours within the two-year period immediately preceding his or her application. The new rule further provides that an applicant who does not meet this 1,500 practice hour requirement must register with the Board as an intern and must satisfy all internship requirements. The applicant also must have passed the MJPE, must be of good moral character and must have undergone the State criminal history background check. If the applicant graduated from a pharmacy school located in a foreign country that is not ACPE-approved, the applicant must also hold a valid FPGEC certification and must meet all licensure transfer criteria utilized by NABP.

Existing rule *N.J.A.C. 13:39-3.3*, concerning proof of character for reciprocal licensure applicants, is proposed to be recodified as N.J.A.C. 13:39-2A.2 with amendments similar to those being proposed to *N.J.A.C. 13:39-2.3* and discussed above. The proposed amendments provide that the Board may consider evidence that the applicant has not had his or her pharmacy license or permit in another jurisdiction suspended or revoked at any period in time. The Board is proposing a new rule at N.J.A.C. 13:39-2A.3, providing that any violation of any law related to the practice of pharmacy by an applicant for initial licensure may result in the Board's refusal to issue a license. Existing rules *N.J.A.C. 13:39-3.6*, concerning criminal history background check requirements for applicants for reciprocal licensure, and *N.J.A.C. 13:39-3.7*, concerning passage of the MJPE for such applicants, are proposed to be recodified as N.J.A.C. 13:39-2A.4 and 2A.5 without change.

The Board is proposing that existing rules *N.J.A.C. 13:39-2.10* through 2.20 be recodified in a new Subchapter 3, Registered Pharmacist Requirements. *N.J.A.C. 13:39-2.10*, which concerns the authorization to practice and the display of a license, is proposed to be recodified as *N.J.A.C. 13:39-3.1*. The Board is proposing to amend the rule in order to delete references to the wall license because the Board believes that display of this document is no longer necessary. The Board believes that the display of a pharmacist's current biennial renewal license, as required under the rule, will be sufficient for identification purposes. Existing rules *N.J.A.C. 13:39-2.11*, concerning replacement licenses; *N.J.A.C. 13:39-2.12*, concerning change of name; *N.J.A.C. 13:39-2.13*, concerning change of address; and *N.J.A.C. 13:39-2.14*, concerning verification of licensure, are proposed to be recodified as *N.J.A.C. 13:39-3.2, 3.3, 3.4 and 3.5*, respectively, without change. The Board is proposing to recodify existing rule *N.J.A.C. 13:39-2.15*, which prohibits the reproduction of licenses, as *N.J.A.C. 13:39-3.6*. Consistent with the amendments being proposed to *N.J.A.C. 13:39-3.1*, discussed above, recodified rule *N.J.A.C. 13:39-3.6* is being amended to delete all references to a pharmacist's wall license. *N.J.A.C. 13:39-2.16*, concerning biennial license renewal is proposed to be recodified as *N.J.A.C. 13:39-3.7* without change. Existing rule *N.J.A.C. 13:39-2.17*, concerning reinstatement from a license suspension, is proposed to be recodified as N.J.A.C. 13:39-3.8, with a technical amendment to correct the cross-reference to recodified rule *N.J.A.C. 13:39-3.7*.

Existing rule *N.J.A.C. 13:39-2.18*, concerning inactive licensure status, and existing rule *N.J.A.C. 13:39-2.19*, which prohibits steering, are proposed to be recodified as N.J.A.C. 13:39-3.9 and 3.10, respectively, without change. Existing rule *N.J.A.C. 13:39-2.20*, which sets forth pharmacists' responsibilities, is proposed to be recodified as N.J.A.C. 13:39-3.11, with a technical amendment to correct the citation to the new Pharmacy Practice Act. In addition, the Board is proposing to amend N.J.A.C. 13:39-3.11 to provide that a pharmacist who violates either the Pharmacy Practice Act or the rules in Chapter 39 shall be subject to disciplinary action. Currently, the rule requires a pharmacist to

have violated both the Act and the rules in order to be subject to discipline.

