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LAW AND PUBLIC SAFETY
DIVISION OF CONSUMER AFFAIRS
BOARD OF PHARMACY

42 N.J.R. 1221(a)

Readoption with Amendments: N.J.A.C. 13:39

Adopted Repeals: N.J.A.C. 13:39-5.9, 5.10, 9.7 and 9.9

Adopted New Rules: N.J.A.C. 13:39-1.7, 4.8, 7.20 and 7.21

Adopted Repeals and New Rules: N.J.A.C. 13:39-4.7 and 7.2

Adopted Recodification with Amendments: N.J.A.C. 13:39-4.12 as 4.9

Board of Pharmacy Rules

Proposed: January 19, 2010 at 42 N.J.R. 132(a).

Adopted: May 12, 2010 by the Board of Pharmacy, Edward G. McGinley, R.Ph, President.

Filed: May 17, 2010 as R. 2010 d.090, **without change.**

Authority: N.J.S.A. 45:1-15.1 and 45:14-47.

Effective Dates: May 17, 2010, Readoption;

June 21, 2010, Amendments, Repeals, New Rules and Recodifications.

Expiration Date: May 17, 2015.

Federal Standards Statement

A Federal standards analysis is not required because the readopted rules and adopted amendments, repeals and new rules are governed by N.J.S.A. 45:14-40 et seq., and are not subject to any Federal standards or requirements. Although the rules in N.J.A.C. 13:39 are not subject to any mandatory Federal requirements or standards, where deemed appropriate, the Board has incorporated Federal standards. Specifically, the Board notes that the requirements for the transmission of prescriptions for controlled substances set forth at N.J.A.C. 13:39-4.19, 7.8, 7.10, 7.11 and 9.27 are consistent with the Federal Drug Enforcement Administration (DEA) standards articulated at 21 CFR 1306.11, 1306.21 and 1306.25. In addition, record retention requirements for controlled dangerous substance prescriptions set forth in N.J.A.C. 13:39-5.8 and 7.6 are consistent with DEA standards set forth in 21 CFR 1306.26 and 1304.04. Moreover, pharmacies dispensing investigational new drugs under N.J.A.C. 13:39-7.5 and 9.10 must comply with Federal Department of Health and Human Services regulations set forth at 45 CFR Part 46. In addition, all pharmacies and pharmacy personnel must comply with all Federal laws, rules and regulations governing the practice of pharmacy pursuant to N.J.A.C. 13:39-6.2(f)9.

Full text of the readopted rules can be found in the New Jersey Administrative Code at N.J.A.C. 13:39.

Full text of the adopted amendments and new rules follows:

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 New Jersey Pharmacy Practice Act, N.J.S.A. 45:14-40 et seq., and regulate the practice of pharmacy within the State of New Jersey.

(b) This chapter shall apply to all pharmacies; pharmacists; applicants for permits, licensure or registration; interns; externs; pharmacy technicians; and anyone within the jurisdiction of the Board of Pharmacy.

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.

...

"Compounding" means the preparation, mixing, assembling, packaging and labeling of a drug or device as the result of a practitioner's prescription or initiative based on the relationship of the practitioner or patient with the pharmacist in the course of professional practice or for the purpose of, or incident to, research, teaching or chemical analysis and not for sale or dispensing. Compounding also includes the preparation of drugs or devices in anticipation of prescription drug orders based on routine, regularly observed prescribing patterns.

...

"Dispense or dispensing" means the procedure entailing the interpretation of a practitioner's prescription or medication order for a drug, biological or device, and, pursuant to that order, the proper [page=1222] selection, measuring, compounding, labeling and packaging in a proper container for the subsequent administration to, or use by, a patient. The act of dispensing shall include all necessary consultation by the pharmacist.

"Drug or medication" means:

1.-4. (No change.)

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

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

1. (No change.)

2. Requires a prescription or order by a practitioner.

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

"Pharmacist" means an individual holding an active license to engage in the practice of pharmacy in this State.

"Pharmacy" means a location permitted by the Board to engage in the practice of pharmacy in this State.

"Pharmacy technician" means an individual registered with the Board and who works under the immediate personal supervision of a pharmacist in compliance with N.J.A.C. 13:39-6.15. For purposes of this definition, interns, externs, cashiers, stocking and clerical help are not pharmacy technicians.

"Practitioner" means an individual currently licensed, registered or otherwise authorized by the jurisdiction in which the individual practices to administer or prescribe drugs and/or devices in the course of professional practice.

...

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

13:39-1.3 Fee schedule

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

1. For pharmacists as follows:

i.-xii. (No change.)

2.-5. (No change.)

13:39-1.4 Payment of penalties

(a) Any penalties levied by the Board shall be paid within 15 business days of the finalization of a penalty letter or final order of the Board unless otherwise prescribed by statute or terms of a final order.

(b) (No change.)

13:39-1.7 Failure to complete application process

If an applicant for a permit, license or registration issued pursuant to the requirements of this chapter fails to complete the application process within two years of the date of initial application, the Board shall administratively close the application. Following such action, an applicant making reapplication to the Board shall resubmit all required documentation and the applicable application fee set forth at N.J.A.C. 13:39-1.3.

SUBCHAPTER 2. REQUIREMENTS FOR INITIAL LICENSURE

13:39-2.6 Internship and externship practical experience requirements

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

...

"Intern preceptor" means a pharmacist licensed in this State who assumes the responsibility to supervise and provide instructional training to a pharmacy intern as set forth in (f) below.

...

(b) (No change.)

(c) A pharmacist who wishes to be an intern preceptor shall apply to the Board and shall furnish evidence that he or she:

1. Has been licensed and employed on a full-time basis as a pharmacist in the area of practice in which he or she is to be engaged as a preceptor for at least two years immediately preceding the date of application and is currently engaged in the practice of pharmacy in the State of New Jersey; and

2. (No change.)

(d)-(f) (No change.)

SUBCHAPTER 3. PHARMACIST REQUIREMENTS

13:39-3.1 Authorization to practice; display of license

(a) (No change.)

(b) Upon issuance of a license, the current biennial renewal license shall be conspicuously displayed in the pharmacist's principal place of employment.

(c) A pharmacist who is employed by more than one pharmacy in the State shall maintain the wallet-sized license issued by the Board on his or her person when he or she is working at a location where his or her current biennial renewal license is not on display.

13:39-3.3 Change of name

If a pharmacist legally changes the name under which he or she engages in the practice of pharmacy, the pharmacist shall notify the Board within 30 days of such change. The pharmacist shall submit original proof of the change of name or a certified copy of the court order or marriage certificate, which shall be retained by the Board. When a replacement license is issued, the initial license shall be returned for cancellation and the pharmacist shall remit the required fee as prescribed in N.J.A.C. 13:39-1.3.

