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

PROPOSED

PUBLIC NOTICE

PLEASE TAKE NOTICE, pursuant to Title 29, Chapter 101 and Title 24, Section 2509 of the **Delaware Code**, the State Board of Pharmacy proposes changes to its regulations affecting the licensure of wholesale distributors. The proposed changes to **8.0 Requirements for Obtaining a Permit to Distribute Drugs on a Wholesale Basis** were prompted by recent changes in the National Association of Boards of Pharmacy's Model Rules for the Licensure of Wholesale Distributors (Model Rules). The proposed changes incorporate some but not all of the changes to the Model Rules. A few minor grammatical, typographic, or stylistic changes are also included.

A public hearing will be held on the proposed regulations on Wednesday, September 20, 2006 at 9:30 a.m. in the 2nd floor Conference Room A of the Cannon Building, 861 Silver Lake Boulevard, Dover, Delaware 19904. The Board will receive and consider input in writing from any person on the proposed regulations. Any written comments should be submitted to the Board in care of Mariah Krass at the above address. The final date to submit written comments shall be at the above scheduled public hearing. Anyone wishing to obtain a copy of the proposed regulations or to make comments at the public hearing should contact Mariah Krass at the above address or by calling (302) 744-4526.

The Board will consider promulgating the proposed regulations immediately following the public hearing.

2500 Board of Pharmacy

1.0 Pharmacist Licensure Requirements

1.1 Examination Requirements

1.1.1 In order to be eligible for examination for licensure, an applicant must provide proof of completion of all requirements for graduation from an approved school or college. An approved school or college of pharmacy is an institution which has established standards in its undergraduate degree program which are at least equivalent to the minimum standards for accreditation established by the American Council on Pharmaceutical Education. Provided, however, that graduates of schools or colleges of pharmacy located outside of the United States, which have not established standards in their respective undergraduate degree programs which are at least equivalent to the minimum standards for accreditation established by the American Council on Pharmaceutical Education, shall be deemed eligible for examination for licensure by providing evidence satisfactory to the Board of Pharmacy of graduation from such school or college and by successfully passing an equivalency examination recognized by the Board of Pharmacy. Certification by the National Association of Boards of Pharmacy (NABP) Foreign Pharmacy Graduate Examination Committee (FPGEC) meets the equivalency examination requirement.

1.1.2 Candidates must obtain a passing grade as determined by the National Association of Boards of Pharmacy (NABP) on the North American Pharmacist Licensure Examination (NAPLEX) and the Multistate Pharmacy Jurisprudence Examination for Delaware (MPJE) to be eligible for a license to practice. A candidate must take an examination within 365 days of the determination of eligibility by the Board. The Secretary will supply the grades obtained to the candidate upon receipt of a written request from that person.

1.1.3 The Board will re-confirm the eligibility of an applicant who fails the NAPLEX. The applicant shall be entitled to take a re-examination at least ninety-one (91) days following the date of the failure. If an applicant has failed the examination three times, he/she shall be eligible to re-take the NAPLEX, provided that he/she produces evidence of working full-time as an intern for a period of six months or has attended an accredited college of pharmacy as a registered student for a minimum of one semester consisting of 12 credits during the interim. A certification of satisfactory completion of such work shall be furnished by the Dean of the College or the preceptor as the case may be.

1.1.4 The Board will re-confirm the eligibility of an applicant who fails the MPJE. The applicant shall be entitled to re-take the MJPE at least thirty-one (31) days following the date of the failure. If an applicant has failed the examination three times, he or she shall be eligible to re-take the examination, provided that he or she produces evidence of working full-time as an intern for a period of three months or has completed a one semester college course on jurisprudence.

1.2 Practical Experience Requirements

1.2.1 An applicant for registration as an intern must submit an application for registration of Internship after entering the first professional year of college of pharmacy which includes an "Affidavit of Class Standing" and "Affidavit of Preceptor." This application must be obtained from the Board of Pharmacy. If the applicant is a graduate of a foreign pharmacy school, he/she must produce evidence that he/she has passed an equivalency examination by the Board.

1.2.2 Persons who register as interns in the State of Delaware shall, in accordance with the requirements of 24 **Del.C.** §2515, complete not less than 1500 hours of Board approved practical experience under the supervision of a licensed pharmacist. A minimum of 1000 hours shall be obtained in the community or hospital settings. The remaining 500 hours may be obtained in other recognized fields of practice, e.g.: Industrial Pharmacist, Drug Information Pharmacist, Military Pharmacist, Mail Order Pharmacist, HMO Pharmacist, Consultant Pharmacist (Nursing Home, Infusion, Medicaid DUR, Etc.), Home Health Care Pharmacist (may include Durable Medical Equipment, etc.), Nuclear Pharmacist, Compliance Pharmacist, Government Pharmacist, Clinical Pharmacist, Contracted Pharmacy Services.

1.2.3 Practical experience must be acquired under the supervision of a licensed pharmacist known as a Preceptor. The Preceptor must be a pharmacist licensed in this State or any other State and must have a minimum of two years of pharmacy practice. A pharmacist affiliated with a College of Pharmacy shall serve as the preceptor for a student participating in the coordinated practical experiance program. The Preceptor must certify that the intern has successfully completed all the requirements outlined in the Responsibilities of the Intern professional assessment form.

1.2.4 Practical experience acquired in another State is acceptable if the State Board in which the applicant acquired the hours submits a letter of certification, or if the applicant's preceptor completes the Delaware State Board of Pharmacy's Affidavit of Intern Experience form. Applicants who have not completed all the practical experience requirements, but who have graduated from an accredited college or have been certified by the NABP Foreign Pharmacy Graduate Examination Committee are eligible to take the examination. However, applicants will not be fully licensed until all the requirements of the Statutes and Regulations are completed.

1.2.5 The hours accrued during the College of Pharmacy Practical Experience Program may be applied to the 1500 hours total. These hours shall be recorded on the College Practical Experience Affidavit supplied by the Board. Registration as an intern in this State is not required for school experience.

1.2.6 An intern must notify the Board of Pharmacy in writing within ten (10) days of a change or preceptor. A change of preceptor affidavit must be completed and filed with the Board.

1.3 Continuing Education Requirements

1.3.1 A pharmacist must acquire 3.0 C.E.U.'s (30 hours) per biennial licensure period. No carry over of credit from one registration period to another period is permitted.

1.3.2 Hardship - Hardship exemptions may be granted by the Board of Pharmacy upon receipt of evidence that the individual was unable to complete the requirements due to circumstances beyond his control.

1.3.3 Criteria for Hardship Exemption as Recommended by the Board of Pharmacy:

1.3.3.1 Applicant must notify the Board in writing concerning the nature of the hardship and the time needed for an extension. In case of medical disability, a letter from the physician with supporting documentation to corroborate the condition and the length of time of extension needed.

1.3.3.2 The Board of Pharmacy will review requests.

1.3.3.3 The Board will notify the registrant of its decision.

1.3.4 Persons who are newly licensed after the registration period begins, must complete continuing education units proportional to the total number of continuing education units required for the biennial licensure renewal. (1.25 hours/per month).

1.4 Continuing Professional Educational Programs

1.4.1 Topics of Study

Topics of study shall be subject matter designed to maintain and enhance the contemporary practice of pharmacy.

1.4.2 Approved Provider

1.4.2.1 Any provider approved by ACPE.

1.4.2.2 In-state organization which meets criteria approved by the Board.

1.4.3 Application for Delaware State Provider

1.4.3.1 Any in-state organization may apply to the Board on forms provided by the Board for initial qualification as an approved provider. The Board shall accept or reject any such application by written notice to such organization within 60 days after receipt of its application. If an organization is approved, the Board will issue a certificate or other notification of qualification to it, which approval shall be effective for a period of two years and shall be renewable upon the fulfillment of all requirements for renewal as set forth by the Board.

1.4.3.2 The Board may revoke or suspend an approval of a provider or refuse to renew such approval if the provider fails to maintain the standards and specifications required. The Board shall serve written notice on the provider by mail or personal delivery at its address as shown on its most current application specifying the reason for suspension, revocation, or failure to renew. The provider so affected shall, upon written request to the Board within ten days after service of the notice, be granted a prompt hearing before the Board at which time it will be permitted to introduce matters in person, or by its counsel, to defend itself against such revocation, suspension, or failure to renew, in accordance with the provisions set forth in the State's Administrative Procedures Act.

1.4.4 Criteria for Approval of Delaware State Providers. Only applicants who are located within the State of Delaware are eligible. Such Continuing Education providers shall provide evidence of ability to meet the following criteria or approval as a Continuing Pharmaceutical Education Provider. Other persons must apply through ACPE for approval or be acceptable to other Boards of Pharmacy that certify continuing education for relicensure.

1.4.4.1 Administration and Organization

1.4.4.1.1 The person who is in charge of making sure that the program meets the quality standards must have a background in the administration of education programs.

1.4.4.1.2 There shall be an identifiable person or persons charged with the responsibility of administering the continuing pharmaceutical education program.

1.4.4.1.3 Such personnel shall be qualified for such responsibilities by virtue of experience and background.

1.4.4.1.4 If an approved provider presents programs in co-sponsorship with other non-approved provider(s), the approved provider has the total responsibility for assurance of quality of that program. If more than one approved provider co-sponsors a program, they have the joint responsibility for assuring quality.

1.4.4.1.5 Administrative Requirements include:

1.4.4.1.5.1 The development of promotional materials which state:

1.4.4.1.5.1.1 Educational objectives.

1.4.4.1.5.1.2 The target audience.

1.4.4.1.5.1.3 The time schedule of the activities.

1.4.4.1.5.1.4 Cost to the participant/covered items.

1.4.4.1.5.1.5 Amount of C.E. credit which will be awarded.

1.4.4.1.5.1.6 Credentials of the faculty, presenters, and speakers.

1.4.4.1.5.1.7 Self-evaluation instruments.

1.4.4.1.5.2 Compliance with a quantitative measure for C.E. credit.

1.4.4.1.5.2.1 The number of C.E.U.'s to be awarded for successful completion shall be determined by the provider and reported in the promotional materials.

1.4.4.1.5.2.2 In cases where the participants' physical presence is required, C.E. credit will only be awarded for that portion of the program which concerns itself with the lecture(s), evaluation and question and answer segments.

1.4.4.1.5.2.3 The measure of credit shall be a fifty-minute contact hour. In the case of other programs such as home study courses, the amount of credit awarded shall be determined by assessing the amount of time the activity would require for completion by the participant if delivered in a more formal and structured format.

1.4.4.1.5.2.4 The provider must provide the Board upon request with appropriate records of successful participation in previous continuing education activities.

1.4.4.1.5.2.5 The provider must present to the participant a form or certificate as documentation of the completion of the program. The form must be at least 4" x 6" and no larger than 8 1/2" x 11". That certificate must show the name, address, and license number of the participant, the name of the provider, the title and date of the program, the number of credits earned, and an authorized signature from the provider.

1.4.4.2 Program Faculty. The selection of program faculty must be based upon proved competency in the subject matter and an ability to communicate in order to achieve a learning experience.

