40 N.J.R. 5170(a)

Proposed Amendments: N.J.A.C. 13:39-1.2, 4.9, 4.18, 6.5, 7.6, 7.12, 7.19, 9.11, 9.19, 9.21, 10.2, 10.4, 11.9, 11.10 and 12.2

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State Board of Pharmacy Rules

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


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

Submit comments by November 14, 2008 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 its existing rules to require all pharmacies throughout the State to maintain an audit trail to record and document the steps associated with filling a prescription. The Board notes that its current rule concerning centralized prescription handling, N.J.A.C. 13:39-4.18, contains an audit trail requirement for all pharmacies that fill prescriptions under a centralized prescription handling agreement. N.J.A.C. 13:39-4.18 requires that any pharmacy involved in centralized prescription handling maintain an audit trail that records and documents the names or other personal identifiers of pharmacists or pharmacy technicians involved in each function associated with prescription handling (defined as intake, processing, fulfillment and
dispensing), and the particular steps performed by the individuals within each function. Currently, no similar audit trail requirement exists for pharmacies that do not participate in centralized prescription handling. The Board believes that requiring all pharmacies throughout the State to maintain an audit trail for prescriptions is vital to ensuring that accurate and detailed prescription records are maintained. In addition, the Board believes that the maintenance of audit trail documentation may assist pharmacies in tracking medication errors that may occur in the prescription filling process and, in turn, aid pharmacies in instituting systemic changes to prevent future errors in order to better serve the needs of New Jersey consumers.

The Board is aware that many pharmacies currently do not have computer systems that will allow prescription filling information to be tracked as required under the proposed amendments. As a result, the Board has determined that the proposed amendments requiring the creation and maintenance of audit trail information for all pharmacies throughout the State will not become effective until 18 months following the effective date of the proposed changes. The Board believes that this 18-month delay in the effective date of the proposed changes will provide pharmacies with sufficient time within which to revamp their current computer systems. The Board notes that this 18-month delay will have no effect on the audit trail requirements currently in place for pharmacies engaging in centralized prescription handling pursuant to N.J.A.C. 13:39-4.18.

N.J.A.C. 13:39-7.6 currently requires a pharmacist who fills or compounds a prescription or who supervises the filling of a prescription by an intern, extern or pharmacy technician, to initial the original prescription or to place his or her personal identifier in the pharmacy's electronic data processing system, if applicable. The Board is proposing that this requirement be deleted and that N.J.A.C. 13:39-7.6 now require all pharmacies to maintain an audit trail that records and documents the unique and secure user identifier of the pharmacist, pharmacy technician, intern or extern who performs each function of the prescription handling process. Any entries to the audit trail made by a pharmacy technician, intern or extern must be reviewed and approved by the pharmacist. The proposed amendments also provide that when more than one pharmacist is involved in filing a prescription, the unique and secure user identifier of the pharmacist who is responsible for the accuracy and appropriateness of each prescription function (that is, intake, processing, fulfillment or dispensing) must be recorded in the audit trail. Audit trail documentation must be generated at the time each function is performed and the pharmacy's computer system must be designed to identify and document the unique and secure identifier of all users of the system.

The proposed amendments to N.J.A.C. 13:39-7.6, as well as amendments that the Board is proposing to the patient profile record system rule, set forth at N.J.A.C. 13:39-7.19, require that all audit trail and patient profile information be maintained or stored in original hard copy form or in any other manner that facilitates the reproduction of the original information. This information must be maintained for five years. The oldest four years of information must be retrievable and readable within two weeks and the most recent one year of information must be retrievable and readable within one business day. Proposed amendments to N.J.A.C. 13:39-7.6 and 7.19 also clarify that any records maintained by the pharmacy that are not currently in use may be stored at off-site facilities, provided the facilities are secure, and that all patient records are kept confidential. All records maintained by the pharmacy must be made available to persons authorized to inspect them under State or Federal law.

The Board notes that similar audit trail and document retention requirements for institutional pharmacies are being proposed in N.J.A.C. 13:39-9.19 and 9.21, for pharmacies engaging in sterile and non-sterile compounding in N.J.A.C. 13:39-11.9 and 11.10, and for nuclear pharmacies in N.J.A.C. 13:39-12.2. The Board is proposing amendments to the audit trail requirements for pharmacies engaging in centralized prescription handling in N.J.A.C. 13:39-4.18 in order to make these provisions consistent with the new requirements being proposed for all other pharmacies in the State as discussed above.