13:39-3.4 Change of address of record; service of process

(a) A pharmacist shall notify the Board in writing of any change in his or her address of record within 30 days.

(b) Failure to notify the Board of any change in a pharmacist's address of record pursuant to (a) above may result in disciplinary action in accordance with N.J.S.A. 45:1-21(h) and N.J.A.C. 13:45C-1.3, and the imposition of penalties set forth in N.J.S.A. 45:1-25.

(c) Service of any administrative complaint or other Board-initiated process at a pharmacist's address of record shall be deemed adequate notice for the purposes of N.J.A.C. 1:1-7.1 and the commencement of any disciplinary proceedings.

13:39-3.5 Verification of licensure

A verification that the license of a pharmacist is in good standing shall be supplied by the Board upon written request and upon payment of the fee set forth in N.J.A.C. 13:39-1.3.

SUBCHAPTER 3A. CONTINUING EDUCATION

13:39-3A.1 Continuing education credit hour requirements

(a) Each applicant for biennial license renewal shall complete a minimum of 30 credits of continuing education during the preceding biennial period, except that the Board shall not require completion of continuing education credits for an

applicant's initial license renewal. At least 10 of the continuing education credits shall be obtained through didactic instruction. For purposes of this subsection, "didactic instruction" means in-person instruction and may include telephonic or electronic instruction that is interactive, but shall not include videotaped [page=1223] instruction. At least three continuing education credits shall be obtained in pharmacy law applicable to the practice of pharmacy in New Jersey .

(b) (No change.)

13:39-3A.2 Criteria for continuing education credit

(a) (No change.)

(b) A licensee seeking credit for attendance at a program or course that is not offered by an American Council of Pharmaceutical Education approved provider and that has not been approved by the Board pursuant to N.J.A.C. 13:39-3A.6, shall submit for Board review and approval, on a form provided by the Board, information similar to that which is required to be submitted by a sponsor pursuant to N.J.A.C. 13:39-3A.6(a), the continuing education review fee set forth at N.J.A.C. 13:39-1.3 and the verification of attendance.

13:39-3A.4 Continuing education credit hour reporting procedure

(a) A licensee shall specify on his or her application for biennial license renewal that the required number of continuing education credits has been completed. Falsification of any information contained in the renewal application may result in an appearance before the Board and the assessment of penalties and/or license suspension pursuant to N.J.S.A. 45:1-21 et seq.

(b)-(c) (No change.)

SUBCHAPTER 4. PHARMACY PERMIT REQUIREMENTS

13:39-4.1 New pharmacies; pharmacy departments; eligibility and application

(a)-(b) (No change.)

(c) The permit application shall include the exact trade name(s), if any; the corporate names, if any; the name and addresses of the owners and operators, if a sole proprietorship, partnership, limited liability partnership or limited liability company; the names and addresses of all officers and stockholders and the names and addresses of all principals duly licensed to write prescriptions if the pharmacy is not a publicly traded corporation; and the names and addresses of the officers, if a publicly traded corporation.

(d) The permit application shall include the name of the pharmacist-in-charge who shall be a pharmacist in good standing in the State of New Jersey .

(e)-(h) (No change.)

13:39-4.2 Issuance of permits; permit renewals

(a) All permits shall be issued by the Board in the name of the pharmacy for the operation of which the permit is issued.

(b)-(c) (No change.)

13:39-4.3 Display of permits

The current permit issued by the Board for the operation of a pharmacy shall be conspicuously displayed.

13:39-4.5 Change of ownership; asset acquisition

(a) When there is a change in the ownership of the business entity holding a permit to operate a pharmacy, the following requirements shall be satisfied, as applicable:

1. When a complete change in ownership occurs and none of the current owners retains any ownership interest, the new owner(s) shall, prior to, or within 10 business days of, such change, submit to the Board a new permit application pursuant to N.J.A.C. 13:39-4.1, the new permit application fee set forth in N.J.A.C. 13:39-1.3, and an inventory of the pharmacy's controlled substances. A new pharmacy permit number shall be issued upon request;
2. When a reallocation of ownership interests occurs among existing owners, the owners shall, prior to, or within 10 business days of, such change, submit to the Board an affidavit explaining the asset reallocation. A new pharmacy permit number shall not be issued upon a reallocation of business assets among existing owners; or
3. When the existing ownership is changed through the addition of a new owner(s) or the subtraction of an existing owner, the owners shall, prior to, or within 10 business days of, the addition of the new owner(s), submit to the Board a new permit application pursuant to N.J.A.C. 13:39-4.1 and the new permit application fee set forth in N.J.A.C. 13:39-1.3. A new pharmacy permit number shall be issued upon request.

(b)-(c) (No change.)

13:39-4.7 Change of location and/or address of licensed premises

(a) When a pharmacy permit holder intends to change the physical location and address of the permitted premises, the permit holder shall apply to the Board, at least 30 days prior to such change, for a new pharmacy permit. If the change in location and address will result in the temporary closing of the pharmacy, the permit holder shall comply with all requirements set forth at N.J.A.C. 13:39-4.10(c) and (d). The permit holder shall submit a new permit application pursuant to N.J.A.C. 13:39-4.1 and the new permit application fee set forth in N.J.A.C. 13:39-1.3. The Board shall issue an amended pharmacy permit reflecting the new location and address of the pharmacy. Before an amended permit may be issued to the permit holder for the new location, the Board shall inspect and approve the premises, fixtures, equipment and inventory of the new location to ensure compliance with this subchapter and all relevant statutes, regulations and ordinances. The permit holder shall ensure that the prescription and profile records from the pharmacy's previous location and address are maintained pursuant to N.J.A.C. 13:39-7.6 and 7.19 after the location and address change.

(b) Whenever there is a change in a pharmacy's address but no change in the physical location of the licensed premises, the permit holder shall, within 10 business days of the change in address, submit an affidavit to the Board explaining such change.

13:39-4.8 Remodeling of licensed premises

(a) Prior to the remodeling of a pharmacy or pharmacy department, where such remodeling entails a change within the premises of the location or size of the prescription area, or a change in the dimensions of the licensed premises, the permit holder shall notify the Board at least 30 days in advance on a form prescribed by the Board. The pharmacy permit holder shall submit plans for the continuation of operations during the remodeling process which the Board shall review and approve, and the anticipated date of completion. The permit holder shall ensure compliance with all requirements set forth in this chapter while services continue during the remodeling process, and if the remodeling will result in the temporary closing of the pharmacy, the permit holder shall comply with all requirements set forth at N.J.A.C. 13:39-4.12(c) and (d).

(b) The pharmacy permit holder shall notify the Board upon completion of the remodeling process. Within 60 days of the completion of the remodeling, the Board shall inspect and approve the premises, fixtures, equipment and inventory of the remodeled pharmacy to ensure compliance with this subchapter and all relevant statutes, regulations and ordinances.