1.4.4.3 Program Content Development

1.4.4.3.1 Such programs shall involve effective advance planning. A statement of educational goals and/or behaviors must be included in promotional materials. Such objectives and goals must be measurable and accessible to evaluation. In determining program content, providers shall involve appropriate members of the intended audience in order to satisfy the educational needs of the participants. All programs of approved providers should pertain to the general areas of professional pharmacy practices which should include, but not be limited to:

1.4.4.3.1.1 The social, economic, behavioral, and legal aspects of health care,

1.4.4.3.1.2 the properties and actions of drugs and drug dosage forms,

1.4.4.3.1.3 the etiology, characteristics, therapeutics and prevention of the disease state,

1.4.4.3.1.4 pharmaceutical monitoring and management of patients.

1.4.4.3.2 All ancillary teaching tools shall be suitable and appropriate to the topic.

1.4.4.3.3 All materials shall be updated periodically to include up-to-date-practice setting.

1.4.4.3.4 It is the responsibility of the provider to be sure that the programs are continuously upgraded to meet educational objectives of the Practice of Pharmacy. The needs of the pharmacist participant must be considered in choosing the method of delivery. Innovation in presentations is encouraged within the limits of budget resources and facilities. Whatever method of delivery is used, it must include the participation of the pharmacist as much as possible within the program, i.e. questions and answers, workshops, etc.

1.4.4.4 Facilities. The facilities shall be adequate for the size of the audience, properly equipped (all appropriate audio/-visual media materials), well lighted and ventilated to induce a proper learning experience.

1.4.4.5 Evaluation. Effective evaluation of programs is essential and is the responsibility of both the provider and participant.

1.4.4.5.1 Participant - Some evaluation mechanisms must be developed by the provider to allow the participant to assess his/her own achievement per the program.

1.4.4.5.2 Provider evaluation - a provider shall also develop an instrument for the use of the participant in evaluating the effectiveness of the program including the level of fulfillment of stated objectives.

1.4.5 Criteria for Awarding Continuing Education Credits. Individual programs must meet the criteria for provider approval in order to be considered. In those cases where the provider is not an ACPE provider, nor a Board of Pharmacy approved provider, a registrant may complete an application provided by the Board for approval of individual programs.

1.4.5.1 In order to receive full credit for non-ACPE approved programs of one-to-two hour lengths, evidence of a post test must be presented. An automatic 25% deduction if no post test presented.

1.4.5.2 In order to receive full credit for non ACPE approved programs of three or more hours in length, evidence of a pre and post test must be presented. Automatic 25% deduction if no pre and post test presented.

1.4.5.3 Credit will be assigned only for the core content of the program which explicitly relates to the contemporary practice of Pharmacy.

1.4.5.4 A maximum of 2 credit hours will be awarded for First Aid, attendance at a Board of Pharmacy meeting and CPR/BCLS courses one time only per registration period.

1.4.5.5 Credit for Instructors of Continuing Education

1.4.5.5.1 Any pharmacist whose primary responsibility is not the education of health professionals, who leads, instructs or lectures to groups of nurses, physicians, pharmacists or others on pharmacy related topics in organized continuing education or inservice programs, shall be granted continuing education credit for such time expended during actual presentation, upon adequate documentation to the Delaware Board of Pharmacy.

1.4.5.5.2 Any pharmacist whose primary responsibility is the education of health professionals shall be granted continuing education credit only for time expended in leading, instructing, or lecturing to groups of physicians, pharmacists, nurses or others on pharmacy related topics outside his/her formal course responsibilities (that is, lectures or instructions must be prepared specifically for each program) in a learning institution.

1.4.5.5.3 Credit for presentations of in-service training programs or other lectures shall be granted only for topics meeting the criteria for continuing pharmacy education, and shall be granted only once for any given program or lecture. (Any topic completely revised would be eligible for consideration.)

1.4.5.5.4 A maximum of 6 hours (0.6 C.E.U.'s) in this category may be applied toward fulfilling the total biennial continuing education requirements.

1.4.5.6 Credit for On the Job Training:

1.4.5.6.1 The Board of Pharmacy does not as a general rule encourage the submission of "on the job training" for fulfilling the continuing education requirements. All programs meeting this definition shall be reviewed on an individual basis.

1.4.5.6.2 All programs that are submitted for credit must meet the criteria for continuing pharmacy education.

1.4.5.6.3 No credit shall be awarded for programs required by an employer for continued employment of the employee. (Examples OSHA training, Infection Control Education required by JCAHO.)

1.4.5.6.4 A maximum of 4 hours (0.4 C.E.U.'s) in this category may be applied toward fulfilling the total biennial continuing education requirements.

1.5 The Verification of Continuing Education - A pharmacist shall retain the supporting documentation, such as certification of completion for a minimum of six years. The Board will randomly audit the documentation of at least 10% of licensed pharmacists every biennial term. Supporting documentation may be requested for up to six years. Pharmacists who were not selected for audit do not send supporting documentation to the Board. Submitting a false documentation may constitute grounds for discipline under 24 **Del.C.** §2518 (a)(1).

1.6 Reciprocal Requirements

1.6.1 An applicant for licensure by reciprocity shall be of good moral character and shall:

1.6.1.1 submit proof that he or she was qualified for licensure in Delaware at the time of initial licensure by examination;

1.6.1.2 submit proof of licensure in good standing from each state where he or she is or has been licensed; and

1.6.1.3 obtain a passing score on the MPJE on the laws applicable in this State as provided in Regulation 1.1.

1.6.2 Reciprocity applicants who took examinations after June 1, 1979, must have passed the NAPLEX or an examination deemed equivalent by the Board and obtained scores required for applicants for licensure by examination.

1.6.3 Applicants who are licensed by reciprocity must begin accruing continuing education units at a rate of 1.25 hours/per month beginning with the month of licensure.

Regulation 1.2 revised 10/11/96
Regulation 1.3.2 revised 2/6/97
Regulation 1.3.2 deleted, 1.3.3.1 amended, 1.4 amended Effective date 10/11/98
1 DE Reg. 1965 (6/1/98)
2 DE Reg. 683 (10/1/98)
4 DE Reg. 163 (7/1/00)

4 DE Reg. 1501 (3/1/01)
6 DE Reg. 488 (10/1/02)
7 DE Reg. 309 (9/1/03)
9 DE Reg. 85 (7/1/05)

2.0 Grounds for Disciplinary Proceeding

2.1 Unprofessional conduct shall include but is not limited to the following act(s) of a pharmacist pursuant to 24 **Del.C.** §2518(A):

2.1.1 Knowingly engaging in any activity which violates State and Federal Statutes and Regulations governing the practice of Pharmacy;

2.1.2 Knowingly dispensing an outdated or questionable product;

2.1.3 Knowingly dispensing the cheaper product and charging third party vendors for a more expensive product;

2.1.4 Knowingly charging for more dosage units than is actually dispensed;

2.1.5 Knowingly altering prescriptions or other records which the law requires the pharmacies or pharmacists to maintain;

2.1.6 Knowingly dispensing medication without proper authorization;

2.1.7 Knowingly defrauding any persons or government agency receiving pharmacy services;

2.1.8 Placing a signature on any affidavit pertaining to any phase of the practice of pharmacy which the pharmacist knows to contain false information.

2.1.9 Fraudulently altering or forging the contents of prescriptions;

2.1.10 Payment of money or the providing of free services to a third party in return for the third party's referral of patients to the pharmacist or pharmacy;

2.1.11 Dispensing any legend drugs either for personal use or for use by another person without a valid order from a prescriber. Valid prescription means that it is not only written correctly, but is for a medical use (i.e. prescriptions written "as directed" are prohibited);

2.1.12 Unauthorized substitution;

2.1.13 Dispensing medications which are not approved for marketing by the Food and Drug Administration nor approved for marketing by State law;

2.1.14 Continuous failure to correct violations of Statutes and Regulations noted in Board of Pharmacy communication;

2.1.15 Knowingly allowing persons who are not registered pharmacists to dispense medication without proper supervision;

2.1.16 Knowingly committing a fraudulent act. This would include destroying or altering any records such as prescriptions, profiles, third party vouchers and receipts;

2.1.17 Knowingly misbranding a drug by using a brand name when a generic is dispensed;

2.1.18 Practicing under the influence of drugs or alcohol;

2.1.19 The placement of an advertisement which the pharmacist knows to be false or misleading;

2.1.20 Knowingly breaching confidentiality of the patient/pharmacist relationship by supplying information to unauthorized persons;

2.1.21 Engaging in activities that would discredit the profession of pharmacy;

2.1.22 Attempting to circumvent the patient counseling requirements or discouraging the patients from receiving patient counseling concerning their prescription drug orders.

2.1.23 Using facsimile equipment to circumvent documentation, authenticity, verification or other standards of pharmacy or drug diversion. (Effective 2/29/96)

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

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.

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)
9 DE Reg. 1253 (2/1/06)

4.0 Pharmacy Closing Procedure

The Executive Secretary of the Delaware State Board of Pharmacy shall be notified by letter via certified mail, or hand delivered written notification of the intent to close a licensed Delaware pharmacy. The Executive Secretary shall be notified at least 14 days in advance of the closing date. In the event of death of the owner/ pharmacist-in-charge, the Executive Secretary will be notified immediately.

The closing procedure will be completed by a Delaware licensed pharmacist-in-charge or in the event of death, a Delaware licensed pharmacist designated to perform the closing procedure. Should the permit to operate a pharmacy be revoked or suspended by the Delaware State Board of Pharmacy, the procedure following such action will be directed by the Board. The Delaware Board of Pharmacy and its authorized agents will enforce this regulation under the authority of 24 **Delaware Code**, Section 2535.

4.1 Permanent Closing of a Pharmacy

4.1.1 Board Notification:

4.1.1.1 Certified letter at least 14 days prior to the planned closing to the Executive Secretary of the Delaware Board of Pharmacy.

4.1.1.2 In the event of death of owner/pharmacist-in-charge, notification immediately to the Executive Secretary of Delaware Board of Pharmacy.

4.1.1.3 In case of fire or water damage, notify the Executive Secretary of the Delaware Board of Pharmacy immediately.

4.1.2 Required Information to be submitted to the Executive Secretary of the Delaware Board of Pharmacy:

4.1.2.1 Name, address and phone number.

4.1.2.2 Pharmacy permit and Delaware Controlled Substance registration number and D.E.A. registration numbers.

4.1.2.3 Name of pharmacist-in-charge responsible for closing.

4.1.2.4 Date of closing.

4.1.2.5 Name, address, phone number of licensed pharmacy to which prescription drugs, (including controlled substances) prescription files and patient profiles will be transferred.

4.1.2.6 A closing inventory signed and dated of all controlled substances to be sent to the Office of Narcotics and Dangerous Drugs for their records.

4.1.2.7 Name, address, and phone number of custodian of controlled substance records (i.e. invoices, etc.) for the two-year period after closing as required by 21 CFR.

4.1.3 Public Notification:

4.1.3.1 A publication in a local newspaper for one week informing the public the pharmacy is closing on a specific date and the name of the pharmacy to which the prescriptions will be transferred.

4.1.3.2 Name and phone number of person to contact in emergency after closing of pharmacy.

4.1.3.3 A sign posted in the window of pharmacy 14 days prior to closing and to remain 14 days after closing informing the public where prescriptions are being transferred.

4.1.3.4 Remove all signs within 30 days of closing that refer to, "pharmacy," "apothecary," "drugs" or "medicine."

4.1.4 Permits and registration to be surrendered upon closing:

4.1.4.1 Pharmacy permit (Executive Secretary, Board of Pharmacy)

4.1.4.2 Delaware Controlled Substance certificate (Delaware Office of Narcotics & Dangerous Drugs).

4.1.4.3 Federal Controlled Substance certificate (D.E.A.).

4.1.4.4 All unused 222 Schedule II order forms (D.E.A.).

4.1.5 Sale of prescription drugs:

Should the pharmacy be sold, including prescription drugs, or if the prescription drugs are sold separately, the Board of Pharmacy must be notified to verify that the buyer is currently licensed to possess these drugs.