The Board is also proposing several amendments to the rules in Subchapter 4, concerning pharmacy permit requirements. The Board is proposing to amend *N.J.A.C. 13:39-4.1*, which sets forth eligibility and application requirements for obtaining a new pharmacy permit, in order to clarify that the requirements in the rule are also applicable to permits to operate pharmacy departments. The existing requirements in the rule provide that an applicant for a new permit must detail the physical arrangements of the proposed pharmacy. The Board is proposing to amend the rule to provide that the submitted plans must also detail any drive-thru areas and any area contiguous or adjacent to the pharmacy or pharmacy department, as well as any area on the premises where drugs will be stored and/or dispensed.

N.J.A.C. 13:39-4.5 establishes requirements for permit holders when a change in pharmacy ownership occurs. The Board is proposing to amend the rule to provide that upon a change in ownership or upon the sale, transfer or acquisition of the business assets of a pharmacy, the new owner must take custodial ownership of the existing pharmacy's previous five years of prescription and profile records and is responsible for ensuring that the records are maintained as required by Board rules. The Board believes that these amendments are necessary to ensure that prescription and patient profile records are maintained in an appropriate manner. Because the requirements in *N.J.A.C. 13:39-4.5* will now also apply to pharmacy departments, the Board is proposing that existing rule *N.J.A.C. 13:39-4.14*, which provides for the permitting of pharmacy departments, be repealed.

The Board is also proposing amendments to its discontinued pharmacies rule at *N.J.A.C. 13:39-4.8*. The Board proposes to reorder the existing subsections of the rule for organizational purposes, and also proposes to amend the rule in order to clarify that the rule's requirements apply when a pharmacy is discontinued for any reason, including the suspension or retirement of the permit holder, or as a result of a sale or insolvency. The rule currently provides that upon discontinuation of the pharmacy, the permit holder must notify the Board, the Office of Drug Control and the Drug Enforcement Administration (the DEA) by telephone. The Board is proposing to amend the rule to require such notification to be made in writing. The rule continues to require the notification to be made at least 15 days prior closing.

The Board is also proposing to further amend *N.J.A.C. 13:39-4.8* to impose notification requirements in cases when a pharmacy must be discontinued because of an unanticipated occurrence, such as the death of the permit holder. In such cases, the proposed amendments provide that the permit holder's representative must send written notification to the Board, the Office of Drug Control and the DEA as soon as possible prior to the actual closing date. The Board is proposing other amendments to the rule that will require the discontinued pharmacy's prescription legend and controlled drugs to be transferred or to be disposed of in a manner prescribed by the Board, the Office of Drug Control and/or the DEA. Currently, the rule provides that the medications must remain on the pharmacy premises until they are disposed of in the manner prescribed by the Board, the Office of Drug Control and/or the DEA. The proposed amendments will now permit the medications to be transferred to a current pharmacy permit holder, a wholesaler, a reverse distributor and/or a manufacturer, in order to ensure the proper disbursement of medications. In addition, the Board is proposing to amend the rule's existing requirements that a pharmacy's signs be removed and the Board be notified of the location of the discontinued pharmacy's prescription records, to clarify that all signs must be removed within 30 days of the pharmacy's closing, and that the permit holder or his or her representative must notify the Board in writing of the location of the previous five years of pharmacy records.

As noted above, existing rule *N.J.A.C. 13:39-4.14* is proposed to be repealed. In its place the Board is proposing a new rule, which sets forth security requirements applicable to both pharmacies and pharmacy departments. The proposed new rule provides that the registered pharmacist on duty in a pharmacy is responsible for ensuring the security of the pharmacy and its contents. Specifically, the pharmacist must keep 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 [page=374] 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. The proposed new rule, however, provides an exception to this requirement in the case of a pharmacy or pharmacy department that has been issued an institutional permit. The rule provides that for these pharmacies, 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. The Board believes that this exception is necessary in light of the fact that many institutional pharmacies are located within health care facilities, and that in such facilities, the pharmacist on duty is required to leave the pharmacy in order to respond to patient emergencies.

