

4. The name and address of the delegating physician, and the name and address of the licensed pharmacist administering the dose, and the immunization location, if different from the pharmacy practice site; and

5. The name and address of the patient's primary care provider, if provided.

(j) The licensed pharmacist shall document in detail and immediately report all clinically significant adverse events to the delegating physician, and to the primary care provider, if identified and if authorized on the informed consent form consistent with (h) above. The licensed pharmacist shall, within 72 hours, report such events to the appropriate government reporting system.

(k) The licensed pharmacist shall provide a copy of all patient related documentation and a copy of the signed informed consent form to each patient receiving an immunization, or to the patient's representative, to the patient's primary care provider, if provided and if authorized on the informed consent form consistent with (h) above, and if applicable, to the appropriate government reporting system.

(l) All documentation and records required to be maintained by this section shall be maintained in either hard copy or electronic form for a period of not less than seven years from the date of most recent entry and shall be supplied to any physician or health care provider upon receipt of a signed patient release of health information form. All records shall be made available to persons authorized to inspect them under State and Federal statutes and regulations. The oldest six 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. Patient records shall be kept confidential.

(m) In the case of immunization programs implemented pursuant to a physician's standing order, a licensed pharmacist shall be supervised by the delegating physician. Supervision by the delegating physician shall be deemed adequate if the delegating physician:

1. Is responsible for formulating or approving a standing order, periodically reviewing the order and the services provided to patients under the order;
2. Is geographically located to be easily accessible to the pharmacy practice site and, if applicable, to the immunization location.
3. Is available through direct telecommunication for consultation, assistance, and direction; and
4. Receives annual status reports on the immunization program as administered by the pharmacist.

New Rule, R.2009 d.104, effective April 6, 2009.  
See: 40 N.J.R. 1072(a), 41 N.J.R. 1493(a).

Recodified from N.J.A.C. 13:39-4.20 by R.2010 d.090, effective June 21, 2010.  
See: 42 N.J.R. 132(a), 42 N.J.R. 1221(a).

## SUBCHAPTER 5. RETAIL FACILITY REQUIREMENTS

### 13:39-5.1 Purpose and scope

The rules in this subchapter shall apply to all retail pharmacies, retail pharmacy departments and all institutional pharmacies filling prescriptions for outpatient use. For purposes of this subchapter, "pharmacy" means a retail pharmacy, retail pharmacy department or an institutional pharmacy filling prescriptions for outpatient use.

New Rule, R.2005 d.25, effective January 18, 2005.  
See: 36 N.J.R. 3345(a), 37 N.J.R. 295(a).

Former N.J.A.C. 13:39-5.1, Imprinted prescription blanks, repealed.  
Amended by R.2010 d.090, effective June 21, 2010.  
See: 42 N.J.R. 132(a), 42 N.J.R. 1221(a).  
Rewrote the section.

#### Case Notes

Out-of-state applicant could not be deemed an institutional pharmacy because: (1) the applicant's Wisconsin license stated only that it was a "pharmacy" and did not further describe the licensee as either retail or institutional; (2) the Justice Department registration recognized petitioner as a retail pharmacy; (3) an "institutional pharmacy" under New Jersey regulations must be within a healthcare facility or system licensed as such by the Board; and (4) the New Jersey regulations also state that the term "pharmacy" standing alone indicates a retail pharmacy. Because the applicant was not deemed an institutional pharmacy, its authorization as a Medicaid provider was not proscribed under N.J.A.C. 10:51-2.2(b)1. Phoenix Pharmacy, Inc. v. DMAHS, OAL Dkt. No. HMA 03266-07, 2007 N.J. AGEN LEXIS 489, Initial Decision (July 6, 2007).

### 13:39-5.2 Pharmacy access and egress

Pharmacies shall maintain entrances which are easily and safely accessible to the general public. Access to and egress from the pharmacy shall not be such that the public must traverse or traffic through any area in which prescriptions are prepared.

Recodified from N.J.A.C. 13:39-7.1 and amended by R.2005 d.25, effective January 18, 2005.

See: 36 N.J.R. 3345(a), 37 N.J.R. 295(a).

Rewrote the section. Former N.J.A.C. 13:39-5.2, Lack of directions on original prescription, recodified to N.J.A.C. 13:39-7.2.

### 13:39-5.3 Pharmacy signs

(a) Pharmacies shall post a sign on the exterior of the building or a sign which is otherwise visible from a public roadway, conspicuously identifying the existence of a pharmacy on the premises, unless prohibited by lease agreement or municipal ordinance. In such case, a copy of the lease or ordinance shall be furnished to the Board.

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

(c) In the case of a pharmacy department, the hours that the department is open and the name of the 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.

Recodified from N.J.A.C. 13:39-7.2 and amended by R.2005 d.25, effective January 18, 2005.

See: 36 N.J.R. 3345(a), 37 N.J.R. 295(a).

Rewrote (a); added (b). Former N.J.A.C. 13:39-5.3, Authorization for renewal of prescriptions, recodified to N.J.A.C. 13:39-7.3.

Amended by R.2009 d.247, effective August 3, 2009.

See: 41 N.J.R. 371(a), 41 N.J.R. 2969(b).

In (b), inserted "hours that the pharmacy is open and the", and substituted "in plain view at all consumer entrances and consumer access points to the pharmacy, including drive-thru windows and drop-off boxes" for "on the entrance to the pharmacy in such a way as to be visible to the public"; and added (c).

Amended by R.2010 d.090, effective June 21, 2010.

See: 42 N.J.R. 132(a), 42 N.J.R. 1221(a).

In (b) and (c), deleted "registered" preceding "pharmacist-in-charge".

#### 13:39-5.4 Spatial requirement of pharmacy prescription area

(a) For pharmacies in operation prior to July 1, 1963, the space devoted to the prescription area and laboratory shall not be less than 10 percent of the main floor area of the pharmacy, and in no instance shall it be less than 50 square feet. If the main floor area of such pharmacy exceeds 1,200 square feet, the 10 percent requirement does not apply and the minimum requirement for the prescription area shall not be less than 120 square feet.

(b) For all other pharmacies including pharmacies subject to the provisions of (a) above which are moving to a new location, the prescription area must occupy exclusively a minimum of 150 square feet.

Recodified from N.J.A.C. 13:39-7.3 and amended by R.2005 d.25, effective January 18, 2005.

See: 36 N.J.R. 3345(a), 37 N.J.R. 295(a).

In (a), deleted "or drugstore" following "floor area of the pharmacy"; in (b), deleted "retail" preceding "pharmacies". Former N.J.A.C. 13:39-5.4, Approval of FDA necessary, recodified to N.J.A.C. 13:39-7.5.

#### 13:39-5.5 Prescription counter

Pharmacies shall contain a prescription counter or counters on which to work, and the free working space shall not be less than 18 inches in width and not less than 12 total feet in length. This minimum working surface shall be kept clear at all times for the processing and/or compounding of prescriptions.

Amended by R.1999 d.214, effective July 19, 1999.

See: 31 N.J.R. 1151(a), 31 N.J.R. 1932(a).

