CHAPTER 39

STATE BOARD OF PHARMACY

Authority

N.J.S.A. 45:1-15.1 and 45:14-1 et seq.

Source and Effective Date

R.2005 d.25, effective December 10, 2004
See: 36 N.J.R. 3345(a), 37 N.J.R. 295(a).

Chapter Expiration Date

Chapter 39, State Board of Pharmacy, expires on December 10, 2009.

Chapter Historical Note

Chapter 39, State Board of Pharmacy, was adopted and became effective prior to September 1, 1969.

Chapter 39, State Board of Pharmacy, was repealed and adopted as new rules by R.1989 d.314, effective June 19, 1989. See: 20 N.J.R. 1648(a), 21 N.J.R. 1712(a).

Pursuant to Executive Order No. 66(1978), Chapter 39, State Board of Pharmacy, was readopted as R.1994 d.351, effective June 16, 1994. See: 26 N.J.R. 1596(a), 26 N.J.R. 2905(b), 26 N.J.R. 3878(a).

Pursuant to Executive Order No. 66(1978), Chapter 39, State Board of Pharmacy, was readopted as R.1999 d.214, effective June 16, 1999. See: 31 N.J.R. 1151(a), 31 N.J.R. 1932(a).

Subchapter 10, Automated Medication Systems, was adopted as R.2000 d.28, effective January 18, 2000. See: 31 N.J.R. 2293(b), 32 N.J.R. 317(a).

Subchapter 3A, Continuing Education, was adopted as R.2003 d.130, effective March 17, 2003. See: 34 N.J.R. 1089(a), 35 N.J.R. 1433(a).

Chapter 39, State Board of Pharmacy, was readopted as R.2005 d.25, effective December 10, 2004. See: Source and Effective Date. See, also, section annotations.

Subchapter 2, Licensure Requirements, was renamed Requirements for Initial Licensure; Subchapter 2A, Requirements for Reciprocal Licensure, was adopted in part as new rules and recodified in part from Subchapter 3, Licensure by Reciprocity; Subchapter 3, Licensure by Reciprocity, was renamed Registered Pharmacist Requirements; and Subchapter 8, Pharmacy Training Sites, was repealed by R.2009 d.247, effective August 3, 2009. See: 41 N.J.R. 371(a), 41 N.J.R. 2969(b).

CHAPTER TABLE OF CONTENTS

SUBCHAPTER 1. GENERAL PROVISIONS

13:39-1.1 Purpose and scope

(a) This chapter is promulgated by the New Jersey State Board of Pharmacy. The rules contained in this chapter implement the provisions of the Pharmacy Act, N.J.S.A. 45:14-1 et seq. and regulate the practice of pharmacy within the State of New Jersey.

(b) This chapter shall apply to all registered pharmacies, pharmacists, pharmacist applicants, interns, externs, pharmacy technicians and anyone within the jurisdiction of the Board 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.2005 d.25, effective January 18, 2005.
See: 36 N.J.R. 3345(a), 37 N.J.R. 295(a).
In (b), substituted "pharmacy technicians" for "supportive personnel" preceding "and anyone within the jurisdiction".

Case Notes

Violations of N.J.A.C. 13:39-8.14(b)2, 10 and 13 found as controlled substances records were improperly kept, misbranded drugs were in pharmacy and drugs were improperly stored, respectively; penalties (also cited as N.J.A.C. 13:39-8.12). New Jersey State Bd. of Pharmacy v. Yanuzzi, 4 N.J.A.R. 489 (1981).

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.

"Address of record" means an address designated by a licensee or registrant. "Address of record" may be a licensee's or registrant's home, business or mailing address, but shall not be a post office box unless the licensee or registrant also provides another address which includes a street, city, state and zip code.

"Authorized prescriber" means a licensed practitioner who is authorized by law to write prescriptions and/or medication orders.

"Board" means the New Jersey State Board of Pharmacy.

"Compounding" means the act of preparing pharmaceutical components into medications, pursuant to an authorized prescriber's prescription or medication order, including, but not limited to prescription compounding, and intravenous admixture preparation.

"Device" means an instrument, apparatus, implement, machine, contrivance, implant, in vitro reagent or other similar or related article, including any component part or accessory, which is required under Federal or State law to be prescribed by an authorized prescriber and dispensed by a pharmacist, in the usual scope of pharmacy practice.

"Dispense or dispensing" means the procedure entailing the interpretation of an authorized prescriber's prescription order for a drug or device, and pursuant to that order, the proper selection, measuring, labeling, and packing in a proper container. The act of dispensing shall include all necessary consultation by the pharmacist.

"Drug or medicine" means:

1. Articles recognized in the official United States Pharmacopoeia/National Formulary, official Homeopathic Pharmacopoeia of the United States, or any official supplement to any of them;

2. Articles intended for use in the diagnosis, cure, mitigation, treatment or prevention of disease in human beings or animals;

3. Articles (other than food) intended to affect the structure of any function of the body of human beings or animals; and

4. Articles intended for use as components of any article specified in 1, 2 or 3 above, but not including devices or their components, parts or accessories.

"Immediate personal supervision" means that the registered pharmacist is physically present in the compounding/dispensing area when interns, externs and pharmacy technicians are performing delegated duties, and the pharmacist conducts any necessary in-process checks and the final check in preparation and compounding of medications, including the checking of each ingredient used, the quantity of each ingredient whether weighed, measured or counted, and the finished label.

"Legend drug or device" means any drug or device that:

1. Bears, at a minimum, the symbol "Rx only" or words of similar import; and/or

2. Requires a prescription or order by an authorized prescriber.

"Licensed practitioner" means a duly licensed physician, dentist, optometrist, veterinarian, certified nurse midwife, nurse practitioner/clinical nurse specialist or physician assistant, or other health care practitioner licensed or approved to write prescriptions intended for the treatment or prevention of disease, as set forth in N.J.S.A. 45:14-14.

"Pharmaceutical services" means all services provided by a registered pharmacist. These services shall be concerned with, but not limited to: interpreting the prescription or medication order; selecting, preparing, compounding, packaging, labelling, distributing and dispensing prescribed drugs; the proper and safe storage of drugs; the monitoring of drug therapy; the reporting and recording of adverse drug reactions and the provision of appropriate drug information; teaching and counselling on the proper and safe use of drugs and medications.

"Pharmacy technician" means an individual employed by a pharmacy whose responsibilities do not require professional judgment in the preparation and distribution of medications and who works under the immediate personal supervision of a pharmacist in compliance with N.J.A.C. 13:39-6.15. For purposes of this definition, interns, externs, cashiers, stocking and clerical help are not pharmacy technicians.

"Prescription" means any order for drugs and related items as defined in N.J.S.A. 45:14-14.

"Professional judgment" means judiciousness and discretion based upon thorough knowledge and sound application of the specialized body of knowledge peculiar to the practice of pharmacy, and an understanding of the relationship of this knowledge and its application to the well-being of the patient and to the judgment of the prescriber.

"Registered pharmacist" or "pharmacist" means a person whose license is in good standing for the current license renewal period.

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).
Inserted "Address of record"; in "Legend drug or device", rewrote 1; rewrote "Licensed practitioner"; and in "Registered pharmacist" or "pharmacist", substituted a reference to licenses for a reference to certificates, and substituted a reference to the current license renewal period for a reference to the current registration period.
Amended by R.2005 d.25, effective January 18, 2005.
See: 36 N.J.R. 3345(a), 37 N.J.R. 295(a).
Rewrote "Address of record", added "Immediate personal supervision" and "Pharmacy technician", deleted "Direct supervision" and "Supportive personnel".
Amended by R.2007 d.283, effective September 4, 2007.
See: 38 N.J.R. 3137(a), 39 N.J.R. 3774(b).
In definition "Address of record", inserted "or registrant" twice and inserted "or registrant's"; and in definition "Pharmacy technician", updated the N.J.A.C. reference.

13:39-1.3 Fee schedule

(a) The following fees shall be charged by the Board:

1. For pharmacists as follows:

i.	Application for licensure	125.00.
ii.	Verification of licensure	25.00.
iii.	Application for reciprocity	125.00.
iv.	Application for reinstatement	
	(1) Disciplinary suspension	225.00.
	(2) Administrative suspension	225.00.
v.	Initial licensure fee	
	(1) If paid during the first year of a biennial renewal period	140.00.
	(2) If paid during the second year of a biennial renewal period	70.00.
vi.	Biennial license renewal	140.00.
vii.	Replacement biennial license	25.00.
viii.	Inactive license renewal	(To be determined by future rulemaking)
ix.	Late renewal fee	100.00.
x.	Replacement of initial wall license	40.00.
xi.	Continuing education review fee	10.00.
xii.	Continuing education program or course: sponsor review fee	50.00.
xiii.	Yearly fee for distribution of minutes and agenda	60.00.

2. For in-State pharmacies as follows:

i.	Pharmacy permits	
	(1) Application for permit	275.00.
	(2) Annual permit renewal	175.00.
	(3) Change of ownership/name	275.00.
	(4) Change of location	275.00.
ii.	Replacement of annual permit	25.00.
iii.	Late renewal fee	100.00.
iv.	Verification of permit	25.00.

3. For pharmacy technicians as follows:

i.	Application for registration	$50.00;
ii.	Initial registration fee:	
	(1) If paid during the first year of a biennial renewal period	$70.00;
	(2) If paid during the second year of a biennial renewal period	$35.00;
iii.	Biennial registration renewal	$70.00;
iv.	Replacement biennial registration	$25.00;
v.	Late renewal fee	$25.00;
vi.	Verification of registration	$25.00; and
vii.	Reinstatement fee:	
	(1) Disciplinary suspension	$125.00;
	(2) Administrative suspension	(To be determined by future rulemaking).

4. For out-of-State pharmacies as follows:

i.	Pharmacy permits	
	(1) Application for permit	175.00
	(2) Annual permit renewal	175.00
	(3) Change of ownership/name	175.00
	(4) Change of location	175.00
ii.	Replacement of annual permit	25.00
iii.	Late renewal fee	100.00
iv.	Verification of permit	25.00

5. For pharmacy interns as follows:

i.	Application for registration	50.00
ii.	Initial registration fee	70.00
iii.	Registration renewal (One time only)	70.00

Inserted "of a publicly traded corporation" preceding ", the corporation shall file". Former N.J.A.C. 13:39-4.6, Change of location; remodeling of premises, recodified to N.J.A.C. 13:39-4.7.

13:39-4.7 Change of location; remodeling of premises

(a) Whenever a pharmacy or licensed establishment changes location, the pharmacy or licensed establishment shall apply for a new permit on a form prescribed and furnished by the Board. The pharmacy or licensed establishment shall pay a fee for the new permit pursuant to N.J.A.C. 13:39-1.3. The permit holder shall not operate a pharmacy under an existing permit for more than 60 days following a change of location. Before a permit may be issued to the permit holder for the new location, the Board shall inspect and approve the premises, fixtures, equipment and inventory of the new location to ensure compliance with this subchapter and all relevant statutes, regulations and ordinances.

(b) Prior to the remodeling of a pharmacy, pharmacy department or licensed establishment, where such remodeling entails a physical change of location or size of the prescription area within the premises or a change of the physical specifications of the licensed premises, it shall be necessary to notify the Board at least 30 days in advance on a form prescribed by the Board. The permit holder shall not operate a pharmacy under an existing permit for more than 60 days following the remodeling of a pharmacy. Within 60 days of the remodeling, the Board shall inspect and approve the premises, fixtures, equipment and inventory of the remodeled pharmacy to ensure compliance with this subchapter and all relevant statutes, regulations and ordinances.

Amended by R.1999 d.214, effective July 19, 1999.
See: 31 N.J.R. 1151(a), 31 N.J.R. 1932(a).
Rewrote (a); and in (b), added the second and third sentences.
Recodified from N.J.A.C. 13:39-4.6 and amended by R.2005 d.25, effective January 18, 2005.
See: 36 N.J.R. 3345(a), 37 N.J.R. 295(a).
Former N.J.A.C. 13:39-4.7, New pharmacies; eligibility and application, recodified to N.J.A.C. 13:39-4.1.

13:39-4.8 Discontinued pharmacies

(a) Whenever a pharmacy is to be discontinued and closed for any reason, including suspension or retirement of the permit holder, sale or insolvency, the permit holder shall immediately send written notification of the anticipated closing to the State Board of Pharmacy, the Office of Drug Control and the Drug Enforcement Administration at least 15 days prior to the anticipated closing date. Whenever a pharmacy is to be discontinued and closed as a result of an unanticipated occurrence, such as the death of the permit holder, the permit holder's representative shall send written notification to the Board, the Office of Drug Control and the Drug Enforcement Administration, as soon as possible prior to the actual closing date. All medications, including prescription legend and controlled drugs, should be transferred to the holder of a current pharmacy permit; a wholesaler; a reverse distributor; and/or a manufacturer. All medications not properly transferred shall remain on the licensed pharmacy premises with all licenses and registrations in effect until such medications are disposed of in the manner prescribed by the Board, the Office of Drug Control and/or the Drug Enforcement Administration.

