13:39–8.3 Pharmacy training site requirements

(a) To serve as a training site for interns, 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 a reference library for use by the pharmacy intern.

(b) Notwithstanding the provisions of (a) above, a pharmacy which does not dispense medications but which serves as a pharmacy training site shall not be required to satisfy the requirements of (a)2 and 3 above.

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), rewrote the introductory paragraph and 4; and added (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 certified 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 shall 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 20 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 under the supervision of a certified or faculty preceptor. Not more than 45 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).
Amended by R.1998 d.167, effective April 6, 1998.
See: 29 N.J.R. 4740(b), 30 N.J.R. 1298(a).
In (d), deleted language regarding practical experience hours in an approved training pharmacy.
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)2, substituted a reference to certified preceptors for a reference to preceptors; in (c), substituted "20 hours" for "35 hours" following "less than"; and in (d), inserted a reference to faculty preceptors in the first sentence, and substituted "40 hours" for "45 hours" in the last sentence.

13:39–8.5 Change in intern status

(a) 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. Certified 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).

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)5, substituted a reference to certified preceptors for a reference to preceptors.

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 certified 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) The President of the Board shall designate a member of the Board to be the chairperson of the Committee.

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)4, substituted a reference to certified preceptors for a reference to preceptors; deleted a former (c); and recodified former (d) as (c), and deleted a former first sentence.

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 or medication orders 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. Three examples 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;

iv. The certified preceptor's report;

v. Any atypical prescriptions compounded;

vi. Any change in status of any over the counter product;

vii. Any revision or addition in any Federal law or regulation or in New Jersey law or regulation concerning the practice of pharmacy;

viii. Any products or particular compounds removed from the market; and

ix. Any changes in product formulation.

(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).
Amended by R.1998 d.167, effective April 6, 1998.
See: 29 N.J.R. 4740(b), 30 N.J.R. 1298(a).
In (a)2iii, substituted "Three examples" for "One example".
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)2, inserted a reference to medication orders in i, substituted a reference to certified preceptors for a reference to preceptors in iv, and added v through ix.

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:

"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 patients and/or residents 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. 13:39–9.20.

"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 dose:

1. Product name;
2. Strength;
3. Lot number;
4. Beyond use date; and
5. Manufacturer or repackager.

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".

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.

13:39–9.3 Control of institutional pharmaceutical services

(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.

(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 institution, it may enter into an agreement with a pharmacy licensed by the Board. The registered pharmacist-in-charge of that pharmacy and the designated pharmacist of the institution, if appropriate, shall direct, control, supervise and be responsible for the pharmaceutical services provided to the facility.

(c) The registered pharmacist-in-charge, 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.

13:39–9.4 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).

13:39–9.5 Pharmaceuticals

(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 approved 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, emergency and disaster drug therapy;

(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. 13:39–5.4. 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.

(e) The pharmacist-in-charge shall establish a system of control for all drugs dispensed for use in the drug therapy of patients of the facility. Inspections shall be conducted of all medication areas located in the facility or any other service of the facility. These inspections shall be fully documented. Written inspection reports shall be prepared and signed by the inspecting pharmacist or by supportive personnel and co-signed by the supervising pharmacist. The pharmacist-in-charge shall be responsible for ensuring that, prior to performing any inspections pursuant to this subsection, supportive personnel are trained and can successfully demonstrate competency. Procedures for the review of these reports shall be developed and instituted by the pharmacist-in-charge and can be incorporated into the overall quality assurance program of the hospital.

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.

13:39–9.6 Drug disbursement; written orders; outpatient prescriptions

(a) The pharmacist shall review the prescriber's original order, a direct copy thereof, or an electro-mechanical facsimile before any initial dose of medication is dispensed, except as provided for in N.J.A.C. 13:39–9.9.

(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) Orders involving abbreviations and chemical symbols shall be carried out only if the abbreviations and symbols are included on a standard list that has been approved by the medical staff.

(d) When appropriate, the pharmacist shall make necessary entries into the patient medical record relative to drug use after consultation with the prescriber.

(e) Prescriptions written for employees of the institution or their dependents, or for outpatients of the facility's clinic, shall conform to the prescription requirements of N.J.S.A. 45:14–14.

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

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).

13:39–9.7 Drug disbursement; oral orders

(a) The mandatory requirements 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 prescriber's 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 medication for out-patient use pursuant to labelling 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. 13:39–7.14; 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).