Inserted "or counters" following "counter", and substituted "total" for "continuous" following "12".

Recodified from N.J.A.C. 13:39-7.4 and amended by R.2005 d.25, effective January 18, 2005.

See: 36 N.J.R. 3345(a), 37 N.J.R. 295(a).

Rewrote the section. Former N.J.A.C. 13:39-5.5, Copies of prescriptions; transfers, recodified to N.J.A.C. 13:39-7.7.

#### 13:39-5.6 Prescription area sink

An adequate sink with hot and cold running water shall be provided in the prescription area, easily accessible to the prescription counter.

Amended by R.1999 d.214, effective July 19, 1999.

See: 31 N.J.R. 1151(a), 31 N.J.R. 1932(a).

Substituted a reference to anterooms for a reference to rooms.

Recodified from N.J.A.C. 13:39-7.5 and amended by R.2005 d.25, effective January 18, 2005.

See: 36 N.J.R. 3345(a), 37 N.J.R. 295(a).

Deleted "of retail and institutional pharmacies," preceding "easily accessible" in the first sentence, deleted the second sentence. Former N.J.A.C. 13:39-5.6, Record of pharmacist filling prescription, recodified to N.J.A.C. 13:39-7.6.

#### 13:39-5.7 Adequate storage

There shall be sufficient shelf, drawer or cabinet space within the prescription area for proper storage of prescription drugs and chemicals and the minimum equipment required pursuant to N.J.A.C. 13:39-5.8. All prescription drugs and chemicals shall be maintained under adequate storage conditions, including proper lighting, ventilation and temperature control, as recommended by the drug manufacturer.

Recodified from N.J.A.C. 13:39-7.6 and amended by R.2005 d.25, effective January 18, 2005.

See: 36 N.J.R. 3345(a), 37 N.J.R. 295(a).

Rewrote the section. Former N.J.A.C. 13:39-5.7 Availability of records upon termination of business, recodified to N.J.A.C. 13:39-4.9.

Amended by R.2010 d.090, effective June 21, 2010.

See: 42 N.J.R. 132(a), 42 N.J.R. 1221(a).

Section was "Storage and adequate stock". Inserted the last sentence.

#### 13:39-5.8 Minimum equipment and supplies; cleanliness

(a) All prescription areas shall contain the following minimum equipment and supplies, which shall be stored, so as to be readily accessible:

1. An up-to-date, comprehensive pharmaceutical reference text(s) and suitable current reference texts encompassing the pharmaceutical services provided by the pharmacy, drug interactions, drug product composition and patient counseling. Unabridged electronic versions of such reference texts shall be acceptable;

2. Over the counter Schedule V Record Book or an electronic recording system, as permitted by Federal law pursuant to 21 CFR 1306.26 and 1304.04, to maintain all required information consistent with N.J.A.C. 8:65-7.19(a)5, if Schedule V controlled substances are sold without a prescription;

3. Permanent prescription filing device and patient profile record system;

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

5. Suitable volumetric devices;

6. A steel spatula and a spatula of rubber or composition;

7. Refrigerator, as required by United States Pharmacopoeia Standards, to be used only for the storage of pharmaceuticals;

8. Suitable counting trays or approved counting device;

9. Labels;

10. Auxiliary labels;

11. Two Drug Utilization Review Council Placards and the 29th edition of the list of "Approved Drug Products with Therapeutic Equivalence Evaluations," commonly known as the "Orange Book," incorporated herein by reference, as amended and supplemented, consistent with Department of Health and Senior Services rules set forth at N.J.A.C. 8:71-1. The Orange Book can be obtained by contacting the Superintendent of Documents, Government Printing Office, PO Box 371954, Pittsburgh, PA 15250-7954, (202) 512-1800 or toll free (866) 512-1800, and is available on-line at <http://www.fda.gov/cder/orange/default.htm> and at <http://www.fda.gov/cder/ob/default.htm>;

12. Assorted stock of prescription containers and child safety closures or caps that meet United States Pharmacopoeia/National Formulary standards on light resistance and tightness; and

13. Copies of, or access to, current State statutes and rules relating to the practice of pharmacy.

(b) All prescription areas where non-sterile compounding is performed shall contain the following minimum equipment and supplies, which shall be stored, so as to be readily accessible:

1. Class A prescription balance with a complete set of metric weights or equivalent electronic weighing device;

2. A glass mortar and pestle;

3. Glass funnels;

4. Stirring rods;

5. Ointment tile or parchment paper; and

6. Suppository mold.

(c) The prescription area and all related equipment and supplies shall be kept in a clean, orderly and sanitary condition at all times.

Amended by R.1994 d.351, effective July 18, 1994.

See: 26 N.J.R. 1596(a), 26 N.J.R. 2905(b).

Amended by R.1999 d.196 effective June 21, 1999.

See: 30 N.J.R. 4113(a), 31 N.J.R. 253(a), 31 N.J.R. 1618(a).

In (a), added a reference to equivalent electronic weighing devices at the end of 5, and rewrote 15.

Amended by R.1999 d.214, effective July 19, 1999.

See: 31 N.J.R. 1151(a), 31 N.J.R. 1932(a).

In (a), rewrote 1, 2 and 13.

Recodified from N.J.A.C. 13:39-7.7 and amended by R.2005 d.25, effective January 18, 2005.

See: 36 N.J.R. 3345(a), 37 N.J.R. 295(a).

Rewrote the section. Former N.J.A.C. 13:39-5.8 Prescriptions and medication orders transmitted by technological devices in an institution. Recodified to N.J.A.C. 13:39-9.27.

Amended by R.2009 d.247, effective August 3, 2009.

See: 41 N.J.R. 371(a), 41 N.J.R. 2969(b).

In (a)4, substituted "Storage place of substantial construction, which is capable of being securely locked when the pharmacist is not present in the prescription dispensing area," for "Securely locked, substantially constructed storage place", and inserted a comma following "substances".

Amended by R.2010 d.090, effective June 21, 2010.

See: 42 N.J.R. 132(a), 42 N.J.R. 1221(a).

Section was "Minimum equipment and facilities". Rewrote the introductory paragraph of (a), (a)1, (a)2 and (a)5; deleted former (a)6 through (a)9; recodified (a)10 as (a)6; deleted former (a)11; recodified former (a)12 through (a)15 as (a)7 through (a)10; in (a)10, deleted "including poison labels" from the end; deleted (a)16; recodified (a)17 and (a)18 as (a)11 and (a)12; rewrote (a)11 and (a)12; and added (a)13, (b), and (c).

### §13:39-5.9 Prescription balances, scales, weights and automatic counting devices

(a) All pharmacies shall have all balances, scales, weights and automatic counting devices inspected every 12 months by the Department of Weights and Measures of the municipality or county in which the pharmacy is located, and such balances, scales, weights and automatic counting devices shall be properly sealed by the applicable authority.

(b) Counting trays or counting devices that meet the requirements of (a) above shall be used to count oral, solid drugs or medications.

*The following annotations apply to N.J.A.C. 13:39-5.9 prior to its repeal by R.2010 d.090:*

Recodified from N.J.A.C. 13:39-7.8 by R.2005 d.25, effective January 18, 2005.