(b) Within 30 days of closing a pharmacy pursuant to (a) above, the permit holder or his or her representative shall remove all drug signs from both the inside and outside of the discontinued pharmacy and shall notify the Board in writing of the location of the previous five years of prescription and patient profile records, consistent with the requirements of N.J.A.C. 13:39-7.6 and 7.19. The permit holder or his or her representative shall return the permit to the Board for cancellation within 30 days of the closing. Prescription records and other information may be requested by the Board as outlined in N.J.A.C. 13:39-7.6 and 7.19.

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), changed N.J.A.C. reference.
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.2009 d.247, effective August 3, 2009.
See: 41 N.J.R. 371(a), 41 N.J.R. 2969(b).
Added new (a); deleted former (b); recodified former (a) as new (b); and rewrote (b).

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

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

1. Notification in writing to the Board;

2. Publication, once weekly for two successive weeks in a newspaper whose circulation encompasses the major area of the licensee's former practice, of a notice advising patrons of the right to retrieve their prescriptions and the location of the prescriptions for a six-month period following publication; and

3. A sign placed in the pharmacy location informing the patrons of the right to retrieve their prescriptions and the location of the prescriptions.

Recodified from N.J.A.C. 13:39-5.7 and amended by R.2005 d.25, effective January 18, 2005.
See: 36 N.J.R. 3345(a), 37 N.J.R. 295(a).
Former N.J.A.C. 13:39-4.9, Business hours, recodified to N.J.A.C. 13:39-4.10.

13:39-4.10 Business hours; unauthorized closing

(a) All pharmacies shall be kept open for the transaction of business at least 40 hours per week and at least five days per week.

(b) If any permanent changes are made in the opening or closing hours of a pharmacy or other Board-licensed establishment, the Board office shall be notified in writing of these changes within 30 days.

(c) A notice shall be conspicuously displayed on the exterior of any pharmacy or other Board-licensed establishment indicating any temporary changes in the opening or closing hours of the pharmacy or establishment, or indicating a temporary closing of the pharmacy or establishment whenever such changes occur.

(d) Any temporary closing of a pharmacy or other Board-licensed establishment for more than 48 hours shall be reported to and approved by the Board. Notification to the Board shall include contingency plans for accessing patient records. Any temporary closing of more than 48 hours without prior Board approval shall result in the pharmacy being deemed a discontinued pharmacy requiring compliance with the requirements of N.J.A.C. 13:39-4.8.

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. 13:39-4.9 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 (b), inserted "permanent" following "If any"; added (c) and (d).
Former N.J.A.C. 13:39-4.10, Duplicate permit, recodified to N.J.A.C. 13:39-4.11.

13:39-4.11 Replacement permit

A replacement permit may be issued by the Board upon payment of a fee pursuant to N.J.A.C. 13:39-1.3 and submission of an affidavit describing the loss or destruction of the permit originally issued, or upon return of the damaged permit.

Recodified from N.J.A.C. 13:39-4.10 and amended by R.2005 d.25, effective January 18, 2005.
See: 36 N.J.R. 3345(a), 37 N.J.R. 295(a).
Substituted "replacement" for "duplicate". Former N.J.A.C. 13:39-4.11, Change of name, recodified to N.J.A.C. 13:39-4.12.

13:39-4.12 Change of name

(a) A change in the name of a pharmacy or other Board-licensed establishment shall be made upon the submission to the Board for approval of the new name and of prescription labels bearing the new name.

(b) The Board shall issue an amended permit bearing the new name upon return of the permit bearing the previous name to the Board for cancellation and payment of the permit fee as prescribed in N.J.A.C. 13:39-1.3.

Recodified from N.J.A.C. 13:39-4.11 and amended by R.2005 d.25, effective January 18, 2005.
See: 36 N.J.R. 3345(a), 37 N.J.R. 295(a).
Rewrote (b). Former N.J.A.C. 13:39-4.12, Reproduction of permits, recodified to N.J.A.C. 13:39-4.13.

13:39-4.13 Reproduction of permits

(a) Any permit issued by the Board for the operation of a pharmacy or other board-licensed establishment may only be photocopied for State agencies and other business entities with whom the permit holder does pharmacy related business.

(b) Any reproduction of a pharmacy permit by a permit holder for any unlawful purpose shall subject a permit holder to disciplinary action pursuant to N.J.S.A. 45:1-21.

Recodified from N.J.A.C. 13:39-4.12 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. 13:39-4.13, Certification of records, repealed.

13:39-4.14 Security of pharmacies and pharmacy departments

(a) The registered pharmacist(s) on duty in all pharmacies, including pharmacy departments, shall be responsible for:

1. Keeping the pharmacy or pharmacy department closed and the security system turned on at all times when he or she is not present within the permitted premises in the case of a pharmacy, or, in the case of a pharmacy department, when he or she is not present within the department, except as provided in N.J.A.C. 13:39-6.4;

i. In the case of a pharmacy or pharmacy department that has been issued an institutional permit, pharmacy technicians may remain within the permitted premises when the pharmacy or pharmacy department is closed and secured, if the pharmacist determines, based on his or her professional judgment, that the security of prescription legend drugs, devices and controlled substances will be maintained in the pharmacist's absence;

2. Ensuring that the security of the prescription dispensing area and its contents are maintained at all times, including the restriction of persons unauthorized by the pharmacist on duty from being present in the prescription dispensing area; and

3. Reporting all thefts or diversions of prescription legend drugs and devices and controlled substances, and any significant loss of prescription legend drugs and devices and controlled substances, to the registered pharmacist-in-charge and/or the pharmacy permit holder upon discovery. When determining whether a loss of prescription legend drugs or devices or controlled substances is significant, the following factors shall be considered, consistent with 21 CFR 1301.74(c):

i. The actual quantity of prescription legend drugs, devices or controlled substances missing in relation to the type of business;

ii. The specific prescription legend drug, device or controlled substance missing;

iii. Whether the loss of the prescription legend drug, device or controlled substance can be associated with access to those drugs, devices or controlled substances by specific individuals, or whether the loss can be attributed to unique activities that may take place involving the drugs, devices or controlled substances;

iv. A pattern of losses over a specific time period, whether the losses appear to be random and the results of efforts taken to resolve the losses;

v. If known, whether the specific prescription legend drugs, devices or controlled substances are likely candidates for theft or diversion; and

vi. Local trends and other indicators of the theft or diversion potential of the missing prescription legend drug, device or controlled substance.

(b) The holder of a pharmacy or pharmacy department permit and the registered pharmacist-in-charge of the pharmacy or pharmacy department shall ensure that:

1. All entrances to the pharmacy or pharmacy department are capable of being locked and are connected to a monitored security system that transmits an audible, visual or electronic signal warning of intrusion. The security system shall be equipped with a back-up mechanism to ensure notification or continued operation if the security system is tampered with or is disabled. Only the registered pharmacist-in-charge of the permitted premises or the pharmacy department shall be responsible for the security of the keys and the security system access code to the pharmacy or pharmacy department;

2. If a theft or diversion of prescription legend drugs or devices or controlled substances, or a significant loss of prescription legend drugs or devices or controlled substances, as delineated in (a) above, is reported to the registered pharmacist-in-charge, the registered pharmacist-in-charge shall notify the holder of the pharmacy or pharmacy department permit of such report. The registered pharmacist-in-charge and the holder of the pharmacy or pharmacy department permit shall ensure that:

i. A written report is filed with the Board upon discovery of the theft or diversion or the significant loss of prescription legend drugs or devices; and

ii. A written report is filed with the Federal Drug Enforcement Administration upon discovery of the theft or diversion or any significant loss of controlled substances, consistent with Federal requirements. A copy of such report shall be filed with the Office of Drug Control, consistent with State requirements and with the Board;

3. There is a secure area for receiving packages known to contain prescription legend drugs and devices and controlled substances. No prescription drug shall be accepted during the hours the pharmacy or pharmacy department is closed unless adequate security for the storage of such shipments has been provided; and

4. If a drop-off device is utilized for prescriptions, it is of a one-way, irretrievable and secure design.

(c) In addition to the requirements set forth in (b) above, the holder of a pharmacy department permit and the registered pharmacist-in-charge of the pharmacy department shall also ensure that:

1. The pharmacy department is constructed so as to enable the closing off and securing of the department from the main store area. The department shall be separated from the main store area by a secured barrier or partition extending from the floor or fixed counter to the ceiling of either the department or main store and attached thereto;

2. All medications requiring supervision of a pharmacist, including dispensed medication, remain within the confines of the department when the pharmacist is not in the pharmacy department;

3. The pharmacy department has a published telephone number different from that of the establishment in which the department is located. No extensions of this phone shall be located outside the department; and

4. The telephone number of the registered pharmacist-in-charge is available in the office of the manager of the establishment.

(d) The holder of a pharmacy or pharmacy department permit shall comply with any law and/or ordinance of the municipality in which the pharmacy or pharmacy department is located requiring the placement of a security key box on the exterior of the pharmacy or the premises in which the pharmacy department is located for purposes of permitting emergency access to the premises.

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 (b), substituted references to registered pharmacists-in-charge for references to pharmacists-in-charge in 2 and 8.
Recodified from N.J.A.C. 13:39-4.15 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. 13:39-4.14, Contract pharmaceutical services, recodified to N.J.A.C. 13:39-9.4.
Repeal and New Rule, R.2009 d.247, effective August 3, 2009.
See: 41 N.J.R. 371(a), 41 N.J.R. 2969(b).
Section was "Permitting of pharmacy department".

13:39-4.15 Permits; specialized permits

(a) The Board may issue a special permit, wherein the type of service is of a limited nature. The permit so issued, being based on special conditions of use imposed by the Board, may necessitate the waiver of certain rule requirements.

(b) Specialized permits shall pertain to pharmacies providing specific services as may be necessary and proper to efficiently meet a limited public need for pharmaceutical

services. An applicant for any specialized pharmacy permit shall provide the Board with an application and a policy and procedure manual which sets forth a detailed description of the type of specialized pharmacy services to be provided within the pharmacy practice. The policy and procedure manual shall also contain detailed provisions which ensure the protection of the public welfare as determined by the Board.

Recodified from N.J.A.C. 13:39-4.16 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. 13:39-4.15, Retail permit; prescription department or pharmacy department, recodified to N.J.A.C. 13:39-4.14.

13:39-4.16 Steering prohibited

It shall be unlawful for a pharmacy permit holder to enter into an arrangement with a health care practitioner who is licensed to issue prescriptions for the purpose of directing or diverting patients to or from a specified pharmacy or restraining in any way a patient's freedom of choice to select a pharmacy.

Recodified from N.J.A.C. 13:39-4.17 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. 13:39-4.16, Permits; specialized permits, recodified to N.J.A.C. 13:39-4.15.

Case Notes

Division of Medical Assistance and Health Services did not present any cogent reason for denying an out-of-state pharmacy's application for Medicaid provider authorization where the applicant's 24-hour emergency response arrangement with a New Jersey-based pharmacy resolved any question about emergency services, as that arrangement did not constitute prohibited steering as defined in the regulations, and the Division admitted that out-of-state mail order services had been authorized. Thus, the Division's decision denying the out-of-state provider's application was arbitrary, capricious, and unreasonable as well as otherwise not in accordance with law. Phoenix Pharmacy, Inc. v. DMAHS, OAL Dkt. No. HMA 03266-07, 2007 N.J. AGEN LEXIS 489, Initial Decision (July 6, 2007).

13:39-4.17 Responsibilities of permit holders

(a) All permit holders shall be responsible for compliance with all the rules, regulations and laws governing the practice of pharmacy.

(b) Any permit holder may be held liable for violations of the Pharmacy Act, N.J.S.A. 45:14-1 et seq., and the rules in this chapter and may be subject to disciplinary action.

Recodified from N.J.A.C. 13:39-4.18 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. 13:39-4.17, Steering prohibited, recodified to N.J.A.C. 13:39-4.16.

13:39-4.18 Procedures for centralized prescription handling

(a) The four component functions of handling a prescription are intake, processing, fulfillment and dispensing.

(b) Central prescription handling entails two or more licensed pharmacies sharing responsibility for performing the four component functions of handling a prescription.

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

1. An intake or originating pharmacy, which is a licensed pharmacy that received the patient's or prescribing practitioner's request to fill or refill a prescription. A central processing pharmacy or a central fill pharmacy, as delineated in (c)2 and 3 below, may be considered the intake or originating pharmacy if the prescription was transmitted by the prescribing practitioner directly to the centralized pharmacy as provided in N.J.A.C. 13:39-5.8A and 5.8B or if the patient requested the refill from that pharmacy;

2. A central processing pharmacy, which is a licensed pharmacy that engages in prescription review by performing functions that may include, but are not limited to, data entry, prospective drug review, refill authorizations, interventions, patient counseling, claims submission, claims resolution and adjudication;

3. A central fill pharmacy, which is a licensed pharmacy engaging in central prescription handling by filling and/or refilling prescriptions which includes the preparation and packaging of the medication; and

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.