13:39-4.9 Change of name

(a) When a pharmacy permit holder intends to change the name of the pharmacy, the permit holder shall apply to the Board, at least 30 days prior to such change, for an amended permit. The permit holder shall submit a new permit application pursuant to N.J.A.C. 13:39-4.1 and the new permit application fee set forth in N.J.A.C. 13:39-1.3. The Board shall issue an amended pharmacy permit reflecting the new name of the pharmacy.

(b) (No change.)

(c) If a change in pharmacy name is associated with a change in ownership, the permit holder shall ensure that the requirements set forth in N.J.A.C. 13:39-4.5 are satisfied.

13:39-4.10 Discontinued pharmacies

(a) Whenever a pharmacy is to be discontinued and closed for any reason, including suspension or retirement of the permit holder, sale or insolvency, the permit holder shall immediately send written notification of the anticipated closing to the State Board of Pharmacy, the Office of Drug Control and the Drug Enforcement Administration at least 15 days prior to the anticipated closing date. Whenever a pharmacy is to be discontinued and closed as a result of an unanticipated occurrence, such as the death of the permit holder, the permit holder's representative shall send written notification to the Board, the Office of Drug Control and the Drug Enforcement Administration, as soon as possible prior to the actual closing date. All medications, including prescription legend and [page=1224] controlled drugs, should be transferred to the holder of a current pharmacy permit; a wholesaler; a reverse distributor; and/or a manufacturer. All medications not properly transferred shall remain on the pharmacy premises with all licenses and registrations in effect until such medications are disposed of in the manner prescribed by the Board, the Office of Drug Control and/or the Drug Enforcement Administration.

(b) (No change.)

13:39-4.11 Availability of records upon termination of business

(a) When a pharmacy ceases operation as the result of a suspension, retirement or death of the owner, sale or other cause including insolvency, the permit holder, or the one responsible for supervising the disposition of the practice, shall make every effort to notify patrons that they have the right to obtain copies of currently valid prescriptions and/or copies of their patient profile and the location of the prescriptions and patient profile for a one-year period following notice, using all of the following methods:

1. (No change.)

2. Publication, once weekly for two successive weeks in a newspaper whose circulation encompasses the geographic area in which the pharmacy is located, of a notice advising patrons that they have the right to obtain copies of their prescriptions and/or patient profile, and the location of the prescriptions and patient profile for a one-year period following publication; and

3. A sign placed in the pharmacy location informing the patrons that they have the right to obtain copies of their prescriptions and/or patient profile, and the location of the prescriptions and patient profile.

13:39-4.12 Business hours; unauthorized closing

(a) (No change.)

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

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

(d) Any temporary closing of a pharmacy for more than 48 hours shall be reported to and approved by the Board. Notification to the Board shall include contingency plans for accessing patient records. Any temporary closing of more than 48 hours without prior Board approval shall result in the pharmacy being deemed a discontinued pharmacy requiring compliance with the requirements of N.J.A.C. 13:39-4.10 and 4.11.

13:39-4.13 (No change in text.)

13:39-4.14 Reproduction of permits

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

(b) (No change.)

13:39-4.15 Security of pharmacies and pharmacy departments

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

1.-2. (No change.)

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

i.-vi. (No change.)

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

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

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

i.-ii. (No change.)

3.-4. (No change.)

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

1.-3. (No change.)

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

(d) (No change.)

13:39-4.16 (No change in text.)

13:39-4.17 Steering prohibited

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

13:39-4.18 Responsibilities of permit holders

(a) (No change.)

(b) Any permit holder may be held liable for violations of the New Jersey Pharmacy Practice Act, N.J.S.A. 45:14-40 et seq., and the rules in this chapter and may be subject to disciplinary action.

13:39-4.19 Procedures for centralized prescription handling

(a)-(b) (No change.)

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

1. An intake or originating pharmacy, which is a pharmacy that received the patient's or prescribing practitioner's request to fill or refill a prescription. A central processing pharmacy or a central fill pharmacy, as delineated in (c)2 and 3 below, may be considered the intake or originating pharmacy if the prescription was transmitted by the prescribing practitioner directly to the centralized pharmacy as provided in N.J.A.C. 13:39-7.10 and 7.11 or if the patient requested the refill from that pharmacy;
2. A central processing pharmacy, which is a pharmacy that engages in prescription review by performing functions that may include, but are not limited to, data entry, prospective drug review, refill authorizations, interventions, patient counseling, claims submission, claims resolution and adjudication;
3. A central fill pharmacy, which is a pharmacy engaging in central prescription handling by filling and/or refilling prescriptions, which includes the preparation and packaging of the medication; and
4. A dispensing pharmacy, which is a pharmacy that receives the processed prescription and/or the filled or refilled prescription for dispensing to the patient or to the patient's authorized representative and that offers patient counseling regarding the dispensed medication.

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

1.-3. (No change.)

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

i. The brand name, or if a generic, the brand name and the name of the generic in the following form, with the generic name and brand name inserted as appropriate:

"----- Generic for -----";

ii.-vi. (No change.)

vii. The practitioner name;

[page=1225] viii.-xii. (No change.)

5.-9. (No change.)

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

13:39-4.20 Out-of-State pharmacy registration

(a)-(b) (No change.)

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

1.-4. (No change.)

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

6. (No change.)

(d)-(e) (No change.)

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

1.-4. (No change.)

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

(g)-(k) (No change.)

13:39-4.21 (No change in text.)

SUBCHAPTER 5. RETAIL FACILITY REQUIREMENTS

13:39-5.1 Purpose and scope

The rules in this subchapter shall apply to all retail pharmacies, retail pharmacy departments and all institutional pharmacies filling prescriptions for outpatient use. For purposes of this subchapter, "pharmacy" means a retail pharmacy, retail pharmacy department or an institutional pharmacy filling prescriptions for outpatient use.

13:39-5.3 Pharmacy signs

(a) (No change.)

(b) Pharmacies shall post the hours that the pharmacy is open and the name of the pharmacist-in-charge in plain view at all consumer entrances and consumer access points to the pharmacy, including drive-thru windows and drop-off boxes.

(c) In the case of a pharmacy department, the hours that the department is open and the name of the pharmacist-in-charge shall be posted in plain view at the entrance to the department and at all consumer entrances and consumer access points to the premises, including drive-thru windows and drop-off boxes. When the premises in which the pharmacy department is located maintains different hours of operation from the pharmacy department, all advertising, announcements, signs and statements indicating hours of operation and the presence of the pharmacy department shall clearly and distinctly indicate the hours that the pharmacy department is open.

