

DEPARTMENT OF STATE
DIVISION OF PROFESSIONAL REGULATION
Statutory Authority: 24 Delaware Code, Section 2506(a)(1) (24 **Del.C.** §2506(a)(1))
24 **DE Admin. Code** 2500

FINAL

ORDER

2500 Board of Pharmacy

After due notice in the Delaware *Register of Regulations* and two Delaware newspapers, a public hearing was held on August 19, 2015 at a scheduled meeting of the Delaware Board of Pharmacy ("Board") to receive comments regarding the Board's proposed revisions to its rules and regulations.

The proposed revisions address the subject of pharmaceutical compounding. Regulation 5.1.7 is amended to provide that compounded products may not be sold to a practitioner for use in his or her office to administer to patients. Regulation 10.0 is re-written to establish comprehensive requirements for non-sterile and sterile compounding consistent with USP Chapters 795 and 797.

The proposed changes to the rules and regulations were published in the Delaware *Register of Regulations*, Volume 19, Issue 1, on July 1, 2015. Notice of the August 19, 2015 hearing was published in the *News Journal* (Exhibit 1) and the *Delaware State News*. Exhibit 2. Pursuant to 29 **Del.C.** §10118(a), the date to receive final written comments was September 3, 2015, 15 days following the public hearing. The Board deliberated on the proposed revisions at its regularly scheduled meeting on September 16, 2015.

Summary of the Evidence and Information Submitted

The following exhibits were made a part of the record:

Board Exhibit 1: *News Journal* Affidavit of Publication.

Board Exhibit 2: *Delaware State News* Affidavit of Publication.

There was no comment presented by testimony or in writing as of the hearing date, August 19, 2015. However, the following documents were received by the date of deliberations, September 16, 2015, and were marked as exhibits and considered by the Board.

1. Email from Richard N. Spencer, Jr., VMD, White Clay Creek Veterinary Hospital, dated 9/2/15
2. Letter from Tracey Barkus, LVT, VCA Newark Animal Hospital, received 8/31/15
3. Letter from Melanese Jones, LVT, VCA Newark Animal Hospital, dated 8/26/15
4. Letter from Jennifer Arculus, DVM, VCA Newark Animal Hospital, dated 8/27/15
5. Letter from Shelly Boulware, VCA Newark Animal Hospital, dated 8/26/15
6. Letter from Amy Haines, LVT, VCA Newark Animal Hospital, dated 8/31/15
7. Letter from, Pecos Olurin, MD, et al., Delaware Academy of Ophthalmology, dated 9/2/15
8. Email from Joseph P. Olekszyk, DO, Nanticoke Ear, Nose and Throat, dated 9/3/15
9. Letter from Tarek S. Hassan, MD, et al., American Society of Retina Specialists, received 9/3/15
10. Letter from Alfonse Muto, RPh, Pine Pharmacy, dated 9/3/15
11. Letter from Michael Teixido, MD, et al., ENT & Allergy of Delaware, dated 9/3/15
12. Letter from Terri Corbo, PharmD, et al., Christiana Care Health Services, dated 8/21/15
13. Letter from David W. Dryden, RPh., JD, Executive Secretary, Delaware Board of Pharmacy, dated 9/2/15

Findings of Fact and Conclusions

Pursuant to 24 **Del.C.** §2506(a)(1), the Board has the statutory authority to promulgate rules and regulations.

The public was given notice and an opportunity to provide the Board with comments in writing and by testimony on the proposed amendments to the Board's rules and regulations.

The written comments submitted primarily addressed the issue of office use of compounded products, as set forth in Regulation 5.1.7.

With respect to Regulation 10.0, the Board finds that the re-written Regulation appropriately serves to update the Board's Regulations to comply with USP Chapters 795 and 797 and thereby advances professional practice standards and is in the best interest of the public. The Board, therefore, adopts the amendments to Regulation 10.0 as proposed.