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

1. Any or all of the pharmacies participating in central prescription handling have a contractual agreement to provide such services or have the same owner;

2. Prior to engaging in central prescription handling, all pharmacies that are parties to the central prescription handling obtain Board approval. If a participating pharmacy is located outside the State of New Jersey, the pharmacy shall have registered with the Board pursuant to N.J.A.C. 13:39-4.19. The pharmacies shall make a single application to the Board, delineating the scope of practice of each pharmacy and the specific rules in this chapter with which each pharmacy shall comply;

3. An audit trail is maintained that records and documents the name(s) or other personal identifier(s) of the pharmacist(s) or pharmacy technician(s) and the component function(s) performed by each, at the time the functions are performed, for each step of prescription handling.

The audit trail 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;

4. The dispensed prescription for any product bears a permanently affixed label with at least the following information:

i. The brand name or generic name, and if generic, the name of the manufacturer;

ii. The strength of medication, where applicable;

iii. The quantity dispensed;

iv. The date upon which prescription medication is dispensed;

v. A CDS cautionary label, where applicable and when permitted by law;

vi. The patient name;

vii. The prescriber name;

viii. The prescription number;

ix. Directions for use;

x. The phrase "use by" followed by the product's use by date, if dispensed in any packaging other than the manufacturer's original packaging. For purposes of this paragraph, "use by date" means the earlier of one year from the date of dispensing or the expiration date on the manufacturer's container;

xi. All auxiliary labeling as recommended by the manufacturer and/or as deemed appropriate in the professional judgment of the dispensing pharmacist; and

xii. The name, address and telephone number of any or all of the following:

(1) The intake pharmacy;

(2) The central processing pharmacy;

(3) The central fill pharmacy; and/or

(4) The dispensing pharmacy;

5. The patient name, the brand or generic name of the medication, and the directions for use appear in larger type, in a different color type, or in bolded type, in comparison to the other information required to appear on the label of the dispensed container pursuant to (d)4 above;

6. The patient is provided with written information, either on the prescription label or with the prescription container, that indicates which pharmacy to contact if the patient has any questions about the prescription or the medication. The written information provided to the patient shall be in bold print, easily read, and shall include the hours a pharmacist is available and a telephone number where a pharmacist may be reached. The telephone service shall be available at no cost to the pharmacy's primary patient population;

7. All pharmacies that are to engage in central prescription handling maintain a common policies and procedures manual which designates who shall be responsible for each of the component functions of handling the prescription and for ensuring compliance with the Board rules set forth in this chapter. The policies and procedures manual shall also include maintenance of the audit trail required by (d)3 above. The policies and procedures manual shall be made available to the Board upon request;

8. All pharmacies that are to engage in central prescription handling share a common electronic file; and

9. All pharmacies that are to engage in central prescription handling are responsible for ensuring that the prescription has been properly filled.

(e) A prescription for a controlled substance may be filled or refilled by pharmacies engaging in central prescription handling when permitted by law, consistent with Federal requirements set forth at 21 C.F.R. §§ 1300 et seq.

New Rule, R.2004 d.380, effective October 4, 2004.
See: 36 N.J.R. 11(a), 36 N.J.R. 4480(a).
Recodified from N.J.A.C. 13:39-5.10 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. 13:39-4.18, Responsibilities of pharmacists and permit holders, recodified to N.J.A.C. 13:39-4.17.
Amended by R.2007 d.351, effective November 19, 2007.
See: 38 N.J.R. 4630(a), 39 N.J.R. 4935(a).
In (d)2, inserted the second sentence.

13:39-4.19 Out-of-State pharmacy registration

(a) Any pharmacy located in a state other than New Jersey (hereinafter "out-of-State pharmacy") that ships, mails, distributes or delivers in any manner, legend drugs or devices or controlled dangerous substances pursuant to a prescription into the State, or which participates in a central prescription handling arrangement pursuant to N.J.A.C. 13:39-4.18, shall be registered with the Board pursuant to this section.

(b) It shall be unlawful for any out-of-State pharmacy not registered with the Board pursuant to this section to ship, mail, distribute or deliver in any manner, legend drugs or devices or controlled dangerous substances pursuant to a prescription into the State of New Jersey. Such conduct shall be deemed a violation of N.J.S.A. 45:14-73 and this section.

(c) An out-of-State pharmacy seeking to register with the Board shall submit a completed application for registration to the Board which shall include the following:

1. The name under which the pharmacy is to be operated, the type of practice in which the pharmacy will be engaging, the weekly hours of operation for the pharmacy, and a copy of the prescription label to be used by the pharmacy;

2. The location, names and titles of all principal corporate officers, if the applicant is a corporation, or the location, names and titles of any individuals in whom ownership is or will be vested, if the applicant is not a corporation;

3. The name of the pharmacist-in-charge and his or her license number in the state in which the pharmacy is located, and his or her weekly hours of employment;

4. A dated copy of the most recent inspection report resulting from an inspection of the out-of-State pharmacy conducted by the regulatory or licensing agency in the state in which the pharmacy is located;

5. A letter of good standing from the state licensing authority in the state in which the out-of-State pharmacy is licensed, permitted or registered; and

6. The application fee specified in N.J.A.C. 13:39-1.3(a)4.

(d) An out-of-State pharmacy registered with the Board shall maintain, at all times, a valid unexpired license, permit, or registration to conduct the pharmacy in compliance with the laws and regulations of the state in which it is located. The pharmacy shall notify the Board immediately upon the permanent closing of the pharmacy or upon the commencement of any action by the licensing authority in the state in which it is located concerning its license, permit or registration to conduct the pharmacy. Suspension or revocation of a pharmacy's license, permit or registration in the state in which it is located shall result in the immediate commencement of proceedings by the Board to suspend or revoke the out-of-State pharmacy's registration in New Jersey.

(e) An out-of-State pharmacy registered with the Board shall submit on an annual basis, prior to the expiration of the registration, a renewal application which shall contain the information set forth in (c)1 through 5 above, and the renewal fee set forth in N.J.A.C. 13:39-1.3(a)4. A registered out-of-State pharmacy that fails to submit the renewal application within 30 days after the registration expiration shall submit the late renewal fee set forth in N.J.A.C. 13:39-1.3(a)4 in

addition to the renewal fee. An out-of-State pharmacy that continues to ship, mail, distribute or deliver legend drugs or devices or controlled dangerous substances into the State, or continues to participate in a central prescription handling arrangement pursuant to N.J.A.C. 13:39-4.18, with an expired registration shall be deemed to be engaging in the unauthorized practice of pharmacy and shall be subject to the penalties set forth in N.J.S.A. 45:1-25 et seq.

(f) An out-of-State pharmacy registered with the Board shall submit the information set forth in (c)1 though 5 above and the fee set forth in N.J.A.C. 13:39-1.3(a)4, if applicable, within 30 days of the following:

1. Any change in ownership of the individual equity holder(s) or business entity holding the license, permit or registration to operate the pharmacy;

2. A change of registered agents or officers or a change of stock ownership involving 10 percent or more of the outstanding stock of a publicly traded corporation holding the license, permit or registration to operate the pharmacy;

3. A change in the location of the licensed, permitted or registered pharmacy;

4. A change in the name of the licensed, permitted or registered pharmacy; or

5. A change in the registered pharmacist-in-charge.

(g) An out-of-State pharmacy may obtain a replacement registration upon payment of the fee specified in N.J.A.C. 13:39-1.3(a)4 and upon submission of an affidavit describing the loss or destruction of the registration originally issued, or upon return of the damaged permit.

(h) An out-of-State pharmacy registered with the Board shall:

1. Inform the Board, upon request, of the results of any inspections or investigations conducted by the regulatory or licensing agency of the state in which the pharmacy is licensed, permitted or registered or by a Federal agency, including the filing of any action against the pharmacy by the agency;

2. Inform the Board, upon request, of any directions to, and requests for information from, the pharmacy issued by the regulatory or licensing agency of the state in which the pharmacy is licensed, permitted or registered or by a Federal agency; and

3. Comply with directions concerning compliance with this section and any requests for information issued by the Board.

(i) An out-of-State pharmacy registered with the Board shall maintain its record of prescriptions for patients in the State of New Jersey 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 record information shall be retrievable and readable within one business day.

(j) An out-of-State pharmacy registered with the Board shall, during its regular hours of operation, but not less than five days per week, and for a minimum of 40 hours per week, provide a toll-free telephone service to facilitate communication between patients in the State of New Jersey and a pharmacist who has access to the patients' records. This toll-free number shall be disclosed on a label affixed to each container of drugs dispensed to patients in the State of New Jersey or the out-of-State pharmacy shall meet the requirements set forth in N.J.A.C. 13:39-4.18(d)6.

(k) The Board may forward a complaint against any out-of-State pharmacy registered with the Board for alleged violations of any New Jersey or Federal law or regulation, or any information concerning alleged violations of New Jersey or Federal law by the pharmacy, to the regulatory or licensing agency in the state in which the pharmacy is located, or the Board may institute disciplinary proceedings in New Jersey pursuant to N.J.S.A. 45:1-21 et seq., to resolve the complaint or alleged violation.

New Rule, R.2007 d.351, effective November 19, 2007.
See: 38 N.J.R. 4630(a), 39 N.J.R. 4935(a).

13:39-4.20 Procedures for physician ordered or government sponsored immunizations performed by pharmacists

(a) The provisions of this section set forth the requirements for licensed pharmacists authorized to administer vaccines and related emergency medications, which shall be limited to diphenhydramine and epinephrine, to eligible patients who are 18 years of age and older, consistent with the requirements of N.J.S.A. 45:14-63, under the following circumstances:

1. Pursuant to a prescription by a New Jersey licensed physician for a vaccine, related emergency medications, and pharmacist administration of the vaccine that is patient specific;

2. In immunization programs implemented pursuant to a New Jersey licensed physician's standing order for the vaccine, related emergency medications, and administration instructions that are not patient specific; and/or

3. In immunization programs sponsored by government agencies that are not patient specific.

(b) In order to administer vaccines and related emergency medications pursuant to this section, a licensed pharmacist shall be pre-approved by the Board to perform such functions. In order to obtain such prior Board approval, a pharmacist shall submit documentation to the Board which establishes that he or she has satisfied the following education and training requirements:

Department of Weights and Measures of the municipality or county in which the pharmacy or other Board-licensed establishment is located, and such balances, scales, weights and automatic counting devices shall be properly sealed by the applicable authority.

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).

13:39-5.12 Restriction on storage of prescription legend drugs and controlled dangerous substances

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

(b) Prescription legend drugs, devices and controlled dangerous substances shall only be stored in areas of the premises that are part of the permitted pharmacy or pharmacy department.

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).

SUBCHAPTER 6. REGISTERED 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 Registered pharmacist-in-charge

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

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

(c) A registered pharmacist shall not assume the responsibilities of a registered pharmacist-in-charge of more than one pharmacy or pharmacy department simultaneously.

(d) Whenever there is a change of a registered pharmacist-in-charge of a pharmacy or other Board-licensed establishment, 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 registered pharmacist assumes or terminates the duties as a registered pharmacist-in-charge of a pharmacy or other Board-licensed establishment, the registered 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 registered pharmacist-in-charge shall be a full-time employee, employed for a minimum of 35 hours per week and shall be physically present in the pharmacy or pharmacy department for that amount of time necessary to supervise and ensure that:

1. Adequate staffing is present to fulfill the needs of the pharmacy or pharmacy department;

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 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.

13:39-6.3 Identification tag

All personnel working in the pharmacy shall wear an identification tag which shall include at least the person's first 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.

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 (a)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 prepared or compounded by pharmacy externs, interns or pharmacy technicians

A pharmacy intern, extern or technician may prepare or compound prescriptions only under the immediate personal supervision of a registered pharmacist of this State. The registered pharmacist shall be personally responsible for the accuracy and appropriateness of the filled prescription.

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.

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.

13:39-7.3 Authorization for renewal of prescriptions

(a) A prescription for medication or devices which pursuant to State or Federal law may be sold, dispensed or furnished only upon prescription, shall not be renewed without specific authorization of the prescriber, and the prescription may not be refilled after one year from the date of original prescription.

1. Prescriptions marked "PRN" or other letters or words meaning refill as needed shall not be renewed beyond one year past the date of original prescription.

(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 prescriber as provided in N.J.S.A. 45:14-14, which must be reduced to writing by the pharmacist and entered into either a manual or into the electronic data processing system as a new prescription. A new prescription shall be generated and the original prescription shall remain in the prescription file in chronological order.

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.

13:39-7.4 Emergency dispensing

(a) 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 (except controlled dangerous substances) 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 licensed practitioner; and

2. The pharmacist documents the communication and requires the patient or caregiver to provide suitable identification and sign a statement attesting to the need before dispensing.

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.

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 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, 45 C.F.R. Part 46, Protection of Human Subjects of Research; incorporated by reference herein, as amended and supplemented.

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.

13:39-7.6 Record of pharmacist filling prescription

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

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

(c) Initials and/or access code number(s) of the pharmacist responsible for the filled prescription shall be entered into the system each time a prescription is filled or refilled. Computer programs which automatically generate a pharmacist's initials without requiring a direct entry by the pharmacist responsible for the filled prescription at the time of dispensing are prohibited.

