

DEPARTMENT OF STATE
DIVISION OF PROFESSIONAL REGULATION
2500 Board of Pharmacy
Statutory Authority: 24 Delaware Code, Section 2509 (24 Del.C. §2509) 24 DE Admin.
Code 2500

FINAL

ORDER

A hearing was held to receive comments on January 13, 2006 at a regularly scheduled meeting of the State Board of Pharmacy. The Board considered proposed changes to Regulations 3.0, 5.0 and 13.0 as published in the *Register of Regulations* at 9 DE Reg 951 12-01-05.

Summary of the Evidence and Information Submitted

1. The Board received a letter dated January 4, 2006 supporting the proposed changes from the National Association of Chain Drug Stores.

**Findings of Fact with Respect to the Evidence
and Information Submitted**

The Board finds that the changes to Regulation 3.0 protect the public with specific requirements for a pharmacy while providing flexibility for the various practice settings.

Regulation 5.0 is updated to eliminate "reconstitution" in the definition of compounding. In addition, selling compounded products on the order of a practitioner for his or her office use with individual patients is permitted.

Centralized prescription processing is governed by new Regulation 5.12 as a means to make dispensing based on a central database efficient and safe.

Regulation 13.0 applicable to Nuclear Pharmacies was simplified and updated to provide for some consistency with other jurisdictions.

Decision and Effective Date

The Board hereby adopts the changes to Regulations 3.0, 5.0 and 13.0 to be effective 10 days following publication of this order in the *Register of Regulations*.

Text and Citation

The text of the revised rules remains as published in Register of Regulations at 9 DE Reg 951 12-01-05.

SO ORDERED this 13th day of January, 2006.

STATE BOARD OF PHARMACY

John E. Murphy, R.Ph., President

Don Holst, R.Ph., Vice President

Daniel Hauser, Pharm. D.

Karen J. Dey, R.Ph.

Angelo Chiari, R.Ph.

2500 Board of Pharmacy

3.0 Pharmacy Requirements

3.1 Pharmacist in Charge

3.1.1 Application for permit to operate a pharmacy in the State of Delaware must be on a form approved by the Board. The form shall include the statement to be signed by the pharmacist in charge, "I understand that I am

responsible for conducting and managing the prescription department in compliance with applicable State and Federal laws."

3.1.2 The Board interprets the responsibilities of the Pharmacist-in-Charge to include, but not be limited to the following:

3.1.2.1 Maintain necessary pharmaceutical equipment and reference texts in accordance with the State Board of Pharmacy requirements.

3.1.2.2 Maintain records required by the Uniform Controlled Substances Act and other relevant State and Federal regulations.

3.1.2.3 Maintain proper security of particular pharmacy operation during and after normal business hours.

3.1.2.4 Establish procedures within operation that maintain standard of practice as it relates to the dispensing of pharmaceuticals. These procedures shall include proper supervision of supportive personnel and delegation of authority to another pharmacist when not on duty.

3.1.2.5 The pharmacist on duty is directly responsible for his own actions.

3.1.2.6 Notify the Board of Pharmacy in writing within 10 days of termination as pharmacist-in-charge.

3.2 Owner's Affidavit. The owner or owners and, in the case of a corporation, an authorized official of the corporation must present an affidavit properly notarized containing the statement, "I hereby swear or affirm that the foregoing statements are correct and do hereby agree to abide by the pharmacy laws of the State of Delaware and to all rules and regulations of the Delaware State Board of Pharmacy." The Board must be notified within 10 days of change of ownership.

3.3 Equipment and Reference Materials. ~~Each pharmacy shall have the following equipment and maintain a library of the latest edition and supplements of current reference sources (either hard copy or electronically accessible) appropriate to the individual pharmacy practice and to the care of the patients served. The reference sources must:~~

~~3.3.1 References:~~

~~3.3.1.1 Provide information on the therapeutic use, dosing, pharmacology, adverse effects, and interactions of drugs dispensed to patient.~~

~~3.3.1.2 Provide information helpful in the counseling of patients on the use of drugs dispensed.~~

~~3.3.1.3 Enable the pharmacist to properly compound medicines within accepted standards of pharmacy practice.~~

~~3.3.1.4 Include a listing of therapeutic equivalents for drugs dispensed.~~

~~3.3.1.5 Include current Delaware and federal laws and regulations governing pharmacy and controlled substances.~~

~~3.3.1.6 Provide any other information necessary to the safe and effective practice of pharmacy for the specific practice setting.~~

~~3.3.2 Equipment~~

~~3.3.2.1 Prescription Scale, Class A~~

~~Set of Metric Weights if balance is used~~

~~3.3.2.2 Graduates, (must be glass) Metric~~

~~One of Each:~~

~~— 30 ml~~

~~— 60 ml~~

~~125 ml~~

~~500 ml~~

~~(or Set with both metric and Apothecary Graduations may be used)~~

~~3.3.2.3 Mortars and Pestles~~

~~One 8 ounce glass~~

~~One 8 ounce wedgewood~~

~~3.3.2.4 Filter Paper~~

~~3.3.2.5 Prescription/physician Order Files~~

~~3.3.2.6 Two Spatulas~~

~~3.3.2.7 One Glass Funnel~~

~~3.3.2.8 One Glass Stirring Rod~~

3.3.2.9 Ointment Slab or Papers

3.3.2.10 Distilled Water

Each Pharmacy shall have such additional equipment as is necessary to perform a specific procedure.

All equipment must be clean and must be maintained in such a manner that allows the pharmacist to accurately weigh, measure and compound ingredients.

3.3.1 Equipment: Each pharmacy shall have all equipment appropriate to the individual pharmacy practice and to the care of the patients served.

3.3.1.1 All equipment must be clean and must be maintained in such a manner that allows the pharmacist to accurately weigh, measure and compound ingredients.

3.3.1.2 Equipment may include such things as prescription scale, metric graduates, mortars and pestles, filter paper, spatulas, funnel, stirring rod, ointment slab or papers, distilled water, and prescription/physician order files.

3.3.2 References: Each pharmacy shall maintain a library of the latest edition and supplements of current reference sources, either hard copy or electronically accessible, appropriate to the individual pharmacy practice and to the care of the patients served. References must:

3.3.2.1 Provide information on the therapeutic use, dosing, pharmacology, adverse effects, and interactions of drugs dispensed.

3.3.2.2 Provide information helpful in the counseling of patients on the use of drugs dispensed.

3.3.2.3 Enable the pharmacist to properly compound medicines within accepted standards of pharmacy practice.

3.3.2.4 Include a listing of therapeutic equivalents for drugs dispensed.

3.3.2.5 Include current Delaware and Federal laws and regulations governing pharmacy and controlled substances.

3.3.2.6 Provide any other information necessary to the safe and effective practice of pharmacy for the specific practice setting.

