CHAPTER 39

STATE BOARD OF PHARMACY

Authority

N.J.S.A. 45:14–1 et seq.

Source and Effective Date

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).

Executive Order No. 66(1978) Expiration Date

Chapter 39, State Board of Pharmacy, expires on June 16, 1999.

Chapter Historical Note

Chapter 39, State Board of Pharmacy, was filed and became effective prior to September 1, 1969. Chapter 39 was repealed and replaced with new rules by R.1989 d.314, effective June 19, 1989.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 was readopted as R.1994 d.351. See: Source and Effective Date. See also, section annotations.

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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, supportive personnel 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).

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.

"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.

SUBCHAPTER 6. DISPENSING AND ADVERTISING DRUGS

13:39–6.1 Professional judgment in dispensing drugs

(a) 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.

(b) 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 in the absence of a current valid prescription, if, in his or her professional judgment, refusal would endanger the health or welfare of the patient.

1. The pharmacist must first ascertain to the best of his or her ability, by direct communication with the patient, that such a medication or device was prescribed for that patient by order of a licensed practitioner.

2. The pharmacist shall document the communication and require the patient to provide suitable identification and sign a statement attesting to the need before dispensing.

3. A patient's signature is not required for emergency refilling of a previously valid prescription.

13:39–6.2 Prescription prepared, compounded or dispensed by pharmacy externs or interns

A pharmacy intern or extern may prepare, compound or dispense prescriptions only under the direct supervision of a registered pharmacist of this State.

13:39–6.3 (Reserved)

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".

13:39–6.4 Direct supervision of dispensing and compounding

The registered pharmacist supervising the activities of supportive personnel shall be physically present in the compounding/dispensing area and shall be personally responsible for the accuracy of the filled prescription.

13:39–6.5 Restriction on display of prescription legend drugs and controlled dangerous substances

Prescription legend drugs, devices and controlled dangerous substances shall not be displayed in the licensed establishment in such a manner that they can be accessible to the public.

13:39–6.6 Foreign prescriptions

Only those prescriptions written or signed by an authorized prescriber licensed to write prescriptions in the United States, District of Columbia, or any territory of the United States shall be considered valid prescription orders.

Amended by R.1994 d.351, effective July 18, 1994.
See: 26 N.J.R. 1596(a), 26 N.J.R. 2905(b).

13:39–6.7 Supportive personnel

(a) Supportive personnel may assist the registered pharmacist in a clerical manner such as the retrieving of prescription files, profile cards, and other such records, the typing of labels and the completing of prescription receipts and other such forms.

(b) Supportive personnel shall not interpret a prescription order or consult with a patient or prescriber or the agent of the prescriber. Supportive personnel may, however, count, weigh, measure, or pour prescription medication under the direct supervision of the registered pharmacist as long as the contents and finished-product are verified by a registered pharmacist.

(c) There shall be no more than two supportive personnel, not including cashier, stocking and clerical help, being supervised by one pharmacist at any given time. Those personnel who do computer processing of prescriptions are to be included in the 2 to 1 ratio.

(d) Supportive personnel shall wear an identification tag, which shall include at least their first name, the first initial of their last name, and title.

(e) On yearly pharmacy permit renewal applications, the pharmacy shall list the name and address of all supportive personnel which it currently employs.

(f) When supportive personnel are engaged in any activity permitted by (b) above, the registered pharmacist in charge shall be responsible for all the activities of the supportive personnel.

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).
Added (d) through (f).

13:39–6.8 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 quota-

tions 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 be required to give price information 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. No advertisement shall rely in any way on techniques to obtain attention that demonstrate a clear and intentional lack of relevance to the selection of professional services.

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.

13:39–6.9 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).

SUBCHAPTER 7. PHARMACY FACILITY AND RECORDS

13:39–7.1 Retail pharmacy access and egress

Retail pharmacies shall be required to maintain entrances which are easily and safely accessible to the general public. Access to and egress from the pharmacy shall not be such that the public must traverse or traffic through any enterprise in which prescriptions are generated.

13:39–7.2 Retail pharmacy signs

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

13:39–7.3 Spatial requirement of a retail pharmacy prescription area

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

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

13:39–7.4 Prescription counter

There shall be a prescription counter on which to work, and the free working space shall not be less than 18 inches in width and not less than 12 continuous feet in length. This minimum working surface must be kept clear at all times for the compounding of prescriptions and other pharmaceutical manufacturing.

13:39–7.5 Prescription area sink

An adequate sink with hot and cold running water shall be provided in the prescription area of retail and institutional pharmacies, easily accessible to the prescription counter. A similarly equipped sink must be easily accessible to institutional satellite pharmacies as well as institutional and retail pharmacy intravenous admixture rooms.