(d) Appropriate documentation identifying handwritten initials with the handwritten signature and printed name of the pharmacist shall be maintained by the pharmacy for a period of six years after the last date of employment.

(e) All prescription records, including original and refilled prescription data, and the number of refills authorized by the prescriber shall be maintained for a period of not less than five years. The oldest four years of record information shall be maintained in such a manner so as to be retrievable and readable within two weeks. The most recent one year of a record information shall be immediately retrievable and readable.

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.

13:39-7.7 Copies of prescriptions

(a) A pharmacy shall immediately comply with the patient's request for copies of prescriptions. 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 labeled prescription container or a prescription marked "COPY—FOR INFORMATION ONLY" 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.

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, consistent with this section, one time only, pursuant to N.J.A.C. 8:65-7.14(h) and 7.18(d).

(e) A prescription may be transferred electronically by pharmacists between pharmacies for the purpose of refill dispensing consistent with the requirements in N.J.A.C. 13:39-7.11.

(f) A prescription may be transferred by telephone between pharmacies for the purpose of refill dispensing 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 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, address 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) Date of original dispensing;

(3) Original number of refills authorized on original prescription;

(4) Complete refill record from original prescription;

(5) Number of valid refills remaining; 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".

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 which permits identification by prescription number and retrieval of original documents by the prescriber's name, patient's name, drug dispensed and date filled, then the requirement to mark the hard copy prescription with a red "C" shall be waived.

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.

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. 45:14-14, 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 pursuant to N.J.S.A. 45:14-15. 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.

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.

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. 45:14-14, 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 permitholder 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.

(d) The computer or device used to receive electronically transmitted prescriptions shall be located within the pharmacy prescription area.

(e) An electronic 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 a handwritten original signature and an NJPB shall not be required for the prescription.

(f) A pharmacist shall seek verbal verification of an electronic 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 an electronic prescription from a prescribing practitioner's authorized agent. A pharmacist shall not fill the electronic 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 an electronic prescription, or a record of an electronic prescription that is readily retrievable and printable, for a minimum of five years pursuant to N.J.S.A. 45:14-15. The printed copy shall be of non-fading legibility.

(h) A pharmacist may fill a prescription for a Schedule II controlled substance transmitted electronically, provided that the original signed prescription is presented to the pharmacist prior to the dispensing of the controlled substance. If permitted by Federal law, and in accordance with Federal requirements, an electronic prescription shall serve as the original signed prescription.

(i) A pharmacist may fill a prescription for a Schedule III, IV or V controlled substance transmitted electronically, provided that the pharmacist has obtained the original signed prescription, an oral prescription, or a facsimile prescription from the prescribing practitioner or the prescribing practitioner's authorized agent prior to the dispensing. If permitted by Federal law, and in accordance with Federal requirements, an electronic prescription shall serve as the original signed prescription.

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

(k) Two or more permit holders may establish a common electronic filing system to maintain required dispensing information.

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

New Rule, R.2003 d.373, effective September 15, 2003.
See: 34 N.J.R. 3064(a), 35 N.J.R. 4290(a).
Recodified from N.J.A.C. 13:39-5.8B and amended by R.2005 d.25, effective January 18, 2005.
See: 36 N.J.R. 3345(a), 37 N.J.R. 295(a).
Added (k) and (*l*). Former N.J.A.C. 13:39-7.11, Prescription balances, scales, weights and automatic counting devices, recodified to N.J.A.C. 13:39-5.11.

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. The pharmacy name and address;
2. The pharmacy telephone number;
3. The brand name or generic name and if generic, the name of the manufacturer;
4. The strength of medication, where applicable;
5. The quantity dispensed;
6. The date upon which prescription medication is dispensed;
7. A CDS cautionary label, where applicable;
8. The patient name;
9. Initials of the dispensing pharmacist;
10. The prescriber name;
11. The prescription number;
12. Directions for use; and

13. The phrase "use by" followed by the product's use by date, if dispensed in any packaging other than the manufacturer's original packaging.

i. For purposes of this paragraph, "use by date" means the earlier of one year from the date of dispensing or the expiration date on the manufacturer's container.

(b) The patient name, the brand or generic name of the medication, and the directions for use shall appear in larger type, in a different color type, or in bolded type, in comparison to the other information required to appear on the label of the dispensed container pursuant to (a) above.

(c) In addition to the requirements set forth in (a) and (b) above, the dispensed container for any product shall bear all auxiliary labeling as recommended by the manufacturer.

(d) When, in the judgment of the pharmacist, directions to the patient or cautionary messages are necessary, either for clarification or to ensure proper administration, storage or use of the medication, the pharmacist may add such directions or cautionary messages to those indicated by the prescriber on the original prescription.

New Rule, 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).
Recodified from N.J.A.C. 13:39-5.9 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 (b) and added (c). Former N.J.A.C. 13:39-7.12, Disposal of unwanted drugs, recodified to N.J.A.C. 13:39-7.17.
Amended by R.2004 d.380, effective October 4, 2004 (operative April 2, 2005).
See: 36 N.J.R. 11(a), 36 N.J.R. 4480(a).
Rewrote the section.
Administrative correction.
See: 37 N.J.R. 1535(a).

13:39-7.13 Professional judgment in dispensing drugs

The pharmacist shall have the right to refuse to fill a prescription if, in his or her professional judgment, the prescription is outside the scope of practice of the prescriber; or if the pharmacist has sufficient reason to question the validity of the prescription; or to protect the health and welfare of the patient.

Recodified from N.J.A.C. 13:39-6.1 and amended by R.2005 d.25, effective January 18, 2005.
See: 36 N.J.R. 3345(a), 37 N.J.R. 295(a).
Undesignated (a) and deleted (b). Former N.J.A.C. 13:39-7.13, Outdated drugs or drugs marked "sample", recodified to N.J.A.C. 13:39-7.18.

Case Notes

Board of Pharmacy adopted the Initial Decision (2006 N.J. AGEN LEXIS 1077) that a pharmacist engaged in dishonesty, fraud, deception, or misrepresentation, and gross negligence, by accepting bundled prescriptions delivered by a sales representative, filling those prescriptions without question, dispensing medications in bulk to an unknown end user, and then collecting $90,000 in reimbursement; the pharmacist's actions posed a risk to the public at large, and the Board suspended the pharmacist's license for five years and ordered payment of a civil penalty and attorney fees. In re Suspension or Revocation of License of Sorr, OAL Dkt. No. BDS 10231-05, 2007 N.J. AGEN LEXIS 884, Final Decision (June 18, 2007).

Board of Pharmacy adopted the Initial Decision (2006 N.J. AGEN LEXIS 1077), which concluded that a pharmacist failed to use professional judgment when filling 104 prescriptions delivered by a pharmaceutical sales representative; the State's expert opinion that any reasonable pharmacist would have noticed and questioned the drastically similar handwriting on the face of prescriptions that supposedly were written by different physicians, coupled with the fact that so many patients would be suffering from concurrent infections covered by the products made by the same pharmaceutical company, and the fact that the drugs prescribed posed potential interactions that the pharmacist never questioned, demonstrated that the pharmacist had sufficient reason to question the validity of the prescriptions and failed to do so. In re Suspension or Revocation of License of Sorr, OAL Dkt. No. BDS 10231-05, 2007 N.J. AGEN LEXIS 884, Final Decision (June 18, 2007).

Board of Pharmacy adopted the Initial Decision (2006 N.J. AGEN LEXIS 1077), which concluded that the standard of care applicable to a licensed pharmacist who filled bundled prescriptions delivered by a pharmaceutical sales representative was that of a pharmacist, not a pharmaceutical representative delivering samples. In re Suspension or Revocation of License of Sorr, OAL Dkt. No. BDS 10231-05, 2007 N.J. AGEN LEXIS 884, Final Decision (June 18, 2007).

13:39-7.14 Advertising and sale of prescription drugs

(a) "Advertisement" means any attempt directly or indirectly by publication, dissemination, or circulation in print or electronic media which directly or indirectly induces or attempts to induce any person or entity to purchase or enter into an agreement to purchase services or goods from a Board licensee.

(b) Price quotations for prescription drugs appearing in any advertisement shall stipulate the strength and quantity required to be purchased for the offered cost. Price quotations shall include the usual and customary prescription cost. All services including, but not limited to, delivery charges rendered by the pharmacy which will add additional costs to the price quoted, must be set forth in the advertisement.

(c) Any reference in any form of advertisement to the quality of a drug or its beneficial use is prohibited.

(d) Price quotations for drugs appearing in any advertisement shall stipulate the effective period of price quotation.

(e) Upon request by any consumer, the pharmacist shall give usual and customary price information for a non-third party paying customer over the telephone and shall stipulate the effective period of the price quotation.

(f) All advertisements shall be predominantly informational and shall not be misleading, confusing or false. Any advertisement demeaning the quality of professional services rendered by another licensee or permittee shall be prohibited.

Recodified from N.J.A.C. 13:39-6.8 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 (e); in (f), deleted the second sentence. Former N.J.A.C. 13:39-7.14, Patient profile record system, recodified to N.J.A.C. 13:39-7.19.

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 which 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 overfilled;

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;

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.

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) shall be devised so as to enable the immediate retrieval of information necessary to enable the dispensing pharmacist to identify previously dispensed medication 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 and the initials of the dispensing pharmacist, if said initials and such date are not recorded on the back of the original prescription or in any other Board-approved record;

5. The number or designation identifying the prescription;

6. The prescriber's name;

7. The name, strength and quantity of the drug dispensed; and

8. Pharmacist's comments relevant to the patient's drug therapy.

(c) The pharmacist shall attempt to ascertain and shall record any allergies and idiosyncrasies of the patient and any medical conditions which may relate to drug utilization, as communicated to the pharmacist by the patient.

1. If there are no patient allergies, idiosyncrasies or medical conditions which may relate to drug utilization, the pharmacist shall so indicate on the patient profile record system.

(d) 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.

(e) Upon receipt of a new or refill prescription, a pharmacist shall examine the patient's profile record either in a manual or electronic data processing system before dispensing the medication, to determine the possibility of a potentially significant drug interaction, reaction or misutilization of the prescription. Upon determining a potentially significant drug interaction, reaction or misutilization, the pharmacist shall take the appropriate action to avoid or minimize the problem, which shall, if necessary, include consultation with the patient and/or the prescriber.

1. Except as set forth in (e)5 below, before dispensing a new prescription, the pharmacist shall make reasonable efforts to counsel the patient or caregiver. Counseling may, but need not, include the following:

i. The name and description of the medication;

ii. The dosage form, dosage, route of administration, and duration of drug therapy;

iii. Special directions and precautions for preparation, administration and use by the patient;

iv. Common adverse or severe side effects or interactions and contraindications that may be encountered, including their avoidance, and the action required if they occur;

v. Techniques for self-monitoring drug therapy;

vi. Proper storage;

vii. Prescription refill information; and

viii. Action to be taken in the event of a missed dose.

2. The offer to counsel may be made by ancillary personnel. However, counseling may be performed only by the pharmacist.

3. A pharmacist shall not be required to counsel a patient or caregiver when the patient or caregiver refuses such consultation. The absence of any record of a failure to accept the pharmacist's offer to counsel shall be presumed to signify that the offer was accepted and that the counseling was provided.

4. If the patient or caregiver is not physically present, the offer to counsel shall be made by telephone or in writing on a separate document accompanying the prescription. A written offer to counsel shall be in bold print, easily read, and shall include the hours a pharmacist is available and a telephone number where a pharmacist may be reached. The telephone service must be available at no cost to the pharmacy's primary patient population.

5. The requirements to counsel the patient or caregiver upon receipt of a new prescription, as set forth in (e)1 through 4 above, shall not apply to a pharmacist who dispenses any drug to an inpatient at a hospital or a long term care facility in which the resident is provided with 24 hour nursing care.

6. Upon receipt of a refill prescription, a pharmacist shall determine if a substantial time, as is appropriate for that drug in the reasonable and prudent pharmacist's professional judgment, has elapsed from the last filling. When necessary, the pharmacist shall consult with the prescriber and/or the patient to assure himself or herself that continued use is appropriate.

7. When patient profile records indicate sporadic, erratic or irrational use of medication by a patient, the pharmacist shall consult with the patient and/or the prescriber to determine if continued use is appropriate.

8. 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.

9. All of the foregoing assumes the patient is willing and capable of participating in his or her own plan of care.

(f) A patient profile record shall be maintained for a period of not less than five years from the date of the last entry in the profile record. In using an electronic data processing system, the system shall have the capability of producing retrievable and readable documents of all original and refilled prescription data for a period of not less than five years, including the number of refills authorized by the prescriber. The oldest four years of record information shall be maintained in such a manner so as to be retrievable and readable within two weeks. The most recent one year of a record information shall be immediately retrievable and readable.

(g) If the pharmacy uses an electronic data processing system, an auxiliary recordkeeping system shall be established when the electronic data processing system is inoperative for any reason. When the electronic data processing system is restored to operation, the patient profile information and number of refills authorized during the time the electronic system was inoperative shall be entered into the electronic data processing system within 72 hours.

