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Chapter 39, State Board of Pharmacy, was repealed and adopted as new rules by R.1989 d.314, effective June 19, 1989.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: 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.

(b) Presentation of a prescription label or a prescription marked "COPY—FOR INFORMATION ONLY" shall be for information purposes only and have no legal status as a valid prescription order. The recipient pharmacist of such copy or prescription label shall contact the prescribing practitioner or transferor pharmacy and obtain all information required by (c)2 below for authorization to dispense the prescription, which is the same as obtaining an original prescription order.

(c) A copy of a prescription may be transferred by telephone or electronic transfer by pharmacists between pharmacies for the purpose of refill dispensing provided that:

1. The transferor pharmacist invalidates the prescription on file as of the date the copy is transferred by writing "VOID" on its face, and records on the back of the invalidated prescription order that a copy has been issued, the date of issuance of such copy, to which pharmacy and pharmacist, and the initials of the pharmacist issuing the transferred prescription order.

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

i. The name, address and original prescription number of the pharmacy from which the prescription was transferred;

ii. The name of the transferor pharmacist;

iii. All information constituting a prescription order, including the following:

(1) Date of issuance of original prescription;

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

(3) Complete refill record from original prescription;

(4) Date of original dispensing;

(5) Number of valid refills remaining.

3. The transferee pharmacist informs the patient that the original prescription has been cancelled at the pharmacy from which it was obtained.

(d) When a copy of a prescription is issued by telephone, refill authorizations shall be cancelled on the original prescription and the fact that a copy has been issued shall be noted on the original prescription along with the date the copy was issued. Two or more permit holders may establish a common electronic filing system to maintain required dispensing information and the required documentation, pursuant to N.J.A.C. 13:39–5.6.

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.

13:39–5.6 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 or extern shall place his or her signature or readily identifiable initials on the face of the original prescription. In using an electronic data processing system, the initials of the pharmacist responsible for the filled prescription shall also be recorded.

(b) A registered pharmacist who refills a prescription shall place his or her signature or readily identifiable initials on the reverse side of the original prescription next to the date of the refill and the amount dispensed in refilling the prescription if it is different from the original amount prescribed. In using an electronic data processing system, the identical refill information shall also be recorded.

(c) A record identifying such initials with the signature and name and address of the pharmacist shall be maintained for a period of five years after the termination of employment of said pharmacist.

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

(e) Except when they are kept in a separate file, prescriptions for all controlled substances listed in schedules III, IV and V shall be stamped in red ink in the lower right corner with the letter "C" no less than one-inch high.

(f) Prescriptions for all controlled substances listed in schedules III, IV and V shall be maintained in a single file separate from all other prescriptions, unless an electronic data processing system is utilized which meets the requirements of (i) below. If such an electronic data processing system is utilized, prescriptions for all substances listed in schedules III, IV and V shall be filed either in the prescription file for controlled substances listed in schedule II or in the usual consecutively numbered prescription file for non-controlled substances.

(g) If an electronic data processing system is utilized in connection with the dispensing of medication and the required recording of prescription information, a means acceptable to the Board shall be utilized to identify the pharmacist or intern or extern dispensing the medication.

(h) In using an electronic data processing system, the pharmacist in charge shall maintain a document log. The document log shall be maintained at the pharmacy for a period of five years after the date of the last entry. The five years of record information, including refills, shall be kept in such a manner as to be sight-readable within two weeks. The most recent one year of record information shall be immediately retrievable.

(i) In using an electronic data processing system, the system shall have the capability of producing sight-readable

documents of all original and refilled prescription data, and, in addition, the number of refills authorized by the prescriber for a period of not less than five years. Five 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 record information shall be immediately reviewable on-line and available in printed form within three business days. The term "sight-readable", as it appears in all rules of the Board, shall mean that the Board or Attorney General shall be able to examine and read the record of information. During the course of an on-site inspection, the record may be read from a cathode ray tube (CRT), microfiche, microfilm, hard copy printout or other Board acceptable method. For the purpose of administrative proceedings before the Board, records shall be provided in a paper printout form.

(j) Initials and/or access code number(s) of the dispensing pharmacist and intern or extern, if applicable, 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 dispensing pharmacist at the time of dispensing are prohibited.

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).

13:39–5.7 Availability of records upon termination of business

(a) Where 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.