13:39–7.6 Storage and adequate stock

There shall be sufficient shelf, drawer or cabinet space within the prescription area for proper storage of a representative stock of prescription labels, an assorted stock of prescription containers, an adequate stock of prescription drugs and chemicals and the required equipment.

13:39–7.7 Minimum equipment and facilities

(a) The following minimum amount of equipment and facilities shall be required to be in every prescription area, and this equipment shall be stored so as to be readily accessible and shall be kept in a clean condition:

1. The current USP DI and supplements and suitable current reference texts encompassing the general practice of pharmacy, drug interactions and drug product composition. Unabridged computerized versions of these reference texts shall be acceptable;
2. Over the counter Schedule V Record Book;
3. Permanent prescription filing device and patient profile record system;
4. Properly safeguarded storage place for Schedule II controlled substances if not dispersed;
5. Class A prescription balance;
6. Set of metric weights;
7. Devices capable of measuring 0.3 ml to 500 ml;
8. A glass mortar and pestle;
9. Glass funnels;
10. Stirring rods;
11. A steel spatula and a spatula of rubber or composition;
12. Ointment tile or parchment paper;
13. Refrigerator;
14. Suitable counting trays or approved counting device;
15. Labels, upon dispensing to contain the name of the registered pharmacist-in-charge, and the address and telephone number of the pharmacy;
16. Auxiliary labels, including poison labels;
17. Suppository mold; and
18. Two Drug Utilization Review Council Placards and the current Drug Utilization Review Council Formulary.

Amended by R.1994 d.351, effective July 18, 1994.
See: 26 N.J.R. 1596(a), 26 N.J.R. 2905(b).

Cross References

Reference materials, sterile admixture service, see also N.J.A.C. 13:39–11.16.

13:39–7.8 Cleanliness, orderliness and sanitation

The entire prescription area shall at all times be kept in a clean, orderly and sanitary condition.

13:39–7.9 Television in prescription area prohibited

No commercial television, other than for security measures, may be operated in a prescription area or in any location outside of a prescription area such that its operation may be viewed from the prescription area.

13:39–7.10 Return of prescription medication

No prescription medication shall be placed in stock for reuse or resale which has been returned after leaving the pharmacy, except as provided in N.J.A.C. 13:39–9.6(a)13ii.

13:39–7.11 Prescription balances, scales, weights and automatic counting devices

All pharmacies shall prove to the satisfaction of the Board that all balances, scales, weights and automatic counting devices have been annually inspected by the Department of Weights and Measures of the municipality or county in which such pharmacy, drugstore, or other Board-licensed

establishment is located, and that such balances, scales, weights and automatic counting devices have been 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).

13:39–7.12 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.

13:39–7.13 Outdated drugs or drugs marked "sample"

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

13:39–7.14 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, including any failure of the patient to accept the pharmacist's offer to counsel.

(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.

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 must be maintained for a period of not less than five years from the date of the last entry in the profile record. The oldest four years of record information shall be maintained in such a manner so as to be sight-readable within two weeks. The most recent one year of a record information must be immediately retrievable.

(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).

SUBCHAPTER 8. INTERNSHIPS; EXTERNSHIPS; APPROVED TRAINING SITES

13:39–8.1 Definitions

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

"Approved training site" means a site approved by the Board to provide accredited practical experience to pharmacy interns or externs.

"Certified preceptor" means a pharmacist registered in this State who assumes the responsibility to supervise and tutor a pharmacy intern or extern as outlined in N.J.A.C. 13:39–8.2.

"Pharmacy intern" means any person who has graduated from an accredited school or college of pharmacy approved by the Board, or if a foreign pharmacy graduate, any person who has met all of the requirements of the National Association of Boards of Pharmacy Foreign Pharmacy Graduate Examination Commission in order to qualify to take the National Association of Boards of Pharmacy Licensing Examination (NABPLEX), who is employed in an approved training pharmacy for the purpose of acquiring accredited practical experience and who has first registered for said purposes with the Board.

"Pharmacy extern" means any person who is in the fifth or sixth college year (or third or fourth professional year) at an accredited school or college of pharmacy approved by the Board who is assigned to an approved training site for the purpose of acquiring accredited practical experience under the supervision of the school or college at which he or she is enrolled.

"Pharmacy internship or externship" shall mean the program of acquiring practical experience by a pharmacy intern or extern respectively.

Amended by R.1994 d.351, effective July 18, 1994.
See: 26 N.J.R. 1596(a), 26 N.J.R. 2905(b).