4.1.6 All above procedures must be accomplished within 7 days after closing or upon discretion of the Executive Secretary. Drugs must be properly secured in accordance with all laws and regulations until they are removed.

4.2 Temporary Closing of a Pharmacy

4.2.1 The Board office must be notified according to 24 **Del.C.** §2528.

4.2.2 Board notification must include the following:

4.2.2.1 The exact date the pharmacy will be closing.

4.2.2.2 The name, address and telephone number to be used in an emergency.

4.2.3 A public notice must be posted in a highly visible place within the prescription department at least 5 days prior to the temporary closing of a pharmacy (24 **Del.C.** §2528(B)) and also on a window visible to the public from outside the store. The notice must state:

4.2.3.1 Dates the pharmacy will be closed.

4.2.3.2 A contact number in case of emergency.

4.2.4 If the closing extends past the date given to the Board office, the pharmacy would automatically be put into the status of a permanently closed pharmacy and procedure established by Board regulation must be followed.

9 DE Reg. 1984 (06/01/06)

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 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.

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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)
9 DE Reg. 1253 (2/1/06)

6.0 Pure Drug Regulations

6.1 Definition

"Central Nervous System" Central nervous system stimulants are drugs which increase the activity of some portion of the brain or spinal cord. Drugs which act upon the cerebral cortex and subcortical structures including the thalamus (e.g. methylphenidate, etc.) increase motor activity and enhance mental alertness; those which act upon the sensory areas in the brain (e.g. caffeine and its various combinations) increase alertness, brighten spirits and combat mental fatigue; those which act directly or reflexly on the medulla (e.g. nikethamide, pentylenetetrazol and picrotoxin) stimulate the respiratory center; those which act on the spinal cord (e.g. nux vomica and strychnine) facilitate and exaggerate spinal reflexes.

6.2 The Delaware State Board of Pharmacy hereby adopts the rules and regulations officially prescribed for the enforcement of the Federal Food, Drug and Cosmetic Act and Acts amendatory thereof, as far as applicable. This regulation is promulgated to comply with directive in Title 16 **Del.C.** §3315 paragraph b.

6.3 Anyone who repacks and labels drugs in convenient quantities for their own subsequent use must maintain a log on the premises showing the date prepacked, the quantity prepacked, the control number, expiration date and name and strength of the drug. Prepacking must be done under the supervision of a registered pharmacist or any other person authorized to dispense under 24 **Del.C.** §2513. Each container must have a label containing the name of the drug, its strength, the manufacturer's control number, the expiration date if applicable, the name of the manufacturer, or the name and strength of the drug and a conference code number which would

enable the control number, manufacturer and expiration date to be retrieved from the log. Nothing in this regulation precludes the Federal laws and regulations.

6.3.1 Beyond use date for single unit and unit dose containers. The beyond use date for these products shall be one year or less, unless the stability data or the manufacturer's labeling indicates otherwise. To use this date, the dispenser repacking the product must maintain the facility and packaging at controlled room temperature not to exceed 25°C. The plastic material used for repacking must provide better protection against moisture permeation than polyvinyl chloride.

6.4 All biologicals, vaccines, drugs, chemicals, preparations and compounds must be packaged, labeled, stored and preserved in compliance with USP/NF and all other State and Federal standards. A pharmacist may, with the permission of the patient or the patient's agent, provide a “Customized Patient Medication Package” only to patients that are self-medicating. The containers shall meet all of the requirements of the USP/NF standard entitled, "Customized Patient Medication Package."

6.5 Labeling of Over-the-Counter Central Nervous System Stimulants. Over-the-counter central nervous system stimulants must be labeled and packaged in compliance with state and federal requirements.

6.6 Over-the-Counter Medication - Over-the-counter drug is one that can be legally sold without a prescription.

NOTE: The only over-the-counter products which currently can be labeled, advertised promoted, marketed or sold as a stimulant are those that do not contain any active ingredient but caffeine.

4 DE Reg. 1502 (3/1/01)

7.0 Non-pharmacy Outlets Handling Legend Veterinary Drugs

7.1 Persons who dispense must be adults (21 years of age).

7.2 The registrant must provide the Board with a list of persons who will dispense.

7.3 The Board must be notified in writing of any changes concerning those persons within 10 days of the change.

7.4 Storage - All medications must be stored in compliance with USP/NF standards. Example: 36 to 46 degrees Fahrenheit for drugs requiring refrigeration. 59 to 86 degrees Fahrenheit for drugs requiring storage at room temperature. All medications must be stored at the registered premise.

7.5 Security - Drugs requiring a prescription must be secured in a manner to prohibit access by unauthorized person. Self-service display of veterinary drugs which require a prescription is prohibited.

7.6 Labeling - A medication dispensed must be labeled in compliance with 24 **Del.C**. §2536 and other applicable State and Federal Statutes and Regulations.

7.7 Packaging - Medications must be dispensed in containers which comply with USP/NF and Poison Prevention Packaging Act requirements.

7.8 Records:

7.8.1 Invoices for the purchase of veterinary drugs requiring a prescription must be maintained at the registered premise for at least two years after the original date of the invoice.

7.8.2 The written order of confirmation of an oral order must be maintained in a separate file at the registered premise. These documents shall be consecutively numbered. If a written order is not received within 72 hours, the seller must notify the Board of Pharmacy.

7.8.3 When a seller documents that a veterinarian is properly licensed in another state, the following information must be recorded on the back of the order:

7.8.3.1 The name, address and license number of the prescriber.

7.8.3.2 The name, address and phone number of the information source.

7.9 All required records shall at all times be opened to inspection by duly authorized persons. Inspections by duly authorized personnel will be conducted during normal business hours per the authority granted in 24 **Del.C.** §2535.

8**.0 Requirements for Obtaining a Permit to Distribute Drugs on a Wholesale Basis**

~~8.1 Purpose. The purpose of this regulation is to implement the provisions of the prescription Drug Marketing Act of 1987 by defining the minimum standards, terms, and conditions for which a permit may be issued to persons who engage in wholesale distribution of (prescription) drugs within the State of Delaware.~~

8.~~2~~1 Definitions. The following words and terms, when used within Regulation 8.0, shall have the following meaning unless the context clearly indicates otherwise:

~~**"Blood"** means whole blood collected from a single donor and processed either for transfusion or further manufacturing.~~

~~**"Blood Component"** means that part of blood separated by physical or mechanical means.~~

~~**"Drug Sample"** means a unit of a prescription drug that is not intended to be sold and is intended to promote the sale of the drug.~~

"**Entity**" means an individual, partnership, corporation, business firm, or a sole proprietorship.

"Manufacturer" means anyone who is engaged in manufacturing, preparing, propagating, ~~compounding,~~ processing, or packaging, ~~repackaging, or labeling~~ of a prescription drug.

~~**"Person"** means an individual, partnership, corporation, business firm, or a sole proprietorship.~~

"Prescription ~~D~~drug" means any drug required by Federal law or regulation to be dispensed only by a prescription, including finished dosage forms and active ingredients subject to section 503(b) of the Federal Food, Drug, and Cosmetic Act.

"Wholesale ~~D~~distribution" means distribution of prescription drugs ~~to persons~~ an entity other than a consumer or patient~~, but~~ and does not include:

- ~~**"Intracompany Sales"**, being defined as a~~Any transaction or transfer between any division, subsidiary, parent and/or affiliated or related company under the common ownership and control of a corporate entity~~:~~;
- The purchase or other acquisition by a hospital or other health care entity that is a member of a group purchasing organization of a drug for its own use from the group purchasing organization or from other hospitals or health care entities that are members of such organizations;
- The sale, purchase, or trade of a drug or an offer to sell, purchase, or trade a drug by a charitable organization ~~described~~ as defined in section 501(c)(3) of the Internal Revenue Code of 1954 to a nonprofit affiliate of the organization to the extent otherwise permitted by law;
- The sale, purchase, or trade of a drug or an offer to sell, purchase, or trade a drug among hospitals or other health care entities that are under common control~~,~~. ~~f~~For purposes of this section, "common control" means the power to direct or cause the direction of the management and policies of ~~a person~~ an individual or an organization, whether by ownership of stock, voting rights, by contract, or otherwise;
- The sale, purchase, or trade of a drug or an offer to sell, purchase, or trade a drug for emergency medical reasons~~;~~. ~~f~~For purposes of this section, "emergency medical reasons" includes transfers of prescription drugs by a retail pharmacy to another retail pharmacy to alleviate a temporary shortage, except that the gross dollar value of such transfers shall not exceed ~~five (5) percent~~ 5.0% of the total prescription drug sales revenue of either the transferor or transferee pharmacy during any 12 consecutive month period;
- The sale, purchase, ~~or~~ trade, or dispensing of a drug~~,~~ or an offer to sell, purchase, or trade a drug~~, or the dispensing of a drug~~ pursuant to a prescription;
- The distribution of drug samples by manufacturers' representatives or distributors' representatives; or
- The sale, purchase, or trade of blood and blood components intended for transfusion. For purposes of this section, "blood" means whole blood collected from a single donor and processed either for transfusion or further manufacturing, and "blood component" means that part of blood separated by physical or mechanical means.

"Wholesale distributor" means anyone engaged in wholesale distribution of prescription drugs, including but not limited to~~,~~: manufacturers~~,~~; reverse distributors; repackers; own-label distributors; private-label distributors; jobbers; brokers; warehouses, including manufacturers' and distributors' warehouses, chain drug warehouses, and wholesale drug warehouses; independent wholesale drug traders; and retail pharmacies that conduct wholesale distributions.

~~8.3 Permit Requirements. Every wholesale distributor located in the State of Delaware who engages in wholesale distribution out of or within this State will be issued a permit by the Delaware Board of Pharmacy in accordance with the laws and regulations of this State before engaging in wholesale distribution of prescription drugs.~~

~~8.4 Wholesale Distributor Permit Requirement~~

~~8.4.1 The Delaware Board of Pharmacy requires the following from each wholesale drug distributor as part of the initial permit procedure and as part of any renewal of such permit:~~

~~8.4.1.1 The name, full business address, and telephone number of the permittee;~~

~~8.4.1.2 All trade or business names used by the permittee;~~

~~8.4.1.3 Addresses, telephone numbers, and the names of contact persons for the facility used by the permittee for the storage, handling, and distribution of prescription drugs;~~

~~8.4.1.4 The type of ownership or operation (i.e. partnership, corporation, or sole proprietorship); and~~

~~8.4.1.5 The name(s) of the owner and/or operator of the permittee, including:~~

~~8.4.1.5.1 If a person, the name of the person;~~

~~8.4.1.5.2 If a partnership, the name of each partner, and the name of the partnership;~~

~~8.4.1.5.3 If a corporation, the name and title of each corporate officer and director, the corporate names, and the name of the State of incorporation, and the name of the parent company, if any;~~

~~8.4.1.5.4 If a sole proprietorship, the full name of the sole proprietor and the name of the business entity.~~

~~8.4.1.6 Submission of a policy and procedures manual pertinent to employee qualifications and training.~~

~~8.4.2 Changes in any information in this section shall be submitted to the Board of Pharmacy within 30 days after such change.~~

8.2 Requirements for Licensure. Wholesale distributors that operate within this State, whether or not the wholesale distributor is physically located within this State, shall be licensed by the Board and shall biennially renew their license using an application provided by the Board. Wholesale distributors cannot operate from a place of residence. Where wholesale distribution operations are conducted at more than one location, each such location shall be licensed by the Board.