13:39–5.8 Prescriptions and medication orders transmitted by technological devices

(a) A pharmacist may, subject to the conditions set forth in this section, accept for dispensing a prescription or a medication order transmitted by a facsimile (FAX) machine or other technological device as approved by the Board.

(b) A registered pharmacist at a retail pharmacy and a registered pharmacist filling prescriptions under an institutional permit for employees of the institution and their dependents and 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, may accept for dispensing prescriptions for all substances other than Schedule II controlled dangerous substances which have been transmitted by technological device, under the following conditions only:

1. Before releasing to other than an in-patient of a health care facility, as defined in N.J.A.C. 13:39–9.1, any prescription medication for a controlled dangerous substance listed in Schedules III, IV or V, the pharmacist shall obtain and file the original signed prescription.

2. The pharmacist shall, within 24 hours, reduce to hard copy, that is, record in his or her handwriting or enter into a computer, all prescriptions received by technological device other than prescriptions for Schedules III, IV and V controlled dangerous substances and shall place the copy in the permanent prescription file records.

(c) A registered pharmacist who is authorized to fill in-patient medication orders, as defined in N.J.A.C. 13:39–9.1, in an institutional pharmacy may accept all in-patient medication orders, including orders for Schedule II substances, which have been transmitted by technological device.

(d) Whenever a pharmacist has reason to question the accuracy or authenticity of a prescription or medication order transmitted by technological device, the pharmacist shall verify the transmission directly with the prescribing practitioner.

(e) It shall be deemed professional misconduct for a pharmacist to use a technological device in order to circumvent his or her responsibilities with regard to documenting, authenticating and verifying medication orders and prescriptions or in order to circumvent other standards of pharmacy practice.

(f) No licensee or permit holder registered under N.J.S.A. 45:14–1 et seq. shall under any circumstances provide a technological device to, or accept a technological device from, any practitioner licensed to write prescriptions.

(g) No licensee or permit holder shall enter into any agreement with an authorized practitioner which denies the patient the right to have his or her prescription transmitted by technological device to a pharmacy of the patient's choice.

New Rule, R.1992 d.166, effective April 6, 1992.
See: 23 N.J.R. 2469(a), 24 N.J.R. 1371(a).

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. 13:39–9.15(a)2.

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.

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.

"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 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).
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.

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 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 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 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).

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 by a pharmacist 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. 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).

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 as required by 42 CFR 463.

(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).
Inserted new (a); recodified existing (a) through (c) as (b) through (d); and added (e).

13:39–9.8 Compounding

(a) Compounding of individual medication orders or prescriptions, the formulation of special drug needs and all bulk compounding (sterile or non-sterile) shall be done by or under the direct supervision of a pharmacist.

(b) Asceptic control procedures shall be maintained for the preparation of intravenous admixtures, the reconstitution of other sterile parenteral preparations, and the compounding and sterilization of other pharmaceutical products as needed.

(c) All prepackaging and labeling of drugs shall be done by or under the direct supervision of a pharmacist. Procedures shall be established for maintaining the integrity and manufacturer's control identity of prepackaged material. The prepackaging records shall be initialed by the supervising pharmacist.

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).

13:39–9.9 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).

13:39–9.10 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).

13:39–9.11 Drug labeling

(a) Whenever drugs are added to intravenous solutions, supplementary labeling shall be affixed to the container indicating the names and amounts of all ingredients, the name and location of the patient, the date and time of expiration and the initials of the supervising or dispensing pharmacist.

(b) 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. Dispensing and labeling of outpatient prescriptions shall conform to N.J.S.A. 45:14–14.

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).

13:39–9.12 Use of patient's own medication

(a) No drugs shall be administered to a patient except those provided through the pharmacy. Any exception to this rule must be governed by written policies and procedures developed by the pharmacist-in-charge 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).

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).

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.

13:39–11.11 Information required to appear on prescription label

(a) The dispensed container for any sterile admixture product shall bear a permanently affixed label with at least the following information:

1. The date and 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 of the base solution;

6. The name and quantity of drug(s) added;

7. The name or identifying code of the pharmacist who checked or prepared the sterile admixture product;

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

9. The pharmacy's Drug Enforcement Administration (DEA) number, if the sterile admixture product contains any controlled dangerous substances;

10. The expiration date and time of the sterile admixture product (If no time is stated, it is presumed to be 11:59 P.M. of the stated expiration date);

11. Any ancillary and cautionary instructions as needed;

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

13. 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.