See: 36 N.J.R. 3345(a), 37 N.J.R. 295(a).

Former N.J.A.C. 13:39-5.9, Labeling, recodified to N.J.A.C. 13:39-7.12.

*The following annotations apply to N.J.A.C. 13:39-5.9 subsequent to its recodification from N.J.A.C. 13:39-5.11 by R.2010 d.090:*

Amended by R.1994 d.351, effective July 18, 1994.

See: 26 N.J.R. 1596(a), 26 N.J.R. 2905(b).

Recodified from N.J.A.C. 13:39-7.11 and amended by R.2005 d.25, effective January 18, 2005.

See: 36 N.J.R. 3345(a), 37 N.J.R. 295(a).

Recodified from N.J.A.C. 13:39-5.11 and amended by R.2010 d.090, effective June 21, 2010.

See: 42 N.J.R. 132(a), 42 N.J.R. 1221(a).

Inserted designation (a); in (a), deleted "or other Board-licensed establishment" following "pharmacy"; and added (b). Former N.J.A.C. 13:39-5.9, Cleanliness, orderliness and sanitation, repealed.

### §13:39-5.10 Restriction on storage of prescription legend drugs and controlled dangerous substances

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

(b) Prescription legend drugs, devices and controlled dangerous substances shall be stored only in areas of the premises that are part of the pharmacy or pharmacy department, except that in a health care facility, prescription legend drugs, devices and controlled dangerous substances shall be stored consistent with the requirements of N.J.A.C. 13:39-9.23.

(c) Prescription legend drugs, devices and controlled dangerous substances that are received during hours the pharmacy or pharmacy department is closed shall be stored consistent with the requirements of N.J.A.C. 13:39-4.15(b)3.

*The following annotations apply to N.J.A.C. 13:39-5.10 prior to its repeal by R.2010 d.090:*

Amended by R.1999 d.214, effective July 19, 1999.

See: 31 N.J.R. 1151(a), 31 N.J.R. 1932(a).

Inserted references to pharmacy training and patient counseling.

Recodified from N.J.A.C. 13:39-7.9 by R.2005 d.25, effective January 18, 2005.

See: 36 N.J.R. 3345(a), 37 N.J.R. 295(a).

Former N.J.A.C. 13:39-5.10, Procedures for Centralized Prescription Handling, recodified to N.J.A.C. 13:39-4.18.

*The following annotations apply to N.J.A.C. 13:39-5.10 subsequent to its recodification from N.J.A.C. 13:39-5.12 by R.2010 d.090:*

Recodified from N.J.A.C. 13:39-6.5 and amended by R.2005 d.25, effective January 18, 2005.

See: 36 N.J.R. 3345(a), 37 N.J.R. 295(a).

Substituted “stored” for “displayed” following “shall not be” and substituted “pharmacy” for “licensed establishment” preceding “in such a manner”.

Amended by R.2009 d.247, effective August 3, 2009.

See: 41 N.J.R. 371(a), 41 N.J.R. 2969(b).

Inserted designation (a); in (a), inserted “or pharmacy department” and substituted “as to” for “that they can”; and added (b).

Recodified from N.J.A.C. 13:39-5.12 and amended by R.2010 d.090, effective June 21, 2010.

See: 42 N.J.R. 132(a), 42 N.J.R. 1221(a).

Rewrote (b); and added (c). Former N.J.A.C. 13:39-5.10, Television in prescription area prohibited, repealed.

### 13:39-5.11 (Reserved)

Recodified to N.J.A.C. 13:39-5.9 by R.2010 d.090, effective June 21, 2010.

See: 42 N.J.R. 132(a), 42 N.J.R. 1221(a).

Section was “Prescription balances, scales, weights and automatic counting devices”.

### 13:39-5.12 (Reserved)

Recodified to N.J.A.C. 13:39-5.10 by R.2010 d.090, effective June 21, 2010.

See: 42 N.J.R. 132(a), 42 N.J.R. 1221(a).

Section was “Restriction on storage of prescription legend drugs and controlled dangerous substance”.

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

### 13:39-6.1 Purpose and scope

The rules in this subchapter shall apply to all pharmacies and pharmacy departments in the State. For purposes of this subchapter, “pharmacy” means a retail pharmacy or a retail

pharmacy department, an institutional pharmacy or a nuclear pharmacy.

New Rule, R.2005 d.25, effective January 18, 2005.

See: 36 N.J.R. 3345(a), 37 N.J.R. 295(a).

Former N.J.A.C. 13:39-6.1, Professional judgment in dispensing drugs, recodified to N.J.A.C. 13:39-7.13.

### 13:39-6.2 Pharmacist-in-charge

(a) Every pharmacy shall name a pharmacist whose license is in good standing in New Jersey as the pharmacist-in-charge of the pharmacy. No pharmacy shall operate without a pharmacist-in-charge for longer than 30 days.

(b) Whenever the pharmacist-in-charge is absent from the pharmacy for more than 30 days, the pharmacist-in-charge and the permit holder shall notify the Board of the name of the pharmacist who shall act as the interim pharmacist-in-charge.

(c) A pharmacist shall not assume the responsibilities of a pharmacist-in-charge of more than one pharmacy or pharmacy department simultaneously, except as provided in (c)1 below.

1. If an area within a health care facility is permitted as both an institutional pharmacy and a retail pharmacy, the health care facility may employ one individual to act as the pharmacist-in-charge for both the institutional pharmacy and the retail pharmacy.

(d) Whenever there is a change of a pharmacist-in-charge of a pharmacy, an inventory of all controlled dangerous substances as defined in N.J.A.C. 8:65-10.1 through 10.5 shall be performed consistent with the requirements of N.J.A.C. 8:65-5.4 and 5.5.

(e) Whenever a pharmacist assumes or terminates the duties as a pharmacist-in-charge of a pharmacy, the pharmacist-in-charge and the permit holder shall so advise the Board in writing within 30 days by completing a form provided by the Board.

(f) A 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. The pharmacy is staffed by sufficient, competent personnel in keeping with the size, scope and complexity of the pharmaceutical services provided by the pharmacy;
2. Accurate records of all prescription medication received and dispensed are maintained;
3. Policies are in place regarding accurate dispensing and labeling of prescriptions and that such policies are followed;

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

5. Only pharmacists and interns or externs under immediate personal supervision provide professional consultation with patients and physicians;

6. Only pharmacists, interns or externs accept telephone prescriptions and only pharmacists, interns or externs, or pharmacy technicians consistent with the requirements of N.J.A.C. 13:39-6.6(b), accept renewal authorizations;

7. No misbranded, deteriorated, adulterated, improperly stored or outdated drugs or any drugs marked "sample" or with any like designation or meaning are dispensed or present in the active stock in the pharmacy;

8. The prescription area is maintained in an orderly and sanitary manner; and

9. The pharmacy and all pharmacy personnel provide pharmaceutical services in accordance with acceptable professional standards and comply with all Federal and State statutes, rules and regulations governing the practice of pharmacy.

Amended by R.1994 d.351, effective July 18, 1994.