8.2.1 Wholesale distributors shall provide information required by a Board-approved application, including but not limited to:

8.2.1.1 All trade or business names used by the licensee, e.g. “doing business as” or “formerly known as” Trade or business names cannot be identical to the name used by another, unrelated wholesale distributor licensed to purchase drugs in the State;

8.2.1.2 Name of the owner or owners and operator or operators of the licensee (if not the same entity), including:

8.2.1.2.1 If an individual: the full name, business address, Social Security number, and date of birth;

8.2.1.2.2 If a partnership: the full name, business address, Social Security number, and date of birth of each partner; the name of the partnership; and the partnership’s federal employer identification number;

8.2.1.2.3 If a corporation: the full name, business address, Social Security number, date of birth, and title of corporate officers and directors; the corporate name or names; the name of the state of incorporation; the corporation’s federal employer identification number; the name of the parent company, if any; and the full name, business address, and Social Security number of each shareholder owning 10% or more of the voting stock of the corporation, including over-the-counter (OTC) stock, unless the stock is traded on a major stock exchange and not OTC;

8.2.1.2.4 If a sole proprietorship: the full name, business address, Social Security number, and date of birth of the sole proprietor; and the name and federal employer identification number of the business entity;

8.2.1.3 A copy of the wholesale distributor’s written policies and procedures as required in Section 13 (Policies and Procedures).

8.2.1.4 A list of all state and federal licenses, registrations, or permits, including the license, registration, or permit numbers, authorizing the wholesale distributor to purchase, possess, and distribute drugs;

8.2.1.5 A list of all disciplinary actions by state and federal agencies against the

wholesale distributor, as well as any actions against principals, owners, directors, or officers;

8.2.1.6 A plan and full description of each facility and warehouse, including all locations utilized for drug storage, distribution, or both. The description should include the following:

8.2.1.6.1 square footage;

8.2.1.6.2 security and alarm system descriptions;

8.2.1.6.3 terms of lease or ownership;

8.2.1.6.4 quarantined area for damaged, outdated, deteriorated, misbranded, or adulterated drugs; and

8.2.1.6.5 temperature and humidity controls.

8.2.1.7 A copy of the deed or lease for the property on which the wholesale distributor's establishment is located. If leased, the lease must be for an original term of not less than one (1) calendar year.

8.2.2 Changes in any information required by section 8.2.1 shall be submitted to the Board within 30 days after such change.

8.2.3 Wholesale distributors shall submit an application fee to be determined by the Division of Professional Regulation.

8.2.4 Wholesale distribution facilities must undergo an inspection by the Board or its authorized agent prior to initial licensure and periodically thereafter in accordance with a schedule to be determined by the Board. Subsequent inspections will occur at least once every three (3) years. Manufacturing facilities are exempt from inspection by the Board if the Manufacturing facilities are currently registered with the Food and Drug Administration in accordance with Section 510 of the Federal Act.

8.2.5 Wholesale distributors must publicly display or have readily available all licenses and the most recent inspection report administered by the Board.

8.2.6 All out-of-state wholesale distributors must comply with all rules and regulations of the State in which they are physically located and permitted.

8.2.7 Information submitted to the Board or its authorized agent that is considered trade secret or proprietary information as defined under Delaware privacy, trade secret, and proprietary information laws shall be maintained accordingly and as required by law and be exempt from public disclosure.

8.~~5~~3 Minimum Qualifications. The Delaware Board of Pharmacy will consider the following factors in determining eligibility for granting a permit to persons who engage in the wholesale distribution of prescription drugs:

8.~~5~~3.1 Any findings by the Board that the applicant has violated or been disciplined by a regulatory agency in any state for violating ~~convictions of the applicant under~~ any ~~F~~federal, ~~S~~state, or local laws relating to ~~drug samples, wholesale or retail~~ drug distribution~~, or distribution of controlled substances~~;

8.~~5~~3.2 Any ~~felony~~ criminal convictions of the applicant under ~~F~~federal, ~~S~~state, or local laws;

8.~~5~~3.3 The applicant's past experience in the manufacture or distribution of prescription drugs, including controlled substances;

8.~~5~~3.4 The furnishing by the applicant of false or fraudulent material in any application made in connection with drug manufacturing or distribution;

8.~~5~~3.5 Suspension, sanction, or revocation by ~~F~~federal, ~~S~~state, or local government ~~of~~ against any license currently or previously held by the applicant ~~for the manufacture or distribution of any drugs, including controlled substances~~ or any of its owners for violations of any federal, state, or local laws relating to drugs;

8.~~5~~3.6 Compliance with the requirements of ~~this regulation under~~ previously granted ~~permits if any~~ licenses of any kind;

8.~~5~~3.7 Compliance with the requirements to maintain and/or make available to the ~~State~~ Board ~~authority~~ or to ~~F~~federal, ~~S~~state, or local law enforcement officials those records required to be maintained by wholesale ~~drug~~ distributors.

8.3.8 Any other factors or qualifications the Board considers relevant to and consistent with the public health and safety.

8.3.9 The Board shall consider the results of a criminal and financial background check of the applicant to determine if an applicant or others associated with the ownership, management, or operations of the wholesale distributor have committed criminal acts that would constitute grounds for denial of licensure. The background check shall include all key personnel involved in the operations of the wholesale distributor. Key personnel includes, but is not limited to: the most senior individual or individuals responsible for facility operations, purchasing, and inventory control and the individual or individuals he or they report to; company officers; key

management; principals, and; owners with 10% or greater ownership interest in the company (applying to non-publicly held companies only). The background check will be conducted in compliance with any applicable federal, state, or local laws. The background check will be conducted at the applicant's expense and will be sufficient to include all states of residence since the individuals have been adults. Manufacturers shall be exempt from criminal and financial background checks.

8.~~6.~~4 Personnel. As a condition for receiving and retaining a wholesale drug distributor ~~permit~~ license, the ~~permittee~~ licensee shall:

8.4.1 ~~r~~Require each ~~person~~ individual employed in any prescription drug wholesale distribution activity to have any combination of education, training, and experience~~, or any combination thereof,~~ sufficient for that ~~person~~ individual to perform the assigned functions in such a manner as to provide assurance that the drug product quality, safety, and security will at all times be maintained as required by law~~.~~;

8.4.2 ~~The permittee must m~~Maintain records evidencing that each employee has been trained in accordance with the policy and procedure manual approved at the time of the issuance of the ~~permit~~ license. These records shall be kept two (2) years from the date of separation of the employee from the company. Records on all current employees shall be available at any time for inspection~~.~~ ;

8.4.3 Designate a registered agent in this State for service of process. Any licensed wholesale distributor that does not so designate a registered agent shall be deemed to have designated the Secretary of State of Delaware to be its true and lawful attorney, upon who may be served all legal processes in any action or proceeding against such licensed wholesale distributor growing out of or arising from such distribution. A copy of any such service of process shall be mailed to such wholesale distributor by the Board by certified mail, return receipt requested, postage prepaid, at the address such licensed wholesale distributor has designated on its application for licensure in Delaware. If any such wholesale distributor is not licensed in Delaware, service on the Secretary of State only shall be sufficient service.

~~8.7 Facilities. All facilities at which drugs are stored, warehoused, handled, held, offered, marketed, or displayed shall:~~

~~8.7.1 Be of suitable size and construction to facilitate cleaning, maintenance and proper operations.~~

~~8.7.2 Have storage areas designed to provide adequate lighting, ventilation, temperature, sanitation, humidity, space, equipment, and security conditions.~~

~~8.7.3 Have a quarantined area for storage of drugs that are outdated, damaged, deteriorated, misbranded, or adulterated.~~

~~8.7.4 Be maintained in a cleaned and orderly condition; and be free from infestation of insects, rodents, birds, or vermin of any kind.~~

~~8.8 Storage. All prescription drugs shall be stored at appropriate temperatures and under appropriate conditions in accordance with requirements, if any, in the labeling of such drugs, or with requirements in the current edition of an official compendium, such as the United States Pharmacopeia/National Formulary (USP/NF).~~

~~8.8.1 If no storage requirements are established for a prescription drug, the drug may be held at "controlled" room temperature, as defined in an official compendium, to help ensure that its identity, strength, quality, and purity are not adversely affected.~~

~~8.8.2 Appropriate manual, electromechanical, or electronic temperature and humidity recording equipment, devices, and/or logs shall be utilized to document proper storage of prescription drugs.~~

~~8.9 Record Keeping Requirements. Wholesale drug distributors shall establish and maintain inventory and records. Records shall include the following information:~~

~~8.9.1 Sources of the drugs, the identity and quantity of the drugs received and distributed or disposed of, and the date of receipt and distribution or other disposition of the drugs.~~

~~8.9.2 Records for all personnel and training.~~

~~8.9.3 All inventories and records shall be made available for inspection and photocopying by authorized Federal, State, or Local law enforcement agency officials for a period of two years following the disposition of the drugs.~~

~~8.9.4 Records described in this section that are kept at the inspection site or that can be immediately retrieved by computer or other electronic means shall be readily available for authorized inspection during the retention period. Records kept at a central location apart from the inspection site and not electronically retrievable shall be made available for inspection within 2 working days of a request by an authorized official of a Federal, State, or local law enforcement agency.~~

~~8.10 Written Policies and Procedures~~

~~8.10.1 There shall be written policies and procedures which shall be followed for the receipt, security, storage, inventory, and distribution of drugs including policies for identifying, recording, and reporting losses or thefts, and for correcting all errors, inaccuracies, and inventories. There shall be:~~

~~8.10.1.1 A procedure whereby the oldest approved stock of a drug product is distributed first. Deviation from this requirement is permitted if such deviation is temporary and appropriate.~~

~~8.10.1.2 A procedure must be established for the handling of recalls and withdrawals of manufacturer/distributor drugs due to any action initiated at the request of the manufacturer, the FDA or other Federal, State, or local enforcement or government agencies.~~

~~8.10.1.3 A procedure whereby drugs that are outdated, damaged, deteriorated, misbranded or adulterated are physically separated until they are destroyed or returned to their supplier.~~

~~8.11 Salvaging and Reprocessing. Compliance with applicable Federal, State, or local law or regulations relating to drug product salvaging is required.~~

~~8.12 Security~~

~~8.12.1 All facilities shall be secured from unauthorized entry.~~

~~8.12.2 The outside of the premises shall be well lighted.~~

~~8.12.3 Entry into areas where drugs are held shall be limited to authorized personnel.~~

~~8.12.4 All facilities shall be equipped with an alarm system to detect entry after hours subject to approval by the Secretary of the Board.~~

~~8.12.5 There must be a security system that will provide suitable protection against theft and diversions. When appropriate, the system shall provide protection against theft or diversion that is facilitated or hidden by tampering with computers or electronic records.~~

8.5 Minimum Requirements for the Storage and Handling of Drugs and for Establishment and Maintenance of Drug Records. The following are required for the storage, handling, transport, and shipment of drugs and for the establishment and maintenance of wholesale distribution records by wholesale distributors and their officers, agents, representatives, and employees:

