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ISSUE DATE: AUGUST 5, 2013
RULE ADOPTIONS

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

Adopted Amendments: N.J.A.C. 13:39-1.2, 6.5, 6.15, 7.6, 9.19, and 12.2

Pharmacy Technician Duties and Pharmacist-Technician Ratios; Required Records and Documents; Records and Reports; Documentation; and General Requirements for Pharmacies Providing Radiopharmaceutical Service

Proposed: February 4, 2013 at 45 N.J.R. 201(a).

Adopted: May 29, 2013 by the State Board of Pharmacy, Edward McGinley, R.Ph, President.

Filed: July 2, 2013 as R.2013 d.098, **without change**.

Authority: N.J.S.A. 45:14-47, specifically, 45:14-80.

Effective Date: August 5, 2013.

Expiration Date: May 17, 2017.

Summary of Public Comment and Agency Response:

The official comment period ended April 5, 2013. **The Board of Pharmacy received no comments.**

Federal Standards Statement

A Federal standards analysis is not required because the adopted amendments are governed by N.J.S.A. 45:14-47 of the Pharmacy Practice [page=1920] Act. The adopted amendments are not subject to any Federal standards or requirements.

Full text of the adoption follows:

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.

...

"Pharmacy extern" or "extern" means a "pharmacy extern" as defined at N.J.A.C. 13:39-2.6(a).

"Pharmacy intern" or "intern" means a "pharmacy intern" as defined at N.J.A.C. 13:39-2.6(a).

...

SUBCHAPTER 6. PHARMACIST-IN-CHARGE; PHARMACY PERSONNEL

13:39-6.5 Prescription handling by pharmacy externs, pharmacy interns, pharmacy technicians, pharmacy technician applicants, or unlicensed or unregistered personnel

(a) A pharmacy intern, pharmacy extern, pharmacy technician, or pharmacy technician applicant in any pharmacy may perform the component functions of prescription handling described in N.J.A.C. 13:39-4.19, consistent with the requirements of this chapter. On or after April 5, 2011, all steps performed by a pharmacy technician, pharmacy technician applicant, pharmacy intern, or pharmacy extern shall be documented in the pharmacy audit trail consistent with the requirements of N.J.A.C. 13:39-7.6.

(b) Pharmacy interns and pharmacy externs may assist the pharmacist in performing the following tasks:

1. Retrieval of prescription files, patient files, and profiles and other such records pertaining to the practice of pharmacy;
2. Data entry of prescription medication information, including the original or refill date of the prescription, the number or designation identifying the prescription, the practitioner's information, and the name, strength, and quantity of the prescribed medication;
3. The collection of the following demographic information for the patient profile: the name, address, and telephone number of the patient; the patient's age, date of birth; or age group (infant, child, adult); gender; any allergies and idiosyncrasies of the patient; and any medical conditions that may relate to drug utilization;

4. Transcription of scanned prescription or medication order information into the patient record;

5. Label preparation;

6. The counting, weighing, measuring, pouring, and compounding of prescription medication or stock legend drugs and controlled substances, including the filling of an automated medication system; and

7. Accepting authorization from a patient for a prescription refill, or from a practitioner or his or her agent for a prescription renewal, provided that the prescription remains unchanged.

(c) The collection of the demographic information under (b)3 above may be performed by unlicensed or unregistered personnel.

13:39-6.15 Pharmacy technician duties and pharmacist-technician ratios

(a) Pharmacy technicians and pharmacy technician applicants may assist the pharmacist in performing the following tasks:

1. (No change.)

2. Data entry of prescription medication information, including the original or refill date of the prescription, the number or designation identifying the prescription, the practitioner's information, and the name, strength, and quantity of the prescribed medication;

3. The collection of the following demographic information for the patient profile: the name, address, and telephone number of the patient; the patient's age, date of birth; or age group (infant, child, adult); gender; any allergies and idiosyncrasies of the patient; and any medical conditions that may relate to drug utilization;

4. Transcription of scanned prescription or medication order information into the patient record;

Recodify existing 3.-4. as 5.-6. (No change in text.)

7. Accepting authorization from a patient for a prescription refill, or from a practitioner or his or her agent for a prescription renewal, provided that the prescription remains unchanged, consistent with (a)7i below:

i. (No change.)

(b)-(h) (No change.)

SUBCHAPTER 7. DRUG DISPENSING AND PRESCRIPTION RECORDS

13:39-7.6 Required records and documents

(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 intake, processing, fulfillment, and dispensing of prescriptions as defined in N.J.A.C. 13:39-4.19, which are required to be performed by a pharmacist, pharmacy technician, intern, or extern pursuant to the requirements of this chapter. The collection of demographic information for the patient profile as provided for in N.J.A.C. 13:39-6.15(a)3 is not required to be, but may be, recorded 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. 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 each component function he or she performed or reviewed and approved, and his or her unique and secure user identifier(s) shall be recorded in the audit trail. Audit trail documentation shall be generated at the time each component function(s) is performed.

(b)-(e) (No change.)

SUBCHAPTER 9. PHARMACEUTICAL SERVICES FOR HEALTH CARE FACILITIES

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 pharmacist-in-charge. 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 intake, processing, fulfillment, and dispensing of prescriptions as defined in N.J.A.C. 13:39-4.19, which are required to be performed by a pharmacist, pharmacy technician, intern, or extern pursuant to the requirements of this chapter. The collection of demographic information for the patient profile as provided for in N.J.A.C. 13:39-6.15(a)2i is not required to be, but may be, recorded 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. 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 each component function

he or she performed or reviewed and approved, and his or her unique and secure user identifier(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)-(f) (No change.)

[page=1921] 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. 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. The collection of demographic information for the patient profile as provided for in N.J.A.C. 13:39-6.15(a)2i is not required to be, but may be, recorded 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. The pharmacist shall be responsible for the accuracy and appropriateness of the radiopharmaceutical services performed. When more than one pharmacist is involved in performing radiopharmaceutical services pursuant to this subchapter, each pharmacist shall be responsible for the accuracy and appropriateness of the radiopharmaceutical services he or she performed or reviewed and approved, and his or her unique and secure user identifier(s) 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)-(1) (No change.)