See: 26 N.J.R. 1596(a), 26 N.J.R. 2905(b).

Amended by R.1999 d.214, effective July 19, 1999.

See: 31 N.J.R. 1151(a), 31 N.J.R. 1932(a).

In (c), through (e), substituted references to registered pharmacist-in-charge for references to pharmacist-in-charge.

Amended by R.2004 d.380, effective October 4, 2004.

See: 36 N.J.R. 11(a), 36 N.J.R. 4480(a).

In (e), deleted existing 8, recodified former 9 to 14 as 8 to 13.

Recodified from N.J.A.C. 13:39-3.18 and amended by R.2005 d.25, effective January 18, 2005.

See: 36 N.J.R. 3345(a), 37 N.J.R. 295(a).

Rewrote the section. Former N.J.A.C. 13:39-6.2, Prescription prepared, compounded or dispensed by pharmacy externs or interns, recodified to N.J.A.C. 13:39-6.5.

Amended by R.2009 d.247, effective August 3, 2009.

See: 41 N.J.R. 371(a), 41 N.J.R. 2969(b).

Rewrote (f)4.

Amended by R.2010 d.090, effective June 21, 2010.

See: 42 N.J.R. 132(a), 42 N.J.R. 1221(a).

Section was "Registered pharmacist-in-charge". Deleted "registered" preceding "pharmacist-in-charge" throughout; in (a), substituted "whose license is" for "licensed and"; in (b), the introductory paragraph of (c) and in (e), deleted "registered" preceding "pharmacist"; in the introductory paragraph of (c), inserted ", except as provided in (c)1 below"; added (c)1; in (d) and (e), deleted "or other Board-licensed establishment" following "pharmacy"; rewrote (f)1; and in (f)9, inserted "provide pharmaceutical services in accordance with acceptable professional standards and".

### 13:39-6.3 Identification tag

All personnel working in the pharmacy, except personnel engaging in the compounding of sterile preparations consistent with the requirements of N.J.A.C. 13:39-11, shall wear an identification tag, which shall include at least the person's first name, first initial of their last name and job title. The identification tag of any employee in training shall reflect the status of the employee as a trainee.

Repealed by R.1994 d.351, effective July 18, 1994.

See: 26 N.J.R. 1596(a), 26 N.J.R. 2905(b).

Section was "Sale of controlled dangerous substances and prescription legend drugs by other than a registered pharmacist in a Board-licensed establishment".

New Rule, R.1998 d.166, effective April 6, 1998.

See: 29 N.J.R. 5051(a), 30 N.J.R. 1297(b).

Amended by R.2005 d.25, effective January 18, 2005.

See: 36 N.J.R. 3345(a), 37 N.J.R. 295(a).

Rewrote the section.

Amended by R.2007 d.283, effective September 4, 2007.

See: 38 N.J.R. 3137(a), 39 N.J.R. 3774(b).

Inserted the final sentence.

Amended by R.2010 d.090, effective June 21, 2010.

See: 42 N.J.R. 132(a), 42 N.J.R. 1221(a).

Rewrote the section.

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

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

1. The pharmacist shall remain in the pharmacy or, in the case of a pharmacy department, in the pharmacy department building, and shall be accessible for emergencies or for counseling, if requested;

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. The receipt of new written prescriptions; and
- ii. The dispensing of prescription medications which have been checked by the pharmacist; and

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

New Rule, R.2005 d.25, effective January 18, 2005.

See: 36 N.J.R. 3345(a), 37 N.J.R. 295(a).

Former N.J.A.C. 13:39-6.4, Direct supervision of dispensing and compounding, repealed.

Amended by R.2009 d.247, effective August 3, 2009.

See: 41 N.J.R. 371(a), 41 N.J.R. 2969(b).

Section was "Meal breaks". In the introductory paragraph of (a), substituted "restroom breaks and" for the first occurrence of "a" and substituted "meal breaks" for "meal break"; in the introductory paragraph of (i)2, inserted "restroom or" and substituted "breaks, provided a pharmacy employee remains present in the pharmacy," for "break"; and in (a)3, substituted "prescription dispensing area" for "pharmacy" and deleted "meal" preceding "break".

### 13:39-6.5 Prescription handling by pharmacy externs, interns or pharmacy technicians

A pharmacy intern, extern or technician in any pharmacy may perform the component functions of prescription handling described in N.J.A.C. 13:39-4.18, consistent with the requirements of this chapter. On or after April 5, 2011, all steps performed by a pharmacy technician, intern or extern shall be documented in the pharmacy audit trail consistent with the requirements of N.J.A.C. 13:39-7.6.

Recodified from N.J.A.C. 13:39-6.2 and amended by R.2005 d.25, effective January 18, 2005.

See: 36 N.J.R. 3345(a), 37 N.J.R. 295(a).

Rewrote the section. Former N.J.A.C. 13:39-6.5 Restriction on display of prescription legend drugs and, recodified to N.J.A.C. 13:39-5.12.

Amended by R.2009 d.293, effective October 5, 2009.

See: 41 N.J.R. 1637(a), 41 N.J.R. 3840(a).

Section was "Prescription prepared or compounded by pharmacy externs, interns or pharmacy technicians". Rewrote the section.

Amended by R.2010 d.090, effective June 21, 2010.

See: 42 N.J.R. 132(a), 42 N.J.R. 1221(a).

Rewrote the section.

### 13:39-6.6 Pharmacy technician registration and pharmacy technician applicants

(a) A person wishing to be registered with the Board as a pharmacy technician shall:

1. Be 18 years of age or older;
2. Possess a high school diploma or its equivalent;
3. Submit a certification attesting to the fact that he or she is proficient in written and spoken English;
4. Apply to the Board for registration and submit the application fee set forth in N.J.A.C. 13:39-1.3;
5. Submit his or her name, address and fingerprints for purposes of a criminal history background check pursuant to N.J.S.A. 45:1-28 et seq., (P.L. 2002, c. 104) to determine whether criminal history record information exists which may disqualify the applicant from being registered by the Board; and
6. Submit, as part of the application for registration, evidence of good moral character which is an ongoing requirement for registration, and evidence that he or she:
  - i. Is not presently engaged in drug or alcohol use that is likely to impair the ability to practice as a pharmacy technician 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;
  - iv. Has not been convicted of a crime involving moral turpitude; and
  - v. 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 which 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.

(b) By March 2, 2008, a pharmacy shall only employ a person registered with the Board as a pharmacy technician pursuant to (a) above, or a pharmacy technician applicant, consistent with (c) below, to perform pharmacy technician functions.

(c) By March 2, 2008, any person who is hired as a pharmacy technician who is not registered with the Board shall be designated a pharmacy technician applicant. A person may only be considered a pharmacy technician applicant one time and only for a maximum of 180 consecutive days. During the first 10 days of employment, the pharmacy technician applicant shall file an application with the Board to begin the pharmacy technician registration process. The applicant shall retain proof of filing the application until he or she receives his or her registration. If at the conclusion of the 180 day period, the pharmacy technician applicant has not completed the pharmacy technician registration process, consistent with (a) above, the applicant shall cease performing pharmacy technician functions in the pharmacy.