(h) If an electronic data processing system is used, the system shall provide adequate safeguards against manipulation and alteration of records and to protect confidentiality of the information contained in the data bank.

(i) The holder of the pharmacy permit shall make arrangements with the supplier of data processing services or materials to ensure that the pharmacy will continue to have adequate and complete prescription and dispensing records if the relationship with such supplier terminates for any reason.

(j) Failure to comply with this section shall subject the pharmacist to disciplinary sanctions.

Amended by R.1993 d.307, effective June 21, 1993.
See: 24 N.J.R. 266(a), 25 N.J.R. 2697(a).
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. 13:39-7.14 and amended by R.2005 d.25, effective January 18, 2005.
See: 36 N.J.R. 3345(a), 37 N.J.R. 295(a).

Case Notes

Board of Pharmacy adopted the Initial Decision (2006 N.J. AGEN LEXIS 1077) that a pharmacist engaged in dishonesty, fraud, deception, or misrepresentation, gross negligence, and violated N.J.A.C. 13:39-7.19(b) by accepting bundled prescriptions delivered by a sales representative, filling those prescriptions without question, and dispensing medications in bulk to an unknown end user; the patient's telephone number and gender must be listed in the patient profile system. In re Suspension or Revocation of License of Sorr, OAL Dkt. No. BDS 10231-05, 2007 N.J. AGEN LEXIS 884, Final Decision (June 18, 2007).

SUBCHAPTER 8. (RESERVED)

SUBCHAPTER 9. PHARMACEUTICAL SERVICES FOR HEALTH CARE FACILITIES

13:39-9.1 Purpose and scope

(a) The rules in this subchapter shall apply to all retail pharmacies which contract to provide pharmaceutical services for healthcare facilities and to all institutional pharmacies which provide pharmaceutical services for their own health care system.

(b) An institutional pharmacy filling prescriptions for outpatient use shall comply with all retail pharmacy requirements of this chapter.

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. 13:39-9.1, Definitions, recodified to N.J.A.C. 13:39-9.2.

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).

13:39-9.2 Definitions

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

"Drug administration" means a procedure in which a prescribed drug is given to a patient by an authorized person in accordance with all laws and rules governing such procedures.

"Formulary" means a continually revised compilation of pharmaceuticals available in the pharmacy for use in the facility developed by the Pharmacy and Therapeutics Committee.

"Health care facility" means a facility or institution licensed by the Department of Health and Senior Services pursuant to N.J.S.A. 26:2H-1 et seq.

"Health care system" means one or more health care facilities which are owned or controlled by the same legal entity.

"Institutional pharmacy" means the area in a health care facility or a health care system licensed by the Board as a pharmacy that maintains an institutional permit. "Institutional pharmacy" includes any areas of the health care facility or the health care system where pharmaceuticals are stored, compounded or dispensed.

"Medication order" means a written request for medication originated by an authorized prescriber and intended for patient use in the health care facility, and not for use of the institution's employees or their dependents or outpatients of the facility's clinics. A valid medication order contains the date ordered, the patient's name and location within the facility, the name, dose, route, and frequency of administration of the medication, and any additional instructions. Computer-generated medication orders within an institutional setting, utilizing the prescriber's electronic signature or password will meet legal requirements for a prescriber's original handwritten signature on medication orders. Computerized signatures or passwords will be accepted provided that the facility has adequate safeguards which assure the confidentiality of each

electronic signature or password and which prohibit their improper or unauthorized use.

"Pharmacy and Therapeutics Committee" means the active standing committee of the institution or health care facility which is the organizational line of communication and liaison between the medical service and pharmacists and which acts to review and promote rational drug therapy and utilization in the facility.

"Unit dose drug distribution system" means a system of dispensing drugs to be administered to patients of the facility whereby the medications are delivered daily (or more frequently) by the pharmacy to the patient care units in amounts equal to a 24-hour supply or less and are prepared, whenever possible, in single unit use packaging.

"Unit use packaging" means a single unit use medication provided in sealed packaging which contains the following information for each unit in the package:

1. Product name;

2. Strength and/or quantity and/or volume, where appropriate;

3. Lot number;

4. Use by date;

5. Manufacturer or repackager; and

6. If there is more than one product in the single unit, a physical description of each medication in the single unit.

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.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 in "Pharmacy and Therapeutics Committee" definition.
Amended by R.1999 d.214, effective July 19, 1999.
See: 31 N.J.R. 1151(a), 31 N.J.R. 1932(a).
Deleted "Authorized prescriber" and "Direct supervision"; in "Health care facility", substituted a reference to patients and residents for a reference to the sick and injured; in "Unit dose drug distribution system", deleted a reference to biologicals; and added "Unit use packaging".
Amended by R.2000 d.457, effective November 20, 2000.
See: 31 N.J.R. 3044(a), 32 N.J.R. 4123(a).
Inserted "Health care system"; in "Institutional pharmacy", inserted references to health care systems throughout, substituted "any" for "other" following "includes", and deleted "manufactured," following "stored,".
Recodified from N.J.A.C. 13:39-9.1 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 "Health care facility"; in "Pharmacy and Therapeutics Committee", substituted "medical service and pharmacists" for "medical and pharmacy staff" and deleted the last sentence; rewrote "Unit use packaging". Former N.J.A.C. 13:39-9.2, Licensure of institutional pharmacies, recodified to N.J.A.C. 13:39-9.3.

13:39-9.3 Licensure of institutional pharmacies

(a) Any institutional pharmacy as defined under N.J.A.C. 13:39-9.2 shall be registered with and possess an institutional permit issued by the Board. The permit shall be conspicuously displayed in the facility's pharmacy. The institutional pharmacy is subject to and shall be conducted in accordance with all existing State and Federal rules and regulations.

(b) An institutional pharmacy that is part of a health care system may fill medication orders for health care facilities that are part of the health care system and that provide pharmaceutical services directly to the patients of the health care system.

Amended by R.2000 d.457, effective November 20, 2000.
See: 31 N.J.R. 3044(a), 32 N.J.R. 4123(a).
Designated existing section as (a); and added (b).
Recodified from N.J.A.C. 13:39–9.2 and amended by R.2005 d.25, effective January 18, 2005.
See: 36 N.J.R. 3345(a), 37 N.J.R. 295(a).
In (a), amended the N.J.A.C. reference. Former N.J.A.C. 13:39–9.3, Control of institutional pharmaceutical, recodified to N.J.A.C. 13:39–9.8

13:39–9.4 Contract pharmaceutical services; institutional permit required

An institutional permit is required for any area within an institution serviced by an outside vendor that performs on-site pharmaceutical services as defined in N.J.A.C. 13:39–1.2.

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. 13:39–4.14 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 "where drugs are stored, manufactured or compounded and which is" following "within an institution" and inserted "on-site" preceding "pharmaceutical services". Former N.J.A.C. 13:39–9.4, Pharmaceutical services, recodified to N.J.A.C. 13:39–9.9.

13:39–9.5 Advisory committees

The registered pharmacist-in-charge, or designee, shall be an actively participating member on any committees of the facility that may be concerned with drugs and their utilization.

Recodified from 13:39–9.10 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).
Substituted a reference to registered pharmacist-in-charge for a reference to pharmacist-in-charge.
Recodified from N.J.A.C. 13:39–9.19 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. 13:39–9.5, Pharmaceuticals, recodified to N.J.A.C. 13:39–9.10.

13:39–9.6 Pharmacy and Therapeutics Committee; applicability; polices and procedures

(a) In all health care facilities providing pharmaceutical services to patients, an active standing committee of the institution entitled the Pharmacy and Therapeutics Committee or other appropriate name shall be established if required pursuant to Department of Health and Senior Services rules. A Pharmacy and Therapeutics Committee shall be multidisciplinary and include a pharmacist.

(b) In all health care facilities providing pharmaceutical services to patients that are not required to maintain a Pharmacy and Therapeutics Committee pursuant to Department of Health and Senior Services rules, the pharmacist-in-charge of the provider pharmacy, in cooperation with the health care facility, shall create policies and procedures as needed to provide pharmaceutical services to the health care facility. The written policies and procedures shall be available to the Board.

Recodified from 13:39–9.11 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. 13:39–9.20 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. 13:39–9.6, Drug disbursement; written orders; outpatient prescriptions, recodified to N.J.A.C. 13:39–9.11.

13:39–9.7 Institutional pharmacy staff

The institutional pharmacy shall be staffed by sufficient, competent personnel in keeping with the size, scope and complexity of the pharmaceutical services provided consistent with the requirements of N.J.A.C. 13:39–6.2(f)1.

Recodified from 13:39–9.12 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. 13:39–9.21 and amended by R.2005 d.25, effective January 18, 2005.
See: 36 N.J.R. 3345(a), 37 N.J.R. 295(a).
Inserted "consistent with the requirements of N.J.A.C. 13:39–6.2(f)1" at the end of the paragraph. Former N.J.A.C. 13:39–9.7, Drug disbursement; oral orders, recodified to N.J.A.C. 13:39–9.12.

13:39–9.8 Control of health care pharmaceutical services; responsibilities of the registered pharmacist-in-charge of the provider pharmacy

(a) The pharmaceutical services of the health care facility shall be the responsibility of and under the control, supervision, and direction of the registered pharmacist-in-charge of the provider pharmacy.

(b) If a health care facility does not have an institutional pharmacy on its premises or chooses to utilize the services of a pharmacy outside the health care system, it may enter into an agreement with a retail pharmacy licensed by the Board. The registered pharmacist-in-charge of the retail pharmacy shall direct, control, supervise and be responsible for the pharmaceutical services provided to the facility.

(c) The registered pharmacist-in-charge of the provider pharmacy, with the cooperation of the Pharmacy and Therapeutics Committee, shall develop written policies and procedures as needed to provide pharmaceutical services to the facility. The written policies and procedures shall be available to the Board.

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).
Substituted references to registered pharmacists-in-charge for references to pharmacists-in-charge throughout.
Recodified from 13:39-9.6 and 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).
Recodified from N.J.A.C. 13:39-9.3 and amended by R.2005 d.25, effective January 18, 2005.
See: 36 N.J.R. 3345(a), 37 N.J.R. 295(a).
Rewrote the section. Former N.J.A.C. 13:39-9.8, Compounding, repealed.

13:39-9.9 Pharmaceutical services

The pharmaceutical services shall be provided in accordance with accepted professional principles and standards and appropriate Federal, State and local laws. These services shall be responsive to the medication needs of the patient.

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. 13:39-9.4 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. 13:39-9.9, Monitoring of patient drug therapy, recodified to N.J.A.C. 13:39-9.13.

13:39-9.10 Pharmaceuticals; drug supply; investigational drugs; controlled dangerous substances

(a) The pharmacist-in-charge shall be responsible for determining the specifications for drugs and pharmaceutical preparations used in the treatment of patients of the facility as to quality, quantity and source of supply. An authorized purchasing agent and/or materials manager and/or pharmacy buyer of the facility may perform the actual procurement. In such a case, the purchase shall be supervised by the pharmacist-in-charge or his or her designee, who shall be a pharmacist.

(b) Drugs approved by the Pharmacy and Therapeutics Committee for use in the facility shall be of an amount sufficient to compound or dispense all medication orders and prescriptions which may reasonably be expected to be compounded or dispensed by the pharmacist.

(c) The institutional pharmacy shall have an adequate inventory of drugs and biologicals to assure timely initiation of routine, and disaster drug therapy. Limited quantities of drugs shall be placed under controlled conditions in locations within the facility to assure immediate access by authorized licensed health care personnel for use in an emergency situation. Written policies and procedures for the maintenance, content, control and accountability of drugs supplied and located throughout the facility shall be developed by the registered pharmacist-in-charge and approved by the Pharmacy and Therapeutics Committee.

(d) The storage 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 these drugs shall not be construed to be a violation of N.J.A.C. 13:39-7.5(a). A facility participating in experimental research involving residents must be in compliance with Federal Department of Health and Human Services regulations, 45 C.F.R. Part 46, Protection of Human Subjects of Research, which is incorporated by reference herein, as amended and supplemented.

(e) Investigational drugs shall be properly labeled and stored in the pharmacy until dispensed. Essential information on the investigational drug shall be maintained in the pharmacy. The investigational drug may be administered only after basic chemical, pharmaceutical and pharmacological information has been made available to all concerned and all the requirements of the Food and Drug Administration and the facility are satisfied.

(f) Controlled dangerous substances shall be purchased, received, stored, dispensed, administered, recorded and controlled in accordance with State and Federal laws and regulations. Written policies and procedures concerning control, use and accountability of controlled drugs shall be developed by the registered pharmacist-in-charge.

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 (e), deleted "by a pharmacist" following "conducted" in the second sentence, added "or by supportive personnel and co-signed by the supervising pharmacist" at the end of the fourth sentence, and inserted a new fifth sentence.
Recodified from N.J.A.C. 13:39-9.5 and amended by R.2005 d.25, effective January 18, 2005.
See: 36 N.J.R. 3345(a), 37 N.J.R. 295(a).
In (a), substituted "supervised" for "approved" following "the purchase shall be"; rewrote (c); in (d)' amended N.J.A.C. reference and inserted ", which is incorporated by reference herein, as amended and supplemented"; deleted existing (e); added a new (e) and (f). Former N.J.A.C. 13:39-9.10, Medication not dispensed in finished form, recodified to N.J.A.C. 13:39-9.14.