13:39–11.12 Expiration date of sterile preparation

(a) The expiration date of a sterile admixture product shall be 24 hours or as otherwise stated by the manufacturer or current literature at the time of preparation.

(b) Any expiration date that extends beyond 24 hours or the manufacturer's expiration date shall be substantiated by documentation satisfactory to the Board.

(c) In an institutional pharmacy, any sterile admixture product which is prepared under the pharmacy's control in a class 100 laminar air flow hood which is in an environment which meets the requirements of N.J.A.C. 13:39–11.23, 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 product 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 product 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 class 100 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.

13:39–11.13 Handling, packaging and delivery

(a) The pharmacy shall be responsible for the proper handling and packaging of compounded sterile preparations for delivery from the pharmacy to the patient in order to assure and maintain sterility and stability of these preparations. To ensure the integrity and efficacy of compounded sterile admixture products, 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.

13:39–11.14 Policy and procedure manual

(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 sterile admixture services.

(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 sterile admixture 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. 13:39–7.7 and 11.25;

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. 13:39–11.16;

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

9. A quality assurance program as set forth in N.J.A.C. 13:39–11.15;

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. 13:39–11.10;

13. Description of appropriate garb;

14. Conduct guidelines for personnel in the controlled areas;

15. Personnel responsibilities;

16. Patient education (retail patients); and

17. Protocol and procedures to maintain the integrity of the interior work area of the laminar air flow hoods.

(c) The pharmacist in charge shall review and, if necessary, amend the policy and procedure manual on at least an annual basis. Documentation of the annual review shall be made available to the Board upon request.

Recodified from N.J.A.C. 13:39–11.8 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 (b). Former N.J.A.C. 13:39–11.14, Controlled environment: maintenance and supplies, was recodified to N.J.A.C. 13:39–11.19(c) through (e).

13:39–11.15 Quality assurance program

(a) This section shall apply both to commercially available sterile drug products that are dispensed to patients without compounding or other manipulation, and to sterile admixture products, which, prior to dispensing, have been in any way repackaged, reconstituted, diluted, admixed, blended, or otherwise manipulated (collectively referred to as "compounded").

(b) The dispensing pharmacist shall ensure that the sterile admixture product retains its quality attributes within acceptable limits through a written quality assurance program. The quality assurance program shall require at least that:

1. A reasonable effort shall be made by the dispensing pharmacist to assure that sterile admixture products shall be kept under appropriate controlled conditions at the location of use by providing adequate labeling and verbal or written instructions regarding proper storage and administration as set forth by the product manufacturer, with each sterile admixture product dispensed;

2. The quality assurance program encompasses all phases of sterile admixture product preparation, distribution, storage, administration, and directions for use for each type of product dispensed;

3. All compounding processes representative of all types of manipulations, products and batches must be sterile tested and validated at least every 12 months.

4. Air and surface sampling for microbial organisms in class 100 laminar air flow hoods and class 1,000 clean rooms is done twice annually and at any time when microbial contamination is suspected pursuant to United States Pharmacopoeia/National Formulary guidelines;

5. Laminar air flow hoods shall be certified every six months by an independent certification company;

6. The class 1,000 clean room and class 10,000 anteroom shall be certified every six months by an independent certification company; and

7. All unused drugs and materials used in the preparation of sterile admixture products, including antineoplastic agents, are disposed of properly in accordance with accepted professional standards and applicable laws, including the Medical Waste Act (N.J.S.A. 13:1E–48.1 et seq., P.L. 1989, c.34).

Recodified from N.J.A.C. 13:39–11.9 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), substituted "sterile" for "injectable" following "available"; and rewrote (b). Former N.J.A.C. 13:39–11.15, Clean room, was recodified to N.J.A.C. 13:39–11.20.

13:39–11.16 Patient profile records

(a) The pharmacist in charge shall ensure that a patient profile record is maintained and monitored for each patient. The patient profile record shall include, but is not limited to, the following:

1. Available medical information consistent with N.J.A.C. 13:39–7.14; and

2. All medication orders for institutional patients.

(b) The pharmacist in charge shall ensure that a reasonable, documented attempt is made to include in the record over-the-counter and home remedies used by noninstitutional patients.

(c) The pharmacist in charge shall ensure that initial and ongoing multidisciplinary clinical monitoring and comprehensive care plans are maintained and readily available.