13:39-5.7 Adequate storage

There shall be sufficient shelf, drawer or cabinet space within the prescription area for proper storage of prescription drugs and chemicals and the minimum equipment required pursuant to N.J.A.C. 13:39-5.8. All prescription drugs and chemicals shall be maintained under adequate storage conditions, including proper lighting, ventilation and temperature control, as recommended by the drug manufacturer.

13:39-5.8 Minimum equipment and supplies; cleanliness

(a) All prescription areas shall contain the following minimum equipment and supplies, which shall be stored, so as to be readily accessible:

1. An up-to-date, comprehensive pharmaceutical reference text(s) and suitable current reference texts encompassing the pharmaceutical services provided by the pharmacy, drug interactions, drug product composition and patient counseling. Unabridged electronic versions of such reference texts shall be acceptable;
2. Over the counter Schedule V Record Book or an electronic recording system, as permitted by Federal law pursuant to 21 CFR 1306.26 and 1304.04, to maintain all required information consistent with N.J.A.C. 8:65-7.19(a)5, if Schedule V controlled substances are sold without a prescription;
- 3.-4. (No change.)
5. Suitable volumetric devices;
6. (No change in text.)

Recodify existing 12.-14. as 7.-9. (No change in text.)

10. Auxiliary labels;

11. Two Drug Utilization Review Council Placards and the 29th edition of the list of "Approved Drug Products with Therapeutic Equivalence Evaluations," commonly known as the "Orange Book," incorporated herein by reference, as amended and supplemented, consistent with Department of Health and Senior Services rules set forth at N.J.A.C. 8:71-1. The Orange Book can be obtained by contacting the Superintendent of Documents, Government Printing Office, PO Box 371954, Pittsburgh, PA 15250-7954, (202) 512-1800 or toll free (866) 512-1800, and is available on-line at <http://www.fda.gov/cder/orange/default.htm> and at <http://www.fda.gov/cder/ob/default.htm>;

12. Assorted stock of prescription containers and child safety closures or caps that meet United States Pharmacopoeia/National Formulary standards on light resistance and tightness; and

13. Copies of, or access to, current State statutes and rules relating to the practice of pharmacy.

(b) All prescription areas where non-sterile compounding is performed shall contain the following minimum equipment and supplies, which shall be stored, so as to be readily accessible:

1. Class A prescription balance with a complete set of metric weights or equivalent electronic weighing device;
2. A glass mortar and pestle;
3. Glass funnels;
4. Stirring rods;
5. Ointment tile or parchment paper; and
6. Suppository mold.

(c) The prescription area and all related equipment and supplies shall be kept in a clean, orderly and sanitary condition

at all times.

13:39-5.9 Prescription balances, scales, weights and automatic counting devices

(a) All pharmacies shall have all balances, scales, weights and automatic counting devices inspected every 12 months by the Department of Weights and Measures of the municipality or county in which the pharmacy is located, and such balances, scales, weights and automatic counting devices shall be properly sealed by the applicable authority.

(b) Counting trays or counting devices that meet the requirements of (a) above shall be used to count oral, solid drugs or medications.

13:39-5.10 Restriction on storage of prescription legend drugs and controlled dangerous substances

(a) (No change.)

(b) Prescription legend drugs, devices and controlled dangerous substances shall be stored only in areas of the premises that are part of the pharmacy or pharmacy department, except that in a health care facility, prescription legend drugs, devices and controlled dangerous substances shall be stored consistent with the requirements of N.J.A.C. 13:39-9.23.

(c) Prescription legend drugs, devices and controlled dangerous substances that are received during hours the pharmacy or pharmacy department is closed shall be stored consistent with the requirements of N.J.A.C. 13:39-4.15(b)3.

SUBCHAPTER 6. PHARMACIST-IN-CHARGE; PHARMACY PERSONNEL

13:39-6.2 Pharmacist-in-charge

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

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

[page=1226] (c) A pharmacist shall not assume the responsibilities of a pharmacist-in-charge of more than one pharmacy or pharmacy department simultaneously, except as provided in (c)1 below.

1. If an area within a health care facility is permitted as both an institutional pharmacy and a retail pharmacy, the health care facility may employ one individual to act as the pharmacist-in-charge for both the institutional pharmacy and the retail pharmacy.

(d) Whenever there is a change of a pharmacist-in-charge of a pharmacy, an inventory of all controlled dangerous substances as defined in N.J.A.C. 8:65-10.1 through 10.5 shall be performed consistent with the requirements of N.J.A.C. 8:65-5.4 and 5.5.

(e) Whenever a pharmacist assumes or terminates the duties as a pharmacist-in-charge of a pharmacy, the pharmacist-in-charge and the permit holder shall so advise the Board in writing within 30 days by completing a form provided by the Board.

(f) A pharmacist-in-charge shall be a full-time employee, employed for a minimum of 35 hours per week and shall be physically present in the pharmacy or pharmacy department for that amount of time necessary to supervise and ensure that:

1. The pharmacy is staffed by sufficient, competent personnel in keeping with the size, scope and complexity of the pharmaceutical services provided by the pharmacy;

2.-8. (No change.)

9. The pharmacy and all pharmacy personnel provide pharmaceutical services in accordance with acceptable professional standards and comply with all Federal and State statutes, rules and regulations governing the practice of pharmacy.

13:39-6.3 Identification tag

All personnel working in the pharmacy, except personnel engaging in the compounding of sterile preparations consistent with the requirements of N.J.A.C. 13:39-11, shall wear an identification tag, which shall include at least the person's first name, first initial of their last name and job title. The identification tag of any employee in training shall reflect the status of the employee as a trainee.

13:39-6.5 Prescription handling by pharmacy externs, interns or pharmacy technicians

A pharmacy intern, extern or technician in any pharmacy may perform the component functions of prescription handling described in N.J.A.C. 13:39-4.18, consistent with the requirements of this chapter. On or after April 5, 2011, all steps performed by a pharmacy technician, intern or extern shall be documented in the pharmacy audit trail consistent with the requirements of N.J.A.C. 13:39-7.6.

13:39-6.6 Pharmacy technician registration and pharmacy technician applicants

(a)-(d) (No change.)

(e) If an applicant for registration as a pharmacy technician is being investigated for any alleged violation of the New Jersey Pharmacy Practice Act, N.J.S.A. 45:14-40 et seq., or the pharmacy laws, rules or regulations of any other jurisdiction, the Board in its discretion may deny the applicant the opportunity to register as a pharmacy technician.

(f) (No change.)

13:39-6.7 Authorization to practice as a pharmacy technician; display of registration

(a)-(b) (No change.)

(c) A registered pharmacy technician who is employed by more than one pharmacy in the State shall maintain the wallet-sized registration issued by the Board on his or her person when he or she is working at a location where his or her current biennial renewal registration is not on display.

