RULE ADOPTIONS
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LAW AND PUBLIC SAFETY
DIVISION OF CONSUMER AFFAIRS
BOARD OF PHARMACY

Adopted 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

Rules

Proposed: September 15, 2008 at 40 N.J.R. 5170(a).
Adopted: March 25, 2009 by the Board of Pharmacy, Edward G. McGinley, R.Ph, President.

Filed: September 11, 2009 as R.2009 d.305, **with substantive changes** not requiring additional public notice and comment (see N.J.A.C. 1:30-6.3).

Authority: N.J.S.A. 45:1-15.1 and 45:14-47.

Effective Date: October 5, 2009.
Expiration Date: December 10, 2009.

Federal Standards Statement

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

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

SUBCHAPTER 1. GENERAL PROVISIONS

13:39-1.2 Definitions

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

. . .

"Prescription" means 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 that they have the right to obtain copies of currently valid prescriptions and the location of the prescriptions and patient profile for a 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 that they have the right to obtain copies of their prescriptions and the location of the prescriptions and patient profile for a one-year period following publication; and

3. A sign placed in the pharmacy location informing the patrons that they have the right to 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 [page=3842] 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 unique and secure user identifier(s) of the pharmacist(s), 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 handling by pharmacy externs, interns or pharmacy technicians

A pharmacy intern, extern or technician may 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]* ***On or after April 5, 2011, 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. 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 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 Required records and documents

(a) *[A]* ***On or after April 5, 2011, 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.

(b) 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 systems that automatically generate the unique and secure user identifier of a pharmacist, pharmacy technician, intern or extern without requiring an entry by the responsible party are prohibited.

(c) Appropriate documentation identifying 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.

(d) All 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 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.)

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;

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 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 [page=3843] 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

(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. *[A]* ***On or after April 5, 2011, 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 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 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) 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 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 retrievable and readable within one business day.

(c) All outpatient prescriptions dispensed and outpatient profile records in the institutional pharmacy shall 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 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 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. 13:39-5.11 or a mechanical drug dispensing device operated pursuant to N.J.A.C. 13:39-9.17.

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. 13:39-7.19;

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) *[A]* ***On or after April 5, 2011, 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 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 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.

13:39-11.10 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.)

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 [page=3844] 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]* ***On or after April 5, 2011, 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.)