The Board is also proposing amendments to N.J.A.C. 13:39-6.5, which concerns prescriptions handled by pharmacy externs, interns and technicians, to clarify that all functions performed by such personnel must be documented in the pharmacy audit trail and must be reviewed and approved by a pharmacist. The amendments to N.J.A.C. 13:39-6.5 clarify that when more than one pharmacist is involved in functions of prescription handling, each pharmacist is
responsible for the accuracy and appropriateness of the functions he or she performed or reviewed.

The Board believes that the audit trail requirements now being proposed obviate the need to require the initials of the dispensing pharmacist to appear on the prescription label or in the patient profile record, as is now required under N.J.A.C. 13:39-7.6, 7.12, 7.19, 9.19, and 11.10. This requirement is proposed to be deleted from the above referenced rules. The name of the pharmacist responsible for each function associated with the filled prescription will now be maintained as part of a pharmacy's audit trail documentation.

The Board is also proposing amendments to N.J.A.C. 13:39-4.9, concerning the availability of patient records upon the termination of business. Currently, the rule requires a pharmacy to notify patients of their right to retrieve prescriptions and of the location of prescription records for a six-month period following dissemination of a notice that the pharmacy will be closing. The Board is proposing that this timeframe be extended to one year in order to allow patients additional time to obtain copies of their prescriptions and patient profile records.

The Board is also proposing to amend the definition of "prescription" in N.J.A.C. 13:39-1.2 to reflect the new definition for the term as it appears in the New Jersey Pharmacy Practice Act at N.J.S.A. 45:14-41. Under the proposed amendments, a "prescription" means a lawful order of a practitioner for a drug, device or diagnostic agent for a specific patient.

The Board notes that it is also proposing various technical amendments as part of this rulemaking to N.J.A.C. 13:39-4.18, 7.19 and 9.21. These amendments are intended to clarify the existing meaning of the above referenced rules.

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 proposed amendments to N.J.A.C. 13:39-6.5, 7.6, 9.19, 11.9 and 12.2, which will require all pharmacies in the State to maintain an audit trail to record and document all steps associated with filling a prescription, as well as the proposed amendments to N.J.A.C. 13:39-4.18, 7.19 and 9.21, which establish record retention requirements for audit trail and other patient record documentation, will positively impact pharmacies and consumers by ensuring the creation and maintenance of accurate and detailed prescription records. The Board believes that these requirements will assist pharmacies in tracking medication errors that may occur in the prescription filling process and may assist pharmacies in instituting systemic changes in order to prevent future medication errors.

The Board also believes that the proposed amendments to N.J.A.C. 13:39-4.9, which will require a pharmacy that ceases operation to make prescription and patient profile records available to consumers for one year, will benefit consumers by providing them with an additional six-month period during which they may obtain their records following a pharmacy's closing.

Economic Impact

The proposed amendments to N.J.A.C. 13:39-6.5, 7.6, 9.19, 11.9 and 12.2, which will require pharmacies throughout the State to create and maintain a detailed audit trail for all filled prescriptions, may have an economic impact upon some permitted pharmacies. Pharmacies that currently do not have computer systems capable of creating and maintaining an audit trail will be required to update their computer systems to ensure compliance with the new requirements. Because the Board is aware that computer system upgrades may be costly, it has determined that the newly proposed audit trail requirements will not become mandatory until 18 months following the effective date of the proposed amendments. The Board believes that delaying the effective date of the new requirements may help pharmacies to defray some of the economic costs associated with making the required computer upgrades by providing
pharmacies more discretion as to when such upgrades should be made. The Board believes that the economic impact that may be borne by pharmacies as a result of the new audit trail requirements will be outweighed by the benefit to consumers in ensuring that accurate and detailed prescription records are maintained by each pharmacy in the State.

**Federal Standards Statement**

A Federal Standards analysis is not required because the proposed amendments are governed by *N.J.S.A. 45:14-40* et seq., and are not subject to any Federal requirements or standards.

**Jobs Impact**

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

**Agriculture Industry Impact**

The proposed amendments 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. If Board licensees and permit holders 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 will not impose any reporting requirements upon licensed pharmacists and permitted pharmacies in the State. The proposed amendments, however, will impose various recordkeeping and compliance requirements upon licensed pharmacists and permitted pharmacies throughout the State. These requirements are discussed in the Summary above.