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

(a) The pharmacist shall review the prescriber's original order, a direct copy thereof, or a facsimile before any initial dose of medication is dispensed, except as provided for in N.J.A.C. 13:39-9.13.

(b) Drugs not specifically limited as to time or number of doses when ordered shall be controlled by the automatic stop order procedure or other methods in accordance with written policies of the facility.

(c) The Pharmacy and Therapeutics Committee shall develop a list of unapproved or unacceptable abbreviations and symbols which shall not be used in the facility. Orders involving symbols or abbreviations shall only be dispensed consistent with this list.

(d) When appropriate, the pharmacist shall make necessary entries into the patient medical record relative to drug use in accordance with health care facility policies and, where applicable, pursuant to regulations of the Department of Health and Senior Services and/or Centers for Medicare and Medicaid Services.

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. 13:39–9.6 and amended by R.2005 d.25, effective January 18, 2005.
See: 36 N.J.R. 3345(a), 37 N.J.R. 295(a).
In (a), substituted "a" for "an electro-mechanical" preceding "facsimile" and amended N.J.A.C. reference; rewrote (c) and (d); deleted (e). Former N.J.A.C. 13:39–9.11, Drug labeling, recodified to N.J.A.C. 13:39–9.15.

Case Notes

Violation not found due to failure of Board to prove pharmacist's knowledge or receipt of equipment and test requirements. New Jersey State Bd. of Pharmacy v. Yanuzzi, 4 N.J.A.R. 489 (1981).

13:39–9.12 Drug disbursement; oral orders

(a) The provisions of this section shall be implemented in accordance with the policy and protocols of the Pharmacy and Therapeutics Committee.

(b) A pharmacist shall receive oral orders only from an authorized prescriber. Such orders shall be immediately recorded and signed by the person receiving the order on the medication order sheet or into the electronic data processing system.

(c) Oral orders for Schedule II controlled substances shall be permitted only in the case of a bona fide emergency situation.

(d) Oral orders shall be countersigned by the prescriber.

(e) The pharmacist may release to the patient at discharge any remaining medication in a multiple dose container (for example, inhalers, multiple dose injectable medications such as insulin, topical preparation, drops, ointments, and topical irrigation solutions), provided that the pharmacist:

1. Labels the medications for out-patient use pursuant to labeling requirements set forth in N.J.S.A. 45:14–24;

2. Counsels the patient prior to discharge from the hospital or medical facility pursuant to N.J.A.C. 13:39–7.19; and

3. Ensures that discharge orders contain the attending physician's authorizations to release the remaining doses of the prescription to the patient or guardian.

Recodified from 13:39–9.6 and 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.1997 d.502, effective December 1, 1997.
See: 28 N.J.R. 5048(a), 29 N.J.R. 5072(a).
Inserted new (a); recodified existing (a) through (c) as (b) through (d); and added (e).
Amended by R.1999 d.214, effective July 19, 1999.
See: 31 N.J.R. 1151(a), 31 N.J.R. 1932(a).
In (d), deleted "as required by 42 CFR 463" at the end.
Recodified from N.J.A.C. 13:39–9.7 and amended by R.2005 d.25, effective January 18, 2005.
See: 36 N.J.R. 3345(a), 37 N.J.R. 295(a).
In (a), substituted "provisions" for "mandatory requirements" following "The"; in (b), substituted "medication" for "prescriber's " preceding "order sheet"; in (e), amended the N.J.A.C. reference in 2. Former N.J.A.C. 13:39–9.12, Use of patient's own medication, recodified to N.J.A.C. 13:39–9.16.

13:39–9.13 Monitoring of patient drug therapy

(a) The pharmacist shall be responsible for monitoring drug therapy of patients in the facility. This shall include, but is not limited to, maintaining and reviewing the patient medication profile prior to the dispensing of medications.

(b) In instances involving the issuance and administration of STAT orders (orders requiring immediate attention) these drugs shall be documented on the patient's medication profile immediately after dispensing.

(c) When the pharmacy is closed, these drugs shall be documented on the patient's medication profile immediately after the pharmacy is reopened.

Recodified from 13:39–9.6 and 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. 13:39–9.9 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.13:39–9.13, Investigational drugs; removal of outdated and recalled drugs; emergency drug supply; controlled dangerous substances, repealed.

13:39–9.14 Medication not dispensed in finished form

The pharmacist shall be responsible for providing medication in a form that requires little or no further alterations, preparation, reconstitution, dilution or labeling by other licensed personnel. The pharmacist shall provide adequate instructions for those products that are not dispensed in finished form.

Recodified from 13:39–9.6 and 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. 13:39–9.10 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. 13:39-9.14, Drug-dispensing devices, recodified to N.J.A.C. 13:39-9.17.

13:39-9.15 Drug labeling

Labeling of medications, other than intravenous solutions, shall be in conformance with written policies and procedures controlling the drug distribution system in use within the facility and in accord with current acceptable standards of pharmaceutical practice.

Recodified from 13:39-9.6 and 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).
Deleted a former (a); and deleted a former (b) designation.
Recodified from N.J.A.C. 13:39-9.11 and amended by R.2005 d.25, effective January 18, 2005.
See: 36 N.J.R. 3345(a), 37 N.J.R. 295(a).
Deleted the last sentence. Former N.J.A.C. 13:39-9.15, Disposal of unused medications, recodified to N.J.A.C. 13:39-9.18.

13:39-9.16 Use of patient's own medication

(a) No drugs shall be administered to a patient except those provided through the pharmacy or as provided by written policies and procedures developed by the registered pharmacist-in-charge or, where applicable, the director of pharmaceutical services and approved by the Pharmacy and Therapeutics Committee.

(b) Although the use of patient's own medications may be warranted in certain situations, it should be discouraged as a general or routine practice. If a patient's previously acquired medication is to be used, a written order to this effect shall be signed and dated by the patient's physician. Such medications shall be identified by the pharmacist as to contents and dispensing origin. Also, these medications shall be documented as part of the pharmacy's patient profile record system.

Recodified from 13:39-9.6 and 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 (a), substituted "and except as provided" for ". Any exception to this rule must be governed" following "pharmacy", and substituted a reference to registered pharmacists-in-charge for a reference to pharmacists-in-charge.
Recodified from N.J.A.C. 13:39-9.12 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), substituted "or" for "and except" preceding "as provided" and inserted "or, where applicable, the director of pharmaceutical services" following "pharmacist-in-charge". Former N.J.A.C. 13:39-9.16, Records and reports, recodified to N.J.A.C. 13:39-9.19.

Case Notes

Violation found due to having outdated medication and "Not to be Sold" sample medications in prescription area; penalties (also cited as N.J.A.C. 13:39-9.2). New Jersey State Bd. of Pharmacy v. Yanuzzi, 4 N.J.A.R. 489 (1981).

13:39-9.17 Drug-dispensing devices

(a) Where the use of a drug-dispensing device is approved as an integral part of the drug distribution system by the facility, the registered pharmacist-in-charge and the Pharmacy and Therapeutics Committee, the device may be used when the pharmacist is not on duty (absent during either the day or night), provided that any absence of the pharmacist does not exceed 24 hours, or when the pharmacist is on duty, provided that proper review of the use of the drug-dispensing device can be ascertained. The supervision of any drug dispensing device so utilized shall be the responsibility of the registered pharmacist-in-charge servicing the health care facility. The drug-dispensing device data shall be checked for accuracy every 24 hours by a pharmacist and so documented.

(b) Packaging and labeling of medication for drug-dispensing devices, when done in the facility, shall be performed under the immediate personal supervision of a pharmacist in the employ of or under contract to the facility.

(c) Stocking of the drug-dispensing devices with prepackaged medications shall be performed by or under the supervision of a pharmacist.

(d) The cleanliness of the drug dispensing devices shall be maintained by a pharmacist or by a person under the supervision of a pharmacist.

(e) Controlled substances and other medications to which, in the professional judgment of the registered pharmacist-in-charge, access should be limited, shall be secured within the drug dispensing device to limit access to single medications only and shall be checked and documented by the pharmacist or his or her designee who shall be a licensed professional, every 24 hours. Other than a pharmacist, only authorized registered nurses, licensed practical nurses, physicians, authorized prescribers or designated pharmacy technicians, interns and externs shall have access to the medication in each drug-dispensing device. The activity regarding all medication, including the identity of the person accessing the medication, shall be recorded and available to the pharmacist.

(f) All medications withdrawn from a drug dispensing device require a medication order by an authorized prescriber. All such medication orders shall be checked by the pharmacist within 24 hours from the time of the original order and so noted on the pharmacy's patient medication profile.

(g) When there is no licensed pharmacy on the premises and when the drug-dispensing devices are an integral part of the approved drug distribution system of the facility, the devices shall be controlled by the registered pharmacist-in-charge who is responsible for the pharmaceutical services of the institution. Under these circumstances, the time between medication order checks shall not exceed 24 hours.

Recodified from 13:39–9.6 and 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).
Rewrote the section.
Recodified from N.J.A.C. 13:39–9.14 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 (b), substituted "immediate personal" for "direct" preceding "supervisor of a pharmacist"; in (c) and (d), deleted "direct" preceding "supervision of a pharmacist"; in (e), substituted "technicians, interns and externs" for "supportive personnel" following "authorized prescribers or designated pharmacy"; deleted (h). Former N.J.A.C. 13:39–9.17, Drug information and education, recodified to N.J.A.C. 13:39–9.20.

13:39–9.18 Disposal of unused medications

(a) Written policies and procedures governing unused medications shall be established and implemented by the registered pharmacist-in-charge and shall comply with the following requirements:

1. All medications where the drug source, lot or control number, or expiration or use by date are missing, shall be sent to the pharmacy for final disposition, or shall be disposed of by the health care facility according to its written protocol.

2. If a unit dose packaged medication has been stored in a medication room or secure area in the institution and the medication seal and control number are intact, the medication may be recycled and redispensed.

3. Any and all medication returned by out-patients of the facility shall not be redispensed.

4. The record of disposal of unused or nonadministered dispensed controlled dangerous substances expended or wasted either by accident or intent shall be signed and cosigned and witnessed by a licensed nurse, physician or pharmacist, or where allowed by Department of Health and Senior Services rules an administrator of the health care facility, and disposed of by the health care facility according to its written protocol and consistent with all local, State and Federal laws and regulations.

Recodified from 13:39–9.6 and 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 (a), substituted a reference to registered pharmacists-in-charge for a reference to pharmacists-in-charge in the introductory paragraph, and rewrote 1 and 4.
Recodified from N.J.A.C. 13:39–9.15 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), inserted "lot or" following "drug source" and inserted "or use by" following "expiration" in 1 and rewrote 4. Former N.J.A.C. 13:39–9.18, After hours access to the institutional pharmacy, recodified to N.J.A.C. 13:39–9.21.

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. Adequate storage for pharmacy records shall be provided. Records not currently in use need not be stored in the pharmacy, but the storage facilities shall be secure, and the records shall be readily retrievable by the pharmacy staff and authorized inspectors. These records shall be made available to persons authorized to inspect them under State and Federal statutes and regulations. Patient records shall be kept confidential.

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

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

2. All notations made on the inpatients' profile records by pharmacy technicians, interns and externs shall be verified and countersigned, either manually or electronically, by the supervising pharmacist.

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

(c) All outpatient prescriptions dispensed and outpatient profile records in the institutional pharmacy shall be signed or initialed by the dispensing pharmacist, dated, filed and kept for not less than five years from the last dispensing record date.

(d) Records for receipt, use and final disposition of controlled dangerous substances shall be maintained by the institutional pharmacy in compliance with the requirements of Federal and State controlled dangerous substances laws and regulations. Nursing administration and audit records for controlled dangerous substances shall be available for review by the pharmacy.

(e) Records of the receipt, dispensing and disposal of investigational drugs shall be maintained by the institutional pharmacy in compliance with Federal and State laws and regulations.

(f) The registered pharmacist-in-charge shall be responsible for maintaining a system by which all reported adverse drug reactions are recorded and reviewed by the Pharmacy and Therapeutics Committee, where applicable, and are submitted to all appropriate State and local agencies consistent with State and local laws and regulations.

Recodified from 13:39–9.7 and 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 (a) and (f), substituted references to registered pharmacists-in-charge for references to pharmacists-in-charge; in (a), substituted a reference to statutes and regulations for a reference to laws; and in (f), deleted a former second sentence.
Recodified from N.J.A.C. 13:39–9.16 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), (b), (f). Former N.J.A.C. 13:39–9.19, Advisory committees, recodified to N.J.A.C. 13:39–9.5.