13:39-6.15 Pharmacy technician duties and pharmacist-technician ratios

(a) In addition to externs and interns, only pharmacy technicians and pharmacy technician applicants may assist the pharmacist in performing the following tasks:

1.-2. (No change.)

3. Label preparation;

4. The counting, weighing, measuring, pouring and compounding of prescription medication or stock legend drugs and controlled substances, including the filling of an automated medication system; and

5. Accepting authorization from a patient for a prescription refill, or from a practitioner or his or her agent for a prescription renewal, provided that the prescription remains unchanged, consistent with (a)5i below:

i. The pharmacy technician or pharmacy technician applicant shall identify himself or herself as a pharmacy technician when accepting authorization from a practitioner or his or her agent. For purposes of this section, "prescription refill" means the dispensing of medications pursuant to a practitioner's authorization provided on the original prescription. For purposes of this section, "prescription renewal" means the dispensing of medications pursuant to a practitioner's

authorization to fill an existing prescription that has no refills remaining.

Recodify existing (c) and (d) as (b) and (c) (No change in text.)

(d) Except as provided in (e) below, a pharmacist shall not supervise more than two pharmacy technicians at any given time. The pharmacist shall provide immediate personal supervision, as defined in N.J.A.C. 13:39-1.2, of all pharmacy technicians he or she supervises. Those personnel who do computer processing of prescriptions are to be included in the 1 to 2 ratio. A registered pharmacy technician or a pharmacy technician applicant who is receiving in-service training, which shall not exceed 210 days, shall be excluded from the 1 to 2 ratio during such training. A pharmacist shall not supervise more than two persons receiving in-service training at the same time.

(e) A pharmacy that employs a pharmacist to pharmacy technician ratio greater than 1:2 shall:

1. (No change.)

2. Ensure and document that all pharmacy technicians who are working when the ratio exceeds 1:2 have:

i.-ii. (No change.)

iii. Completed a program that includes a testing component, which has been approved by the Board as satisfying the criteria set forth in (f) below. Completion of a program with a Board-approved testing component shall qualify the pharmacy technician to work only for the specific pharmacy and/or corporation for which the pharmacy technician was employed when the training was obtained. If the pharmacy technician becomes employed by another pharmacy and/or corporation, the pharmacy technician shall be required to complete the new employer's training program;

3. (No change.)

4. Ensure that the duties assigned to any pharmacy technician do not exceed the established job descriptions, task protocols and policies and procedures, nor involve any of the prohibited tasks in (b) above;

5.-7. (No change.)

(f) If the pharmacist to pharmacy technician ratio exceeds 1:2, the pharmacy shall maintain a policy and procedure manual with regard to pharmacy technicians, which shall include the following:

1.-12. (No change.)

13. Functions that may not be performed by pharmacy technicians, including at a minimum those functions listed in (b) above; and

14. (No change.)

(g) The pharmacist-in-charge shall review at least every two years and, if necessary, amend the policy and procedure manual. Documentation of the review shall be made available to the Board upon request.

(h) When pharmacy technicians and pharmacy technician applicants are engaged in any permitted activities, the pharmacist(s) shall be responsible for all the activities of the pharmacy technicians and the pharmacy technician applicants.

SUBCHAPTER 7. DRUG DISPENSING AND PRESCRIPTION RECORDS

13:39-7.1 Valid prescriptions

(a) A pharmacist shall only fill a prescription issued by a practitioner licensed to issue prescriptions in New Jersey and practicing in New Jersey if the prescription is on a New Jersey Uniform Prescription Blank pursuant to N.J.S.A. 45:14-55 and N.J.A.C. 13:45A-27, except as provided in N.J.A.C. 13:39-7.10 and 7.11.

[page=1227] (b) A pharmacist shall fill a prescription issued by a practitioner authorized to issue prescriptions in another state, territory or possession of the United States, including prescriptions issued at facilities within or outside of New Jersey that are regulated by the United States Department of Veterans Affairs and/or the Department of Defense. Such prescriptions shall be filled pursuant to New Jersey law. Such prescriptions shall not be required to be issued on a New Jersey Uniform Prescription Blank.

(c) (No change.)

13:39-7.2 Lack of information on original prescription

(a) If a practitioner fails to include on the original prescription any information that he or she is required to include pursuant to rules governing the practitioner's professional practice, including New Jersey Uniform Prescription Blanks rules set forth at N.J.A.C. 13:45A-27, the pharmacist shall obtain such information.

1. If the practitioner has failed to include directions for use and the practitioner cannot be contacted, the pharmacist shall indicate on the prescription label the words "use as directed" or "as ordered by the physician" or similar words to the same effect.

(b) All information required for a valid prescription shall be recorded on the prescription, or in the patient profile record system maintained pursuant to N.J.A.C. 13:39-7.19, or in the pharmacy's other manual or electronic files.

13:39-7.3 Authorization for renewal of prescriptions; new 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 practitioner or the practitioner's authorized agent, and the prescription may not be filled or refilled after one year from the date the original prescription was issued. A pharmacist obtaining authorization from a practitioner's authorized agent shall document the name and title of the agent.

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

(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 practitioner.

(c) Prescription information obtained from a practitioner shall be documented at the time of receipt as a new prescription in hard copy form or by direct entry into the electronic prescription records system.

13:39-7.4 Emergency dispensing

(a) Except as provided in (b) below, in the absence of a current, valid prescription, a pharmacist may dispense an emergency supply (no more than a 72-hour quantity) of a chronic maintenance drug or device if, in his or her professional judgment, refusal would endanger the health or welfare of the patient, provided the following conditions are satisfied:

1. The pharmacist first ascertains to the best of his or her ability, by direct communication with the patient or caregiver, that such a medication or device was prescribed for that patient by order of a practitioner. The pharmacist shall require the patient or caregiver to provide suitable identification. Such communication shall be documented in the patient profile record system maintained pursuant to N.J.A.C. 13:39-7.19 or in the pharmacy's other manual or electronic files; and

2. The pharmacist documents the dispensing of the emergency supply in the prescription record system.

(b) A pharmacist may dispense an emergency supply of a Schedule II controlled dangerous substance in the absence of a current, valid prescription upon receipt of oral authorization from a practitioner as provided under Federal law

pursuant to 21 CFR 1306.11, consistent with the requirements of N.J.A.C. 8:65-7.8.

13:39-7.5 Approval of FDA necessary

(a) (No change.)