With respect to Regulation 5.1.7, the Board considered the written comments. However, the Board determines that, pursuant to Federal requirements, compounded products, that are not patient specific, must be obtained from an outsourcing facility. The Board also finds that Regulation 5.1.7 is not clear and would benefit from revision. The Board, therefore, declines to adopt Regulation 5.1.7 as proposed. An amended version of Regulation 5.1.7 will be published in the *Register of Regulations* for subsequent hearing.

Decision and Effective Date

The Board hereby adopts the proposed amendments to the rules and regulations to be effective 10 days following final publication of this Order in the *Register of Regulations*.

Text and Citation

The text of the revised rules and regulations is attached hereto as Exhibit "A."

IT IS SO ORDERED this 18th day of November, 2015 by the Delaware Board of Pharmacy.

Susan Esposito, R.Ph., Professional Member, Vice President

Hooshang Shanehsaz, R.Ph., Professional Member, Vice President

Jay Galloway, Public Member

Bonnie Wallner, R.Ph., Professional Member

Tejal Patel, R.Ph., PharmD, Professional Member

Julia Wheatley, Public Member

Kimberly Robbins, R.Ph., Professional Member

2500 Board of Pharmacy

1.0 Pharmacist Licensure Requirements

1.1 Definitions

Words and terms defined in **Delaware Code** Title 1, Section 302 and Title 24, Section 2502 of the **Delaware Code** are applicable to these regulations. The following additional words and terms, when used within these regulations, shall have the following meaning unless the context clearly indicates otherwise or an alternate definition has been given:

"Automated Data Processing System (ADPS)" means a system utilizing computer software and hardware for the purposes of recordkeeping.

"Cell" means any container that holds the medication for automatic dispensing.

"Central Prescription Processing" means 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 Database" means a file or database created by an ADPS that enables authorized users to have common access to this file regardless of physical location.

"Compounding" means 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.

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

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

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

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

"Dispensing" means 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" means that period of time when a computer is not operable.

"Facsimile (FAX) Prescription" means 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).

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

"Patient Counseling" means an oral communication process between a pharmacist, or a registered intern or a pharmacy student working under the direct supervision of a pharmacist, and a patient, in which the pharmacist

obtains information from the patient and the patient's pharmacy records, assesses that information and provides the patient with professional advice regarding the safe and effective use of the prescription drug for the purpose of assuring therapeutic appropriateness.

"Pertinent Patient Medication Information" means 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" means a practitioner authorized to prescribe and acting within the scope of this authorization.

"Prescription" or **"Prescription drug order"** means the lawful written or verbal order of a practitioner for a drug, 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.)

"Printout" means a hard copy produced by computer that is readable without the aid of any special device.

"Reduced to Writing" means the preparation of a paper document containing all the information required for a written prescription including the State requirement 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" means any Federal or State agency charged with enforcement of pharmacy or drug laws and regulations.

"Stop Date" means 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.

1.2 Examination Requirements

- 1.2.1 All applicants 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 in Delaware.
- 1.2.2 In order for Delaware to be able to make a candidate eligible to take the NAPLEX or MPJE exam(s), the candidate must first register with and pay the exam fee to the National Association of Boards of Pharmacy (NABP). For more information on this process, please refer to the Registration Bulletin at: <http://www.napb.net.ftfiles/bulletins/NAPLEXMPJE.pdf> on the NAPB website and <http://www.dpr.delaware.gov/boards/pharmacy/newpharmacist.shtml> on the Division of Professional Regulation website.
- 1.2.3 In order to be made eligible to take either exam, an applicant must submit the appropriate processing fee along with a completed Pharmacist application, which will contain the following information:
 - 1.2.3.1 Proof of completion of all of the requirements for graduation from an approved school or college. Proof of completion should either be a "Certificate of Graduation in Pharmacy" form, a "Foreign pharmacy graduate Committee (FPGEC) Certification or a letter from the pharmacy school or college that the graduate has met all of the requirements for graduation."
 - 1.2.3.1.1 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.
 - 1.2.3.1.2 Graduates of schools or colleges of pharmacy located outside of the United States, which have not established standards in their respective undergraduate degree programs but are equivalent to the minimum standards for accreditation established by the American Council on Pharmaceutical Education, shall be deemed eligible to take the NAPLEX and MPJE examinations. Applicants must provide evidence of 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.
 - 1.2.3.1.3 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 Statute and Regulations are completed.