(d) All persons who are employed as pharmacy technicians on September 4, 2007 shall be registered with the Board by March 2, 2008. Such persons shall satisfy the requirements set forth in (a) above, except that such persons shall be exempt from satisfying the requirement established in (a)2 above. Such persons shall present proof of employment to the Board which establishes that they have been practicing as pharmacy technicians prior to September 4, 2007.

(e) If an applicant for registration as a pharmacy technician is being investigated for any alleged violation of the New Jersey Pharmacy Practice Act, N.J.S.A. 45:14-40 et seq., or the pharmacy laws, rules or regulations of any other jurisdiction, the Board in its discretion may deny the applicant the opportunity to register as a pharmacy technician.

(f) A pharmacy shall not employ as a pharmacy technician applicant any person who was previously employed as a pharmacy technician applicant at a pharmacy in the State and who failed to complete the pharmacy technician registration process or any person who has been the subject of disciplinary action by the Board.

New Rule, R.2007 d.238, effective September 4, 2007.

See: 38 N.J.R. 3137(a), 39 N.J.R. 3774(b).

Former N.J.A.C. 13:39-6.6, Pharmacy technicians, recodified to N.J.A.C. 13:39-6.15.

Public Notice: Board of Pharmacy: Extension of Deadline for Registration as a Pharmacy Technician.

See: 40 N.J.R. 900(a), 7005(a).

Amended by R.2010 d.090, effective June 21, 2010.

See: 42 N.J.R. 132(a), 42 N.J.R. 1221(a).

In (e), updated the N.J.S.A. reference.

beyond one year past the date the original prescription was issued.

(b) When the renewals listed on the original prescription have been depleted, no additional renewals may be added to the original prescription. For additional dispensing, a new prescription must be authorized by the practitioner.

(c) Prescription information obtained from a practitioner shall be documented at the time of receipt as a new prescription in hard copy form or by direct entry into the electronic prescription records system.

Amended by R.1994 d.351, effective July 18, 1994.

See: 26 N.J.R. 1596(a), 26 N.J.R. 2905(b).

Recodified from N.J.A.C. 13:39-5.3 and amended by R.2005 d.25, effective January 18, 2005.

See: 36 N.J.R. 3345(a), 37 N.J.R. 295(a).

Former N.J.A.C. 13:39-7.3, Spatial requirement of a retail pharmacy prescription area, recodified to N.J.A.C. 13:39-5.4.

Amended by R.2010 d.090, effective June 21, 2010.

See: 42 N.J.R. 132(a), 42 N.J.R. 1221(a).

Section was "Authorization for renewal of prescriptions". In the introductory paragraph of (a) and in (a)1, substituted "the" for "of" preceding "original" and inserted "was issued"; in the introductory paragraph of (a), inserted a comma following "devices", inserted "filled or", inserted the last sentence, and substituted "practitioner or the practitioner's authorized agent" for "prescriber"; rewrote (b) and added (c).

#### 13:39-7.4 Emergency dispensing

(a) Except as provided in (b) below, in the absence of a current, valid prescription, a pharmacist may dispense an emergency supply (no more than a 72-hour quantity) of a chronic maintenance drug or device if, in his or her professional judgment, refusal would endanger the health or welfare of the patient, provided the following conditions are satisfied:

1. The pharmacist first ascertains to the best of his or her ability, by direct communication with the patient or caregiver, that such a medication or device was prescribed for that patient by order of a practitioner. The pharmacist shall require the patient or caregiver to provide suitable identification. Such communication shall be documented in the patient profile record system maintained pursuant to N.J.A.C. 13:39-7.19 or in the pharmacy's other manual or electronic files; and

2. The pharmacist documents the dispensing of the emergency supply in the prescription record system.

(b) A pharmacist may dispense an emergency supply of a Schedule II controlled dangerous substance in the absence of a current, valid prescription upon receipt of oral authorization from a practitioner as provided under Federal law pursuant to 21 CFR 1306.11, consistent with the requirements of N.J.A.C. 8:65-7.8.

New Rule, R.2005 d.25, effective January 18, 2005.

See: 36 N.J.R. 3345(a), 37 N.J.R. 295(a).

Former N.J.A.C. 13:39-7.4, Prescription counter, recodified to N.J.A.C. 13:39-5.5.

Amended by R.2010 d.090, effective June 21, 2010.

See: 42 N.J.R. 132(a), 42 N.J.R. 1221(a).

In the introductory paragraph of (a), substituted "Except as provided in (b) below, in" for "In" and deleted "(except controlled dangerous substances)" following "drug"; in (a)1, substituted "practitioner" for "licensed practitioner; and" and inserted the second and third sentences; rewrote (a)2; and added (b).

#### 13:39-7.5 Approval of FDA necessary

(a) No drug or medicine other than a compounded prescription order shall be sold or dispensed in any pharmacy within the State of New Jersey until such drug or medicine has received New Drug Application (NDA), Abbreviated New Drug Application (ANDA), Investigational New Drug Application (INDA) or other Federal Food and Drug Administration approval, where required.

(b) The storage, labeling and dispensing of all Investigational New Drugs shall be a pharmaceutical service provided in cooperation with, and in support of the principal investigator. Under these parameters the dispensing of such drugs shall not be construed to be a violation of (a) above. A pharmacy participating in experimental research shall comply with Federal Department of Health and Human Services regulations set forth at 45 CFR Part 46, Protection of Human Subjects of Research, incorporated by reference herein, as amended and supplemented and with the New Jersey Department of Health and Senior Services' Policy on the Protection of Human Research Subjects, incorporated by reference herein, as amended and supplemented, and which is available at <http://www.state.nj.us/health/irb/policies.shtml>.

Recodified from N.J.A.C. 13:39-5.4 and amended by R.2005 d.25, effective January 18, 2005.

See: 36 N.J.R. 3345(a), 37 N.J.R. 295(a).

Rewrote (a) and added (b). Former N.J.A.C. 13:39-7.5, Prescription area sink, recodified to N.J.A.C. 13:39-5.6.

Amended by R.2010 d.090, effective June 21, 2010.

See: 42 N.J.R. 132(a), 42 N.J.R. 1221(a).

Rewrote (b).

#### 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 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.

(e) Notwithstanding the requirements of (d) above, a pharmacy shall maintain prescription records for controlled dangerous substances as required by Federal law consistent with the provisions of 21 CFR 1304.04.

Amended by R.1991 d.355, effective July 15, 1991.

See: 22 N.J.R. 1866(b), 23 N.J.R. 2161(a).

Added new (d) through (f).

Redesignated existing (d)-(g) as (g)-(j).

Amended by R.1994 d.351, effective July 18, 1994.

See: 26 N.J.R. 1596(a), 26 N.J.R. 2905(b).

Recodified from N.J.A.C. 13:39-5.6 and amended by R.2005 d.25, effective January 18, 2005.

See: 36 N.J.R. 3345(a), 37 N.J.R. 295(a).

Rewrote the section. Former N.J.A.C. 13:39-7.6, Storage and adequate stock, recodified to N.J.A.C. 13:39-5.7.