Proposed new rule *N.J.A.C. 13:39-4.14* also requires the pharmacist on duty to ensure the security of the prescription dispensing area and its contents at all times, and to report thefts, diversions and losses of prescription legend drugs and controlled substances, to the registered pharmacist-in-charge and/or the pharmacy permit holder upon discovery. The proposed new rule requires the permit holder and the registered pharmacist-in-charge to ensure that all entrances to the pharmacy or pharmacy department are capable of being locked and are connected to a monitored security system. If a theft, diversion or a significant loss of prescription drugs is reported, a written report must be filed with the Board. If a theft, diversion or a significant loss of controlled substances is reported, a written report must be filed with the DEA.

Proposed new rule *N.J.A.C. 13:39-4.14* also requires the pharmacy or pharmacy department to be equipped with a secure area for receiving packages known to contain prescription legend drugs and controlled substances. The rule prohibits the acceptance of prescription drugs during the hours the pharmacy or pharmacy department is closed unless adequate security for the storage of such shipments has been provided. If a drop-off device is utilized for prescriptions, it must be of a one-way, irretrievable and secure design. The proposed new rule continues to impose the following security requirements for pharmacy departments, which are currently required under existing rule *N.J.A.C. 13:39-4.14*: the department must be constructed so as to enable the closing off and securing of the department from the main store area; all medications requiring supervision of a pharmacist must remain within the confines of the department when the pharmacist is not in the pharmacy department; the department must have a published telephone number different from that of the establishment in which the department is located; and the telephone number of the registered pharmacist-in-charge must be available in the office of the manager of the establishment. The Board is also proposing an additional security requirement with which all pharmacies and pharmacy departments must comply as part of proposed new rule *N.J.A.C. 13:39-4.14*. The new provision requires compliance with any law and/or ordinance of the municipality where the pharmacy or department is located that requires the placement of a security key box on the exterior of the pharmacy or the premises in which the pharmacy department is located, in order to permit emergency access to the premises.

The Board is also proposing amendments to *N.J.A.C. 13:39-5.3*, which requires the posting of the name of the registered pharmacist-in-charge on the entrance to the pharmacy. The proposed amendments to the rule will require pharmacies and pharmacy departments to post the name of the pharmacist-in-charge, in addition to the hours that the pharmacy is open, in plain view at all customer entrances and all drive-thru windows and drop-off boxes. The proposed amendments also provide, in the case of a pharmacy department, when the premises in which the pharmacy department is located maintains different hours of operation from the pharmacy department, all advertising, announcements and signs noting hours of operation and the presence of the pharmacy department must clearly indicate the hours that the pharmacy department is open.

N.J.A.C. 13:39-5.8, which currently requires, in part, that every prescription area contain a locked storage container, is proposed to be amended to require the storage place to be capable of being securely locked when the pharmacist is not present in the prescription dispensing area, consistent with the security requirements of proposed new rule *N.J.A.C. 13:39-4.14*. The Board is also proposing amendments to *N.J.A.C. 13:39-5.12*, which imposes certain restrictions on the storage of prescription drugs and controlled dangerous substances, to provide that such medications shall only be stored in areas of the premises that are part of the permitted pharmacy or pharmacy department.

The Board is proposing to amend *N.J.A.C. 13:39-6.2*, which delineates the responsibilities of the pharmacist-in-charge, to delete the rule's specific requirements relating to the security of the prescription area and its

contents, and to provide a cross-reference to proposed new rule *N.J.A.C. 13:39-4.14*. The Board is also proposing amendments to its meal break rule at *N.J.A.C. 13:39-6.4*. Currently, the rule permits a sole pharmacist on duty to take a meal break if the requirements in the rule are satisfied. The Board is proposing to amend the rule in order to permit a sole pharmacist on duty to take restroom breaks in addition to meal breaks.

The Board is also proposing to amend *N.J.A.C. 13:39-7.1*, concerning the filling of prescriptions. The Board is proposing to amend the rule to eliminate the reference in the rule to written prescriptions because existing Board rules permit pharmacists to accept prescriptions transmitted by facsimile or electronic means. The Board is proposing a further amendment to *N.J.A.C. 13:39-7.1* in order to clarify that a pharmacist may fill a prescription issued by a prescriber authorized to write prescriptions in any 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. The proposed amendments clarify that such prescriptions need not be issued on New Jersey Uniform Prescription Blanks.