8.5.1 All facilities at which drugs are received, stored, warehoused, handled, held, offered, marketed, displayed, or transported from shall:

8.5.1.1 Be of suitable construction to ensure that all drugs in the facilities are maintained in accordance with the product labeling of such drugs or in compliance with official compendium standards such as the *United States Pharmacopeia–USP/NF;*

8.5.1.2 Be of suitable size and construction to facilitate cleaning, maintenance, and proper wholesale distribution operations;

8.5.1.3 Have adequate storage areas that provide adequate lighting, ventilation, temperature, sanitation, humidity, space, equipment, and security conditions. If no storage requirements are established for a prescription drug, the drug may be held at "controlled" room temperature, as defined in an official compendium, to help ensure that its identity, strength, quality, and purity are not adversely affected. Appropriate manual, electromechanical, or electronic temperature and humidity recording equipment, devices, or logs shall be utilized to document proper storage of prescription drugs;

8.5.1.4 Have a quarantine area for storage of drugs that are: outdated; damaged; deteriorated; misbranded; adulterated; counterfeit, or suspected of being counterfeit; otherwise unfit for distribution; or are in immediate or sealed secondary containers that have been opened;

8.5.1.5 Be maintained in a clean and orderly condition;

8.5.1.6 Be free from infestation of any kind;

8.5.1.7 Be a commercial location and not a personal dwelling or residence;

8.5.1.8 Provide for the secure and confidential storage of information with restricted access by developing and adhering to policies and procedures to protect the integrity and confidentiality of the information;

8.5.1.9 Maintain records of sources of the drugs, the identity and quantity of the drugs received and distributed or disposed of, and the date of receipt and distribution or other disposition of the drugs;

8.5.1.10 Maintain records of all personnel and their training; and

8.5.1.11 Have records available for inspection and photocopying by the authorized federal, state, or local law enforcement agency officials for a period of three (3) years following the disposition of the drugs. Records shall be kept at the inspection site or must be immediately retrievable by computer or other

electronic means. Records may be kept at a central location apart from the inspection site and not electronically retrievable. Such records shall be made available for inspection within two (2) working days of a request by an authorized official of a federal, state, or local law enforcement agency.

8.5.2 Wholesale distributors involved in the distribution of controlled substances shall be duly registered with Drug Enforcement Administration (DEA) and the Office of Narcotics and Dangerous Drugs (ONDD) and in compliance with all applicable laws and rules for the storage, handling, transport, shipment, and distribution of controlled substances.

8.6 Written Policies and Procedures. Wholesale distributors shall establish, maintain, and adhere to written policies and procedures for the receipt, security, storage, inventory, transport, shipping, and distribution of drugs. Wholesale distributors shall also establish, maintain, and adhere to written policies and procedures for: identifying, recording, and reporting losses or thefts; for correcting all errors and inaccuracies in inventories; and implementing and maintaining a continuous quality improvement system. Wholesale distributors shall include in their written policies and procedures the following:

8.6.1 A procedure to be followed for handling recalls and withdrawals of drugs. Such procedure shall be adequate to deal with recalls and withdrawals due to:

8.6.1.1 Any action initiated at the request of FDA or any other federal, state, local law enforcement, or other government agency including the Board;

8.6.1.2 Any volunteer action by the manufacturer to remove defective or potentially defective drugs from the market; or

8.6.1.3 Any action undertaken to promote public health and safety by the replacing of existing merchandise with an improved product or new package design.

8.6.2 A procedure to ensure that wholesale distributors prepare for, protect against, and handle any crisis that affects security or operation of any facility in the event of a strike, fire, flood, other natural disaster, or other situations of local, state, or national emergency.

8.6.3 A procedure to ensure that any outdated drugs shall be segregated from other drugs and either returned to the manufacturer or destroyed in accordance with federal, state, or local laws, including all necessary documentation and the appropriate witnessing. This procedure shall provide for written documentation of the disposition of outdated drugs. This documentation shall be maintained for two (2) years after disposition of the outdated drugs.

8.6.4 A procedure for the destruction of outdated drugs in accordance with federal, state, or local laws. The procedure shall include maintaining all necessary documentation for a minimum of three (3) years, and the appropriate witnessing of the destruction of outdated or expired drugs in accordance with all applicable federal, state, or local requirements.

8.6.5 A procedure for reporting criminal or suspected criminal activities involving the inventory of a drug or drugs to the Board, FDA, and, if applicable, DEA and ONDD, within three (3) business days.

8.7 Salvaging and Reprocessing. Wholesale distributors shall be subject to the provisions of any applicable federal, state, or local laws or rules that relate to drug product salvaging or reprocessing, including Chapter 21, parts 207, 210, and 211k of the Code of Federal Regulations.

8.8 Security and Anti-Counterfeiting. All facilities:

8.8.1 Shall be secure from unauthorized entry;

8.8.1.1 Access from outside the premises shall be kept to a minimum and be well-controlled,

8.8.1.2 The outside perimeter of the premises shall be well-lighted, and

8.8.1.3 Entry into areas where drugs are held shall be limited to authorized personnel.

8.8.2 Shall be equipped with a security system that will provide suitable protection against theft and diversion. Appropriateness of security systems is subject to approval by the Board's Executive Secretary. When appropriate, the security system shall provide protection against theft or diversion that is facilitated or hidden by tampering with computers or electronic records;

8.8.3 Shall be equipped with inventory management and control systems that protect against, detect, and document any instances of theft, diversion, or counterfeiting;

8.8.4 Should possess and maintain, in good working order, technology and equipment that allows the wholesale distributor to authenticate, track, and trace prescription drugs. The technology and equipment shall satisfy standards set by the Board. The technology and equipment shall be used to conduct tracking, tracing, and authentication of prescription drugs. Wholesale distributors shall employ, train, and document the training of

personnel in the proper use of such technology and equipment; and

8.8.5 Shall be equipped with security systems to protect the integrity and confidentiality of data and documents and make such data and documents readily available to the Board and other federal, state, or local law enforcement officials.

9.0 Hospital Pharmacy

9.1 Definition:

A hospital pharmacy is defined as a pharmacy registered with the Board located in a hospital facility. "Hospital pharmacy" shall not include a pharmacy operated by a hospital facility at a location other than the site of a permanent facility at which in-patient care and medical services are rendered.

9.2 Personnel

9.2.1 Director of Pharmacy. The storage, compounding, repackaging, dispensing and distribution of drugs by a hospital pharmacy shall be under the direction, supervision and responsibility of the pharmacist-in-charge, hereinafter referred to as the Director of Pharmacy, who shall be responsible for operating the pharmacy in compliance with appropriate State and Federal Statutes and Regulations. Written policies and procedures will be established defining the operation and scope of services provided by the hospital pharmacy. The Manual shall include policy and procedures concerning:

9.2.1.1 Preparation and sterilization of parenteral medications if done within the hospital pharmacy.

9.2.1.2 Establishment of specifications for procurement of drugs, chemicals and biologicals. The procedures are subject to the approval of the appropriate committee of the hospital.

9.2.1.3 Maintaining readily available inventory of emergency drugs both in the pharmacy and patient care areas. Current antidote information and telephone numbers of regional poison control centers must also be available.

9.2.1.4 Participation in the development of a Formulary or drug list for the hospital.

9.2.1.5 The filling and labeling of all containers from which drugs are to be administered in compliance with applicable Statutes and Regulations.

9.2.1.6 The records of the transactions of the pharmacy that are required by applicable law and that are necessary for accurate control and accountability. This should include procedures for wastage of controlled substances in all areas of the hospital.

9.2.1.7 Polices and procedures shall specify the duties to be performed by pharmacy personnel.

9.2.1.8 Discontinued drug procedures to insure that discontinued drugs and containers with worn, illegible or missing labels are returned to the pharmacy for proper disposition or disposal. All outdated products should be removed from all areas and stored in a separate section in the pharmacy for proper disposition or disposal.

9.2.1.9 A recall procedure that can be implemented to insure proper disposition of the recalled materials.

9.2.1.10 A policy for drugs brought in by patients.

9.2.1.11 A policy for the proper handling of investigational drugs must be in compliance with FDA and State requirement.

9.2.1.12 The pharmacist shall be involved with the utilization review process as it pertains to drug therapy.

9.2.2 Registered Pharmacists. The Director of Pharmacy may be assisted by additional registered pharmacists who are also responsible for compliance with the applicable laws.

9.2.3 Supportive Personnel. Supportive personnel may be utilized in assisting the pharmacist. These persons must be supervised by a registered pharmacist who is present within the hospital and is responsible for the activities of those persons.

9.3 Absence of Pharmacist. When a pharmacist is not on duty, drugs may be provided for use by physicians and other authorized staff via night cabinets or other areas designated by the hospital, and in emergency circumstances by access to the pharmacy. A pharmacist shall be available to provide professional services.

9.4 Night Cabinets or Other Designated Areas

9.4.1 These drug storage areas must be securely locked and substantially constructed in a manner which prevents easy entry.

9.4.2 Access must be limited to authorized personnel.

9.4.3 Contents and use procedures should be determined by the pharmacy and those departments with access to the night cabinet or other designated areas in accordance with the hospital's policies and procedures.

9.4.4 Drugs must be properly labeled and prepackaged in sufficient quantities as defined by the hospital.

9.4.5 Accountability records documenting withdrawal and replacement of controlled drugs must be readily available.

9.4.6 The transaction shall be reviewed by the pharmacy when it reopens and incorporated into the hospital pharmacy's medication recordkeeping system.

9.5 Access to Pharmacy. When a pharmacist is not available and medications cannot be obtained immediately from any other source, authorized persons may enter the pharmacy and obtain drugs per procedures established by the hospital. The procedures must include the following stipulations:

9.5.1 Entry shall be by two persons; registered nurse or physician with another nurse, physician, or security person present approved by the hospital.

9.5.2 Persons authorized to enter the pharmacy shall indicate the name and strength and amount of drug removed, the date, time and their signature, and the name and location of the patient. The transaction shall be reviewed by the pharmacy when it reopens and incorporated into the hospital pharmacy's medication recordkeeping system.

9.6 Emergency Drugs. Emergency drugs must be available for use by authorized personnel at strategic locations throughout the hospital. The drugs must be available to authorized personnel and must be stored in a manner to preserve the integrity of the contents.

9.6.1 Emergency Drugs Defined - Emergency drugs are those drugs which may be required to meet the immediate therapeutic needs of patients and which are not available from any other authorized source in sufficient time to prevent risk or harm to patients.

9.6.2 Emergency drug supplies shall be clearly identified for emergencies. A list showing the contents and the strength and quantity of each item shall be attached to the exterior.

9.6.3 Removal of Drugs - Drugs shall be removed from an emergency drug supply only pursuant to a valid physician's order or by authorized personnel.

9.6.4 Notification - Whenever an emergency drug supply is accessed, the pharmacy or its designee shall be notified within 24 hours, and the pharmacy or its designee shall restock and reseal or replace the kit or cart within forty-eight hours.

9.7 Equipment and Texts. Each hospital pharmacy shall have the equipment and texts required by Board Regulation 3.0 and Regulation 10.0.

9.8 Drug Storage. Drugs must be stored in compliance with State and Federal Statutes and Regulations and according to USP/NF requirements.

9.9 Labeling

9.9.1 The drug dispensed for inpatient use shall contain a label, shall show the brand or established name and the strength of the medication. If the medication is prepacked, it must also show the source, lot number and expiration date, in compliance with the Board's prepacking regulation.