Amended by R.2009 d.293, effective October 5, 2009.

See: 41 N.J.R. 1637(a), 41 N.J.R. 3840(a).

Section was "Record of pharmacist filling prescription". Rewrote the section.

Amended by R.2010 d.090, effective June 21, 2010.

See: 42 N.J.R. 132(a), 42 N.J.R. 1221(a).

Added (e).

### 13:39-7.7 Copies of prescriptions and/or patient profile

(a) A pharmacy shall immediately comply with the patient's request for copies of prescriptions and/or patient profile. Copies of prescriptions issued directly to the patient shall state in letters at least equal in size to those describing the medication dispensed, the underlined statement: "COPY—FOR INFORMATION ONLY."

(b) Presentation of a prescription marked "COPY—FOR INFORMATION ONLY" or a labeled prescription container shall be for information purposes only and shall have no legal status as a valid prescription order. The pharmacist in receipt of such copy or labeled prescription container shall contact the prescribing practitioner for a new prescription or the last dispensing pharmacy to transfer the prescription pursuant to N.J.A.C. 13:39-7.8.

Amended by R.1997 d.502, effective December 1, 1997.

See: 28 N.J.R. 5048(a), 29 N.J.R. 5072(a).

In (c), added "or electronic transfer"; and in (d), added the second sentence.

Amended by R.1999 d.214, effective July 19, 1999.

See: 31 N.J.R. 1151(a), 31 N.J.R. 1932(a).

In (a), added the last sentence; and added (e).

Recodified from N.J.A.C. 13:39-5.5 and amended by R.2005 d.25, effective January 18, 2005.

See: 36 N.J.R. 3345(a), 37 N.J.R. 295(a).

Rewrote the section. Former N.J.A.C. 13:39-7.7, Minimum equipment and facilities, recodified to N.J.A.C. 13:39-5.8.

Amended by R.2010 d.090, effective June 21, 2010.

See: 42 N.J.R. 132(a), 42 N.J.R. 1221(a).

Section was "Copies of prescriptions". In (a), inserted "and/or patient profile"; and in (b), inserted "prescription marked 'COPY—FOR INFORMATION ONLY' or a" and deleted "or a prescription marked 'COPY—FOR INFORMATION ONLY'" following the first occurrence of "container".

### 13:39-7.8 Transfer of prescriptions between pharmacies

(a) When a patient, the patient's caregiver, or a pharmacy acting on behalf of a patient or caregiver requests the transfer of a valid prescription between pharmacies, a pharmacy shall immediately comply with the patient's request.

(b) Except as provided in (c) and (d) below, a prescription may be transferred between pharmacies, consistent with this section, for one year from the date the prescription was written, provided refills of the prescription are available.

(c) A prescription for a Schedule II controlled substances may not be transferred.

(d) A prescription for a Schedule III, IV or V controlled substance may be transferred between pharmacies pursuant to N.J.A.C. 8:65-7.14(h) and 7.18(d). A prescription for a Schedule III, IV or V controlled substance that has been transferred shall not be transferred a second time. This prohibition shall not apply to the transfer of such prescriptions between pharmacies engaged in central prescription handling pursuant to N.J.A.C. 13:39-4.18(e) and to pharmacies that share a real-time, on-line database consistent with the requirements of 21 CFR 1306.25.

(e) A prescription may be transferred between pharmacies for the purpose of refill dispensing by telephone, or by facsimile or electronic means as provided in N.J.A.C. 13:39-7.10 and 7.11, provided that:

1. The sending pharmacy invalidates the prescription on file as of the date the prescription is transferred and records on the back of the invalidated prescription order or in the electronic system the following:

- i. That the prescription has been transferred and the date of transfer;
- ii. The name and address or store identifier of the pharmacy to which the prescription was transferred;
- iii. The name or personal identifier of the pharmacist, intern or extern to whom the prescription was transferred; and
- iv. The initials or personal identifier of the pharmacist, intern, or extern issuing the transferred prescription order;

2. The receiving pharmacy, upon receiving such prescription directly from another pharmacy, records the following:

- i. The name and address or store identifier and original prescription number of the pharmacy from which the prescription was transferred;
- ii. The name or personal identifier of the sending pharmacist, intern or extern;
- iii. All information constituting a prescription order, as well as the following:
  - (1) Date of issuance of original prescription;
  - (2) Original number of refills authorized on original prescription;
  - (3) Number of valid refills remaining; and
  - (4) Date the prescription was last filled; and

3. The pharmacist, intern, extern, or technician at the receiving pharmacy informs the patient or caregiver that the original prescription has been cancelled at the sending pharmacy.

New Rule, R.2005 d.25, effective January 18, 2005.

See: 36 N.J.R. 3345(a), 37 N.J.R. 295(a).

Former N.J.A.C. 13:39-7.8, Cleanliness, orderliness and sanitation, recodified to N.J.A.C. 13:39-5.9.

Amended by R.2007 d.283, effective September 4, 2007.

See: 38 N.J.R. 3137(a), 39 N.J.R. 3774(b).

In (f)3, deleted "receiving" preceding "pharmacist" and inserted "at the receiving pharmacy".

Amended by R.2010 d.090, effective June 21, 2010.

See: 42 N.J.R. 132(a), 42 N.J.R. 1221(a).

In (d), deleted ", consistent with this section, one time only," following the first occurrence of "pharmacies" and inserted second and third sentences; deleted former (e); recodified former (f) as (e); rewrote the introductory paragraph of (e); in (e)1ii, inserted "and address or store identifier"; in (e)2i, substituted "and" for a comma following "name" and inserted "or store identifier"; deleted former (e)2iii(2); recodified

former (e)2iii(3) as (e)2iii(2); deleted former (e)2iii(4); recodified former (e)2iii(5) as (e)2iii(3); and added new (e)2iii(4).

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

(a) Prescriptions for all controlled substances listed in Schedule II shall be maintained in a separate prescription file.

(b) Prescriptions for all controlled substances listed in Schedules III, IV and V shall be maintained in a separate prescription file for such controlled substances only or in such form that they are readily retrievable from other prescription records of the pharmacy. Prescriptions will be deemed readily retrievable if, at the time they are initially filed, the face of the prescription is stamped in red ink in the lower right corner with the letter "C" no less than one-inch high and filed either in the prescription file for controlled substances listed in Schedule II or in the prescription file for non-controlled substances. If a pharmacy employs an electronic recordkeeping system for prescriptions that permits identification by prescription number and retrieval of original documents by the practitioner'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.

New Rule, R.2005 d.25, effective January 18, 2005.

See: 36 N.J.R. 3345(a), 37 N.J.R. 295(a).

Former N.J.A.C. 13:39-7.9, Television in prescription area prohibited, recodified to N.J.A.C. 13:39-5.10.

Amended by R.2009 d.247, effective August 3, 2009.

See: 41 N.J.R. 371(a), 41 N.J.R. 2969(b).

In (b), substituted "Schedule" for "schedule", deleted "usual consecutively numbered" preceding the fifth occurrence of "prescription", and inserted the last sentence.

Amended by R.2010 d.090, effective June 21, 2010.