13:39–9.20 Drug information and education

(a) The registered pharmacist-in-charge shall be responsible for maintaining drug standards, references and sources of drug information current and adequate to meet the needs of the pharmacists, physicians, nurses, other health care personnel, and patients of the facility. Reference texts shall include, but not be limited to, those required by the Board under N.J.A.C. 13:39–5.8.

(b) On each patient care unit, the pharmacist shall maintain the following:

1. A copy of the current institutional formulary;

2. A reference drug compendium which will give basic information concerning drugs approved by the Pharmacy and Therapeutics Committee; and

3. The telephone number of either the local or regional poison control center.

(c) The pharmacist shall participate in the drug education programs of the facility.

Recodified from 13:39–9.8 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 (a), substituted a reference to registered pharmacists-in-charge for a reference to pharmacists-in-charge; and in (b), deleted a former 1, a recodified former 2 through 4 as 1 through 3.
Recodified from N.J.A.C. 13:39–9.17 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), amended the N.J.A.C. reference. Former N.J.A.C. 13:39–9.20, Pharmacy and Therapeutics Committee, recodified to N.J.A.C. 13:39–9.6.

13:39–9.21 After hours access to the institutional pharmacy

(a) Only a pharmacist shall have access to the pharmacy stock of controlled dangerous substances in Schedules II through V.

(b) Only a pharmacist shall have access to the institutional pharmacy except that in a pharmacist's absence from an institution, a registered nurse designated by the registered pharmacist-in-charge may obtain medication from the hospital pharmacy as needed in an emergency and not available as floor stock.

(c) A designated registered nurse shall remove only those medication doses which shall be administered prior to the opening of the pharmacy. The designated registered nurse may remove the following from the pharmacy stock of drugs or automated dispensing device:

1. A drug in its original container or a drug prepackaged by the pharmacy for use in the institution;

2. The required dose(s) of a drug from the original container for a specific patient.

(d) The registered pharmacist in charge shall obtain from the registered nurse on a suitable form a record of any drugs removed showing the following:

1. The name of the drug;

2. The dosage size;

3. The amount taken;

4. The date;

5. The patient's name and location; and

6. The signature of the nurse.

(e) The registered pharmacist in charge shall obtain with the record in (d) above the container from which the required dose(s) was taken for drug administration purposes in order that it may be properly checked by a pharmacist.

(f) All records in (d) above shall be kept by the pharmacy for five years. The oldest four years of information shall be maintained in such a manner so as to be retrievable and readable within two weeks. The most recent one year of information shall be immediately retrievable and readable.

Recodified from 13:39–9.9 and 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).
Rewrote (b) and (c); in (d) and (e), substituted references to registered pharmacists-in-charge for references to pharmacists-in-charge; and in (e), substituted a reference to required doses for a reference to single doses.
Recodified from N.J.A.C. 13:39–9.18 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 (f). Former N.J.A.C. 13:39–9.21, Institutional pharmacy staff, recodified to N.J.A.C. 13:39–9.7.

13:39–9.22 Pharmacy facilities; space

(a) Adequate facilities (space, lighting, equipment, temperature control and supplies) shall be provided for the control of the professional, technical and administrative functions of the institutional pharmacy as needed for the effective and efficient assurance of patient safety through proper purchasing, receipt, storage, dispensing, administration and control of drugs.

See: 36 N.J.R. 3345(a), 37 N.J.R. 295(a).
In (b), substituted "eligible outpatients" for "out-patients who are treated by staff members of the institution in their respective clinics, as permitted pursuant to N.J.S.A.45:14–32" following "institution and their dependents and for" in the introductory paragraph and amended the N.J.A.C. reference in 1; in (c), amended the N.J.A.C. reference and inserted "or for direct administration to patients by parental, intravenous, intramuscular, subcutaneous or intraspinal infusion" following "hospice patients". Former N.J.A.C. 13:39-9.27, Institutional decentralized pharmacies, recodified to N.J.A.C. 13:39–9.25.

SUBCHAPTER 10. AUTOMATED MEDICATION SYSTEMS

13:39–10.1 Purpose and scope

The rules in this subchapter establish standards applicable to all pharmacies and/or facilities that utilize automated medication systems to store, package, dispense and distribute prescriptions or medication orders.

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. 13:39–7.11 or a mechanical drug dispensing device operated pursuant to N.J.A.C. 13:39–9.14.

13:39–10.3 Authority to use automated medication system

(a) A pharmacy may use an automated medication system to fill prescriptions or medication orders provided that:

1. The registered pharmacist in charge or the registered pharmacist under contract with a healthcare facility responsible for the dispensing of medications, pursuant to N.J.S.A. 45:14–32, if an automated medication system is utilized at a location which does not have a pharmacy on-site, is responsible for the supervision of the operation of the system;

2. The Board has conducted an inspection of the pharmacy, including an inspection of the automated medication system;

3. The automated medication system has been tested by the pharmacy and found to dispense accurately. The pharmacy shall make the results of such testing available to the Board upon request; and

4. The pharmacy has made the automated medication system available to the Board for the purpose of inspection, whereby the Board may validate the accuracy of the system.

(b) The registered pharmacist in charge or the registered pharmacist under contract with a healthcare facility responsible for the dispensing of medications shall be responsible for the following:

1. Reviewing and approving all policies and procedures for system operation, safety, security, accuracy and access, patient confidentiality and prevention of unauthorized access and malfunction;

2. Ensuring that medications in the automated medication system are inspected, at least monthly, for expiration or use by date, misbranding and physical integrity, and ensuring that the automated medication system is inspected, at least monthly, for security and accountability;

3. Assigning, discontinuing or changing personnel access to the automated medication system;

4. Ensuring that the automated medication system is stocked accurately and an accountability record is maintained in accordance with the written policies and procedures of operation; and

5. Ensuring compliance with all applicable provisions of N.J.A.C. 13:39.

Amended by R.2005 d.25, effective January 18, 2005.
See: 36 N.J.R. 3345(a), 37 N.J.R. 295(a).
In (b), inserted "or use by" following "for expiration" in 2.

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. Include a table of contents;

2. Include a description of all procedures of operation;

3. Set forth methods that shall ensure retention of each amendment, addition, deletion or other change to the policies and procedures of operation for at least two years after the change is made. Each such change shall be signed or initialed by the registered pharmacist in charge and shall include the date on which the registered pharmacist in charge approved the change;

4. Set forth methods that shall ensure that a pharmacist currently licensed in the transmitting jurisdiction reviews and approves the transmission of each original or new prescription or medication order to the automated medication system before the transmission is made;

5. Set forth methods that shall ensure that access to the records of medications and other medical information

of the patients maintained by the pharmacy is limited to licensed practitioners or personnel approved to have access to the records, for the purpose of complying with N.J.A.C. 13:39–7.14(h);

6. Set forth methods that shall ensure that access to the automated medication system for stocking and retrieval of medications is limited to licensed practitioners or qualified support personnel acting under the supervision of a registered pharmacist. An accountability record which documents all transactions relative to stocking and removing medications from the automated medication system shall be maintained; and

7. Identify the circumstances under which medications may be removed from the automated medication system by a licensed practitioner for distribution to a patient without prior order review by a registered pharmacist.

(b) A pharmacy which uses an automated medication system to fill prescriptions or medication orders shall, at least annually, review its written policies and procedures of operation and revise them if necessary.

(c) A copy of the written policies and procedures of operation adopted pursuant to this section shall be retained at the pharmacy and at the healthcare facility where the automated medication system is utilized. Upon request, the pharmacy shall provide to the Board a copy of the written policies and procedures of operation for inspection and review.

13:39–10.5 Personnel training requirements

The registered pharmacist in charge shall be responsible for ensuring that, prior to performing any services in connection with an automated medication system, all licensed practitioners and pharmacy technicians, interns and externs are trained in the pharmacy's standard operating procedures with regard to automated medication systems as set forth in the written policies and procedures of operation maintained pursuant to N.J.A.C. 13:39–10.4.

Amended by R.2005 d.25, effective January 18, 2005.
See: 36 N.J.R. 3345(a), 37 N.J.R. 295(a).
Substituted "pharmacy technicians, interns and externs" for "supportive personnel"..

13:39–10.6 Written program for quality assurance

(a) A pharmacy which uses an automated medication system to fill prescriptions or medication orders shall operate according to a written program for quality assurance of the automated medication system which:

1. Requires continuous monitoring of the automated medication system;

2. Establishes mechanisms and procedures to test the accuracy of the automated medication system at least every six months and whenever any upgrade or change is made to the system;

3. Establishes a protocol for measuring the effectiveness of the automated medication system;

4. Requires the pharmacy to report to the Board each recurring error of the automated medication system. A "recurring error," for purposes of this section, means any specific type of inaccuracy within the automated medication system that occurs more than twice within a 14 day period; and

5. Requires the pharmacy to maintain all documentation relating to the written program for quality assurance for at least two years.

13:39–10.7 Written plan for recovery

(a) A pharmacy which uses an automated medication system to fill prescriptions or medication orders shall maintain a written plan for recovery from a disaster which interrupts the ability of the pharmacy to provide services. The written plan for recovery shall include:

1. Planning and preparation for a disaster;

2. Procedures for response to a disaster;

3. Procedures for the maintenance and testing of the written plan for recovery; and

4. A procedure to notify the Board, each organization which has contracted with the pharmacy, each patient of the pharmacy, and other appropriate agencies, of a disaster and the date on which the pharmacy expects to recommence the provision of service.

13:39–10.8 Written program for preventative maintenance of automated medication system

A pharmacy which uses an automated medication system to fill prescriptions or medication orders shall maintain a written program for preventative maintenance of the system.

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

13:39–11.1 Purpose and scope

This subchapter shall apply to all retail and institutional pharmacies which compound and dispense sterile and/or non-sterile preparations.

Amended by R.1998 d.297, effective June 15, 1998.
See: 29 N.J.R. 2246(a), 30 N.J.R. 2255(a).
Rewrote the section.
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.

13:39–11.9 Documentation

(a) Consistent with the provisions of N.J.A.C. 13:39–11.5, the dispensing pharmacist shall ensure that compounded preparations have been properly prepared, labeled, controlled, stored, dispensed and distributed in accordance with the provisions of this subchapter.

(b) The pharmacist in charge shall be responsible for ensuring that policies and procedures exist so that all aspects of the dispensing process set out in (d) below are documented and that the pharmacist responsible for each preparation can be identified.

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

(d) Compounding steps which shall be documented are as follows:

1. Receipt of prescription or medication order;

2. Recording of prescription or medication order in the patient record profile system, pursuant to N.J.A.C. 13:39–11.15;

3. Correct selection of the drugs, container, and diluent prior to their being compounded;

4. Verification that all pharmacy sterile preparation compounding is performed within a ISO class 5 laminar air flow hood or ISO class 5 clean room and that proper aseptic procedures are being used at all times to prevent bacterial contamination of this product;

5. Verification that ingredients comply with the prescription or medication order;

6. Verification that the prescription or medication order label complies with the requirements of N.J.A.C. 13:39–11.10; and

7. Verification that the prescription or medication order is complete and ready to be dispensed, including any necessary ancillary supplies.

(e) The completed documentation shall be maintained for not less than five years from the date of the last entry in the record. The oldest four years of record information shall be maintained in such a manner so as to be retrievable and readable within two weeks. The most recent one year of a record shall be immediately retrievable and readable within 24 hours.

Recodified from N.J.A.C. 13:39–11.4 and amended by R.1998 d.297, effective June 15, 1998.
See: 29 N.J.R. 2246(a), 30 N.J.R. 2255(a).
Rewrote the section. Former N.J.A.C. 13:39–11.10, Patient profile records, was recodified to N.J.A.C. 13:39–11.16.
Recodified from N.J.A.C. 13:39–11.10 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. Former N.J.A.C. 13:39–11.9, Batch preparation, recodified to N.J.A.C. 13:39–11.8.

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. The date and, for sterile preparations, the time prepared;

2. In the retail pharmacy only, the name of the prescriber;

3. The name of the patient;

4. Directions for use;

5. The name and quantity of all active ingredients;

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

7. The name, address, and telephone number of the pharmacy;

8. The use by date and, for sterile preparations, the use by time (If no time is stated, it is presumed to be 11:59 P.M. of the stated use by date).

9. Any ancillary and cautionary instructions as needed;

10. As pertinent, a warning consistent with applicable Federal and State law that cytotoxic products are biohazardous; and

11. As pertinent, the requirements for proper storage.

Recodified from N.J.A.C. 13:39–11.5 and amended by R.1998 d.297, effective June 15, 1998.
See: 29 N.J.R. 2246(a), 30 N.J.R. 2255(a).
In (a), inserted a reference to time in 1, and rewrote 2 and 10.
Former N.J.A.C. 13:39–11.11, Controlled environment: entry, was recodified to N.J.A.C. 13:39–11.17.
Recodified from N.J.A.C. 13:39–11. and amended by R.2005 d.25, effective January 18, 2005.
See: 36 N.J.R. 3345(a), 37 N.J.R. 295(a).
Rewrote (a). Former N.J.A.C. 13:39–11.10, Documentation, recodified to N.J.A.C. 13:39–11.9.