9.9.2 All drugs dispensed for outpatients must be labeled in compliance with the Pharmacy Statutes.

9.9.3 Admixtures in parenteral bags and bottles shall be labeled in accordance with Regulation 10.0.

9.10 Abbreviations. The hospital should establish a standard list of abbreviations to be used whenever medications are prescribed.

9.11 Outpatient Orders. Medication dispensed for outpatients via prescriptions are governed by applicable State and Federal Statutes Regulations. A patient profile must be maintained and counseling must be provided for each person according to Regulation 5.0.

9.12 Suspected Adverse Drug Reaction. When an adverse reaction is documented, the pharmacy department shall receive a copy.

9.13 Maintenance of Medication Orders. Patient Profile - A patient medication profile must be maintained for each inpatient whose medication is directly dispensed from the pharmacy. It must show the patient's name, location, age, allergies and diagnosis(es) as available. The profile must show the name, strength and quantity of the drug dispensed and appropriate directions and the initials of the dispenser. Prior to administration of the first dose, the pharmacist must examine the profile to determine the possibility of a harmful drug interaction or reaction. Upon recognizing a significant potential for harm, the pharmacist should notify the prescriber and other appropriate persons. The profile must be retained and readily retrievable for 30 days after discharge.

9.14 Medication Error. Medication error as defined by the hospital shall be documented and reported immediately to the pharmacy. It should also be reported to the attending physician.

9.15 Monthly Inspections. A member of the pharmacy staff shall conduct monthly inspections of each nursing station and patient care areas where medications are dispensed, administered or stored. Such documented inspections shall verify that:

9.15.1 Disinfectants and drugs for external use are stored separately.

9.15.2 Drugs are stored under proper conditions.

9.15.3 No outdated drugs are present.

9.15.4 Distribution, administration, and disposition of controlled substances audits indicates proper recordkeeping and administration.

9.15.5 Emergency drug supplies and floor stock drug levels are properly maintained.

9.15.6 Drugs are properly secured.

9.16 Hospital Operating with an Off-site Pharmacy Provider.

9.16.1 Definition. A hospital operating with an off-site pharmacy is one that obtains pharmacy services from another hospital, community pharmacy, or infusion pharmacy that can provide services as necessary for operation.

9.16.2 Personnel.

9.16.2.1 There must be a Director of Pharmacy or Consultant Pharmacist available on an on-call procedure 24 hours per day. The storage, compounding, repackaging, dispensing and distribution of drugs by an off-site Provider Pharmacy shall be under the direction, supervision and responsibility of a Pharmacist-in-Charge or Director of Pharmacy. This person shall be responsible for operating the pharmacy in compliance with appropriate State and Federal Statutes and Regulations.

9.16.2.2 The Director of Pharmacy or Pharmacist-in-Charge may be assisted by additional registered pharmacists who are also responsible for compliance with the applicable laws. Any of these registered pharmacists may act as the Consultant Pharmacist for the institution if he/she is licensed to practice pharmacy in the State of Delaware. Additional supportive personnel may be utilized as required.

9.16.2.3 The Director of Pharmacy or Pharmacist-in-Charge must provide written policies and procedures establishing the operation and scope of services provided by the off-site Pharmacy Provider. The Policy and Procedure Manual shall include all items as outlined in 9.2 of this section. In addition, the manual shall include a written statement of pharmaceutical services provided and the responsibilities of the off-site Provider Pharmacy.

9.16.3 Monthly Inspections. The Director of Pharmacy or Consultant Pharmacist must perform monthly medication area inspections as outlined in 9.15 of this section.

9.16.4 Storage

9.16.4.1 Drugs must be stored at the off-site Pharmacy Provider in compliance with State and Federal Statutes and Regulations and according to USP/NF requirements.

9.16.4.2 The Pharmacy Provider must also provide any special handling and/or packaging and/or storage conditions for compounded sterile preparations when delivering from the pharmacy to the institution as necessary to maintain the sterility and stability of the preparation. This includes any product that is frozen or that requires refrigeration.

9.16.5 Patient Profiles. The off-site Pharmacy Provider must maintain complete patient profiles as outlined in Regulation 5.0.

9.16.6 Medication Errors or Adverse Reactions

9.16.6.1 Any medication errors or adverse drug reactions, as defined by the hospital, shall be documented and reported to the off-site Pharmacy Provider.

9.16.6.2 This information shall also be reported to the Director of Pharmacy, Pharmacist-in-Charge, or Consultant Pharmacist for their review and documentation for the patient profile.

9.16.7 Emergency Use Medications

9.16.7.1 Emergency use medications are those which may be required to meet the immediate therapeutic needs of patients, as determined by the prescriber, and which are not available from any other authorized source in sufficient time to prevent risk or harm to patients by delay resulting from obtaining such drugs from other sources.

9.16.7.2 It is the responsibility of the facility and provider pharmacy to determine the supply of emergency use medication that are to be stocked as well as documenting their locations within the facility. A list of current contents must be attached to the medication supply.

9.16.7.3 Accountability for emergency use medications.

9.16.7.3.1 The pharmacy provider must be contacted within 24 hours after medication is used from the supply and the pharmacy must restock the supply within a reasonable time to prevent harm to patients.

9.16.7.3.2 The provider pharmacy is responsible for the accuracy of all emergency use medications at the time of the filling of the medication. This check must also include any medication that became available when the medication is accessed. Records documenting use of an emergency medication must be kept for a minimum of 2 years at the provider pharmacy and must be readily available for inspection by the Board.

9.16.7.3.3 Failure to comply with these procedures can result in the suspension or denial of the use of emergency use medications.

9.16.7.3.4 Violations of accountability procedures for emergency use medications may result in review proceedings before the Board.

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

10.0 Sterile Pharmaceuticals and Antineoplastic Agents

This regulation contains minimum pharmacy practices for the preparation, compounding and dispensing of sterile preparations and antineoplastic agents by licensed pharmacies.

10.1 Definitions. As used in this part, the following terms shall have the meanings specified:

"Admixture" A solution for parenteral administration to which one or more additional drugs have been added.

"Antineoplastic Agent" A drug used to treat various forms of cancer.

"Aseptic Technique" A procedure for compounding sterile preparations designed to minimize/ prevent contamination during the compounding procedure.

"Class 100" A classification of an airflow unit capable of producing an environment containing no more than 100 airborne particles of a size 0.5 micron and larger per cubic foot (3.5 particles/liter) of air.

"Enteral Nutrition" The administration into the gastro-intestinal tract of calories, nitrogen, and/or other nutrients to achieve tissue synthesis and anabolism for patients requiring medically prescribed, defined formula, liquid diets.

"HEPA" (High-efficiency particulate air) Filter - A filter that provides a minimum-efficiency of 99.97% in removal of particles 0.3 micron or larger from the effluent air.

"Laminar Airflow" An entire body of air moving with uniform velocity along parallel flow lines.

"Parenteral" A sterile preparation intended for injection and used in the diagnosis, cure, mitigation, or treatment of disease or modification of physiological functions in human beings, but not including blood or blood products or as otherwise defined in the current United States Pharmacopeia.

"Sterile Pharmaceutical" A dosage form free from living microorganisms.

"Total Parenteral Nutrition" The intravenous administration of calories, nitrogen, and other to achieve tissue synthesis and anabolism.

10.2 General Requirements. A licensed pharmacy in the State of Delaware desiring to compound and dispense prescriptions or physician's orders for sterile pharmaceuticals and antineoplastic agents shall meet the following requirements:

10.2.1 Facilities and Equipment

10.2.1.1 The environment for the preparation of such prescriptions shall be set in a low traffic area, clean and free of contaminants and dust, and equipped to permit controlled aseptic/antineoplastic compounding.

10.2.1.2 The area for preparing sterile/antineoplastic prescriptions shall be segregated from general non-aseptic work and storage areas and shall be used solely for sterile pharmaceutical/ anti-neoplastic compounding. The area shall be maintained at controlled room temperatures as defined by the United States Pharmacopeia.

10.2.1.3 The area(s) shall provide space for a minimum of one class 100 environment. Additionally, the space shall be of a size to accommodate equipment as required herein and sufficient space to allow personnel working therein to safely and accurately fulfill their duties.

10.2.1.4 Minimum requirements for equipment, supplies and publications are as follows:

10.2.1.4.1 Minimally, a class 100 air flow unit

10.2.1.4.1.1 The air flow unit must be in compliance with recommendations from OSHA guidelines.

10.2.1.4.2 Refrigerator

10.2.1.4.3 Sink and wash area easily accessible to the sterile preparation/ antineoplastic compounding area(s)

10.2.1.4.4 Appropriate waste containers for:

10.2.1.4.4.1 Used needles and syringes

10.2.1.4.4.2 All antineoplastic wastes including apparel used in their preparation

10.2.1.4.5 Supplies:

10.2.1.4.5.1 Disposable needles and syringes and other supplies needed for sterile pharmaceutical/antineoplastic compounding

10.2.1.4.5.2 Disinfectant cleaning agents

10.2.1.4.5.3 Single-use lint free towels or air-driers

10.2.1.4.5.4 Handwashing materials with bactericidal action

10.2.1.4.5.5 Equipment and materials for cleaning antineoplastic agent spills

10.2.1.4.6 References: In addition to compliance with the reference requirements as set forth in Delaware Board Regulation 3.0, the pharmacy must have the following texts if chemotherapy agents are prepared:

10.2.1.4.6.1 Procedures for handling Antineoplastic Drugs Technical Bulletin - most current edition published by the American Society of Health Systems Pharmacists.

10.2.1.4.6.2 Most current edition of OSHA Guidelines for the handling of antineoplastic agents.

10.2.1.4.7 Drug Components: All drug components that are received, stored, or used in compounding prescriptions shall meet official compendial requirements. If this cannot be met, pharmacists shall use their professional judgment to procure alternatives.

10.3 Personnel

10.3.1 The compounding of sterile pharmaceuticals/anti-neoplastic agents shall be under the control and supervision of a licensed pharmacist. The licensed pharmacist-in-charge or licensed pharmacist designee shall be on duty and on premises during all hours of operation of said pharmacy.

10.3.2 A pharmacist shall be accessible by telephone 24 hours a day to answer questions and to provide consultation regarding the dispensed preparation.

10.3.3 Supportive Personnel: The pharmacist managing the section of the pharmacy providing sterile/anti-neoplastic product pharmacy services may be assisted by supportive personnel. These personnel must have specialized training in this field, and shall work under the supervision of a licensed pharmacist. The training provided to these personnel must be described in writing in a training manual. The duties and responsibilities of these personnel must be consistent with their training and experience.

10.4 Storage, Preparation, Dispensing, and Handling

10.4.1 A pharmacy shall provide any special handling and/or packaging and/or storage conditions for compounded sterile/antineoplastic preparations when delivering from the pharmacy to the patient or institution as necessary to maintain sterility and stability of the preparation.

10.4.2 Each pharmacy shall develop product sampling plans and shall have the ability to determine or know where to readily procure services to assure the quality of the products compounded or prepared.

10.4.3 Delivery service. The pharmacist managing the section of the pharmacy providing sterile/ antineoplastic product pharmacy services is responsible for the environmental control of all products shipped. Therefore, any compounded, sterile parenteral product or antineoplastic agent that is frozen, or that requires refrigeration, must be shipped or delivered to a patient in appropriate coolers and stored appropriately in the patient's home.