(b) The storage, labeling and dispensing of all Investigational New Drugs shall be a pharmaceutical service provided in cooperation with, and in support of the principal investigator. Under these parameters the dispensing of such drugs shall not be construed to be a violation of (a) above. A pharmacy participating in experimental research shall comply with Federal Department of Health and Human Services regulations set forth at 45 CFR Part 46, Protection of Human Subjects of Research, incorporated by reference herein, as amended and supplemented and with the New Jersey Department of Health and Senior Services' Policy on the Protection of Human Research Subjects, incorporated by reference herein, as amended and supplemented, and which is available at <http://www.state.nj.us/health/irb/policies.shtml>.

13:39-7.6 Required records and documents

(a)-(d) (No change.)

(e) Notwithstanding the requirements of (d) above, a pharmacy shall maintain prescription records for controlled dangerous substances as required by Federal law consistent with the provisions of 21 CFR 1304.04.

13:39-7.7 Copies of prescriptions and/or patient profile

(a) A pharmacy shall immediately comply with the patient's request for copies of prescriptions and/or patient profile. Copies of prescriptions issued directly to the patient shall state in letters at least equal in size to those describing the medication dispensed, the underlined statement: "COPY--FOR INFORMATION ONLY."

(b) Presentation of a prescription marked "COPY--FOR INFORMATION ONLY" or a labeled prescription container shall be for information purposes only and shall have no legal status as a valid prescription order. The pharmacist in receipt of such copy or labeled prescription container shall contact the prescribing practitioner for a new prescription or the last dispensing pharmacy to transfer the prescription pursuant to N.J.A.C. 13:39-7.8.

13:39-7.8 Transfer of prescriptions between pharmacies

(a)-(c) (No change.)

(d) A prescription for a Schedule III, IV or V controlled substance may be transferred between pharmacies pursuant to N.J.A.C. 8:65-7.14(h) and 7.18(d). A prescription for a Schedule III, IV or V controlled substance that has been transferred shall not be transferred a second time. This prohibition shall not apply to the transfer of such prescriptions between pharmacies engaged in central prescription handling pursuant to N.J.A.C. 13:39-4.18(e) and to pharmacies that share a real-time, on-line database consistent with the requirements of 21 CFR 1306.25.

(e) A prescription may be transferred between pharmacies for the purpose of refill dispensing by telephone, or by facsimile or electronic means as provided in N.J.A.C. 13:39-7.10 and 7.11, provided that:

1. The sending pharmacy invalidates the prescription on file as of the date the prescription is transferred and records on the back of the invalidated prescription order or in the electronic system the following:

i. (No change.)

ii. The name and address or store identifier of the pharmacy to which the prescription was transferred;

iii.-iv. (No change.)

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

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

ii. (No change.)

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

(1) (No change.)

(2) (No change in text.)

(3) (No change in text.)

(4) Date the prescription was last filled; and

3. (No change.)

13:39-7.9 Filing and storage of controlled substance prescriptions

(a) (No change.)

(b) Prescriptions for all controlled substances listed in Schedules III, IV and V shall be maintained in a separate prescription file for such controlled substances only or in such form that they are readily retrievable from other prescription records of the pharmacy. Prescriptions will be deemed readily retrievable if, at the time they are initially filed, the face of the prescription is stamped in red ink in the lower right corner with the letter "C" no less than one-inch high and filed either in the prescription file for controlled substances listed in Schedule II or in the [page=1228] prescription file for non-controlled substances. If a pharmacy employs an electronic recordkeeping system for prescriptions that permits identification by prescription number and retrieval of original documents by the practitioner's name, patient's name, drug dispensed and date filled, then the requirement to mark the hard copy prescription with a red "C" shall be waived.

13:39-7.10 Prescriptions transmitted by facsimile

(a) (No change.)

(b) A pharmacist shall not fill a facsimile prescription transmitted by anyone other than a practitioner authorized to prescribe medications pursuant to N.J.S.A. 45:14-40, or the prescribing practitioner's authorized agent.

(c)-(f) (No change.)

(g) A pharmacist shall retain a printed copy of a facsimile prescription, or an electronic reproduction of the facsimile prescription that is readily retrievable and printable, for a minimum of five years. The printed copy shall be of non-fading legibility.

(h)-(j) (No change.)

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

(l) A pharmacist shall not use a technological device in order to circumvent his or her responsibilities with regard to verifying the validity of prescriptions or in order to circumvent other standards of pharmacy practice.

13:39-7.11 Electronically transmitted prescriptions

(a) (No change.)

(b) A pharmacist shall not fill an electronic prescription transmitted by anyone other than a practitioner authorized to prescribe medications pursuant to N.J.S.A. 45:14-40, or the prescribing practitioner's authorized agent. If the electronic prescription is transmitted by the practitioner's authorized agent, the transmission shall include the full name and title of the agent.

(c)-(d) (No change.)

(e) An electronic prescription shall contain all information required to be included on a written prescription pursuant to New Jersey State Board of Medical Examiners rule N.J.A.C. 13:35-7.2(d), except that a handwritten original signature and an NJPB shall not be required for the prescription. Consistent with the requirements of N.J.A.C. 13:35-7.4A, the practitioner's electronic signature or other secure method of validation shall be provided with the electronic prescription unless the prescription is transmitted by the practitioner's authorized agent. If transmitted by an authorized agent, the full name and title of the agent shall be included on the transmission and the agent shall not sign the prescription.

(f) (No change.)

(g) A pharmacist shall retain a printed copy of an electronic prescription, or a record of an electronic prescription that is readily retrievable and printable, for a minimum of five years. The printed copy shall be of non-fading legibility.

(h)-(l) (No change.)

(m) A pharmacist shall not use a technological device in order to circumvent his or her responsibilities with regard to verifying the validity of prescriptions or in order to circumvent other standards of pharmacy practice.

13:39-7.12 Labeling

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

1.-2. (No change.)

3. The brand name, or if a generic, the brand name and the name of the generic in the following form, with the generic name and brand name inserted as appropriate: "----- Generic for -----";

4.-8. (No change.)

9. The practitioner's name;

10.-12. (No change.)

(b)-(c) (No change.)

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

13:39-7.13 Professional judgment in dispensing drugs

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

13:39-7.16 Return of prescription medication

(a)-(b) (No change.)

(c) Prescription medication that has been prepared for a patient, but which has not been dispensed to the patient, may be placed back in stock for reuse or resale provided that:

1.-3. (No change.)

4. In those circumstances in which prescription medications cannot be properly returned to the original manufacturers' stock containers, the medication shall be held in the pharmacy in the labeled container in which it has been repackaged. Prior to redispensing, such medications shall be placed in a new container with a new label or the original label shall be removed and the container shall be relabeled;

5.-6. (No change.)

13:39-7.19 Patient profile record system

(a) A patient profile system must be maintained by all pharmacies for persons for whom prescriptions are dispensed. The Patient Profile Record System (PPRS) may be a manual or electronic system and shall be devised, so as to enable the immediate retrieval of information necessary to enable the dispensing pharmacist to identify previously dispensed medication and patient specific information 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.-5. (No change.)