3.4 Physical Facilities. Have sufficient size, space, sanitation, and environmental control for adequate distribution, dispensing and storage of drugs and devices. Such facilities shall include:

3.4.1 A dispensing area of adequate size and space for proper compounding, dispensing and storage of drugs and devices, to ensure the safety and well being of the public and pharmacy personnel.

3.4.2 Sufficient environmental control, i.e. lighting, ventilation, heating and cooling to maintain the integrity of drugs and devices. The area in which drugs and devices are stored shall be accurately monitored using control devices to maintain room temperature between 59 degrees and 86 degrees Fahrenheit.

3.4.3 The pharmacy department or prescription area must contain a sink with hot and cold running water. It must be large enough to accommodate the equipment required by the Board so that the utensils can be properly washed and sanitized.

3.4.4 Suitable refrigeration with appropriate monitoring device. Refrigerators and freezers (where required) will be maintained within the USP/NF range:

Refrigerator - 36 degrees to 46 degrees Fahrenheit

Freezer - Minus 13 degrees to plus 14 degrees Fahrenheit.

A sign with letters not less than 3/4" in height in the vicinity of the prescription department visible to the public which shows the name of the pharmacists employed at that pharmacy or the name of the pharmacist on duty.

3.5 Building Standards. An application to operate a new pharmacy must include (3) copies of floor plans drawn to scale of the proposed prescription department. The floor plans must include the following:

3.5.1 The requirements listed in §2534(f)(1) through (4).

3.5.2 An area which assures patient privacy will be provided to facilitate counseling. This area must afford the patient privacy from auditory detection by any unauthorized person or persons. An area partitioned by a 5 foot divider on 2 sides with a minimum of 9 square feet would satisfy this requirement in most settings.

3.5.3 The floor plans shall include the location of the sink, all doors, storage room, approved Schedule II controlled substance safe or cabinet, and the method of securing the prescription department from floor to ceiling, when the prescription department is closed and the remainder of the store is open.

3.5.4 The floor plans must include the type of alarm system to be installed, and the name, address and phone number of alarm provider. The alarm system, as required by Regulation 5 of the Delaware Controlled Substance Act, must be reviewed and approved for compliance by the Office of Narcotics and Dangerous Drugs.

3.5.5 The above requirements shall also apply for any remodeling or change of location of the prescription department. The pharmacist-in-charge or applicant for permit must submit the floor plans requirements to the Delaware Board of Pharmacy and the Office of Narcotics and Dangerous Drugs prior to any construction and at least 15 days prior to the next scheduled Board of Pharmacy meeting for its review.

3.6 Security. When the pharmacist is not physically present and the operation is open for business, the pharmacy department shall be physically or electronically secured from floor to ceiling. The partitioned off section required by 24 Del.C. §2534 must be five feet high measured from the floor. A conspicuous sign with letters not less than three inches in height, reading "PRESCRIPTION LABORATORY TEMPORARILY CLOSED, NO PROFESSIONAL SERVICES RENDERED," or words of similar import, must be posted in the front section of the operation or in front of the prescription area, room or partitioned off section where it can be seen by the public.

3.7 Board Interview. Applicants for permit to operate a pharmacy in the State of Delaware must appear before the Board for an interview. The owner or authorized official must be present in addition to the pharmacist-in-charge. Whenever there is a change of pharmacist-in-charge, if that person has never held that position in the State of Delaware, he/she must appear before the Board for an interview within ninety days after assuming the position.

Regulation 3.5.2 revised 6/16/97

Regulation 3.5.6 revised Effective date 10/11/98

2 DE Reg. 683 (10/1/98)

6 DE Reg. 488 (10/1/02)

7 DE Reg. 309 (9/1/03)

7 DE Reg. 1666 (6/1/04)

9 DE Reg. 85 (7/1/05)

(Break in Continuity of Sections)

5.0 Dispensing

5.1 Definitions

"Agent" An employee of the pharmacy supervised by the pharmacist or a person acting on behalf of the ultimate user.

"Automated Data Processing System (ADP)" A system utilizing computer software and hardware for the purposes of recordkeeping.

"Cell" Any container which holds the medication for automatic dispensing.

"Central Prescription Processing" The processing by a Pharmacy of a request from another Pharmacy to fill or refill a prescription drug order or to perform processing functions such as dispensing, DUR, claims adjudication, refill authorizations and therapeutic interventions.

"Common Data Base" A file or data base created by ADP that enables authorized users to have common access to this file regardless of physical location.

"Compounding" The art of the extemporaneous preparation and manipulation of drugs as a result of a practitioner's prescription order or initiative based on the practitioner/patient/pharmacist relationship in the course of professional practice, including ~~the reconstitution of powders for administration~~ and the preparation of drugs in anticipation of drug orders based on routine, regularly observed prescribing patterns. Pharmaceutical compounding must be in compliance with FFDCa Section 503A and any regulations promulgated by FDA concerning compounding, pertaining to this section.

"Computer" Programmable electronic device, capable of multifunctions including but not limited to storage, retrieval and processing of information.

"Controlled Substance" Those drug items regulated by Federal (CSA of 1970) and/or State Controlled (dangerous) Substances Act.

"CRT" Cathode Ray Tube used to impose visual information on a screen.

"Delivery" The transfer of a dispensed prescription to the ultimate user (patient) or his/her agent.

"Dispensing" To furnish or deliver a drug to an ultimate user by or pursuant to the lawful order of a practitioner; including the preparation, packaging, labeling or compounding necessary to prepare the drug for that delivery.

"Downtime" That period of time when a computer is not operable.

"Facsimile (FAX) Prescription" A facsimile prescription is an order which is transmitted by an electronic device over telephone lines which sends an exact copy image to the receiver (pharmacy).

"Final Container" is that which holds the article, designed to hold a quantity of drug product intended for administration as a single dose, multiple dose, or a single finished device intended for use promptly after the container is opened.

"New Medication" A medication not previously dispensed by the pharmacy for the ultimate user.

“Patient Counseling” The offer to discuss the patient's prescription made by the pharmacist or the pharmacist's designee in a face-to-face communication with the patient or his/her agent, unless in the professional judgment of the pharmacist it is deemed impracticable and in such instances, it would be permissible for the offer to counsel to be made through alternative means.

“Pertinent Patient Medication Information” Information which increases the patient's ability to minimize the risks and enhance the benefits of drug use. The type of information the pharmacist should consider is contained in the latest edition of USP DI "Advice for the Patient."

“Prescriber” A practitioner authorized to prescribe and acting within the scope of this authorization.

“Prescription” An order for medication which is dispensed to or for an ultimate user, but does not include an order for medication which is dispensed for immediate administration to the ultimate user, (e.g., an order to dispense a drug to a bed patient for immediate administration in a hospital is not a prescription.) A written order from a practitioner authorized to prescribe and acting within the scope of this authorization, (other terminology: prescription order) or a telephone order reduced to writing by the pharmacist.

“Printout” A hard copy produced by computer that is readable without the aid of any special device.