No additional professional services will be needed to comply with the proposed amendments. The costs of compliance with the proposed amendments are discussed in the Summary and the Economic Impact above. The Board believes that the proposed amendments should be uniformly applied to all licensees and permit holders 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 licensees or permit holders are provided based upon the size of the business. The Board notes, however, that the 18-month delay in the effective date of the proposed changes concerning the creation and maintenance of an audit trail may help pharmacies that qualify as small businesses offset some of the costs that may be associated with complying with these requirements.

**Smart Growth Impact**

The Board does not believe that the proposed amendments 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 will have an insignificant impact on affordable housing in New Jersey and there is an extreme unlikelihood that the amendments would evoke a change in the average costs associated with housing because the proposed amendments concern the practice of pharmacy.

**Smart Growth Development Impact**

The proposed amendments will have an insignificant impact on smart growth and there is an extreme unlikelihood that the amendments 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 proposed amendments concern the practice of pharmacy.

Full text of the proposal follows (additions indicated in boldface thus; deletions indicated in brackets [thus]):

SUBCHAPTER 1. GENERAL PROVISIONS

13:39-1.2 Definitions

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

... "Prescription" means [any order for drugs and related items as defined in N.J.S.A. 45:14-14] a lawful order of a practitioner for a drug, device or diagnostic agent for a specific patient.

...

SUBCHAPTER 4. PHARMACY PERMIT REQUIREMENTS

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

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

1. (No change.)

2. Publication, once weekly for two successive weeks in a newspaper whose circulation encompasses the major area of the licensee's former practice, of a notice advising patrons [of their] that they have the right to [retrieve] obtain copies of their prescriptions and the location of the prescriptions and patient profile [records] for a [six-month] one-year period following publication; and

3. A sign placed in the pharmacy location informing the patrons [of their] that they have the right to [retrieve] obtain copies of their prescriptions and the location of the prescriptions and patient profile.

13:39-4.18 Procedures for centralized prescription handling

(a) (No change.)

(b) Central prescription handling entails two or more licensed pharmacies sharing responsibility for performing the four component functions of handling a prescription. For purposes of this section, the term "prescription" shall include medication orders when a healthcare facility is involved in any of the component functions of central prescription handling.

(c) The following pharmacies may engage in central prescription handling: an intake or originating pharmacy; a central processing pharmacy; a central fill pharmacy; and a dispensing pharmacy. The four component functions of handling a
prescription shall be performed by the following pharmacies:

1. An intake or originating pharmacy, which is a licensed pharmacy that received the patient's or prescribing practitioner's request to fill or refill a prescription. A central processing pharmacy or a central fill pharmacy, as delineated in (c)2 and 3 below, may be considered the intake or originating pharmacy if the prescription was transmitted by the prescribing practitioner directly to the centralized pharmacy as provided in N.J.A.C. 13:39-7.10 and 7.11 or if the patient requested the refill from that pharmacy;

2.-3. (No change.)

4. A dispensing pharmacy, which is a licensed pharmacy that receives the processed prescription and/or the filled or refilled prescription for dispensing to the patient or to the patient's authorized representative and which offers patient counseling regarding the dispensed medication.

(d) Two or more of the licensed pharmacies delineated in (c) above may engage in central prescription handling provided:

1.-2. (No change.)

3. An audit trail is maintained that records and documents the [name(s) or other personal] unique and secure user identifier(s) of the pharmacist(s), [or] pharmacy technician(s), intern(s) or extern(s) and the component function(s) performed by each, at the time the functions are performed, for each step of prescription handling[.] that is required to be performed by a pharmacist, pharmacy technician, intern or extern pursuant to the requirements of this chapter. All steps performed by a pharmacy technician, intern or extern shall be documented in the audit trail. All entries to the audit trail made by a pharmacy technician, intern or extern shall be reviewed and approved by the pharmacist. When more than one pharmacist is involved in the component functions of prescription handling, the unique and secure user identifier(s) of the pharmacist(s) responsible for the accuracy and appropriateness of each component function(s) shall be recorded in the audit trail. The audit trail and prescription information shall be maintained or stored in original hard copy form or in any other media that facilitates the reproduction of the original hard copy and shall be maintained for not less than five years from the date the prescription is filled or refilled. The oldest four years of information shall be maintained in such a manner so as to be retrievable and readable within two weeks. The most recent one year of information shall be retrievable and readable within one business day[.]. Records not currently in use need not be stored in the pharmacy, but the off-site facilities used to store such records shall be secure. Patient records shall be kept confidential, but shall be made available to persons authorized to inspect them under State and Federal statutes and regulations;

4.-9. (No change.)