10.5 Labeling

10.5.1 Each compounded preparation shall bear a label indicating the date beyond which it should no longer be administered and the temperature or conditions under which it should be stored.

10.5.2 If the preparation is an antineoplastic product, it must be labeled with a warning label clearly identifying the product as such.

10.5.3 The following "beyond use" dates shall be used: Admixtures in parenteral bags and bottles shall be labeled with a distinctive supplementary label, indicating the name and amount of the drug added, date, expiration date of the container and name or initials of the person preparing the solution.

10.5.3.1 Admixtures: Maximum of seventy-two hours when stored under refrigerated conditions from the time of compounding unless the manufacturer's recommendation is to store at room temperature and/or longer storage times can be substantiated with documentation.

10.5.3.2 If medications with expiration periods of less than forty-eight hours are added to a parenteral solution, or if the manufacturer indicates an expiration period of less than forty-eight hours, the "beyond use" date of the solution shall be the shorter expiration period and shall appear on the label.

10.6 Policy and Procedures Manual

10.6.1 A Policy and Procedures Manual shall be prepared and be available at each pharmacy site where sterile pharmaceuticals/antineoplastic agents are prepared for inspection by authorized agents of the Board of Pharmacy. The Policy and Procedures Manual shall contain the objectives, operational guidelines and standard operating procedures of the pharmacy pertaining to sterile products/antineoplastic agents. A procedure shall be included that addresses how a contaminated product is detected, recall measures and follow up.

10.6.2 The manual shall include procedures to be used by the pharmacy to prevent contamination of the products during preparation, storage, and dispensing.

10.6.3 The manual shall include written policies and procedures for cleaning and maintenance of the sterile pharmaceutical compounding/antineoplastic agent area(s) with records kept in the pharmacy department for one year.

10.6.4 Documentation of the following shall be included:

10.6.4.1 Replacement of filters and prefilters.

10.6.4.2 Certification of clean air source by an outside agency at least once a year.

10.6.4.3 Cleaning and maintenance of the equipment.

10.6.5 If antineoplastic agents are compounded in the pharmacy, protection shall be provided for its personnel by utilizing the proper equipment and protective garb and having a Policy and Procedures Manual for said antineoplastic agents. The Manual shall include, among the other requirements, the following special requirements outlined in sections 10.2 - 10.5 the following special requirements:

10.6.5.1 Procedures for disposal of all unused drugs and materials used in the preparation of antineoplastic agents in accordance with accepted professional standards, such as the most current OSHA Guidelines, regarding the handling of antineoplastic agents.

10.6.5.2 Safety standards which stress proper technique in handling antineoplastic agents and which include:

10.6.5.2.1 A certified vertical laminar air flow hood.

10.6.5.2.2 Protective garb, i.e., gloves, face and eye protection, and gowns.

10.6.5.3 In the event that antineoplastic agents and other parenterals are prepared within the same air flow unit, procedures shall be provided for a thorough scrub down and air purge of at least twenty minutes after compounding of the antineoplastic agent(s).

10.6.6 The Policy and Procedures Manual shall be maintained on a current basis. It shall be reviewed at least annually and changes shall show the effective date.

Revised Effective Date: April 14, 1997 (10.2 General Requirements revised)

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

11.0 Pharmaceutical Services in Nursing Homes

11.1 Definition: A nursing home is an institution licensed by the Division of Public Health that provides permanent facilities that include in-patient beds and medical services, including continuous nursing services, to provide treatment for patients who do not currently require continuous hospital services. Rest-Residential and Assisted Living beds in licensed nursing homes are exempt from this regulation. They are considered under Health Care Facilities.

11.2 General Requirements

11.2.1 Each facility shall provide a cabinet or medication carts for individual patient medications. These storage units shall be of sufficient size and located where easily accessible. They shall be locked when not in use and the key and/or code for the storage unit shall be carried by or be accessible only to registered nurses, licensed practical nurses, or pharmacists. Controlled substances storage shall be in compliance with State and Federal statutes and regulations.

11.2.2 Internal medications must be stored separately from external medications.

11.2.3 Medications requiring refrigeration must be stored within the USP/NF refrigeration temperature range of 36 to 46 degrees Fahrenheit.

11.2.4 Medications which require room temperature storage must be maintained at either USP/ NF ranges of 59 to 86 degrees Fahrenheit or the manufacturer's labeled range.

11.2.5 No persons except properly authorized personnel shall handle or administer medications.

11.2.6 Schedule II substances shall be secured under two locks in securely fixed boxes or drawers in the medication storage area, medication cart, or emergency use medication supplies.

11.2.7 There shall be accountability procedures for all controlled substances present. There shall be readily retrievable records maintained showing the receipt and disposition of all controlled substances. These records must be maintained for 2 years.

11.3 Emergency Use Medications

11.3.1 Emergency use medications are those which may be required to meet the immediate therapeutic needs of patients, as determined by the prescriber, and which are not available from any other authorized source in sufficient time to prevent risk or harm to patients by delay resulting from obtaining such drugs from other sources.

11.3.2 It is the responsibility of the facility and provider pharmacy to determine the supply of emergency use medication that are to be stocked as well as documenting their locations within the facility. A list of current contents must be attached to the medication supply.

11.3.3 Accountability for emergency use medications.

11.3.3.1 The pharmacy provider must be contacted within 24 hours after medication is used from the supply and the pharmacy must restock the supply within a reasonable time to prevent harm to patients.

11.3.3.2 The provider pharmacy is responsible for the accuracy of all emergency use medications at the time of the filling of the medication. This check must also include any medication that became available when the medication is accessed. Records documenting use of an emergency medication must be kept for a minimum of 2 years at the provider pharmacy and must be readily available for inspection by the Board.

11.3.3.3 Failure to comply with these procedures can result in the suspension or denial of the use of emergency use medications.

11.3.3.4 Violations of accountability procedures for emergency use medications may result in review proceedings before the Board.

11.3.4 There must be an accountability procedure at the facility for needles and syringes.

11.4 Return Medication Procedures.

11.4.1 All unused portions of any patient's discontinued prescription medication shall be immediately isolated. Non-controlled medication shall be destroyed or returned to the pharmacist or provider pharmacy supplying pharmaceutical services within 72 hours with the appropriate notation of disposition. The notation shall include the date, quantity, and name and strength of the medication.

11.4.2 Medications for hospitalized patients must be isolated, and may be held until the patient’s return or permanent discharge.

11.4.3 Destruction of discontinued controlled patient medication and discharged or deceased patient's controlled medication shall be jointly performed by two authorized licensed personnel within 72 hours of the discontinuation of the medication or discharge of the patient. A record of the destruction must be signed by both parties and kept at the facility for 2 years.

11.5 Labeling

11.5.1 Labels on controlled substances must show the actual refill date and amount of medication dispensed.

11.5.2 The provider pharmacy must maintain prescription records required by State and Federal law in addition to a readily retrievable record of the actual refills, amount dispensed and accountability of the amounts used.

11.5.3 A pharmacy providing prescriptions for use in a nursing home may label the prescription, "to be administered according to current physician's orders.

11.5.4 A change in a medication order that involves a direction change must be communicated to the pharmacy within 24 hours, and the labeling on medication currently in the facility may be handled in the following ways:

11.5.4.1 A licensed nurse or pharmacist may apply an accessory label to the medication which denotes that there has been a direction change.

11.5.4.2 A label(s) with new directions may be requested from the pharmacy and applied to the current medication supply by a licensed nurse or pharmacist.

11.6 Duties of Consultant Pharmacist

11.6.1 A consultant pharmacist to a nursing home in the State of Delaware must be licensed to practice pharmacy in the State of Delaware. The consultant pharmacist shall be responsible for the general supervision of the nursing home pharmaceutical services and the direct supervision of registered pharmacy interns, who may assist in chart reviews. Supervision of chart reviews by a pharmacy intern must be documented by the supervising pharmacist.

11.6.2 The consultant pharmacist shall provide the administrator of a nursing home with a statement indicating those minimum professional services that will be provided. This statement shall be incorporated into the nursing home Pharmacy Policy and Procedure Manual.

11.6.3 The consultant pharmacist must notify the Board in writing within ten days of starting as a consultant in the State.

11.6.3.1 If the consultant pharmacist has not served in that position in the State of Delaware, he/she must appear before the Board for an interview within ninety days after assuming that position.

11.6.4 The consultant pharmacist shall be responsible for written policies and procedures which shall include, but not be limited to:

11.6.4.1 Procedures for administering the services outlined in the statement of proposed services.

11.6.4.2 Policies governing practitioner medication orders, medication errors, automatic stop orders, medications for patient discharge and leave of absence.

11.6.4.3 Policies and procedures necessary to insure the safe use, administration, control and accountability of all drugs through out the nursing home in compliance with State and Federal laws.

11.6.4.4 Policies and procedures outlining the destruction of wastage for all controlled medications.

11.6.4.5 Policies governing appropriate storage of medications, an effective drug recall procedure and labeling of all prescription drugs and biologicals in accordance with State and Federal requirements. For registered out-of-state providers an additional labeling requirement is having the toll-free telephone number on the prescription labels.

11.6.4.6 Policies and procedures governing patient drug regimen review, which shall include procedures for reporting irregularities, and documenting that such reviews have been performed. The provider pharmacy is to receive copies of all practitioners' orders to be reviewed with the information on the patient profiles.

11.6.5 If the nursing home has a pharmacy or quality related committee the consultant pharmacist shall serve on that committee.

11.6.6 The consultant pharmacist or designated pharmacy staff shall make inspections of each nursing station and related drug storage areas at least monthly. A pharmacy support person may assist with inspection under the direct supervision of a pharmacist.

11.6.6.1 Nursing station inspections must include, but are not limited to, documentation of the following:

11.6.6.1.1 medication storage area(s) (59 to 86 degrees Fahrenheit) and refrigerator temperatures (36 to 46 degrees Fahrenheit);

11.6.6.1.2 security of all drugs;

11.6.6.1.3 proper labeling, including any accessory or cautionary instructions;

11.6.6.1.4 proper expiration dating;

11.6.6.1.5 cleanliness;

11.6.6.1.6 emergency use medication supplies are properly maintained.

11.6.6.2 A copy of these inspection reports must be maintained at the facility for two years.

11.6.7 The consultant pharmacist shall review the drug regimen of each patient monthly at the facility. Documentation of the review is accomplished in the following manner:

11.6.7.1 If the pharmacist determines that there are no irregularities in the patient's drug regimen, he/she must note in the patient's chart that he/she has reviewed the drug regimen, found no irregularities, and sign and date this notation. This documentation must remain on the patients' charts for a minimum of 12 months.

11.6.7.2 If the pharmacist determines that there are irregularities, he/she must prepare a drug regimen review report which includes any pertinent information such as the patient's diagnosis(es), the drug regimen, any pertinent laboratory findings, dietary considerations, etc., and his/her recommendations for improving the drug therapy of the patient. This written recommendation shall be forwarded to the attending practitioner, with the original documentation maintained in the patient chart.

11.6.7.3 Nursing unit inspections and a summary report of patient drug regimen reviews must be submitted to the Director of Nursing and the Administrator monthly.

11.6.8 The consultant pharmacist is responsible for the accountability of all medications. A random sample will be done monthly to identify overages or shortages of any medications. Documentation will be made of irregularities and will include date of audit, patient identification, a listing of overages or shortages, and an explanation if known. A plan for correction will be included in the documentation where appropriate. Documentation will be maintained for a period of 12 months at the facility.