“Reduced to Writing”

For new prescriptions this means the preparation of a paper document containing all the information required for a written prescription including the State requirement (Section 2553) for drug product selection;

For a refill authorization, it may be handled as a new prescription as in above, or by placing on the original prescription or the patient profile (whichever document is consistently used to document refills) the date, a statement "O.K. for 'x' number of additional refills", or words of similar import, and the pharmacist's initials. In no instance, shall the refill authorizations exceed the legal limits established by State and Federal laws.

If the prescriber authorizing additional refills differs from the Prescriber whose name appears on the signature line of the original prescription, then that authorization is considered a new prescription and must be handled as described above.

“Regulatory Agency” Any Federal or State agency charged with enforcement of pharmacy or drug laws and regulations.

“Stop Date” A date established by an appropriate authority which indicates when medication will no longer be administered or dispensed in the absence of a specific time period directed by the prescriber.

“Supportive personnel” A person who is not registered as an intern or pharmacist with the Board who may perform tasks as authorized by this Regulation.

5.2 The practice of dispensing shall include, but not be limited to the following acts which shall be performed only by a pharmacist, or a pharmacy intern or student participating in an approved College of Pharmacy coordinated, practical experience program under the direct supervision of a pharmacist.

5.2.1 Receive oral prescriptions and reduce them immediately to writing.

5.2.2 Certification of the prescription order - (This involves authenticating the prescription, confirming proper dosage and instructions, and reviewing for incompatibility, etc.)

5.2.3 The pharmacist, intern or student who dispenses the original prescription shall hand-sign or initial the prescription. Initials mechanically or electronically generated are acceptable in lieu of the above provided that the individual verifies either on a daily printout or in a bound log book daily that the information on the prescription is correct. The verification must be hand-signed and dated by the individual.

5.3 Patient Counseling

5.3.1 Before dispensing or delivering a new medication to a patient or his or her agent, a pharmacist or pharmacy intern under the direct supervision of the pharmacist, shall conduct a prospective drug review. A pharmacist or pharmacy intern or student participating in an approved College of Pharmacy coordinated practical experience program and working under the direct supervision of the pharmacist, shall conduct a prospective drug review. A prospective drug review may be conducted before refilling a prescription to the extent deemed appropriate. A prospective drug review shall include screening for potential drug therapy problems due to therapeutic duplication, drug-drug interactions, including serious interactions with over-the-counter drugs, drug-disease contraindications, if disease is known, incorrect drug dosage or duration of drug treatment, drug-allergy interactions, and clinical abuse or misuse based on available information received by the pharmacist.

5.3.2 A pharmacist, or a pharmacy intern or student participating in an approved College of Pharmacy coordinated practical experience program and working under the direct supervision of a pharmacist shall, with each new medication dispensed, provide verbal counseling to the patient or the patient's agent on pertinent medication information. The counseling may include, but not be limited to the following:

5.3.2.1 the name and description of the prescribed drug;

5.3.2.2 the dosage and the dosage form;

5.3.2.3 the method and route of administration;

- 5.3.2.4 the duration of the prescribed drug therapy;
- 5.3.2.5 any special directions and precautions for preparation, administration, and use by the patient that the pharmacist determines are necessary;
- 5.3.2.6 common severe side effects or adverse effects or interactions and therapeutic contraindications that may be encountered, how to avoid them, and what actions should be taken if they occur;
- 5.3.2.7 patient techniques for self-monitoring of the drug therapy;
- 5.3.2.8 proper storage;
- 5.3.2.9 prescription refill information;
- 5.3.2.10 the action to be taken in the event of a missed dose; and
- 5.3.2.11 current over-the-counter medication use.

5.3.3 This section does not apply to a pharmacist dispensing drugs for inpatient use in a hospital or other institution where the drug is to be administered by a nurse or other appropriate health care provider.

5.3.4 Nothing in this section requires a pharmacist or pharmacy intern or student participating in an approved College of Pharmacy coordinated practical experience program and working under the direct supervision of a pharmacist, to provide patient counseling when a patient or the patient's agent refuses the counseling. There must be a record in a uniform place that documents a patient's acceptance or refusal of counseling.

5.3.5 If the dispensed prescription is delivered by an agent of the pharmacy when the pharmacist is not present (i.e. home delivery, pharmacist off duty and non-resident pharmacies) written or printed information shall be included with the prescription. The patient or his/her agent shall be informed that the pharmacist will be available for consultation.

5.4 Supportive personnel

5.4.1 Qualifications and training

5.4.1.1 The pharmacist-in-charge is responsible for ensuring proper training of all supportive personnel. The actual training may be delegated to a pharmacist or other trained supportive personnel.

5.4.1.2 The areas of training required are to be determined by the pharmacist-in-charge and will be appropriate to the practice site and responsibilities assigned to the supportive personnel. Areas of training shall include:

- 5.4.1.2.1 general drug and dosage form knowledge
- 5.4.1.2.2 medical terminology
- 5.4.1.2.3 pharmaceutical calculations
- 5.4.1.2.4 prescription labeling requirements
- 5.4.1.2.5 general filling/dispensing responsibilities
- 5.4.1.2.6 patient profile record system requirements
- 5.4.1.2.7 requirements for patient counseling
- 5.4.1.2.8 confidentiality
- 5.4.1.2.9 safety practices
- 5.4.1.2.10 inventory functions
- 5.4.1.2.11 knowledge of applicable State and Federal Statutes and Regulations
- 5.4.1.2.12 other site-specific parameters

5.4.1.3 The general content of the training program must be maintained in the policy and procedure manual.

5.4.1.4 Documentation of successful training in specific areas by oral or written evaluation will be maintained and will be available for inspection by the Board of Pharmacy.

5.4.2 Supervision. Supportive personnel must be supervised by a registered pharmacist who will be responsible for the activities of these persons.

5.4.3 Activities allowed

5.4.3.1 Supportive personnel will be allowed to perform only those duties permitted by this regulation.

5.4.3.2 Supportive personnel may aid in the dispensing of prescriptions as authorized in Section 2513 under the supervision of a pharmacist by performing the following tasks:

- 5.4.3.2.1 Obtaining the medication from stock.
- 5.4.3.2.2 Typing the label after the pharmacist has interpreted the directions.
- 5.4.3.2.3 Counting, pouring and selecting prefabricated medications and selecting individual prepackaged unit dose medication provided that these are not in conflict with the state and federal law (Federal

Comprehensive Controlled Substances Act) and that a final check by the pharmacist is made after the medication is placed in the final container prior to dispensing and administration to the patient. There will be a final check by a licensed pharmacist prior to dispensing and administration, except where the Board of Pharmacy grants, in writing, an exemption for good cause shown.