(e) (No change.)

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

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

A pharmacy intern, extern or technician may [prepare or compound prescriptions only under the immediate personal supervision of a registered pharmacist of this State.] perform the component functions of prescription handling, as defined in N.J.A.C. 13:39-4.18, consistent with the requirements of this chapter. All steps performed by a pharmacy technician, intern or extern shall be documented in the pharmacy audit trail. All entries to the audit trail shall be reviewed and approved by a pharmacist pursuant to N.J.A.C. 13:39-7.6. [The] When one registered pharmacist is involved in the component functions of prescription handling, by either personally performing the
functions or by reviewing the functions performed by technicians, interns or externs, the pharmacist shall be personally responsible for the accuracy and appropriateness of the filled prescription. When more than one pharmacist is involved in the component functions of prescription handling, each pharmacist shall be responsible for the accuracy and appropriateness of the component function he or she performed or that he or she reviewed and approved.

SUBCHAPTER 7. DRUG DISPENSING AND PRESCRIPTION RECORDS

13:39-7.6 [Record of pharmacist filling prescription] Required records and documents

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

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

(a) A pharmacy shall maintain an audit trail that records and documents the unique and secure user identifier(s) of the pharmacist(s), pharmacy technician(s), intern(s) or extern(s) performing the component functions of each step of prescription handling, as defined in N.J.A.C. 13:39-4.18, which are required to be performed by a pharmacist, pharmacy technician, intern or extern pursuant to the requirements of this chapter. All steps performed by a pharmacy technician, intern or extern shall be documented in the audit trail. All entries to the audit trail made by a pharmacy technician, intern or extern shall be reviewed and approved by the pharmacist. When more than one pharmacist is involved in the component functions of prescription handling, the unique and secure user identifier(s) of the pharmacist(s) responsible for the accuracy and appropriateness of each component function(s) shall be recorded in the audit trail. Audit trail documentation shall be generated at the time each component function(s) is performed.

[(c) (b) Initials and/or access code number(s) of the pharmacist responsible for the filled prescription shall be entered into the system each time a prescription is filled or refilled.] Computer systems employed for audit trail documentation shall be designed to identify and document the unique and secure identifier for all pharmacists, pharmacy technicians, interns and externs who utilize the system. Computer [programs which] systems that automatically generate [a pharmacist's initials] the unique and secure user identifier of a pharmacist, pharmacy technician, intern or extern without requiring [a] an [direct] entry by the [pharmacist] responsible [for the filled prescription at the time of dispensing] party are prohibited.

[(d) (c) Appropriate documentation identifying [handwritten initials with the handwritten signature and printed name of the pharmacist shall be maintained by the pharmacy for a period of six years after the last date of employment.] the unique and secure user identifier of all pharmacists, pharmacy technicians, interns and externs employed by the pharmacy shall be maintained by the pharmacy for a period of not less than five years after the last date of employment. If a pharmacy utilizes a manual system, appropriate documentation identifying the handwritten initials with the handwritten signature and printed name of all pharmacists, pharmacy technicians, interns and externs employed by the pharmacy shall be maintained for a period of not less than five years after the last date of employment. The oldest four years of record information shall be maintained in such a manner so as to be retrievable and readable within two weeks. The most recent one year of a record information shall be retrievable and readable within one business day. Records not currently in use need not be stored in the pharmacy, but off-site facilities used to store such records shall be secure.
[(e)] [(d)] All [prescription records, including original and refilled prescription data, and the number of refills authorized by the prescriber] **audit trail and prescription information shall be maintained or stored in original hard copy form or in any other media that facilitates the reproduction of the original hard copy and shall be maintained for a period of not less than five years.** The oldest four years of record information shall be maintained in such a manner so as to be retrievable and readable within two weeks. The most recent one year of a record information shall be [immediately] retrievable and readable[.] within one business day. **Records not currently in use need not be stored in the pharmacy, but off-site facilities used to store such records shall be secure.** Patient records shall be kept confidential, but shall be made available to persons authorized to inspect them under State and Federal statutes and regulations.

13:39-7.12 Labeling

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

1.-8. (No change.)