13:39–8.2 Preceptor certification application; procedures; responsibilities

(a) A registered pharmacist who wishes to be a certified preceptor shall make application to the Board upon such form as shall be prescribed and shall furnish evidence satisfactory to the Board that he or she:

1. Has been registered and employed as a pharmacist on a full-time basis for at least two years in the State of New Jersey;

2. Has been engaged in the compounding and dispensing of pharmaceutical preparations and prescriptions and the supplying of drug products in a registered pharmacy for a period of at least two years, one year of which must have been immediately prior to the beginning of any pharmacy internship he or she is to supervise;

3. Has a record of law observance deemed satisfactory by the Board; and

4. Has attended professional meetings or preceptor training conferences as may be designated by the Board.

(b) The Board shall assign a certified preceptor to each pharmacy intern. At no time may one certified preceptor supervise the training of more than one pharmacy intern. The Board reserves the right to determine the suitability of pharmacists to serve as preceptors.

(c) The certified preceptor in an approved training pharmacy must indicate a willingness to cooperate with the Board in developing pharmacy intern or extern training and shall report to the Board from time to time as requested by the Board on the progress and aptitude of any pharmacy intern or extern under his or her supervision.

(d) The compounding and dispensing of all prescriptions and drugs by the pharmacy intern or extern must be done under the direct supervision of a registered pharmacist.

(e) The certified preceptor is charged with the responsibility for the following:

1. Supervising the activities of the pharmacy intern or extern and ensuring that the intern or extern will keep abreast of developments in pharmacy by reading current professional literature and journals and by attending seminars and meetings of professional and scientific organizations;

2. Providing the pharmacy intern or extern with experiences that will make the intern or extern proficient in compounding and dispensing of pharmaceutical preparations, drug products, health aids and related items;

3. Providing the pharmacy intern or extern with instruction and guidance in:

i. Procedure for opening and closing a pharmacy;

ii. General pharmacy operation;

iii. Ordering drugs and checking drug orders;

iv. Over the counter preparation, including their composition and consultation with consumers;

v. Drug Enforcement Administration inventory and preparation of Drug Enforcement Administration orders;

vi. Sale of Drug Enforcement Administration Schedule V preparations and sale of poisons;

vii. Third-party prescriptions programs;

viii. Telephone procedure with prescribers and patients;

ix. Consulting with prescribers and patients; and

x. Usage of reference books in the pharmacy and reference material from other sources;

4. Arranging an interview with a physician or other authorized prescriber for the intern or extern; and

5. Preparing the intern or extern in any other area of pharmacy important to good management and professional practice.

Amended by R.1994 d.351, effective July 18, 1994.
See: 26 N.J.R. 1596(a), 26 N.J.R. 2905(b).

13:39–8.3 Training pharmacy approval

(a) To be approved as a training pharmacy for interns and externs, a pharmacy shall meet the following requirements:

1. Have a satisfactory record of observance of Federal, state and municipal laws and ordinances governing the activity in which it is or has been engaged.

2. Have a total number of prescriptions or medication orders filled annually, including renewals, of at least 20,000, with no more than one pharmacy intern or extern in training for each 20,000 prescriptions filled in the pharmacy.

3. Establish and maintain as part of the service it renders, a medication recordkeeping system for its patients that is approved by the Board.

4. Have available an adequate reference library for use by the pharmacy intern or extern.

Amended by R.1994 d.351, effective July 18, 1994.
See: 26 N.J.R. 1596(a), 26 N.J.R. 2905(b).

13:39–8.4 Internship and externship practical experience

(a) The minimum accredited internship and externship practical experience requirement shall be the equivalent of 1,000 hours as follows:

1. One thousand hours for completion of a structured internship conducted after graduation from an accredited college of pharmacy and consisting of no less than 24 weeks supervised by a certified preceptor. Each week of practical experience shall consist of no less than 20 hours and no more than 45 hours of actual service per week. If the intern is a foreign pharmacy graduate, he or she must have met all of the requirements of the National Association of Board of Pharmacy Foreign Pharmacy Graduate Examination Commission.

2. The preceptor and the pharmacy intern shall keep accurate records of the time spent by the pharmacy intern for credit toward the requirements of (a)1 above. The Board shall provide appropriate forms to be submitted to the Board for approval of postgraduate practical experience.

3. No credit shall be given for hours served as an intern prior to the Board's receipt of the written application.

(b) In lieu of the requirements set forth in (a)1 above, an applicant may obtain up to 1,000 hours practical experience by completion of a structured, college-credited externship and clinical pharmacy clerkship program of an accredited college of pharmacy. Such programs shall first be approved by the Board.

(c) In cases of a structured, college-credited externship and clinical pharmacy clerkship program, where less than 1,000 hours are accepted and approved by the Board, the balance of hours to make a total of 1,000 must be gained through completion of a structured internship, conducted after graduation from an accredited college of pharmacy and supervised by a certified preceptor with each week of practical experience consisting of no less than 35 hours and no more than 45 hours of actual service per week.