5.4.3.3 Compounding is the responsibility of the pharmacist or pharmacy intern under the direct supervision of the pharmacist. All compounding must be in compliance with FFDCa Section 503A and any regulations promulgated by FDA concerning compounding pertaining to this section. The pharmacist may utilize the assistance of supportive personnel if the following is performed:

5.4.3.3.1 The formulation is developed by the pharmacist before proceeding with the compounding.

5.4.3.3.2 The compounding ingredients are checked by the pharmacist before proceeding with the compounding.

5.4.3.3.3 Every weight and measurement is checked by the pharmacist before proceeding with the compounding.

5.4.3.3.4 The finished product is checked by the pharmacist before dispensing.

5.4.3.3.5 A log is maintained showing the identity of the person actually compounding the medication and the identity of the pharmacist who has performed each of the checks indicated above for each step of the procedure. If policies and procedures are in place ensuring adequate checks by the pharmacist per regulation, the requirement for a log will be waived.

5.4.3.4 Only supportive personnel or persons being trained as supportive personnel as required by this regulation, may perform the activities defined by this regulation.

5.5 Automatic Dispensing Devices. If any automatic counting device is used by a pharmacy, each cell shall have clearly displayed thereon, the date filled, the name of the drug, the batch number, the manufacturer's name, and the expiration date of the particular batch number. No drug can be added to the cell until the present supply is depleted.

5.6 Authorization for renewal of prescriptions. A prescription written for medication which, pursuant to State and Federal law, may be sold, dispensed, or furnished only upon prescription, shall not be renewed without specific authorization of the prescriber. The pharmacist shall in his/her professional judgment refill prescriptions in keeping with the number of doses ordered and the directions for use. Refills beyond one year of the date of the original prescription shall not be dispensed without further authorization of the prescriber.

5.7 Mandatory Patient Profile Record System

5.7.1 A patient profile record system must be maintained at all pharmacies for persons for whom prescriptions are dispensed. The patient profile system shall be devised so as to entitle the immediate retrieval of information necessary to enable the dispensing pharmacist to identify previously dispensed medication at the time a prescription is presented for dispensing.

5.7.2 The following information shall be recorded by a pharmacist or designee:

5.7.2.1 The family name and first name of the person for whom the medication is intended (the patient);

5.7.2.2 The address of the patient and phone number;

5.7.2.3 The patient's age, or date of birth, and gender;

5.7.2.4 The original date the medication is dispensed pursuant to the receipt of a prescriber's prescription;

5.7.2.5 The number or designation identifying the prescription;

5.7.2.6 The prescriber's name;

5.7.2.7 The name, strength, quantity, directions and refill information of the drug dispensed;

5.7.2.8 The initials of the dispensing pharmacist and the date of dispensing medication as a renewal (refill) if said initials and such date are not recorded on the original prescription;

5.7.2.9 If the patient refuses to give all or part of the required information, the pharmacist shall so indicate and initial in the appropriate area.

5.7.2.10 Pharmacist comments relevant to the patient's drug therapy, including any other information peculiar to the specific patient or drug.

5.7.3 The pharmacist or pharmacy intern under the direct supervision of a pharmacist shall attempt to ascertain and shall record any allergies and idiosyncrasies of the patient and any chronic disease states and frequently used over-the-counter medication as communicated to the pharmacist by the patient. If the answer is none, this must be indicated on the profile.

5.7.4 Upon receipt of a new prescription, a pharmacist, pharmacy intern, or student participating in a College of Pharmacy practical experience program under the direct supervision of a pharmacist must examine the patient's profile record before dispensing the medication to determine the possibility of a harmful drug interaction or

reaction. Upon recognizing a potential harmful reaction or interaction, the pharmacist shall take appropriate action to avoid or minimize the problem with shall, if necessary, include consultation with the prescriber.

5.7.2.5 The number or designation identifying the prescription;

5.7.2.6 The prescriber's name;

5.7.2.7 The name, strength, quantity, directions and refill information of the drug dispensed;

5.7.2.8 The initials of the dispensing pharmacist and the date of dispensing medication as a renewal (refill) if said initials and such date are not recorded on the original prescription;

5.7.2.9 If the patient refuses to give all or part of the required information, the pharmacist shall so indicate and initial in the appropriate area.

5.7.2.10 Pharmacist comments relevant to the patient's drug therapy, including any other information peculiar to the specific patient or drug.

5.7.3 The pharmacist or pharmacy intern under the direct supervision of a pharmacist shall attempt to ascertain and shall record any allergies and idiosyncrasies of the patient and any chronic disease states and frequently used over-the-counter medication as communicated to the pharmacist by the patient. If the answer is none, this must be indicated on the profile.

5.7.4 Upon receipt of a new prescription, a pharmacist pharmacy intern or student participating in a College of Pharmacy practical experience program under the direct supervision of a pharmacist must examine the patient's profile record before dispensing the medication to determine the possibility of a harmful drug interaction or reaction. Upon recognizing a potential harmful reaction or interaction, the pharmacist shall take appropriate action to avoid or minimize the problem which shall, if necessary, include consultation with the prescriber.

5.7.5 A patient profile record must be maintained for a period of not less than one year from the date of the last entry in the profile record unless it is also used as a dispensing record.

5.8 Exchange of Valid Non-Controlled Prescriptions Between Pharmacies

5.8.1 Verbal Exchange of Prescriptions - When a pharmacy receives a verbal request for a prescription transfer, it may be honored provided that:

5.8.1.1 The request comes from a registered pharmacist.

5.8.1.2 The copy is immediately reduced to writing and contains the information required on a written prescription as listed in Regulation 5.0, and includes the first and last name of the pharmacist transmitting the information.

5.8.1.3 The prescription used for refills must be clearly identified as a copy.

5.8.1.4 The copy shows the date and the file number of the original prescription and indicates the name and address of the pharmacy providing the copy.

5.8.1.5 The copy shows the last date of dispensing.

5.8.1.6 Only the actual number of refills remaining are indicated.

5.8.1.7 A notation indicating a copy was given and refills are no longer valid must be placed on either the original prescription or patient profile. The document used must be the same one used for the recording of refills per the pharmacy's policy.

5.8.2 A copy prepared or transmitted that does not meet the requirements of this Regulation is deemed to be an invalid prescription.

5.8.3 Written copies of prescriptions are for information only and are not valid for refilling.

5.9 Automated Data Processing Systems

5.9.1 Profiles. When ADP's are used to maintain patient profile records, all the requirements of Delaware Pharmacy Regulation 5.0 must be met.