Finally, the Board is proposing an amendment to *N.J.A.C. 13:39-7.9*, which imposes requirements for filing and storage of controlled substance prescriptions, to delete the reference to the "usual consecutively numbered" prescription file for non-controlled substances. The requirement to maintain a consecutively numbered prescription file was imposed pursuant to requirements in the previous Pharmacy Act, which was repealed with the passage of the new Pharmacy Practice Act in 2004. In addition, the Board is amending *N.J.A.C. 13:39-7.9* to provide that if a pharmacy uses 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" will be waived, consistent with Department of Health and Senior Services' controlled substances rules set forth at *N.J.A.C. 8:65*.

The Board has provided a 60-day comment period for this notice of proposal. Therefore, this notice is excepted from the rulemaking calendar requirement pursuant to *N.J.A.C. 1:30-3.3(a)5*.

Social Impact

The Board believes that the amendments and new rules that it is proposing will positively impact members of the regulated community, as well as the New Jersey consumers they serve. Proposed new rule *N.J.A.C. 13:39-2.1*, and the proposed amendments to the existing rules in Subchapter 2, will help clarify the requirements that individuals applying for initial licensure must satisfy in order to obtain a license to practice pharmacy in the State. Similarly, proposed new rule *N.J.A.C. 13:39-2A.1*, and the proposed amendments to the rules in Subchapter 2A, will help clarify the requirements that individuals applying for reciprocal licensure must satisfy in order to be licensed to practice pharmacy in New Jersey.

The Board believes that proposed new rules *N.J.A.C. 13:39-2.6* and *2.7*, which establish practical training requirements and impose mandatory registration requirements upon pharmacy interns, will positively impact applicants for licensure who must complete internship training. *N.J.A.C. 13:39-2.6* will provide interns and licensed pharmacists who act as intern preceptors with appropriate direction as to what type of training the internship should entail. In addition, the mandatory registration scheme outlined in *N.J.A.C. 13:39-2.7* will help to ensure that pharmacy interns complete their training in a timely manner.

The Board believes that the proposed recodification of the rules in new Subchapter 3 will have a positive impact upon licensed pharmacists by making the existing rules easier to understand and follow. In addition, the Board believes that the proposed amendments to *N.J.A.C. 13:39-4.5* and [page=375] *4.8* will help to ensure patient access to prescription and patient profile records by imposing maintenance requirements for these records when a pharmacy's assets are sold or transferred or when a pharmacy ceases operation. The proposed amendments to *N.J.A.C. 13:39-4.8* will also help to ensure the proper disbursement of drugs once a pharmacy ceases operation. In addition, the Board believes that the security requirements set forth in proposed new rule *N.J.A.C. 13:39-4.14* will help to ensure that a

pharmacy's medication stock is maintained in a safe manner. The proposed amendments to *N.J.A.C. 13:39-5.8* and *5.12*, which impose storage requirements for controlled substances, will have a similar impact upon permitted pharmacies. The Board also believes that the reporting requirements outlined in proposed new rule *N.J.A.C. 13:39-4.14* that pharmacies must comply with when a drug theft or diversion is suspected, will help pharmacies, as well as the Board and other responsible government agencies, to effectively handle such incidents in a timely manner.

The amendments that the Board is proposing to *N.J.A.C. 13:39-5.3*, concerning the posting of the pharmacy's hours of operation and the name of the pharmacist-in-charge, will have a positive impact upon consumers by ensuring the consumers have access to this information at all consumer entrances and access points to the pharmacy, including drive-thru windows and prescription drop-off boxes. In addition, the Board believes that the proposed amendments to *N.J.A.C. 13:39-6.4*, which impose requirements that must be followed when a sole pharmacist on duty requires a restroom break, will have a positive impact upon pharmacists and consumers by providing direction to pharmacists concerning what steps they must take in order to ensure the proper operation of the pharmacy when such breaks are necessary.

