

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

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

13:39-4.10 Duplicate permit

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

13:39-4.11 Change of name

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

(b) An amended permit bearing the new name may be obtained upon return of the original permit to the Board for cancellation and payment of the permit fee as prescribed in N.J.A.C. 13:39-1.3.

13:39-4.12 Reproduction of permits

Any permit issued by the Board for the operation of a pharmacy or other board-licensed establishment, with the exception of single copies to State agencies shall not be printed, photographed, photostated, duplicated or reproduced by any other means either in whole or in part, without the express authorization of the Board.

13:39-4.13 Certification of records

A certification of any of the information not obtained by the Board on a confidential basis, which appears in the Board records and concerns the ownership or registration of a pharmacy or other Board-licensed establishment, will be supplied only upon written request and payment of a certification fee as prescribed in N.J.A.C. 13:39-1.3.

13:39-4.14 Contract pharmaceutical services

An institutional permit is required for any area within an institution where drugs are stored, manufactured or compounded and which is serviced by an outside vendor that performs pharmaceutical services as defined in N.J.A.C. 13:39-1.2.

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

13:39-4.15 Retail permit; prescription department or pharmacy department

(a) If the area for which a pharmacy permit is sought is less than the total store area of the enterprise, the area

subject to permit shall be known as the "Prescription Department" or "Pharmacy Department".

(b) The holder of a permit to operate a prescription or pharmacy department and the registered pharmacist-in-charge of the department shall be subject to the following additional requirements:

1. The prescription or pharmacy department shall be constructed so as to enable the closing off and securing of the department from the main store area. The department shall be separated from the main store area by a secured barrier or partition extending from the floor or fixed counter to the ceiling of either the department or main store and attached thereto. Any entrance to the prescription or pharmacy department shall be capable of being locked and connected to a security device or other Board approved security system.

2. The registered pharmacist on duty shall be responsible for keeping the prescription department secure and locked and the alarm system turned on at all times when he or she does not have full vision or control of the department or when he or she is not present within the department. Only the pharmacist-in-charge of the licensed premises shall be responsible for the security of the keys to the department.

3. No prescription shall be accepted or prescription medication supplied to anyone during the period that a registered pharmacist is not present within the department.

4. All medications requiring supervision of a pharmacist, including dispensed medication, shall remain within the confines of the department when the pharmacist is not in the prescription department.

5. The hours that the department is open shall be posted in plain view at the entrance to the department and at the public entrance to the enterprise containing the department.

6. When the enterprise in which the department is located maintains different store hours from the pharmacy or prescription department, all advertising, announcements, signs or statements indicating store hours and the presence of the pharmacy or prescription department shall clearly and distinctly indicate the hours that the department is open.

7. The prescription department shall have a published telephone number different from that of the establishment in which the department is located. No extensions of this phone shall be located outside the department.

8. The name of the pharmacist-in-charge shall be posted so as to be visible from outside of the department. The telephone number of the pharmacist-in-charge shall be available in the office of the manager of the establishment.

9. There shall be provided a secure area for the receiving of prescription drugs from suppliers. No prescription drug shall be accepted from any supplier during the hours the prescription or pharmacy department is closed unless adequate security for the storage of department shipments has been provided and approved by the Board.

10. If a drop-off device is utilized for prescriptions it shall be of a one-way, irretrievable design.

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

13:39-4.16 Permits; specialized permits

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

(b) Specialized permits shall pertain to pharmacies providing specific services as may be necessary and proper to efficiently meet a limited public need for pharmaceutical services. An applicant for any specialized pharmacy permit shall provide the Board with an application and a policy and procedure manual which sets forth a detailed description of the type of specialized pharmacy services to be provided within the pharmacy practice. The policy and procedure manual shall also contain detailed provisions which ensure the protection of the public welfare as determined by the Board.

13:39-4.17 Steering prohibited

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

13:39-4.18 Responsibilities of pharmacists and permit holders

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

(b) Any pharmacist and any permit holder may be held liable for violations of the Act and these rules and may be subject to disciplinary action.

SUBCHAPTER 5. PRESCRIPTIONS

13:39-5.1 Imprinted prescription blanks

No prescriber's prescription blanks shall bear the imprint of the name of any pharmacy or other licensed premises or bear the name and address of any person registered under N.J.S.A. 45:14-1 et seq.

13:39-5.2 Lack of directions on original prescription

(a) If the prescriber fails to include on the original prescription directions to the patient for use of the medication, the registered pharmacist shall indicate on the label the words "use as directed" or "as ordered by the physician" or similar words to the same effect.

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

13:39-5.3 Authorization for renewal of prescriptions

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

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

(b) When the renewals listed on the original prescription have been depleted, no additional renewals may be added to the original prescription. For additional dispensing, a new prescription must be authorized by the prescriber as provided in N.J.S.A. 45:14-14, which must be reduced to writing by the pharmacist and entered into either a manual or into the electronic data processing system as a new prescription. A new prescription shall be generated and the original prescription shall remain in the prescription file in chronological order.

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

13:39-5.4 Approval of FDA necessary

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

Cross References

Exception, see N.J.A.C. 13:39-9.5.

13:39-5.5 Copies of prescriptions; transfers

(a) Copies of prescriptions issued directly to the patient by the pharmacy where the medication was dispensed, pursuant to the receipt of the prescription, shall state in letters at least equal in size to those describing the medication dispensed, the underlined statement: "COPY—FOR INFORMATION ONLY".

(b) Presentation of a prescription 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 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.

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 review-

able 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).

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.

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

13:39-6.8 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 quotations shall include the usual and customary prescription cost. All services including, but not limited to, delivery charges rendered by the pharmacy which will add additional costs to the price quoted, must be set forth in the advertisement.

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

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

(e) Upon request by any consumer, the pharmacist shall 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.

13:39-9.3 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) 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.

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

(c) Oral orders shall be countersigned by the prescriber as required by 42 CFR 463.

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).

13:39-9.8 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) Aseptic 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).