5.9.2 Prescription (Drug Order) Information. Prescription information (drug order) shall include, but not be limited to:

5.9.2.1 Original dispensing date

5.9.2.2 Name and address of patient (patient location if in an institution)

5.9.2.3 Name of prescriber

5.9.2.4 DEA number of prescriber in the case of a controlled substance

5.9.2.5 Name, strength, dosage form and quantity, (or Stop Date), and route of administration if other than oral form of drug prescribed

5.9.2.6 Renewals authorized

5.9.2.7 Directions of use for patient

5.9.3 Records of Dispensing. Records of dispensing for original and refill prescriptions are to be made and kept by pharmacies for three years. Information must be immediately accessible for a period of not less than one year from the date of last entry. Information beyond one year but up to three years from the date of last entry may be maintained off-line but must be produced no later than five days upon request from proper authorities. The information shall include, but not be limited to:

- 5.9.3.1 Quantity dispensed
- 5.9.3.2 Date of dispensing
- 5.9.3.3 Serial Number (or equivalent if an institution)
- 5.9.3.4 The identification of the pharmacist responsible for dispensing
- 5.9.3.5 Record of renewals to date
- 5.9.3.6 Name and strength of medicine

5.9.4 Record Retrieval (Documentation of Activity). Any such ADP system must provide via CRT display and or hard copy printout a current history of all authorized prescription activity. This information shall include, but not be limited to:

- 5.9.4.1 Serial number of prescription (equivalent if an institution)
- 5.9.4.2 Date of processing
- 5.9.4.3 Quantity dispensed
- 5.9.4.4 The identification of the pharmacist responsible for dispensing
- 5.9.4.5 Medication dispensed

5.9.5 Auxiliary Recordkeeping System. An auxiliary recordkeeping system shall be established for the documentation of renewals if the ADP is inoperative for any reason. The auxiliary system shall insure that all renewals are authorized by the original prescription and that the maximum number of renewals are not exceeded. When the ADP is restored to operation, the information regarding prescriptions dispensed and renewed during the inoperative period shall be entered into the automated data processing system.

5.9.6 Common Data Base. Two or more pharmacies may establish and use a common data file or base to maintain required or pertinent dispensing information. Pharmacies using such a common file are not required to transfer prescriptions or information for dispensing purposes between or among pharmacies participating in the same common prescription file or data base; provided however, any such common file must contain complete and adequate records of such prescription and renewals dispensed. Where common data base is used, this shall not be considered a transfer under Board Regulation 5.0 for non-controlled substances.

5.9.7 Transfer of Prescriptions via ADP. A pharmacist may transfer a prescription electronically (ADP) for Schedule III, IV, or V controlled substances to another pharmacy for renewal purposes in accordance with Title 21, Code of Federal Regulations Section 1306.26. A pharmacist may transfer a prescription electronically (ADP) for non-controlled drug for renewal purposes in accordance with current State Regulations.

5.9.7.1 Any pharmacy using ADP must comply with all applicable State and Federal regulations.

5.9.7.2 A pharmacy shall make arrangements with the supplier of data processing services or materials to assure that the pharmacy continues to have adequate and complete prescription and dispensing records if the relationship with such supplier terminates for any reason. A pharmacy shall assure continuity in maintenance of records.

5.9.7.3 The computer record shall reflect the fact that the prescription order has been transferred, the name of the pharmacy to which it was transferred, the date of transfer, the name of the pharmacist transferring information, and any remaining refill information, if applicable.

5.9.7.4 The pharmacist receiving the transferred prescription drug order shall reduce it to writing with the following information:

5.9.7.4.1 Write the word "TRANSFER" on the face of the transferred prescription.

5.9.7.4.2 Provide all information required to be on the prescription drug order pursuant to State and Federal laws and regulations.

5.9.7.5 To maintain the confidentiality of patient's prescriptions (drug orders) or other pertinent records, there must exist adequate safeguards of security. This shall also pertain to prevent non-user access.

5.10 Electronic Transmission Of Prescriptions

5.10.1 All Prescription Drug Orders communicated by way of Electronic Transmission shall:

5.10.1.1 be transmitted directly to a Pharmacist in a licensed Pharmacy of the patient's choice with no intervening Person having access to the Prescription Drug Order;

5.10.1.2 identify the transmitter's phone number for verbal confirmation, the time and date of transmission, and the identity of the Pharmacy intended to receive the transmission, as well as any other information required by Federal or State law;

5.10.1.3 be transmitted by an authorized Practitioner or his designated agent; and

5.10.1.4 be deemed the original Prescription Drug Order provided it meets the requirements of this subsection.

5.10.2 The prescribing Practitioner may authorize his agent to communicate a Prescription Drug Order orally or by way of Electronic Transmission to a Pharmacist in a licensed Pharmacy, provided that the identity of the transmitting agent is included in the order.

5.10.3 The Pharmacist shall exercise professional judgment regarding the accuracy, validity, and authenticity of the Prescription Drug Order communicated by way of Electronic Transmission consistent with existing Federal or State laws and rules.

5.10.4 All electronic equipment for receipt of Prescription Drug Orders communicated by way of Electronic Transmission shall be maintained so as to ensure against unauthorized access.

5.10.5 Persons other than those bound by a confidentiality agreement pursuant to Section 2.A. (2)(k) shall not have access to Pharmacy records containing Confidential Information or personally identifiable information concerning the Pharmacy's patients.

5.10.6 Controlled substance prescriptions may only be electronically transmitted via a facsimile.

5.10.7 Facsimile prescriptions must meet the following requirements in addition to the above listed electronic Transmission requirements.

5.10.7.1 The prescription order shall include the fax number of the transmitter, the number of transmitted pages, the name, phone number, and electronic number of the pharmacy intended to receive the transmission, and a confidentiality statement in bold type stating the electronic transmission should not be seen by unauthorized persons.

5.10.7.2 Unless the prescription is written for a schedule II controlled substance, the prescriber should not issue the written prescription to the patient.

5.10.7.3 A facsimile transmitted prescription order must be reduced to writing, unless received as a non-fading document, with a notation that the order was received by facsimile.

5.10.7.4 The receiving facsimile machine must be in the prescription department to protect patient-pharmacist-authorized prescriber confidentiality and security.

5.10.7.5 Both non-controlled and controlled substance prescriptions may be transmitted via facsimile following state and federal requirements. All prescription orders for controlled substances shall be hand-signed by the practitioner.

5.11 Return of Medications and Supply

5.11.1 Prescriptions and items of personal hygiene shall not be accepted for return or exchange by any pharmacist or pharmacy after such prescription or items of personal hygiene have been taken from the premises where sold, distributed or dispensed.

5.11.2 Products under the direct control of a health care professional which are packaged in manufacturer unit dose or tamper-proof unopened bulk containers, tamper proof seal in tact, including unused multi-dose punch cards, may be redispensed in accordance with expiration dating in customized patient medication package. Partially used products may not be redispensed. Nothing in this regulation precludes the Federal laws and regulations.

5.12 Centralized Prescription Processing

5.12.1 A Pharmacy may perform or outsource centralized prescription processing, services provided the parties:

5.12.1.1 have the same owner; or

5.12.1.2 have a written contract outlining the services to be provided and the responsibilities and accountabilities of each party in fulfilling the terms of said contract in compliance with federal and state laws and regulations; and

5.12.1.3 share a common electronic file or have appropriate technology to allow access to sufficient information necessary or required to fill or refill a prescription drug order.