6. The practitioner's name;

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

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

9. Any allergies and idiosyncrasies of the patient and any medical conditions that may relate to drug utilization, as communicated by the patient or the patient's representative.

i. If there are no patient allergies, idiosyncrasies or medical conditions that may relate to drug utilization, such information shall be documented in the patient profile record system.

(c) (No change in text.)

(d) (No change in text.)

(e) A patient profile record shall be maintained or stored in original hard copy form or in any other media that facilitates the reproduction of the original hard copy and shall be maintained for a period of not less than five years from the date of the last entry in the profile record. In using an electronic data processing system, the system shall have the capability of producing retrievable and readable documents of all original and refilled prescription data for a period of not less than five years, including the number of refills authorized by the practitioner. The oldest four years of record information shall be maintained in such a manner so as to be retrievable and readable within two weeks. The most recent one year of record information shall be retrievable and readable within one business day. Records not currently in use need not be stored in the pharmacy, but off-site facilities used to store such records shall be secure. Patient records shall be kept confidential, but shall be made available to persons authorized to inspect them under State and Federal statutes and regulations.

Recodify existing (g)-(i) as (f)-(h) (No change in text.)

13:39-7.20 Drug utilization review

(a) Upon receipt of a new or refill prescription, a pharmacist shall examine the patient's profile record 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 [page=1229] pharmacist shall take the appropriate action to avoid or minimize the problem, which shall, if necessary, include consultation with the patient and/or the practitioner.

(b) Upon receipt of a refill prescription, a pharmacist shall determine if a substantial time, as is appropriate for that drug in the pharmacist's professional judgment, has elapsed from the last filling. When necessary, the pharmacist shall consult with the practitioner and/or the patient to ensure that continued use of the medication is appropriate.

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

13:39-7.21 Patient counseling

(a) Except as provided in (a)5 below, before dispensing a new medication, a pharmacist shall make reasonable efforts to counsel the patient or the patient's caregiver. Counseling may include the following:

1. The name and description of the medication;
2. The dosage form, dosage, route of administration, and duration of drug therapy;
3. Special directions and precautions for preparation, administration and use by the patient;
4. Common adverse or severe side effects or interactions and contraindications that may be encountered, including how to avoid such side effects, interactions and contraindications, and the action required if they occur;
5. Techniques for self-monitoring drug therapy;
6. Proper storage;
7. Prescription refill information; and
8. Action to be taken in the event of a missed dose.

(b) The offer to counsel may be made by pharmacy personnel. However, counseling shall be performed only by a pharmacist, or by a pharmacy intern or pharmacy extern under the immediate personal supervision of a pharmacist consistent with the requirements of N.J.A.C. 13:39-6.2(f)5.

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

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

(e) The requirements of this section shall not apply to a pharmacist who dispenses any drug to an inpatient at a hospital or a long term care facility in which the resident is provided with 24-hour nursing care.

SUBCHAPTER 9. PHARMACEUTICAL SERVICES FOR HEALTH CARE FACILITIES

13:39-9.2 Definitions

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

...

"Medication order" means a written request for medication originated by a practitioner 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 practitioner's electronic signature or password will meet legal requirements for a practitioner'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.

...

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

1.-3. (No change.)

4. The phrase "use by" followed by the product's use by date.

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

5.-6. (No change.)

13:39-9.5 Advisory committees

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

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

(a) (No change.)

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

13:39-9.7 (Reserved)

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

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

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

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

13:39-9.9 (Reserved)

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

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

(b) Written policies and procedures for the maintenance, content, control and accountability of drugs supplied and located throughout the facility shall be developed by the pharmacist-in-charge and approved by the Pharmacy and Therapeutics Committee.

(c) Written policies and procedures for the control, use and accountability of Investigational New Drugs shall be developed by the pharmacist-in-charge and the Pharmacy and Therapeutics Committee. The storage, labeling and dispensing of all Investigational New Drugs shall be a pharmaceutical service provided in cooperation with, and in support of the principal investigator. Under these parameters, the dispensing of these drugs shall not be construed to be a violation of N.J.A.C. 13:39-7.5(a). A facility participating in experimental research involving residents shall comply with Federal Department of Health and [page=1230] Human Services regulations, set forth at 45 CFR Part 46, Protection of Human Subjects of Research, which is incorporated by reference herein, as amended and supplemented and with the New Jersey Department of Health and Senior Services' Policy on the Protection of Human Research Subjects, which is incorporated by reference herein, as amended and supplemented, and which is available at <http://www.state.nj.us/health/irb/policies.shtml>.

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

13:39-9.11 Drug disbursement; written orders

(a) The pharmacist shall review the practitioner's original order or a copy of the original order generated by any media that facilitates the reproduction of the original order before any initial dose of medication is dispensed, except as provided for in N.J.A.C. 13:39-9.13.

(b)-(d) (No change.)

13:39-9.12 Drug disbursement; oral orders

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

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

(c) (No change.)

(d) Oral orders received consistent with the requirements of (b) and (c) above shall be countersigned by the practitioner.

(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), and a limited supply of other medications, provided that the pharmacist:

1. Labels the medications for out-patient use pursuant to labeling requirements set forth in N.J.A.C. 13:39-7.12;
2. Counsels the patient prior to discharge from the hospital or medical facility pursuant to N.J.A.C. 13:39-7.21; and
3. Ensures that discharge orders contain the attending physician's authorizations to dispense the remaining doses of the prescription or the limited supply of other medications to the patient or guardian.

13:39-9.15 Drug labeling

Labeling of medications, other than intravenous solutions, shall be in conformance with written policies and procedures controlling the drug distribution system in use within the facility and in accord with current acceptable standards of pharmaceutical practice. Labeling of intravenous solutions shall be consistent with the labeling requirements set forth in N.J.A.C. 13:39-11.

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

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

(b) (No change.)

13:39-9.17 Drug-dispensing devices

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

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

(c)-(d) (No change.)

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

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

(g) When there is no pharmacy on the premises and when the drug-dispensing devices are an integral part of the approved drug distribution system of the facility, the devices shall be controlled by the pharmacist-in-charge who is

responsible for the pharmaceutical services of the institution. Under these circumstances, the time between medication order checks shall not exceed 24 hours.

13:39-9.18 Disposal of unused medications

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

1.-4. (No change.)