The Board believes that the proposed amendments to *N.J.A.C. 13:39-7.1*, which permit prescriptions issued at facilities regulated by the United States Department of Veterans Affairs or by the Department of Defense to be filled by pharmacists in this State, will have a positive impact upon the pharmacy community by eliminating the confusion that currently exists as to whether such prescriptions may lawfully be filled in the State.

Economic Impact

The Board believes that proposed new rules *N.J.A.C. 13:39-2.1* and 2A.1, which impose practical training requirements upon certain applicants for licensure, as well as the mandatory pharmacy intern registration requirements imposed under proposed new rule *N.J.A.C. 13:39-2.7*, will have an economic impact upon those individuals who will be required to register as pharmacy interns and complete such training prior to becoming licensed pharmacists in the State. Applicants for initial licensure who have graduated from an ACPE approved pharmacy school but who are making application to the Board more than two years following their graduation, and applicants who have graduated from a non-ACPE approved pharmacy school in a foreign country, will be required to complete a practical internship, as will applicants for reciprocal licensure who have not been engaged in the practice of pharmacy for at least 1,500 hours within the two-year period prior to application. Such individuals may incur administrative costs in submitting the required registration application to the Board and will be required to remit a \$ 50.00 application fee, as well as a \$ 70.00 initial registration fee. Registered pharmacy interns who fail to complete the practical internship training during the two-year registration period will incur added costs to renew their registration, including having to remit a \$ 70.00 registration renewal fee. The Board believes that the economic impact that these requirements may have upon applicants for licensure will be outweighed by the benefit to New Jersey consumers in ensuring that all persons licensed to practice pharmacy in the State have met minimum practical training requirements.

The proposed inclusion in the Board's fee schedule at *N.J.A.C. 13:39-1.3* of a \$ 225.00 fee for administrative suspension reinstatement may have an economic impact upon licensees. A licensee seeking to return to the practice of pharmacy following an administrative suspension for failing to renew his or her license will be required to pay this fee under the requirements of *N.J.A.C. 13:39-3.8*.

The Board believes that the proposed amendments to *N.J.A.C. 13:39-4.5* and *4.8*, and proposed new rule *N.J.A.C. 13:39-4.14*, may have an economic impact upon pharmacy permit holders, to the extent that permit holders may incur administrative expenses in meeting the prescription and patient profile record retention and facility security requirements imposed under the rules. The Board believes that these costs will be outweighed by the benefit to New Jersey consumers in ensuring that patients have access to their prescription records when a pharmacy's assets are sold or transferred, or when a pharmacy ceases operation, and in ensuring that a pharmacy's medication stock is maintained in a safe and secure manner.

Federal Standards Statement

A Federal standards analysis is not required because the proposed 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 proposed 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.

Jobs Impact

The Board does not believe that the proposed amendments and new rules will result in the creation or loss of jobs in the State.

Agriculture Industry Impact

The proposed amendments and new rules will have no impact on the agriculture industry in the State.

Regulatory Flexibility Analysis

Currently, the Board licenses approximately 12,741 pharmacists and permits approximately 1,984 pharmacies. The Board cannot estimate at this time how many persons will apply to become registered pharmacy interns if the proposed amendments and new rules become effective. However, if Board licensees, permit holders and pharmacy intern registrants are considered "small businesses" within the meaning of the Regulatory Flexibility Act, *N.J.S.A. 52:14B-16* et seq., then the following analysis applies.

The proposed amendments and new rules will impose various reporting, recordkeeping and compliance requirements upon licensed pharmacists, pharmacy permit holders and registered pharmacy interns in the State of New Jersey. These requirements are discussed in the Summary above.

No additional professional services will be needed to comply with the proposed amendments and new rules. The costs of compliance with the proposed amendments and new rules are discussed in the Economic Impact above. The Board believes that the proposed amendments and new rules should be uniformly applied to all licensed pharmacists, pharmacy permit holders and registered pharmacy interns in order to ensure the health, safety and welfare of the general public in the provision of pharmaceutical services. Therefore, no differing compliance requirements for any licensed pharmacists, pharmacy permit holders or registered pharmacy interns are provided based upon business size.