See: 42 N.J.R. 132(a), 42 N.J.R. 1221(a).

In (b), substituted "that" for "which" preceding "permits" and "practitioner's" for "prescriber's".

### 13:39-7.10 Prescriptions transmitted by facsimile

(a) A pharmacist may accept for dispensing a facsimile prescription, consistent with the requirements of this section. For purposes of this section, "facsimile prescription" means a prescription which is transmitted by a device which sends an exact image to the receiver.

(b) A pharmacist shall not fill a facsimile prescription transmitted by anyone other than a practitioner authorized to prescribe medications pursuant to N.J.S.A. 45:14-40, or the prescribing practitioner's authorized agent.

(c) The facsimile machine used to receive prescriptions shall be located within the pharmacy prescription area.

(d) A facsimile prescription shall contain all information required to be included on a written prescription pursuant to New Jersey State Board of Medical Examiners rule N.J.A.C. 13:35-7.2(d), except that an NJPB shall not be required for the prescription.

(e) The facsimile transmission of the prescription shall contain the following:

1. The identification number of the facsimile machine which is used to transmit the prescription;
2. The date and time of the prescription transmission;
3. The name, address, telephone number and facsimile number of the pharmacy; and
4. If an authorized agent transmits the facsimile prescription, the full name and title of the transmitting agent.

(f) A pharmacist shall seek verbal verification of a facsimile prescription from the prescribing practitioner whenever the pharmacist has reason to question the authenticity, accuracy or appropriateness of the prescription. A pharmacist may accept verbal verification regarding the authenticity or legibility of a facsimile prescription from a prescribing practitioner's authorized agent. A pharmacist shall not fill a facsimile prescription where there is a question regarding authenticity, accuracy or appropriateness if such verification is not provided.

(g) A pharmacist shall retain a printed copy of a facsimile prescription, or an electronic reproduction of the facsimile prescription that is readily retrievable and printable, for a minimum of five years. The printed copy shall be of non-fading legibility.

(h) A pharmacist may fill a prescription for a Schedule II controlled substance transmitted by facsimile provided that the original signed prescription is presented to the pharmacist prior to the dispensing of the controlled substance, except as provided in (h)1, 2 and 3 below.

1. A prescription for a Schedule II narcotic substance prescribed for pain management to be compounded for the direct administration to a patient by parenteral, intravenous, intramuscular, subcutaneous or intraspinal infusion may be transmitted by the practitioner or the practitioner's agent to the dispensing pharmacy by facsimile. The facsimile shall serve as the original written prescription and shall be maintained pursuant to the requirements of (g) above.

2. A prescription for a Schedule II substance prescribed for pain management for a resident of a long-term care facility may be transmitted by the practitioner or the practitioner's agent to the dispensing pharmacy by facsimile. The facsimile shall serve as the original written prescription and shall be maintained pursuant to the requirements of (g) above.

3. A prescription for a Schedule II narcotic substance prescribed for pain management for a patient receiving services from a hospice certified by Medicare under Title XVIII or licensed by the State may be transmitted by the practitioner or the practitioner's agent to the dispensing pharmacy by facsimile. The practitioner or the practitioner's agent shall note on the facsimile prescription that

the patient is a hospice patient. The facsimile shall serve as the original written prescription and shall be maintained pursuant to the requirements of (g) above.

(i) A pharmacist may fill a prescription for a Schedule III, IV or V controlled substance transmitted by facsimile consistent with the requirements of this section. The facsimile prescription shall serve as the original written prescription.

(j) A pharmacist shall not enter into any agreement with a prescribing practitioner that requires that facsimile prescriptions be transmitted to a particular pharmacy or in any way denies a patient the right to have his or her prescription transmitted by facsimile to a pharmacy of the patient's choice.

(k) Nothing in this section shall be construed to preclude the facsimile transfer of information between pharmacies for purposes of transferring prescriptions pursuant to N.J.A.C. 13:39-7.8.

(l) A pharmacist shall not use a technological device in order to circumvent his or her responsibilities with regard to verifying the validity of prescriptions or in order to circumvent other standards of pharmacy practice.

New Rule, R.2003 d.373, effective September 15, 2003.

See: 34 N.J.R. 3064(a), 35 N.J.R. 4290(a).

Administrative correction.

See: 35 N.J.R. 4724(a).

Recodified from N.J.A.C. 13:39-5.8A by R.2005 d.25, effective January 18, 2005.

See: 36 N.J.R. 3345(a), 37 N.J.R. 295(a).

Former N.J.A.C. 13:39-7.10, Return of prescription medication, recodified to N.J.A.C. 13:39-7.16.

Amended by R.2010 d.090, effective June 21, 2010.

See: 42 N.J.R. 132(a), 42 N.J.R. 1221(a).

In (b), updated the N.J.S.A. reference; in (g), deleted "pursuant to N.J.S.A. 45:14-15" following "five years"; and added (k) and (l).

### 13:39-7.11 Electronically transmitted prescriptions

(a) A pharmacist may accept for dispensing an electronic prescription, consistent with the requirements of this section. For purposes of this section, "electronic prescription" means a prescription which is transmitted by a computer device in a secure manner, including computer to computer and computer to facsimile transmissions.

(b) A pharmacist shall not fill an electronic prescription transmitted by anyone other than a practitioner authorized to prescribe medications pursuant to N.J.S.A. 45:14-40, or the prescribing practitioner's authorized agent. If the electronic prescription is transmitted by the practitioner's authorized agent, the transmission shall include the full name and title of the agent.

(c) The permit holder shall ensure that the electronic system utilized to receive prescriptions shall have adequate security and system safeguards designed to prevent and detect unauthorized access, modification or manipulation of the prescriptions.

**Case Notes**

Prohibition against certain premiums or rebates was unconstitutional. *Matter of CVS Pharmacy, Wayne*. 224 N.J.Super. 631, 541 A.2d 242 (A.D.1988) reversed 116 N.J. 490, 561 A.2d 1160, certiorari denied 110 S.Ct. 841, 493 U.S. 1045, 107 L.Ed.2d 836.

**13:39-7.15 Restriction on sale of Schedule V over-the-counter controlled substances**

(a) It shall be considered unprofessional conduct for a pharmacist to dispense a Schedule V over-the-counter controlled substance when:

1. The pharmacist, in his or her professional judgment, knows or reasonably should know that the requested substance will be used for unauthorized or illicit consumption or distribution; or
2. The pharmacist, in his or her professional judgment, knows or reasonably should know that the person requesting the substance previously used it for unauthorized or illicit consumption or distribution.

(b) The standard of professional judgment and care that attends the sale of a Schedule V over-the-counter controlled substance shall conform to the following:

1. All pharmacists shall comply with N.J.A.C. 8:65-7.19, which requires that the sale of specified controlled substances be limited in quantity during any 48-hour period, that the purchaser be at least 18 years of age, and that the pharmacist obtain suitable identification (including proof of age where appropriate) from every purchaser not known to the pharmacist.
2. In all instances, any doubts regarding the propriety of a sale of a Schedule V substance shall be resolved against making the sale.
3. The pharmacist shall enter every sale of a Schedule V substance in the Over-the-Counter Schedule V Record Book pursuant to N.J.A.C. 8:65-7.19. The information to be recorded shall include the purchaser's first and last name, street address, city and state, the name and quantity of the Schedule V substance sold, the date of each sale, and the name or initials of the pharmacist making the sale.