- 1.2.4 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. "College Practical Experience" form or an "affidavit of Intern Experience" must be furnished by the Dean of the College or the preceptor whichever the case may be.
- 1.2.5 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.
- 1.2.6 A candidate must take an examination within 365 Days of the determination of eligibility by the Board or they will have to re-register with NABP to be made re-eligible.

1.3 Practical Experience Requirements

- 1.3.1 In accordance with the requirements of 24 Del.C. §2515, all Pharmacist applicants, with the exception of reciprocity (licensure transfer) applicants, are required to complete a minimum of 1500 hours of Board approved practical experience under the supervision of a licensed pharmacist before being licensed. 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. If the applicant has not completed the required 1500 hours in another state, he or she will be required to register as an intern in Delaware to complete the required hours.
- 1.3.2 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. This application must include an "Affidavit of Class Standing" form and an "Affidavit of Preceptor" form. 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.
- 1.3.3 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 experience program. The Preceptor must certify that the intern has successfully completed all the requirements outlined in the Responsibilities of the Intern professional assessment form.
- 1.3.4 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.
- 1.3.5 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 form supplied by the Board. Registration as an intern in this State is not required for school experience.
- 1.3.6 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.
- 1.3.7 Applicants who have not completed all of the practical experience requirements, but who have graduated from an accredited college or have been certified by the NAPB Foreign Pharmacy Graduate Examination Committee are eligible to take the NAPLEX and/or MPJE examination. However, applicants will not be fully licensed until all the requirements of the licensing statute and regulations are completed. For more information on exam eligibility, please see subsection 1.2 or the Board's website at: <http://www.dpr.delaware.gov/boards/pharmacy/newpharmacist.shtml>.

1.4 Continuing Education Requirements

- 1.4.1 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.
 - 1.4.1.1 At least 2 hours of continuing education per biennial licensure period must be in the area of medication safety/errors.

- 1.4.2 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.
- 1.4.3 Criteria for Hardship Exemption as Recommended by the Board of Pharmacy:
 - 1.4.3.1 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.
 - 1.4.3.2 The Board of Pharmacy will review requests.
 - 1.4.3.3 The Board will notify the registrant of its decision.
- 1.4.4 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).
- 1.5 Continuing Professional Educational Programs
 - 1.5.1 Topics of Study shall be subject matter designed to maintain and enhance the contemporary practice of pharmacy.
 - 1.5.2 Approved Provider
 - 1.5.2.1 Any provider approved by ACPE.
 - 1.5.2.2 In-state organization which meets criteria approved by the Board.
 - 1.5.3 Application for Delaware State Provider
 - 1.5.3.1 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.
 - 1.5.3.2 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.
 - 1.5.4 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.
 - 1.5.4.1 Administration and Organization
 - 1.5.4.1.1 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.
 - 1.5.4.1.2 There shall be an identifiable person or persons charged with the responsibility of administering the continuing pharmaceutical education program.
 - 1.5.4.1.3 Such personnel shall be qualified for such responsibilities by virtue of experience and background.
 - 1.5.4.1.4 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.
 - 1.5.4.1.5 Administrative Requirements include:
 - 1.5.4.1.5.1 The development of promotional materials which state:
 - 1.5.4.1.5.1.1 Educational objectives.
 - 1.5.4.1.5.1.2 The target audience.
 - 1.5.4.1.5.1.3 The time schedule of the activities.
 - 1.5.4.1.5.1.4 Cost to the participant/covered items.
 - 1.5.4.1.5.1.5 Amount of C.E. credit which will be awarded.