Smart Growth Impact

The Board does not believe that the proposed amendments and new rules will have any impact upon the achievement of smart growth or upon the implementation of the State Development and Redevelopment Plan.

Housing Affordability Impact

The proposed amendments and new rules will have an insignificant impact on affordable housing in New Jersey and there is an extreme unlikelihood that the rules would evoke a change in the average costs associated with housing because the rules concern the practice of pharmacy.

Smart Growth Development Impact

The proposed amendments and new rules will have an insignificant impact on smart growth and there is an extreme unlikelihood that the rules would evoke a change in housing production in Planning Areas 1 or 2 or within designated centers under the State Development and Redevelopment Plan in New Jersey because the rules concern the practice of

pharmacy.

[page=376] **Full text** of the rules proposed for repeal may be found in the New Jersey Administrative Code at *N.J.A.C. 13:39-2.2, 2.3, 2.4, 2.7, 2.8, 2.9, 3.1, 3.2, 3.4, 3.5, 4.14* and 8.

Full text of the proposed amendments, new rules and recodifications follow (additions indicated in boldface **thus**; deletions indicated in brackets [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 [(To be determined by future rulemaking)] **225.00**

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** [REQUIREMENTS]

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 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 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-[2.1]2.2 [Examinations;] **Licensure examination** scores

(a) [The examination for licensure by the Board shall be the North American Pharmacist Licensure Examination (NAPLEX).] 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 [examination] **NAPLEX**, he or she shall be required to repeat the examination.

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

(c) If [the] **an** applicant [should] 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-[2.5]2.3 Proof of character

(a) An applicant for [the NAPLEX and MJPE examinations] **initial licensure** shall submit[, in advance, an application containing] evidence of good moral character, which [is] **shall be** an ongoing requirement for licensure[, and evidence that he or she:]. **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 [in the last five years] as a result of any administrative or disciplinary proceedings in this or any other jurisdiction [page=377] 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-[2.6]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.

"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.

"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 hours of practical experience required for the successful completion of a pharmacy internship shall be obtained consistent with the following:

1. The 1,420 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 [page=378] 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*.

(Agency Note: *N.J.A.C. 13:39-2.10* through 2.20 is proposed for recodification with amendments as *N.J.A.C. 13:39-3.1* through 3.11.)

SUBCHAPTER [3.]2A. REQUIREMENTS FOR RECIPROCAL LICENSURE [BY RECIPROCITY]

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;

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

iii. 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-[3.3]2A.2 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:] **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 [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.

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-[2.10]3.1 Authorization to practice; display of license

(a) (No change.)

(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.

[page=379] (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] **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-[2.15]3.6 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]***3.2**.

13:39-[2.16]**3.7** (No change in text.)

13:39-[2.17]**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-[2.16]***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-[2.20]**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. [45:14-1]* **45:14-40** et seq., [and] **or** the rules in this chapter, shall be subject to disciplinary action.

(Agency Note: *N.J.A.C. 13:39-3.3* is proposed for recodification with amendments as *N.J.A.C. 13:39-2A.2*.)

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 [person or corporation] **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 [premises] **area** contiguous **or adjacent** to but not necessarily a part of the [pharmacy] **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 [ensure that] **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.**

[(a)] (b) [Whenever a pharmacy is terminated by suspension, retirement or death of the owner, sale or other cause including insolvency,] **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*.**

[(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.]

13:39-4.14 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;

[page=380] **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 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** [on the entrance to the pharmacy in such a way as to be visible to the public] **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. [Securely locked, substantially constructed storage] **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 [that they can] **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[, 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] **set forth in N.J.A.C. [8:65-2.5(d)] 13:39-4.14;**

5.-9. (No change.)

13:39-6.4 Meal **or restroom** breaks

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

[page=381] 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 [pharmacy] **prescription dispensing area** stating "Pharmacist on [meal] 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 [written] 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 [only] fill a prescription issued by [an authorized] a prescriber licensed to write prescriptions in **another state, territory or possession of the United States [or any territory 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 [orders] 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] **Schedule II** or in the [usual consecutively numbered] 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)