13:39-9.19 Records and reports

(a) Records of the pharmaceutical services of the provider pharmacy for the facility shall be the responsibility of the pharmacist-in-charge. On or after April 5, 2011, a pharmacy shall maintain an audit trail that records and documents the unique and secure user identifier(s) of the pharmacist(s), pharmacy technician(s), intern(s) or extern(s) performing the component functions of prescription handling, as defined in N.J.A.C. 13:39-4.18, which are required to be performed by a pharmacist, pharmacy technician, intern or extern pursuant to the requirements of this chapter. All steps performed by a pharmacy technician, intern or extern shall be documented in the audit trail. All entries to the audit trail made by a pharmacy technician, intern or extern shall be reviewed and approved by the pharmacist. When more than one pharmacist is involved in the component functions of prescription handling, the unique and secure user identifier(s) of the pharmacist(s) responsible for the accuracy and appropriateness of each component function(s) shall be recorded in an audit trail. Audit trail documentation shall be generated at the time the component function(s) is performed. All audit trail and medication order information shall be maintained or stored in original hard copy form or in any other media that facilitates the reproduction of the original hard copy and shall be maintained for a period of not less than five years. The oldest four years of information shall be maintained in such a manner so as to be retrievable and readable within two weeks. The most recent one year of information shall be retrievable and readable within one business day. Records not currently in use need not be stored in the pharmacy, but off-site facilities used to store such records shall be secure. Patient records shall be kept confidential, but shall be made available to persons authorized to inspect them under State and Federal statutes and regulations.

(b)-(e) (No change.)

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

[page=1231] 13:39-9.20 Drug information and education

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

(b)-(c) (No change.)

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

(a)-(c) (No change.)

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

1.-6. (No change.)

(e) The pharmacist-in-charge shall obtain with the record in (d) above the container from which the required dose(s)

was taken for drug administration purposes in order that it may be properly checked by a pharmacist.

(f) (No change.)

13:39-9.22 Pharmacy facilities; space

(a)-(b) (No change.)

13:39-9.23 Storage and security

(a) Provisions shall be made for adequate safe storage of drugs wherever they are stored in the health care facility.

1.-2. (No change.)

3. The pharmacist-in-charge or, where provided for in Department of Health and Senior Services rules, the director of pharmaceutical services shall be responsible for all the medications in the facility.

4. (No change.)

(b) The pharmacist-in-charge or, where provided for in Department of Health and Senior Services rules, the director of pharmaceutical services shall establish a system of control for all drugs dispensed for use in the drug therapy of patients of the facility. Inspections shall be conducted of all medication areas located in the facility or any other service area of the facility at least once every two months to check for expiration or use by dates, proper storage, misbranding, physical integrity, security and accountability of all drugs. These inspections shall be fully documented. Written inspection reports shall be prepared and signed by the inspecting pharmacist or by the pharmacy technician, intern or extern and co-signed by his or her supervising pharmacist. The pharmacist-in-charge shall be responsible for ensuring that, prior to performing any inspections pursuant to this subsection, pharmacy technicians, interns and externs are trained and can successfully demonstrate competency. Procedures for the review of these reports shall be developed and instituted by the pharmacist-in-charge and can be incorporated into the overall quality assurance program of the health care facility.

(c) Procedures shall be established to assure the immediate and efficient removal of all outdated and recalled drugs from patient care areas and from the active stock of the pharmacy. The pharmacist-in-charge shall develop written policies and procedures governing the removal from the facility of outdated or recalled drugs.

13:39-9.24 Equipment

Adequate equipment shall be provided for the compounding, packaging, labeling, refrigeration, sterilization, testing and safe distribution of drugs and other functions.

13:39-9.25 Institutional decentralized pharmacies

(a)-(e) (No change.)

(f) Institutional decentralized pharmacies shall comply with all requirements in this subchapter applicable to the pharmaceutical services provided by the decentralized pharmacy, as determined by the pharmacist-in-charge.

13:39-9.26 Valid medication orders; out-of-State medication orders

(a) Only medication orders issued by a practitioner licensed to write medication orders in the United States or any territory of the United States shall be considered valid medication orders and such medication orders shall be filled pursuant to New Jersey law.

(b) (No change.)

13:39-9.27 Prescriptions and medication orders transmitted by technological devices in an institution

(a) (No change.)

(b) A pharmacist filling prescriptions under an institutional permit for employees of the institution and their dependents and for eligible outpatients may accept for dispensing prescriptions for all substances consistent with the requirements of N.J.A.C. 13:39-7.10 and 7.11.

(c) A pharmacist who is authorized to fill inpatient medication orders, as defined in N.J.A.C. 13:39-9.2, in an institutional pharmacy may accept all inpatient medication orders, including orders for Schedule II substances, which have been transmitted by technological device.

(d)-(e) (No change.)

(f) No licensee or permit holder registered under N.J.S.A. 45:14-40 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 change.)

SUBCHAPTER 10. AUTOMATED MEDICATION SYSTEMS

13:39-10.2 "Automated medication system" definition

As used in this subchapter, "automated medication system" means any process that performs operations or activities, other than compounding or administration, relative to the storage, packaging, dispensing and distribution of medications, and which collects, controls and maintains all transaction information. "Automated medication system" does not mean an automatic counting device operated pursuant to N.J.A.C. 13:39-5.9 or a mechanical drug dispensing device operated pursuant to N.J.A.C. 13:39-9.17.

13:39-10.3 Authority to use automated medication system

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

1. The pharmacist-in-charge shall be responsible for the supervision of the operation of the system, or in the case of an automated medication system utilized at a location with no on-site pharmacy, the pharmacist-in-charge of the provider pharmacy shall be responsible for the supervision of the operation of the system;
2. The pharmacy has conducted a self-inspection of the automated medication system documented on a form provided by the Board and has submitted the self-inspection to the Board;
3. (No change.)
4. The pharmacy has made the automated medication system available to the Board for the purpose of inspection, whereby the Board may validate the accuracy of the self-inspection and/or of the system.

(b) The pharmacist-in-charge shall be responsible for the following:

1. (No change.)
2. Ensuring that medications in the automated medication system are inspected, at least once every two months, for expiration or use by date, misbranding and physical integrity, and ensuring that the automated medication system is inspected, at least once every two months, for security and accountability;

3.-5. (No change.)

13:39-10.4 Written policies and procedures of operation

(a) When an automated medication system is used to fill prescriptions or medication orders, it shall be operated according to written policies and procedures of operation. The policies and procedures of operation shall:

1.-2. (No change.)

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

4. (No change.)

5. Set forth methods to identify the quality control measures in place to ensure the accuracy of the final dispensed product;

6. (No change in text.)

7. Set forth methods that shall ensure that access to the automated medication system for stocking and retrieval of medications is limited to [page=1232] licensed practitioners or qualified pharmacy technicians, interns and externs under the supervision of a pharmacist. An accountability record, which documents all transactions relative to stocking and removing medications from the automated medication system shall be maintained; and

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

(b)-(c) (No change.)

13:39-10.5 Personnel training requirements

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

SUBCHAPTER 12. NUCLEAR PHARMACIES

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.

...

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