5.12.2 The parties performing or contracting for centralized prescription processing services shall maintain a policy and procedures manual and documentation that implementation is occurring in a manner that shall be made available to the Board for review upon request and that includes, but is not limited to, the following:

5.12.2.1 A description of how the parties will comply with federal and state laws and regulations;

5.12.2.2 The maintenance of appropriate records to identify the responsible pharmacist(s) in the dispensing and counseling processes;

5.12.2.3 The maintenance of a mechanism for tracking the prescription drug order during each step in the dispensing process;

5.12.2.4 The maintenance of a mechanism to identify on the prescription label all pharmacies involved in dispensing the prescription drug, order;

5.12.2.5 The provision of adequate security to protect the confidentiality and integrity of patient information;

5.12.2.6 The maintenance of a quality assurance program for pharmacy services designed to objectively and systematically monitor and evaluate the quality and appropriateness of patient care, pursue opportunities to improve patient care, and resolve identified problems.

5.12.3 In addition to the requirements of 24 Del.C. §2536, all drugs dispensed to a patient that have been filled via a centralized prescription processing system shall bear a label containing an identifiable code that provides a complete audit trail of the dispensing of the drug and pharmaceutical care activities.

5.13 Compounded medications for office use

5.13.1 On the order of a practitioner, compounded products may be sold to the practitioner for use in his or her office to administer to individual patients, but not for resale.

Effective Date: October 11, 1996

Effective Date: April 14, 1997 Section 5.4 revised

Effective Date: June 11, 1998

Amended Effective September 11, 1999

1 DE Reg. 1965 (6/1/98)

3 DE Reg. 431 (9/1/99)

4 DE Reg. 163 (7/1/00)

4 DE Reg. 682 (10/1/00)

9 DE Reg. 85 (7/1/05)

(Break in Continuity of Sections)

13.0 Nuclear Pharmacy Regulations

13.1 Purpose and Scope

~~13.1.1 The purpose of this regulation is to recognize the practice of nuclear pharmacy as a specialty of pharmacy practice to be regulated by the Delaware State Board of Pharmacy. As such, the following rules are included to address those areas specific to this specialty practice.~~

~~13.1.2 Nuclear Pharmacy practice refers to a patient oriented service that embodies the scientific knowledge and professional judgment required to improve and promote health through the assurance of the safe and efficacious use of radiopharmaceuticals and other drugs.~~

13.2 Definitions

~~“**Authentication of Product History**” includes, but is not limited to, identifying the purchasing source, the ultimate fate, and any intermediate handling of any component of a radiopharmaceutical.~~

~~“**Authorized Personnel**” means any individual trained through management to be permitted to perform assigned duties in a safe and effective manner.~~

~~“**Authorized User**” means any individual or institution named on a radioactive materials licensed.~~

~~“**Nuclear Pharmacy**” is a pharmacy which provides radiopharmaceutical services.~~

~~“**Qualified Nuclear Pharmacist**” is a currently licensed pharmacist in the State of Delaware who meets either of the following criteria:~~

~~Must be currently certified as a nuclear pharmacist by the Board of Pharmaceutical Specialties.~~

~~Must have successfully completed a minimum of 700 contact hours of instruction in nuclear pharmacy and the safe handling and use of radioactive materials from a nationally accredited college of pharmacy or from an American Council on Pharmaceutical Education (ACPE) approved training program. The training qualifications are described in 13.6.~~

~~“**Radiopharmaceutical Quality Assurance**” means, but is not limited to, the performance of tests on radiopharmaceuticals to ascertain the radionuclidic, radiochemical, chemical, physical, and microbiological purity and the interpretation of the resulting data to determine their suitability for use in humans and animals, including internal test assessment, authentication of product history, and the keeping of proper records.~~

~~“**Radiopharmaceutical Services**” means, but shall not be limited to, the procurement, storage, handling, preparation, labeling, quality assurance testing, dispensing, delivery, record keeping, and disposal of radiopharmaceuticals and other drugs.~~

~~“**Radiopharmaceuticals**” are radioactive drugs as defined by the FDA to include any drug which exhibits spontaneous disintegration of unstable nuclei with the emission of nuclear particles or photons and includes any non radioactive reagent kit or nuclide generator which is intended to be used in the preparation of any such substance. This definition does not include drugs such as carbon containing compounds or potassium containing salts which~~

contain trace quantities of naturally occurring radionuclides. The term radiopharmaceutical also includes any biological product which is labeled with a radionuclide or intended solely to be labeled with a radionuclide.

“Restricted Area” means any area the access to which is controlled by the license for purpose of protection of individuals from exposure to radiation and radioactive materials.

“Unrestricted Area” means any area the access to which is not controlled by the licensee for purpose of protection of individuals from exposure to radiation and radioactive materials.

13.3 Nuclear Pharmacy—general Requirements. The process employed by any permit holder in this state concerning the handling of radioactive materials must involve procedures for the purchase receipt, storage, manipulation, compounding, distribution and disposal of radioactive materials. In order to insure the public health and safety in this respect, a nuclear pharmacy in this state shall meet the following general requirements:

13.3.1 A nuclear pharmacy may be managed only by a qualified pharmacist acting in the capacity of a pharmacist in charge who shall be responsible for the compliance with all laws and regulations, both state and federal pertaining to radiopharmaceuticals and radiopharmaceutical services. An actively licensed qualified nuclear pharmacist must personally supervise the operation of only one nuclear pharmacy when radiopharmaceutical services are being performed.

13.3.2 The nuclear pharmacy area shall be secured from access by unauthorized personnel.

13.3.3 Each nuclear pharmacist shall maintain accurate records of the acquisition, inventory, distribution, and disposal of all radiopharmaceuticals.

13.3.4 All nuclear pharmacies shall provide adequate space for radioactive storage and a product decay area.

13.3.5 Nuclear pharmacies shall comply with all applicable laws and regulations of federal and state agencies for the procurement, secure storage, inventory, preparation, distribution and disposal of radiopharmaceuticals and other drugs.

13.3.6 Radiopharmaceuticals are to be distributed only upon a prescription order from an authorized licensed medical practitioner or through the practitioner's agent.

13.3.7 A nuclear pharmacist shall transfer radioactive materials in accordance with all applicable laws and regulations.

13.3.8 A nuclear pharmacy upon receiving an oral prescription order for a radiopharmaceutical shall immediately have the prescription order reduced to writing or recorded in a data processing system which shall contain at least the following:

13.3.8.1 the name of the authorized user or his agent;

13.3.8.2 the date of distribution and the time of administration of the radiopharmaceutical;

13.3.8.3 the name of procedure;

13.3.8.4 the name of the radiopharmaceutical;

13.3.8.5 the prescription number assigned to the order for the radiopharmaceutical;

13.3.8.6 any specific instructions; and

13.3.8.7 the initials of the person who received the order.

13.3.8.8 When the order is for a therapeutic or blood product radiopharmaceutical, the patient's name must be obtained and recorded prior to dispensing.