11.6.9 The consultant pharmacist shall be responsible for providing information to the nursing home staff, as may be appropriate or required, to ensure safety, understanding and compliance with policies and procedures pertaining to pharmacy-related activities and concerns.

11.6.10 The consultant pharmacist shall assume all other responsibilities required of a consultant pharmacist as set forth in any State or Federal statutes or regulations as enacted or amended or may be enacted or amended.

7 DE Reg. 914 (01/01/04)

12.0 Health Care Facilities

12.1 Definition

A health care facility means any organization, other than a nursing home or hospital, which is licensed or certified by the State to provide a physical environment for patients in which health care services are a primary component. These facilities include, but are not limited to:

12.1.1 Convalescent homes
12.1.2 Extended health facilities
12.1.3 Mental health facilities
12.1.4 Rehabilitation centers
12.1.5 Psychiatric centers
12.1.6 Group homes for mentally retarded
12.1.7 Group homes for mentally ill
12.1.8 Clinics

12.1.9 Residential treatment centers

12.1.10 End Stage Renal Disease Treatment Centers

12.2 Requirements. Any health care facility in which medication is administered and/or dispensed must comply with all State and Federal laws regarding drug storage, labeling, recordkeeping, and security. Only health care personnel authorized by law to handle medication may have access to medication areas.

13.0 Nuclear Pharmacy Regulations

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.

9 DE Reg. 1253 (2/1/06)

14.0 Administration of Injectable Medications

The purpose of this regulation is to implement provisions relating to the training, administration, and documentation of injectable medications, biologicals, and adult immunizations by pharmacists, pursuant to 24 **Del.C.** Ch. 25 relating to Pharmacy.

14.1 Educational Requirements

14.1.1 In order to administer injectable medications, biologicals, and adult immunizations a licensed pharmacist shall provide proof that the following requirements have been satisfied:

14.1.1.1 The satisfactory completion of an academic and practical curriculum approved by the Board of Pharmacy which includes, but is not limited to, disease epidemiology, vaccine characteristics, injection technique, emergency response to adverse events, and related topics.

14.1.1.2 A current Cardio-Pulmonary Resuscitation (CPR) certificate acceptable to the Board of Pharmacy.

14.1.2 A registered pharmacist may only administer injections consistent with public health and safety and in a competent manner consistent with the academic curriculum and training completed.

14.1.3 Continued competency shall be maintained. A minimum of two hours (0.2 C.E.U.) of the thirty hour requirement for continuing education, every licensure period, must be dedicated to this area of practice.

14.1.4 Documentation of the satisfactory completion of the proper academic and practical training requirements shall be listed in a policy and procedures manual available for inspection by the Board of Pharmacy. Maintaining such a policy and procedures manual shall be the responsibility of each registered pharmacist administering injections.

14.2 Practice Requirements

14.2.1 The pharmacist must maintain a manual with policies consistent with OSHA (Occupational Exposure to Bloodborne Pathogens) and procedures for dealing with acute adverse events.

14.2.2 Prescriptions and/or physician-approved written protocols will be maintained and available for inspection by the Board of Pharmacy.

14.2.3 The pharmacist, before administering an injectable medication, biological, or immunization, must counsel the patient and/or the patient's representative about contraindications and inform them in writing in specific and readily understood terms about the risks and benefits. A signed copy of the patient's consent shall be filed and available for inspection by the Board of Pharmacy.

14.2.4 The pharmacist must document all injections made and have such documentation available for inspection by the Board of Pharmacy. Documentation shall include:

14.2.4.1 Patient's name, address, phone number, date of birth, and gender.

14.2.4.2 Medication or vaccine administered, expiration date, lot number, site of administration, dose administered.

14.2.4.3 Date of original order and the date of administration(s).

14.2.4.4 The name of the prescribing practitioner and the pharmacist administering the dose.

14.2.5 The pharmacist must document fully and report all clinically significant adverse events to the primary-care provider and to the Vaccine Adverse Event Reporting System (VAERS) when appropriate.

14.2.6 The pharmacist shall provide documentation to each person receiving immunizations and when appropriate to the Immunization Section of the Department of Health and Social Services so the names of those individuals can be added to the Vaccination Registry.

14.2.7 All documentation and records required by this Regulation must be maintained for a period of not less than three years.

14.3 Classes and Indications of Approved Medications. Classes of medications shall include injectable medications, immunizations, and biologicals contained in the list of Approved Drug Products with Therapeutic Equivalence Evaluations or drugs under clinical study when administered in accordance with indications approved by the Food & Drug Administration.

14.4 Authorization. Only those registered pharmacists meeting the requirements of this Regulation shall administer injectable medications, biologicals, and adult immunizations. The Board of Pharmacy shall maintain a current list of those pharmacists so authorized. It is the responsibility of each registered pharmacist to maintain his or her current status on such list.

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

15.0 Automated Pharmacy Systems

15.1 Purpose and Scope

15.1.1 The purpose of this regulation is to recognize the use of automated pharmacy systems in community, institutional, and long term care pharmacy settings.

15.2 Definitions

15.2.1 **"Automated Pharmacy Systems"** include, but are not limited to, mechanical systems that perform operations or activities, other than compounding or administration, relative to storage, packaging, dispensing, or distribution of medications, and which collect, control, and maintain all transaction information.

15.2.2 Automated Pharmacy Systems can be utilized in licensed pharmacies, remote locations under the jurisdiction of the Board of Pharmacy, and licensed health care facilities when legally permissible. Automated Pharmacy Systems shall be used only in settings where there is an established program of pharmaceutical care that ensures medication orders are reviewed by a pharmacist in accordance with established policies and procedures and good pharmacy practice.

15.3 Approval

15.3.1 Any new Automated Pharmacy System must be presented to the Board for approval prior to installation in the State. The presentation shall focus on patient safety and shall include how the technology functions and its quality control features.

15.3.2 The Board may approve the Automated Pharmacy System pending an inspection of the first installation within the State.

15.3.3 The Board will maintain a list of currently approved automated systems.

15.3.4 To ensure that changes in automation technology are reflected, a repeat presentation will be made to the Board if there is a substantive change in the technology.

15.3.5 A pharmacy wishing to install an Automated Pharmacy System previously approved by the Board will provide the Board with prior written notice of the installation or substantive changes of automated pharmacy systems. Such notice must include, but is not limited to:

15.3.5.1 The name and address of the pharmacy; and the location of the automated equipment;

15.3.5.2 Anticipated go-live date;

15.3.5.3 The identification of the responsible pharmacist;

15.3.5.4 Written policies and procedures for system operations that address at a minimum:

15.3.5.4.1 System operation, including access to and limits on access (e.g., security levels) to the Automated Pharmacy System that comply with State and Federal regulations;

15.3.5.4.2 Prevention of unauthorized access;

15.3.5.4.3 Maintenance of patient confidentiality;

15.3.5.4.4 Quality assurance procedures;

15.3.5.4.5 Procedures that will be followed if the automated dispensing system is unavailable at any time; and

15.3.5.4.6 Record keeping procedures.

15.4 Duties and Responsibilities of the Permit Holder

15.4.1 The Permit Holder has the following responsibilities:

15.4.1.1 Notifying the Board prior to the installation or removal of an approved Automated Pharmacy System.

15.4.1.2 Assuring that the Automated Pharmacy System is in good working order and accurately dispenses the correct strength, dosage form, and quantity of the drug prescribed while maintaining appropriate record keeping and security safeguards.

15.4.1.3 Developing and implementing an ongoing quality assurance program that monitors performance of the Automated Pharmacy System.

15.4.1.4 Developing written policies and procedures for system operation, safety, security, accuracy, patient confidentiality, access, and malfunction or down time.

15.4.1.5 Maintaining documentation at the location where the system is used of at least the following:

15.4.1.5.1 Name and address of the pharmacy and/or licensed health care facility where the automated pharmacy system is being used;

15.4.1.5.2 Manufacturer's name and model;

15.4.1.5.3 Description of how the device is used;

15.4.1.5.4 Quality assurance procedures to determine continued appropriate use of the automated device; and

15.4.1.5.5 Policies and procedures for operation of the Automated Pharmacy System.

15.5 Record Keeping Requirements

15.5.1 Records and/or electronic data kept by Automated Pharmacy Systems shall meet the following requirements:

15.5.1.1 All events involving the contents of the Automated Pharmacy System must be recorded electronically; and

15.5.1.2 Records must be maintained by the pharmacy and must be readily available to the Board. Such records must be maintained for a period of three(3) years and shall include:

15.5.1.2.1 Identity of the system accessed;

15.5.1.2.2 Identification of the individual accessing the system;

15.5.1.2.3 Type of transaction;

15.5.1.2.4 Name, strength, dosage form, and quantity of the drug accessed;

15.5.1.2.5 Name of the patient for whom the drug was ordered; and

15.5.1.2.6 Such additional information as the pharmacist-in-charge may deem necessary.

15.6 General Requirements

15.6.1 The pharmacist-in-charge or authorized designee shall be responsible for:

15.6.1.1 Assigning, discontinuing, or changing access to the system.

15.6.1.2 Ensuring that access to the medication complies with State and Federal regulations.

15.6.1.3 Checking the Automated Pharmacy System for accurate dispensing of medications at appropriate periodic intervals.

15.6.2 Community/Outpatient Pharmacy. A final check by the pharmacist is required after the medication is placed in the final container prior to dispensing and administration to the patient.

15.6.3 Hospital/Institution. Unit based or centralized dispensing requires the same level of supervision required in Regulation 9.2.3 which states: "Supportive personnel may be utilized in assisting the pharmacist. These persons must be supervised by a registered pharmacist who is present within the hospital and is responsible for the activities of those persons".

15.6.4 A record of medication filled/stocked into an Automated Pharmacy System shall be maintained and shall include identification of the persons filling/stocking and checking for accuracy.

15.6.5 All containers of medications stored in Automated Pharmacy System shall be packaged and labeled in accordance with Federal and State laws and regulations.

15.6.6 All aspects of handling controlled substances shall meet the requirements of all State and Federal laws and regulations.

15.6.7 The Automated Pharmacy System shall provide a mechanism for securing and accounting for medications removed from and subsequently returned to the Automated Pharmacy System, all in accordance with existing State and Federal law.

15.6.8 The Automated Pharmacy System shall provide a mechanism for securing and accounting for wasted medications or discarded medications in accordance with existing State and Federal law.

16.0 Crimes substantially related to the practice of pharmacy.

16.1 Conviction of any of the following crimes, or of the attempt to commit or of a conspiracy to commit or conceal the following crimes, is deemed to be a crime substantially related to the practice of pharmacy in the State of Delaware without regard to the place of conviction:

16.1.1 Unlawfully administering a controlled substance or counterfeit substance or narcotic drugs. 11 **Del.C.** §626.

16.1.2 Trafficking in marijuana, cocaine, illegal drugs, methamphetamines, L.S.D., or designer drugs. 16 **Del.C.** §4753A.

16.2 Crimes substantially related to the practice of pharmacy shall be deemed to include any crimes under any federal law, state law, or valid town, city or county ordinance, that are substantially similar to the crimes identified in this rule.

4 DE Reg. 1502 (3/1/01)
7 DE Reg. 1666 (6/1/04)
8 DE Reg. 879 (12/01/04)
10 DE Reg. 311 (08/01/06) (Prop.)