[9. Initials of the dispensing pharmacist;]

Recodify existing 10.-13. as 9.-12. (No change in text.)

(b)-(d) (No change.)

13:39-7.19 Patient profile record system

(a) (No change.)

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

1.-3. (No change.)

4. The original or refill date the medication is dispensed [and the initials of the dispensing pharmacist, if said initials and such date are not recorded on the back of the original prescription or in any other Board-approved record];

5.-8. (No change.)

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

(f) A patient profile record shall be maintained **or stored in original hard copy form or in any other media that facilitates the reproduction of the original hard copy and shall be maintained** for a period of not less than five years from the date of the last entry in the profile record. In using an electronic data processing system, the system shall have the capability of producing retrievable and readable documents of all original and refilled prescription data for a period of not less than five years, including the number of refills authorized by the prescriber. The oldest four years of record information shall be maintained in such a manner so as to be retrievable and readable within two weeks. The most recent one year of a record information shall be [immediately] retrievable and readable[.] within one business day. **Records not currently in use need not be stored in the pharmacy, but off-site facilities used to store such records shall be secure.** Patient records shall be kept confidential, but shall be made available to persons authorized to inspect them under State and Federal statutes and regulations.

(g)-(j) (No change.)
SUBCHAPTER 9. PHARMACEUTICAL SERVICES FOR HEALTH CARE FACILITIES

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

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

13:39-9.19 Records and reports

(a) Records of the pharmaceutical services of the provider pharmacy for the facility shall be the responsibility of the registered pharmacist-in-charge. pharmacy shall maintain an audit trail that records and documents the unique and secure user identifier(s) of the pharmacist(s), pharmacy technician(s), intern(s) or extern(s) performing the component functions of prescription handling, as defined in N.J.A.C. 13:39-4.18, which are required to be performed by a pharmacist, pharmacy technician, intern or extern pursuant to the requirements of this chapter. All steps performed by a pharmacy technician, intern or extern shall be documented in the audit trail. All entries to the audit trail made by a pharmacy technician, intern or extern shall be reviewed and approved by the pharmacist. When more than one pharmacist is involved in the component functions of prescription handling, the unique and secure user identifier(s) of the pharmacist(s) responsible for the accuracy and appropriateness of each component function(s) shall be recorded in an audit trail. Audit trail documentation shall be generated at the time the component function(s) is performed. All audit trail and medication order information shall be maintained or stored in original hard copy form or in any other media that facilitates the reproduction of the original hard copy and shall be maintained for a period of not less than five years. The oldest four years of information shall be maintained in such a manner so as to be retrievable and readable within two weeks. The most recent one year of information shall be retrievable and readable within one business day. Records not currently in use need not be stored in the pharmacy, but the storage facilities shall be secure, and the records shall be readily retrievable by the pharmacy staff and authorized inspectors. Patient records shall be kept confidential, but shall be made available to persons authorized to inspect them under State and Federal statutes and regulations. [Patient records shall be kept confidential.]

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

1. The profile records for inpatients shall contain: the date of each entry; the name; sex; age or birthdate; location of the patient; the drug name, dose, route of administration and quantity dispensed; [the initials of the pharmacist performing the dispensing or supervising;] the reported diagnosis, allergies and chronic condition(s) of the patient.

2. (No change.)

3. The inpatient profile record shall be filed and stored for five years following patient discharge. The oldest four years of information shall be maintained in such a manner so as to be retrievable and readable within two weeks. The most recent one year of information shall be [immediately] retrievable and readable within one business day.

(c) All outpatient prescriptions dispensed and outpatient profile records in the institutional pharmacy shall [be signed or initialed by the dispensing pharmacist, dated, filed and kept for not less than five years from the last dispensing record date] conform to the requirements set forth in N.J.A.C. 13:39-7.6.

(d)-(f) (No change.)

13:39-9.21 After hours access to the institutional pharmacy
(a)-(e) (No change.)

(f) All records in (d) above shall be maintained or stored in original hard copy form or in any other media that facilitates the reproduction of the original hard copy, and shall be kept by the pharmacy for five years. The oldest four years of information shall be maintained in such a manner so as to be retrievable and readable within two weeks. The most recent one year of information shall be [immediately] retrievable and readable [within one business day]. Records not currently in use need not be stored in the pharmacy, but off-site facilities used to store such records shall be secure. Patient records shall be kept confidential, but shall be made available to persons authorized to inspect them under State and Federal statutes and regulations.