13.3.8.9 If the product is for a therapeutic radiopharmaceutical the patient's name must be obtained and recorded (i.e. verified) by a pharmacist when the pharmacy receives an oral prescription.

13.3.9 In addition to other labeling requirements of the Board of Pharmacy for non-radioactive pharmaceuticals, the immediate outer container shield of a radiopharmaceutical to be dispensed shall be labeled with:

13.3.9.1 the name and address of the pharmacy;

13.3.9.2 the name of the prescriber;

13.3.9.3 the name of the procedure;

13.3.9.4 the standard radiation symbol;

13.3.9.5 the words "caution Radioactive material";

13.3.9.6 the prescription number of the radiopharmaceutical;

13.3.9.7 the radionuclide and chemical form;

13.3.9.8 the amount of radioactive material contained in millicuries (mCi), or microcuries (uCi) and the corresponding time that applies to this activity, if different from 13.3.9.9 of this paragraph;

13.3.9.9 the calibration date and time;

13.3.9.10 the expiration date and time;

- ~~13.3.9.11 if a liquid, the volume;~~
- ~~13.3.9.12 if a solid, the number of items or weight;~~
- ~~13.3.9.13 if a gas, the number of ampules or vials;~~
- ~~13.3.9.14 molybdenum-99 content to USP limits; and~~
- ~~13.3.9.15 the name of the patient or the words "Physicians Use Only" in the absence of a patient name.~~

~~If the order is for a therapeutic or blood-product radiopharmaceutical, the patient's name must be obtained and recorded prior to dispensing. The requirements of this subsection shall be met when the name of the patient is readily retrievable from the physician upon demand.~~

~~13.3.10 The immediate inner container label of a radiopharmaceutical to be distributed shall also be labeled with:~~

- ~~13.3.10.1 the standard radiation symbol~~
- ~~13.3.10.2 the words "Caution Radioactive Material"~~
- ~~13.3.10.3 the radionuclide;~~
- ~~13.3.10.4 the amount of radioactivity in mCi or uCi;~~
- ~~13.3.10.5 the calibration date and time~~
- ~~13.3.10.6 the prescription number of the radiopharmaceutical; and~~
- ~~13.3.10.7 the pharmacy name; and~~
- ~~13.3.10.8 the name of the patient or the words "Physicians use only" in the absence of a patient name.~~

~~If the order is for a therapeutic or blood-product radiopharmaceutical, the patient's name must be on the label.~~

~~13.4 Nuclear Pharmacy—minimum Requirements. All nuclear pharmacies must meet the requirements of the Department of Health and Rehabilitative Services for the control of radiation hazards and applicable requirements of the Federal Food and Drug Administration. In addition, in order to insure compliance with general safety requirements, the following additional minimum requirements must be met by a nuclear pharmacy:~~

~~13.4.1 Physical Facilities~~

~~13.4.1.1 Each nuclear pharmacy shall have an area for the storage, compounding, distribution and disposal of radiopharmaceuticals which shall be adequate to completely separate such radioactive pharmaceuticals from pharmacy areas which contain non-radioactive medicinal drugs.~~

~~13.4.1.2 The nuclear pharmacy facility shall have adequate space commensurate with the scope of services.~~

~~13.4.2 Equipment:~~

~~13.4.2.1 Vertical laminar air flow unit (hood) used as a shielded radiation containment drawing station;~~

~~13.4.2.2 Exhaust/fume unit (hood) with engineering controls to assure airborne concentrations in compliance with federal regulations for storage and handling of all volatile radioactive drugs, if applicable;~~

~~13.4.2.3 Vertical laminar flow biological safety cabinet to be used for all compounding of applicable radiopharmaceuticals (i.e. blood products; white blood cells procedures);~~

~~13.4.2.4 Dose calibrator;~~

~~13.4.2.5 Well scintillation counters;~~

~~13.4.2.6 Area rate meters;~~

~~13.4.2.7 Geiger-Mueller (GM) Survey meters;~~

~~13.4.2.8 Refrigerator;~~

~~13.4.2.9 Microscope;~~

~~13.4.2.10 Hemacytometer~~

~~13.4.2.11 Leaded glass syringe shields;~~

~~13.4.2.12 Personal radiation detection devices~~

~~13.4.3 Supplies:~~

~~13.4.3.1 Syringes and vials required to perform practice;~~

~~13.4.3.2 Disposable gloves and protective lab coats;~~

~~13.4.3.2 Supplies to insure sterile practices for I.V. solutions and preparations;~~

~~13.4.3.3 Supplies to perform thin layer chromatography;~~

~~13.4.3.4 Lead transport shields for syringes and vials;~~

~~13.4.3.5 D.O.T. type 7A approved transport containers and other labels and supplies for shipping radioactive materials.~~

~~13.4.4 Library/Current references: In addition to the reference requirements of Regulation 3.0, a nuclear pharmacy shall maintain a reference library which shall include the following:~~

~~13.4.4.1 NRC Title 10 CFR, Code of Federal Regulations;~~

~~13.4.4.2 NRC Title 21 CFR, Code of Federal Regulations;~~

~~13.4.4.3 NRC Title 49 CFR, Code of Federal Regulations;~~

- 13.4.4.4 NABP Nuclear Pharmacy Practice Guidelines;
- 13.4.4.5 A minimum of three current edition texts dealing with nuclear medicine science;
- 13.4.4.6 A copy of the procedure manual.
- 13.4.4.7 Delaware Radiation Control Regulations

13.5 Records.

13.5.1 Policy and procedure manual. All nuclear pharmacies shall maintain a policy and procedure manual. The nuclear pharmacy policy and procedure manual is a compilation of written policy and procedure statements.

13.5.2 A technical operations manual governing all nuclear pharmacy functions shall be prepared. It shall be continually revised to reflect changes in techniques, organization, etc. All pharmacy personnel shall be familiar with the contents of the manual.

13.5.3 The nuclear pharmacy policies and procedures manual shall be prepared by the pharmacist in charge with input from other pharmacy staff members.

13.6 Training Qualifications

13.6.1 A pharmacist licensed to practice pharmacy in this state who performs a radiopharmaceutical service shall, prior to engaging in such specialized practice, be qualified as a nuclear pharmacist and licensed by the Board of Pharmacy.

13.6.2 Qualifications for a nuclear pharmacist are as follows:

13.6.2.1 A pharmacist shall:

13.6.2.1.1 be a pharmacist licensed by the Board to practice pharmacy in Delaware.

13.6.2.1.2 submit to the Board either:

13.6.2.1.2.1 Certification that he or she has successfully completed a minimum of four months on the job training providing radioactive drug services under the supervision of a nuclear pharmacist;

13.6.2.1.2.2 certification that he or she has successfully completed a nuclear pharmacy training program in an accredited college; or

13.6.2.1.2.3 an application, in affidavit form, along with such other information the Board may require, requesting partial or equivalent credit for education and experience gained in programs not sponsored by an accredited college of pharmacy.