Recodified from N.J.A.C. 13:39–11.10 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 (a) and (b) and inserted a new (c). Former N.J.A.C. 13:39–11.16, Anteroom, was recodified to N.J.A.C. 13:39–11.21.

13:39–11.17 Controlled environment: use, access, location; temperature

(a) The pharmacy shall have a designated area for sterile product preparation, known as the "controlled environment," consisting of a clean room and an anteroom unless the pharmacy meets the requirements of N.J.A.C. 13:39–11.23 or 11.24.

(b) A controlled environment shall be:

1. Accessible only to designated personnel;

2. Used only for the preparation of sterile products, or such other tasks that require a controlled environment;

3. Structurally isolated from other areas within the pharmacy by means of restricted entry or access; and

4. Air conditioned to maintain a temperature of 59 to 77 degrees Fahrenheit.

Recodified from N.J.A.C. 13:39–11.11 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 (a); and in (b), substituted "sterile" for "parenteral" in 2 and added a new 4.

13:39–11.18 Controlled environment: construction

(a) The surfaces of ceilings, walls, floors, fixtures, shelving, counters, and cabinets in the controlled environment shall be smooth, impervious, free from cracks and crevices, and nonshedding, thereby minimizing spaces in which microorganisms and other contaminants may accumulate.

(b) All surfaces shall be resistant to damage from sanitizing agents.

(c) Junctures where ceilings meet wall shall be covered, caulked or sealed to avoid cracks and crevices where dirt can accumulate.

(d) Ceilings which consist of inlaid panels shall be impregnated with a polymer to render them impervious and hydrophobic, and shall also be caulked around each perimeter to seal them to the support frame.

(e) Solid walls shall consist either of panels locked together and sealed, or of epoxy-coated gypsum board.

(f) Floors shall have vinyl floor covering and shall be seamless or have heat-welded seams and coving to the sidewall.

(g) There shall be no dust-collection overhangs (such as ceiling utility pipes) or ledges (such as window sills). All sprinkler heads shall be flush with the ceiling.

(h) Ceiling lighting fixtures shall have exterior lens surfaces which are smooth, mounted flush, and air tight.

(i) All areas in ceilings and walls where the surface has been penetrated shall be sealed.

(j) Any clean room construction other than that specified in (a) through (i) above (for example, softwall, prefabricated, modular, portable clean rooms) shall be approved by the Board prior to installation and use.

Recodified from N.J.A.C. 13:39–11.12 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 (b), inserted "damage from"; in (e), substituted "Solid walls" for "Walls"; rewrote (g) and (i); and added a new (j).

13:39–11.19 Controlled environment: stocking, maintenance and supplies

(a) The controlled environment shall contain only the following:

1. Items such as furniture, equipment, supplies, and other goods which are required for the tasks to be performed there;

2. Items which are nonpermeable, nonshedding, and resistant to disinfectants; and

3. Items which have been cleaned and sanitized immediately prior to their being placed in the clean room.

(b) Whenever possible, equipment and other items used in the controlled environment should not be taken from these rooms except for calibration, servicing, or other activity associated with the proper maintenance of the item.

(c) The controlled environment shall be kept clean and arranged in an orderly fashion. All required equipment shall be maintained in good operating condition.

(d) The controlled environment shall not be used for bulk storage, warehousing, or clerical and secretarial functions.

(e) The controlled environment area shall contain the following supplies:

1. Gloves, masks, gowns, and other personal protective equipment;

2. Needles and syringes of various sizes;

3. Disinfectant cleaning agents;

4. Clean towels;

5. Hand-washing materials, including antimicrobial skin cleaner; and

6. Any and all supplies necessary for the aseptic preparation of sterile admixture products.

Recodified from N.J.A.C. 13:39–11.13 and 13:39–11.14 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 (a)3.

13:39–11.20 Controlled environment: clean room

(a) The clean room shall contain no sinks or floor drains.

(b) Work surfaces shall be constructed of smooth, impervious materials, such as stainless steel or molded plastic, so that the work surfaces may be readily cleaned and sanitized.

(c) The clean room shall be a minimum of 100 square feet in size and shall be compatible with the volume of compounding being conducted.

(d) Appropriate environmental control devices capable of maintaining class 1,000 air-quality conditions during normal activity shall be in place.