13:39–11.11 Use by date of sterile preparation

(a) The use by date of a sterile compounded preparation shall be 24 hours or as otherwise stated by the manufacturer or current literature at the time of preparation, but shall not exceed 30 days after preparation.

(b) Any use by date that extends beyond 24 hours or the manufacturer's expiration date shall be substantiated by documentation satisfactory to the Board. Satisfactory documentation shall include, but not be limited to:

1. Manufacturer's criteria on extending beyond use dates;

2. Appropriate literature; and

3. Direct testing.

(c) In an institutional pharmacy, any sterile compounded preparation which is prepared under the pharmacy's control in a ISO class 5 laminar air flow hood which is not in a clean room and which meets the requirements of N.J.A.C. 13:39–11.22, shall be labeled to indicate that administration to a patient shall be initiated and completed within 28 hours of the beginning of the preparation time. If such a compounded preparation is prepared by closed-system aseptic transfer of a single, sterile, nonpyrogenic, finished medication obtained from licensed manufacturers into sterile final containers (for example, syringes, minibags, portable infusion-device cassettes), then the compounded preparation shall be labeled to indicate that administration to a patient shall be completed within the time recommended by the manufacturer but not exceeding 30 days after preparation. A closed system aseptic transfer is one which does not permit exposure of the pharmaceutical components to the environment, and shall be prepared in a ISO class 5 laminar air flow hood.

Recodified from N.J.A.C. 13:39–11.6 and amended by R.1998 d.297, effective June 15, 1998.
See: 29 N.J.R. 2246(a), 30 N.J.R. 2255(a).
In (a), added "or current literature at the time of preparation" at the end of the sentence; and inserted a new (c). Former N.J.A.C. 13:39–11.12, Controlled environment: construction, was recodified to N.J.A.C. 13:39–11.18.
Recodified from N.J.A.C. 13:39–11.12 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. 13:39–11.11, Information required to appear on prescription label, recodified to N.J.A.C. 13:39–11.10.

13:39–11.12 Handling, packaging and delivery

(a) The pharmacy shall be responsible for the proper handling and packaging of compounded preparations for delivery from the pharmacy to the patient in order to assure and maintain integrity, efficacy, stability, and, where applicable, sterility, of these preparations. The pharmacist in charge shall ensure that:

1. A reasonable effort is made to provide tamper-evident packing;

2. Retail delivery is made from the pharmacy to the patient within a reasonable time; and

3. Proper in-transit storage is provided consistent with product labeling.

Recodified from N.J.A.C. 13:39–11.7 and amended by R.1998 d.297, effective June 15, 1998.
See: 29 N.J.R. 2246(a), 30 N.J.R. 2255(a).
In (a), inserted a new first sentence in the introductory paragraph and changed "Delivery" to "Retail delivery" in 2. Former N.J.A.C. 13:39–11.13, Controlled environment: stocking, was recodified to N.J.A.C. 13:39–11.19.
Recodified from N.J.A.C. 13:39–11.13 and amended by R.2005 d.25, effective January 18, 2005.
See: 36 N.J.R. 3345(a), 37 N.J.R. 295(a).
Rewrote the section. Former N.J.A.C. 13:39–11.12, Expiration date of sterile preparation, recodified to N.J.A.C. 13:39–11.11.

13:39–11.13 Policy and procedure manual for compounded sterile preparations

(a) The pharmacist in charge shall maintain a policy and procedure manual which shall set forth in detail the licensee's standard operating procedures with regard to compounded sterile preparations.

(b) The policy and procedure manual shall include policies and procedures governing the following:

1. A risk-management program (including, but not limited to, incident report procedures, an adverse drug reaction system, and a product contamination system);

2. Security measures ensuring that the premises where compounded sterile drugs are present are secured, so as to prevent access by unauthorized personnel;

3. Equipment;

i. Procedures for use; and

ii. Documentation of appropriate certifications;

4. Sanitation standards and procedures;

5. Reference materials as set out in N.J.A.C. 13:39–5.8 and 11.24;

6. Information concerning drug:

i. Preparation;

ii. Storage and handling;

iii. Dispensing;

iv. Labeling;

v. Delivery; and

vi. Destruction, recalls and returns;

7. Patient recordkeeping as set forth in N.J.A.C. 13:39–11.15;

8. Handling, dispensing and documentation of investigational new drugs;

9. A quality assurance program as set forth in N.J.A.C. 13:39–11.14;

10. Verification of training and competency guidelines as set forth in N.J.A.C. 13:39–11.7;

11. Compounding process validation;

12. Documentation as set forth in N.J.A.C. 13:39–11.9;

13. Description of appropriate garb;

14. Conduct guidelines for personnel in the controlled areas;

15. Personnel responsibilities;

16. Patient education (retail patients);

"Designated agent" means an individual under the direct supervision of a practitioner authorized to communicate the practitioner's instructions to the nuclear pharmacy.

"Immediate personal supervision" means that the registered pharmacist is physically present in the compounding/dispensing area when interns, externs and pharmacy technicians are performing delegated duties, and the pharmacist conducts any necessary in-process checks and the final check in preparation and compounding of medications, including the checking of each ingredient used, the quantity of each ingredient whether weighed, measured or counted, and the finished label.

"Internal test assessment" includes, but is not limited to, conducting those tests necessary to insure the integrity of the test.

"Radiopharmaceutical" means any substance defined as a drug in Section 201(g)(1) of the Federal Food, Drug and Cosmetic Act or in the FDA's Nuclear Pharmacy Guidelines and which exhibits spontaneous disintegration of unstable nuclei with the emission of nuclear particles or photons and includes any such drug which is intended to be made radioactive. This definition includes nuclide generators which are intended to be used in the preparation of any such substance but does not include drugs such as carbon-containing compounds or potassium-containing compounds or potassium-containing salts which contain trace quantities of naturally occurring radionuclides.

"Radiopharmaceutical quality assurance" includes, but is not limited to, the performance of appropriate chemical, biological and physical tests on radiopharmaceuticals and the interpretation of the resulting data to determine their suitability for use in humans and animals, including internal test assessment, authentication of product history and the keeping of proper records.

"Radiopharmaceutical service" includes, but is not limited to, the compounding, dispensing, labeling and delivery of radiopharmaceuticals; the participation in radiopharmaceutical utilization reviews; the proper and safe storage and distribution of radiopharmaceuticals; the maintenance of radiopharmaceutical quality assurance; and the offering of those acts, services, operations or transactions necessary in the conduct, operation, management and control of a nuclear 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.2005 d.25, effective January 18, 2005.
See: 36 N.J.R. 3345(a), 37 N.J.R. 295(a).
Deleted "Direct supervision"; added "Immediate personal supervision".

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.

(b) Nuclear pharmacies shall have adequate space, commensurate with the scope of services required and provided, meeting minimal United States Nuclear Regulatory Commission or its successor's requirements and the requirements established by the State of New Jersey Bureau of Radiation Protection. The nuclear pharmacy shall be separate from the pharmacy areas for non-radioactive drugs and shall be inaccessible to all unauthorized personnel. All pharmacies handling radiopharmaceuticals shall be provided with a radioactive storage and decay area. A nuclear pharmacy dispensing radioactive drugs may be exempted from the general space requirements for pharmacies.

(c) The process used for handling radioactive materials by any license holder must involve appropriate procedures for the purchase, receipt, storage, manipulation, compounding, distribution, and disposal of radioactive materials. In order to ensure the public health, safety, and welfare, a nuclear pharmacy shall first meet the following general requirements:

1. The environment where the handling of radioactive materials takes place shall be properly ventilated so that radioactive materials cannot be airborne from that environment to other non-occupationally unrestricted areas;

2. The environment shall be properly located so that the receipt and dispersal of radioactive materials does not result in inadvertent and undesired contamination of other non-occupationally labeled areas; and

3. The area shall be designed in such a manner that radioactive materials can be contained in given areas to ensure adequate safety and protection to personnel working in or near them and to insure proper operation of the corresponding assay equipment.

(d) Nuclear pharmacies shall maintain records of acquisition and disposition of all radioactive drugs in accordance with rules and regulations of the United States Nuclear Regulatory Commission.

(e) The immediate outer container of a radioactive drug to be dispensed shall be labeled with the following:

1. The standard radiation symbol;

2. The words, "CAUTION—RADIOACTIVE MATERIAL";

3. The radionuclide;

4. The chemical form;

5. The amount of radioactive material contained in millicuries or microcuries;

6. If a liquid, the volume in milliliters;

7. The requested calibration time for the radioactivity contained;

8. The name, address, and telephone number of the nuclear pharmacy;

9. The prescription number; and

10. The date and patient's name, if available.

(f) The immediate container shall be labeled with the following:

1. The standard radiation symbol;

2. The words, "CAUTION—RADIOACTIVE MATERIAL";

3. The name of the radiopharmaceutical.

(g) Nuclear pharmacies shall only dispense radiopharmaceuticals which comply with acceptable professional standards of radiopharmaceutical quality assurance.

(h) A nuclear pharmacist may transfer to authorized persons and United States Nuclear Regulatory Commission licensed medical practitioners radioactive materials not intended for drug use, in accordance with the regulations of the United States Nuclear Regulatory Commission or its successor. A nuclear pharmacy may furnish radiopharmaceuticals to these practitioners for patient use.

(i) Nuclear pharmacies shall comply with all applicable laws and regulations of Federal and State agencies including those laws and regulations governing non-radioactive drugs. For nuclear pharmacies handling radiopharmaceuticals exclusively, the Board of Pharmacy may waive rules pertaining to pharmacy permits for nonradiopharmaceuticals which requirements do not pertain to the practice of nuclear pharmacy.

(j) Radioactive drugs are to be dispensed only upon a non-refillable prescription order from a United States Nuclear Regulatory Commission licensed medical practitioner (or the designated agent) authorized to possess, use and administer radiopharmaceuticals.

(k) Prescription orders for delivery of radioactive drugs for use in the medical practice of a United States Nuclear Regulatory Commission licensed medical practitioner may be placed on a telephone answering and recording device, only if the practitioner (or the designated agent) is identified in such a manner that is clearly recognized by the nuclear pharmacist dispensing the radioactive drug.

(*l*) A qualified nuclear pharmacist shall have the authority to delegate to any qualified and properly trained person or persons, acting under his or her immediate personal supervision, any nuclear pharmacy act which a reasonable and prudent pharmacist would find is within the scope of sound pharmaceutical judgment to delegate. Such delegation may only occur if, in the professional opinion of the qualified nuclear pharmacist, the act may be properly and safely performed by the person to whom the pharmacy act is delegated. The delegated act may only be performed in its customary manner, not in violation of other statutes. The person to whom a nuclear pharmacy act is delegated shall not hold himself or herself out to the public as being authorized to practice pharmacy.

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) and (*l*), substituted "immediate personal" for "direct".

13:39-12.3 General requirements for a nuclear pharmacist

(a) A qualified nuclear pharmacist shall meet the following requirements:

1. He or she is a pharmacist licensed to practice in the State of New Jersey; and

2. He or she meets minimal standards of training and experience in the handling of radioactive materials in accordance with the requirements of the United States Nuclear Regulatory Commission or its successor and the State of New Jersey Bureau of Radiation Protection.

13:39-12.4 Minimum requirements for space, equipment, supplies, and library

(a) Each nuclear pharmacy must meet the following requirements for space:

1. The area for the storage, compounding and dispensing of radioactive drugs shall be completely separate from pharmacy areas for non-radioactive drugs;

2. Hot lab and storage area shall be a minimum of 120 square feet; and

3. The compounding and dispensing area shall be a minimum of 300 square feet.

(b) Each nuclear pharmacy shall be equipped with at least the following items of equipment:

1. Dose calibrator;

2. Refrigerator;

3. Drawing station;

4. Well scintillation counter;

5. Microscope;

6. Chromatographic apparatus or comparable means of effectively assuring tagging efficiency;

7. Radiation survey equipment of the appropriate type and calibration to detect quantities of radioactive materials as prescribed in the appropriate radioactive material licenses; and

8. Other equipment deemed necessary for radiopharmaceutical quality control for products compounded or dispensed as may be determined by the United States Nuclear Regulatory Commission or its successor and the State of New Jersey Bureau of Radiation Protection.

(c) Each nuclear pharmacy shall have on the premises the following, up-to-date reference books:

1. An up-to-date, comprehensive pharmaceutical reference text(s) and suitable reference texts encompassing the general practice of pharmacy, drug interactions, drug product composition and patient counseling. Unabridged computerized versions of these reference texts shall be acceptable;

2. State statutes and rules relating to pharmacy;

3. State and Federal regulations governing the use of applicable radioactive materials; and

4. Text relating to the practice of nuclear pharmacy and radiation safety.

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), rewrote the introductory paragraph and 1.

13:39–12.5 Quality control

The holder of a nuclear pharmacy permit shall be responsible for the radioactive quality control of all drugs, including biologicals, dispensed or manufactured. Radioactive pharmaceutical quality controls include, but are not limited to, the carrying out and interpretation of data resulting from chemical, biological and physical tests on potentially radioactive pharmaceuticals to determine the suitability for use in humans and other animals, including internal test assessment and authentication of product history.