13.6.2.2 A qualified pharmacist seeking licensure as a nuclear pharmacist in the state shall submit to the Board of Pharmacy a course outline from an accredited college of pharmacy or other program recognized by the Delaware Board of Pharmacy (a program comparable to those offered by accredited colleges of pharmacy for the training of nuclear pharmacists), and a certificate of training which provides a minimum of 200 clock hours of formal didactic training, which includes:

13.6.2.2.1 Radiation protection (45 hours);

13.6.2.2.2 Radiation physics and instrumentation (85 hours);

13.6.2.2.3 Mathematics of radioactivity (20 hours);

13.6.2.2.4 Radiation biology (20 hours); and

13.6.2.2.5 Radiopharmaceutical chemistry (30 hours).

13.6.2.3 Proof of attaining a minimum of 500 hours of clinical nuclear pharmacy training under the supervision of a qualified nuclear pharmacist. The training and experience shall include, but shall not be limited to the following:

13.6.2.3.1 Procurement

13.6.2.3.2 Compounding

13.6.2.3.3 Quality Assurance

13.6.2.3.4 Dispensing

13.6.2.3.5 Distribution

13.6.2.3.6 Health and Safety

13.6.2.3.7 Provisions of Information and Consultation

13.6.2.3.8 Monitoring patient outcome

13.6.2.3.9 Research and Development

13.7 Nuclear Pharmacist Continuing Education

13.7.1 Proof satisfactory that a nuclear pharmacist licensed pursuant to this section, has met the requirements necessary for biennial renewal of this license shall be constituted by the following:

13.7.1.1 The licensee has completed no less than ten (10) out of the total requirements of 30 hours of coursework each two year period by or through a committee approved provider (e.g. ACPE), instructionally designed to provide in depth treatment of nuclear pharmacy practice.

13.7.1.2 Content of nuclear pharmacist continuing education program can include, but not be limited to the following:

13.7.1.2.1 Formulation and quality control issues in nuclear pharmacy
13.7.1.2.2 Radionuclide therapy in nuclear pharmacy
13.7.1.2.3 Radiopharmaceutical updates for target organs
13.7.1.2.4 Current concepts in radiation physics, radiation biology and exposure.
13.7.1.2.5 Current principles of radiation safety
13.7.1.2.6 Current principles of nuclear pharmacy management
13.7.1.2.7 Advances in drug, radiopharmaceutical, or related technology (including but not limited to monoclonal antibodies, peptides, magnetic resonance imaging, positron emission tomography, novel radionuclide therapy and other applicable issues.

Effective 09/23/95

13.1 Purpose and Scope.

The Practice of Nuclear/Radiological Pharmacy is hereby recognized as a specialty of Pharmacy practice, regulated by the Delaware Board of Pharmacy. As such, the following rules are included to address those areas specific or unique to this specialty practice. Nuclear/Radiological Pharmacy Practice refers to patient-oriented and institutional services that embody the scientific knowledge and professional judgment required to improve and promote health through the assurance of the safe and efficacious use of radiopharmaceuticals and other drugs.

13.2 Definitions

“Authentication of Product History” means, but is not limited to, identifying the purchase sources, and any handling of any Component of a radiopharmaceutical.

“Internal Test Assessment” means, but is not limited to, conducting those tests of quality assurance necessary to ensure the integrity of the product.

“Nuclear Pharmacy” means a Pharmacy providing radiopharmaceutical services or, as provided in Section 3 of these rules, an appropriate area of any Institutional Facility.

“Qualified Nuclear Pharmacist” means a currently licensed Pharmacist in the State of Delaware, who is certified as a Nuclear Pharmacist by a certification Board recognized by the Delaware Board of Pharmacy, or who meets the following standards set by the Delaware Board of Pharmacy:

Satisfied the minimum standards of training for “authorized user status” of radioactive material as included in the Nuclear Regulatory Commission (NRC) licensure guide.

Completed a minimum of 200 contact hours of instruction in nuclear Pharmacy and the safe handling and the use of radioactive materials from a program approved by the NRC or the Office of Radiation Control (ORC), with emphasis in the following areas: radiation physics and instrumentation; radiation protection; mathematics of radioactivity; radiation biology; and radiopharmaceutical chemistry.

Attained a minimum of 500 hours of clinical nuclear Pharmacy training under the supervision of a qualified nuclear Pharmacist.

“Radiopharmaceutical Quality Assurance” means, but is not limited to, the performance of appropriate chemical, biological, and physical tests on potential radiopharmaceuticals and the interpretation of the resulting data to determine their suitability for use in humans and animals, including internal test assessment, authentication of product history, and the keeping of proper records.

“Radiopharmaceutical Service” means, but is not limited to, the procurement, storage, handling preparation, labeling, quality assurance testing, dispensing, delivery, recordkeeping, and disposal of radiopharmaceuticals and other drugs.

“Radiopharmaceuticals” are radioactive drugs as defined by the FDA.

13.3 General Requirements for Pharmacies Providing Radiopharmaceutical Services.

13.3.1 Nuclear Pharmacy License. A License to operate a Pharmacy providing radiopharmaceutical services shall only be issued to a Qualified Nuclear Pharmacist. All personnel performing tasks in the preparation and distribution of radioactive drugs shall be under the direct supervision of a Qualified Nuclear Pharmacist. A Qualified Nuclear Pharmacist shall be responsible for all operations of the Pharmacy and shall be in personal attendance at all times that the Pharmacy is open for business.

13.3.2 Nuclear Pharmacies shall have adequate space and equipment, commensurate with the scope of services required and provided, meeting minimal space requirements established for all pharmacies in the State or as otherwise defined by the Delaware State Board of Pharmacy.

13.3.3 The Nuclear Pharmacy area shall be secured from unauthorized personnel.

13.3.4 Nuclear Pharmacies shall maintain records of acquisition, inventory, and disposition of all radioactive drugs and other radioactive materials in accordance with NRC statute(s) and regulation(s).

13.3.5 All pharmacies handling radiopharmaceuticals shall provide a radioactive storage and product decay area. Detailed floor plans shall be submitted to the State Board of Pharmacy and the State Office of Radiation Control and NRC before approval of the license.

13.3.6 Radiopharmaceuticals are to be dispensed only upon a Prescription Drug Order from a Practitioner authorized to possess, use, and administer radiopharmaceuticals.

13.3.7 The permit to operate a Nuclear Pharmacy is conditioned upon an approved State Office of Radiation Control or NRC license. Copies of the Radiation Control Agency, ORC and NRC inspection reports shall be made available upon request for Board inspection.

***Please Note: As the rest of the sections were not amended they are not being published. A complete set of the rules and regulations for the Board of Pharmacy is available at:**

<http://dpr.delaware.gov/boards/pharmacy/index.shtml>

9 DE Reg. 1253 (02/01/06) (Final)