13:39-10.2 "Automated medication system" definition

As used in this subchapter, "[Automated] automated medication system" means any process that performs operations or activities, other than compounding or administration, relative to the storage, packaging, dispensing and distribution of medications, and which collects, controls and maintains all transaction information. "Automated medication system" does not mean an automatic counting device operated pursuant to N.J.A.C. 13:39-7.11 or a mechanical drug dispensing device operated pursuant to N.J.A.C. 13:39-9.14.

13:39-10.4 Written policies and procedures of operation

(a) When an automated medication system is used to fill prescriptions or medication orders, it shall be operated according to written policies and procedures of operation. The policies and procedures of operation shall:

1.-4. (No change.)

5. Set forth methods that shall ensure that access to the records of medications and other medical information of the patients maintained by the pharmacy is limited to licensed practitioners or personnel approved to have access to the records, for the purpose of complying with N.J.A.C. 13:39-7.14(h);

6.-7. (No change.)

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

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

13:39-11.9 Documentation

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

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

(c) A pharmacy shall maintain an audit trail that records and documents the unique and secure user identifier(s) of the pharmacist(s), pharmacy technician(s), intern(s) or extern(s) involved, consistent with the requirements of this chapter, in the steps of the compounding process set out in (d) below. All steps performed by a pharmacy technician, intern or extern shall be documented in the audit trail. All entries to the audit trail made by a pharmacy technician, intern or extern shall be reviewed and approved by the pharmacist. When more than one pharmacist is involved in the steps of the compounding process, the unique and secure user identifier(s) of the
The pharmacist(s) responsible for the accuracy and appropriateness of each step shall be recorded in the audit trail. Audit trail documentation shall be generated at the time each step is performed.

(d) (No change.)

(e) The audit trail information shall be maintained or stored in original hard copy form or in any other media that facilitates the reproduction of the original hard copy and shall be maintained for not less than five years from the date of the last entry in the record. The oldest four years of record information shall be maintained in such a manner so as to be retrievable and readable within two weeks. The most recent one year of a record shall be immediately retrievable and readable within [24 hours.] one business day. Records not currently in use need not be stored in the pharmacy, but off-site facilities used to store such records shall be secure. Patient records shall be kept confidential, but shall be made available to persons authorized to inspect them under State and Federal statutes and regulations.

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

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

1.-5. (No change.)

[6. The name or identifying code of the pharmacist who checked or prepared the compounded preparation;]

Recodify existing 7.-11. as 6.-10. (No change in text.)

SUBCHAPTER 12. NUCLEAR PHARMACIES

13:39-12.2 General requirements for pharmacies providing radiopharmaceutical service

(a) The application for a specialized retail permit to operate a pharmacy providing radiopharmaceutical services shall only be issued to a site employing a qualified nuclear pharmacist. All personnel performing tasks in the preparing and distribution of drugs shall be under the immediate personal supervision of the nuclear pharmacist who shall be responsible for all nuclear operations of the licensed area and shall be in personal attendance at all times when the nuclear pharmacy is open for business. Nuclear pharmacies shall maintain an audit trail that records and documents the unique and secure user identifier(s) of the pharmacist(s), pharmacy technician(s), intern(s) or extern(s) performing the radiopharmaceutical services, which are required to be performed by a pharmacist, pharmacy technician, intern or extern pursuant to the requirements of this chapter. All steps performed by a pharmacy technician, intern or extern shall be documented in the audit trail. All entries to the audit trail made by a pharmacy technician, intern or extern shall be reviewed and approved by the pharmacist. When more than one pharmacist is involved in performing radiopharmaceutical services pursuant to this subchapter, the unique and secure user identifier(s) of the pharmacist(s) responsible for the accuracy and appropriateness of the services performed shall be recorded in the audit trail. Audit trail documentation shall be generated at the time each service is performed. Such documentation shall be maintained or stored in original hard copy form or in any other media that facilitates the reproduction of the original hard copy and shall be kept by the pharmacy for five years. The oldest four years of information shall be maintained in such a manner so as to be retrievable and readable within two weeks. The most recent one year of information shall be retrievable and readable within one business day. Records not currently in use need not be stored in the pharmacy, but off-site facilities used to store such records shall be secure. Patient records shall be kept confidential, but shall be made available to persons authorized to inspect them under State and Federal statutes and regulations.
(b)-(l) (No change.)