4. Upon an individual's second request for a Schedule V substance within a short period of time (two to four days), the pharmacist shall determine, through direct communication with the purchaser, whether the substance is being used correctly. In that regard, the pharmacist shall ascertain how many people are using the substance and whether the condition which the substance is being used to treat is improving.

5. Upon an individual's third request for a Schedule V substance within a short period of time relative to the number of persons using it (two to four days subsequent to the second purchase), the pharmacist shall advise the purchaser of the substance's abuse potential and shall caution

the purchaser to consult a physician if the condition for which the substance is being used does not improve.

6. Upon an individual's fourth request for a Schedule V substance within a short period of time (two to four days subsequent to the third purchase), the pharmacist shall determine, through direct communication with the purchaser, how many people are using the substance, whether continued use will be therapeutic, whether the purchaser is treating a condition which requires a physician's consultation, whether the purchaser is exhibiting signs of drug abuse and whether the purchaser is making similar requests of other local pharmacies.

7. If a pharmacist determines that an individual's request for a Schedule V substance within a short period of time (two to four days) subsequent to his or her fourth purchase is warranted, the pharmacist shall document in the Over-the-Counter Schedule V Record Book the justification for such sale. In addition, the pharmacist shall recommend that the purchaser consult with a physician for medical evaluation due to the substance's abuse potential as well as the potential hazard presented by the substance's continued use.

8. If any Schedule V substance is dispensed to one individual more than five times within any 12-month period, the pharmacist shall obtain oral or written confirmation from the purchaser's physician as to the continued need for the substance and shall document such confirmation in the Over-the-Counter Schedule V Record Book.

New Rule, R.1990 d.478, effective October 1, 1990.

See: 22 N.J.R. 1329(a), 22 N.J.R. 3153(b).

Recodified from N.J.A.C. 13:39-6.8 by R.2005 d.25, effective January 18, 2005.

See: 36 N.J.R. 3345(a), 37 N.J.R. 295(a).

**13:39-7.16 Return of prescription medication**

(a) Prescription medication correctly dispensed to a patient may be accepted for return by the pharmacist but shall not be placed in stock for reuse or resale, except as provided in N.J.A.C. 13:39-9.18(a)2.

(b) Prescription medication incorrectly dispensed to a patient shall be accepted for return by the pharmacist and shall not be placed back in stock for reuse or resale.

(c) Prescription medication that has been prepared for a patient, but which has not been dispensed to the patient, may be placed back in stock for reuse or resale provided that:

1. In the professional judgment of the pharmacist, the prescription medication is eligible for re-dispensing. Eligible medications are those medications that are able to be consumed by a patient within the original time frame established for the medication's stability and expiration. Products that have a limited shelf life and/or that have not been stored consistent with manufacturers' storage requirements may not be re-dispensed;

2. The prescription medication shall not be placed in manufacturers' stock containers of different lot numbers and/or with different expiration dates;

3. Manufacturers' stock containers shall not be over-filled;

4. In those circumstances in which prescription medications cannot be properly returned to the original manufacturers' stock containers, the medication shall be held in the pharmacy in the labeled container in which it has been repackaged. Prior to redispensing, such medications shall be placed in a new container with a new label or the original label shall be removed and the container shall be relabeled;

5. If the manufacturer or the FDA orders a recall of a drug product, the pharmacist shall assume products held in labeled containers without lot numbers are included in the recall and proceed accordingly; and

6. Medications held for re-dispensing shall be used as soon as possible. Such medications, lacking original lot numbers and expiration dates, shall not be dispensed to patients beyond six months from the date the medications were originally prepared for dispensing. Re-dispensed medications shall be marked with the same use by date as the medication which was originally prepared for dispensing.

Amended by R.1998 d.167, effective April 6, 1998.

See: 29 N.J.R. 4740(b), 30 N.J.R. 1298(a).

Amended N.J.A.C. reference.

Amended by R.1999 d.214, effective July 19, 1999.

See: 31 N.J.R. 1151(a), 31 N.J.R. 1932(a).

Rewrote the section.

Recodified from N.J.A.C. 13:39-7.10 and amended by R.2005 d.25, effective January 18, 2005.

See: 36 N.J.R. 3345(a), 37 N.J.R. 295(a).

Rewrote the section.

Amended by R.2010 d.090, effective June 21, 2010.

See: 42 N.J.R. 132(a), 42 N.J.R. 1221(a).

In the introductory paragraph of (c), substituted "that" for "which" following "medication"; and in (c)4, inserted the last sentence.

### 13:39-7.17 Disposal of unwanted drugs

Unwanted drugs shall be disposed of in a manner that does not cause them to become a health hazard, and in accordance with all local, State, and Federal codes.

Recodified from N.J.A.C. 13:39-7.12 by R.2005 d.25, effective January 18, 2005.

See: 36 N.J.R. 3345(a), 37 N.J.R. 295(a).

### 13:39-7.18 Outdated drugs or drugs marked "sample"

No outdated, misbranded, deteriorated, improperly stored or adulterated drugs, or any drugs marked "sample" or with any like designation or meaning shall be dispensed or placed or maintained in active stock for use or sale.

Recodified from N.J.A.C. 13:39-7.13 and amended by R.2005 d.25, effective January 18, 2005.

See: 36 N.J.R. 3345(a), 37 N.J.R. 295(a).

### 13:39-7.19 Patient profile record system

(a) A patient profile system must be maintained by all pharmacies for persons for whom prescriptions are dispensed. The Patient Profile Record System (PPRS) may be a manual or electronic system and shall be devised, so as to enable the immediate retrieval of information necessary to enable the dispensing pharmacist to identify previously dispensed medication and patient specific information at the time a prescription is presented for dispensing. One profile record may be maintained for members of a family living at the same address and possessing the same family name.

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

1. The family name and the first name of the person for whom the medication is intended (the patient);
2. The address and telephone number of the patient;
3. Indication of the patient's age, birth date or age group (infant, child, adult) and gender;
4. The original or refill date the medication is dispensed;
5. The number or designation identifying the prescription;
6. The practitioner's name;
7. The name, strength and quantity of the drug dispensed;
8. Pharmacist's comments relevant to the patient's drug therapy; and
9. Any allergies and idiosyncrasies of the patient and any medical conditions that may relate to drug utilization, as communicated by the patient or the patient's representative.
  - i. If there are no patient allergies, idiosyncrasies or medical conditions that may relate to drug utilization, such information shall be documented in the patient profile record system.

(c) The pharmacist shall use professional judgment to review and monitor the patient profile, determine if there should be any adjustment in the original patient information and so indicate the appropriate change in the patient profile record.

(d) All prescription patients who patronize a pharmacy shall have a profile record as specified by this section, and the pharmacist shall inquire as to whether other prescription drugs are being concomitantly utilized in order to establish a current drug history for the patient.

(e) 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