(e) The clean room shall contain the following equipment:

1. A laminar airflow hood or suitable HEPA filter system;

2. Waste containers in compliance with Occupational Safety and Health Administration (OSHA) standards for used needles and syringes, and for chemotherapy waste; and

3. Ancillary supplies required for proper compounding.

Recodified from N.J.A.C. 13:39–11.15 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 (d); and in (e), deleted former 2 and recodified former 3 and 4 as 2 and 3.

13:39–11.21 Controlled environment: anteroom

(a) The anteroom shall have an air quality of Class 10,000 or better.

(b) The anteroom shall contain the following equipment:

1. A sink with hot and cold running water;

2. Waste containers for all personal protective equipment;

3. An eyewash station; and

4. A hazardous waste spill kit.

(c) A refrigerator, as required by United States Pharmacopoeia Standards, shall be reasonably accessible to the anteroom to ensure the integrity of the sterile admixture product, but shall not be located within the controlled environment.

Recodified from N.J.A.C. 13:39–11.16 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 (b), deleted former 2 and recodified former 3 through 5 as 2 through 4; and deleted (d).

13:39–11.22 Vertical air laminar flow hoods

(a) Pharmacies shall compound antineoplastic agents and other hazardous substances in a class 100 vertical air laminar flow hood.

(b) Personnel who compound and dispense antineoplastic agents and other hazardous substances shall adhere to OSHA Work Practice Guidelines, as set forth in CPL 2–2.20B CH–4, Chapter 21, incorporated herein by reference, as amended and supplemented.

New Rule, R.1998 d.297, effective June 15, 1998.
See: 29 N.J.R. 2246(a), 30 N.J.R. 2255(a).

13:39–11.23 Laminar air flow hoods not in a clean room

Institutional pharmacy class 100 laminar air flow hoods not located in a clean room may only be located in an area which is maintained under sanitary conditions and traveled by persons engaging in sterile product preparation. Such hoods shall be certified by an independent certification company prior to use when first installed or after being moved and at six-month intervals.

New Rule, R.1998 d.297, effective June 15, 1998.
See: 29 N.J.R. 2246(a), 30 N.J.R. 2255(a).

13:39–11.24 Controlled environment: self-contained sterile glove boxes

Self-contained class 10 to class 100 glove boxes, barrier isolation technology or the equivalent not located in a clean room may only be located in an area which is maintained under sanitary conditions and traveled by persons engaging in sterile product preparation. Such boxes shall be certified by an independent certification company prior to use when first installed or after being moved and at six-month intervals.

New Rule, R.1998 d.297, effective June 15, 1998.
See: 29 N.J.R. 2246(a), 30 N.J.R. 2255(a).

13:39–11.25 Library references

In addition to the minimum reference library mandated in N.J.A.C. 13:39–7.7, each sterile admixture service shall contain recognized references pertinent to specialized sterile admixture practice.

New Rule, R.1998 d.297, effective June 15, 1998.
See: 29 N.J.R. 2246(a), 30 N.J.R. 2255(a).

13:39–11.26 Disposal of drugs and materials

All unused drugs and materials used in the preparation of sterile admixture products, including antineoplastic agents, shall be disposed of properly in accordance with accepted professional standards and applicable laws, including the Medical Waste Act (N.J.S.A. 13:1E–48.1 et seq., P.L. 1989, c.34), so as not to endanger the public health.

New Rule, R.1998 d.297, effective June 15, 1998.
See: 29 N.J.R. 2246(a), 30 N.J.R. 2255(a).

13:39–11.27 Security

The sterile admixture area and its contents and other areas where sterile admixture drugs are present shall be secured, so as to prevent access by unauthorized personnel.

New Rule, R.1998 d.297, effective June 15, 1998.
See: 29 N.J.R. 2246(a), 30 N.J.R. 2255(a).

SUBCHAPTER 12. NUCLEAR PHARMACIES

Subchapter Historical Note

Subchapter 12, Nuclear Pharmacies, was recodified from Subchapter 11 by R.1994 d.476, effective September 19, 1994. See: 26 N.J.R. 1303(a), 26 N.J.R. 3878(b).

13:39–12.1 Definitions

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

"Authentication of product history" includes, but is not limited to, identifying the purchase source, the ultimate use or disposition and any intermediate handling of any components of a radiopharmaceutical.

"Authorized practitioner" means a practitioner duly authorized by applicable Federal and State law to possess, use and administer radiopharmaceuticals.

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

"Direct supervision" means that a qualified nuclear 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 of 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.

"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.