(d) A Board-approved college of pharmacy externship program shall provide that no less than 75 percent of the hours credited toward the practical experience requirement of the Board be gained in settings in which there is direct involvement with consumers or patients, registered pharmacists, and other licensed health care practitioners such as physicians, dentists and nurses. No less than 50 percent of the hours credited toward the practical experience requirement of the Board shall be acquired in an approved training pharmacy under the supervision of a certified preceptor. Not more than 40 hours of Board-accredited experience shall be acquired per week.

(e) Credit for college externships or other experience programs shall not be allowed for experience gained prior to the fifth college year (or third professional year) in the college of pharmacy program.

(f) The pharmacy college shall certify that the requirements of (b) above have been met. The Board shall provide appropriate forms for such certification.

Amended by R.1994 d.351, effective July 18, 1994.
See: 26 N.J.R. 1596(a), 26 N.J.R. 2905(b).

13:39–8.5 Change in intern status

A pharmacy intern applying for registration as a pharmacist in the State of New Jersey shall notify the Board within 10 days of any change in:

1. Beginning of a term of internship;

2. Termination of an internship;

3. Number of hours of employment;

4. Scheduled hours of employment;

5. Preceptor; and/or

6. Employing pharmacy.

Amended by R.1994 d.351, effective July 18, 1994.
See: 26 N.J.R. 1596(a), 26 N.J.R. 2905(b).

13:39–8.6 Committee on Pharmacy Internship and Externship

(a) A Committee on Pharmacy Internship and Externship shall be established which shall consist of:

1. Two members of the Board of Pharmacy;

2. Two faculty members of the College of Pharmacy of Rutgers, the State University of New Jersey;

3. Two fifth or sixth year pharmacy students from the College of Pharmacy of Rutgers, the State University of New Jersey; and

4. Four approved pharmacy preceptors, one of whom shall be a practicing pharmacist in an independent pharmacy, one of whom shall be a practicing pharmacist in a chain pharmacy, one of whom shall be a practicing pharmacist in an institution, and one of whom shall be a registered pharmacist whose primary employment is in the pharmaceutical manufacturing industry.

(b) The Committee is established to advise and assist the Board in all matters relating to the pharmacy internship/externship program.

(c) All meetings of the Committee shall be held in accordance with the Open Public Meetings Act, N.J.S.A. 10:4–6 et seq.

(d) All members of the Committee shall be approved by the Board. The President of the Board shall designate a member of the Board to be the chairperson of the Committee.

13:39–8.7 Pharmacist intern log

(a) Pharmacist interns shall maintain a log for the internship period which meets the following requirements:

1. The log shall consist of an 8 by 11 inch looseleaf notebook.

2. Entries shall be made in the log weekly and shall contain:

i. The total number of prescriptions filled in the pharmacy and the number filled by the intern;

ii. A brief summary of all new prescription drug products (new generic entities only) dispensed, such as

physical-chemical characteristics, dosage, forms, and usage;

iii. One example of each of the following professional responsibilities:

(1) The use of the patient profile record requiring contact with patient, prescriber or hospital to resolve potential problems;

(2) Consultation with the patient or prescriber concerning special instructions regarding the use of medications;

(3) In a retail setting, consultation with the patient concerning over the counter medication; and

iv. The preceptor's report.

(b) The log shall be submitted to the Board at the completion of the internship period.

Amended by R.1994 d.351, effective July 18, 1994.
See: 26 N.J.R. 1596(a), 26 N.J.R. 2905(b).

SUBCHAPTER 9. PHARMACEUTICAL SERVICES WITHIN HEALTH CARE FACILITIES

13:39–9.1 Definitions

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

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

"Direct supervision" means that the registered pharmacist shall be physically present in the compounding/dispensing area where the supportive personnel are performing delegated duties, and shall conduct in-process and final checks of all steps in preparation, compounding, and dispensing drugs. This supervision shall include, but is not limited to, the checking of each ingredient used, the quantity of each ingredient whether weighed, measured or counted, and the finished label.

"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 place where the sick and injured are cared for under a common roof such as hospitals; long term care facilities; and establishments similar to those delineated in N.J.S.A. 45:14–32.

"Institutional pharmacy" means the area in the health care facility licensed by the Board as a pharmacy that maintains an institutional permit. This area shall include, but is not limited to, other areas of the health care facility where pharmaceuticals are stored, manufactured, compounded and 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 and pharmacy staff and which acts to review and promote rational drug therapy and utilization in the facility. Its organization and function are described under N.J.A.C. 13:39–9.11.

"Unit dose drug distribution system" means a system of dispensing drugs and biologicals 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.

Amended by R.1994 d.351, effective July 18, 1994.
See: 26 N.J.R. 1596(a), 26 N.J.R. 2905(b).

13:39–9.2 Licensure of institutional pharmacies

Any institutional pharmacy as defined under N.J.A.C. 13:39–9.1 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.