- 1.5.4.1.5.1.6 Credentials of the faculty, presenters, and speakers.
- 1.5.4.1.5.1.7 Self-evaluation instruments.
- 1.5.4.1.5.2 Compliance with a quantitative measure for C.E. credit.
 - 1.5.4.1.5.2.1 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.
 - 1.5.4.1.5.2.2 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.
 - 1.5.4.1.5.2.3 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.
 - 1.5.4.1.5.2.4 The provider must provide the Board upon request with appropriate records of successful participation in previous continuing education activities.
 - 1.5.4.1.5.2.5 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.
- 1.5.4.2 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.
- 1.5.4.3 Program Content Development
 - 1.5.4.3.1 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:
 - 1.5.4.3.1.1 The social, economic, behavioral, and legal aspects of health care,
 - 1.5.4.3.1.2 the properties and actions of drugs and drug dosage forms,
 - 1.5.4.3.1.3 the etiology, characteristics, therapeutics and prevention of the disease state,
 - 1.5.4.3.1.4 pharmaceutical monitoring and management of patients.
 - 1.5.4.3.2 All ancillary teaching tools shall be suitable and appropriate to the topic.
 - 1.5.4.3.3 All materials shall be updated periodically to include up-to-date-practice setting.
 - 1.5.4.3.4 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.
- 1.5.4.4 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.
- 1.5.4.5 Evaluation. Effective evaluation of programs is essential and is the responsibility of both the provider and participant.
 - 1.5.4.5.1 Participant - Some evaluation mechanisms must be developed by the provider to allow the participant to assess his/her own achievement per the program.
 - 1.5.4.5.2 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.
- 1.5.5 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.
 - 1.5.5.1 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.

- 1.5.5.2 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.
- 1.5.5.3 Credit will be assigned only for the core content of the program which explicitly relates to the contemporary practice of Pharmacy.
- 1.5.5.4 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.
- 1.5.5.5 Credit for Instructors of Continuing Education
 - 1.5.5.5.1 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.
 - 1.5.5.5.2 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.
 - 1.5.5.5.3 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.)
 - 1.5.5.5.4 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.
- 1.5.5.6 Credit for On the Job Training:
 - 1.5.5.6.1 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.
 - 1.5.5.6.2 All programs that are submitted for credit must meet the criteria for continuing pharmacy education.
 - 1.5.5.6.3 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.)
 - 1.5.5.6.4 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.
- 1.6 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).
- 1.7 Reciprocal Requirements
 - 1.7.1 An applicant for licensure by reciprocity shall meet the requirements of 24 **Del.C.** §2510 and shall:
 - 1.7.1.1 submit proof of licensure in good standing from each state where he or she is or has been licensed;
 - 1.7.1.2 obtain a passing score on the MPJE on the laws applicable in this State as provided in subsection 1.2; and
 - 1.7.1.3 get fingerprinted at your local police agency and have the original state and federal criminal history record or statement that there is no criminal history record sent directly to the Board office.
 - 1.7.2 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.
 - 1.7.3 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.
- 1.8 Late Renewal - If a pharmacist license or pharmacy permit expire for failure to renew before the deadline, the license or permit may be renewed at any time within the 60 days immediately following expiration upon application and payment of the renewal fee and a late fee. In accordance with 24 **Del.C.** §§2507 and 2526, it is

unlawful for a licensee or permittee to practice or operate while their license or permit is expired. All late pharmacist license renewals will be audited for compliance with the CE renewal requirement.

- 1.9 Pharmacy Licenses. Pharmacy licenses shall include retail, hospital, nuclear and specialty institutional pharmacy licenses.

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)

11 DE Reg. 1065 (02/01/08)

13 DE Reg. 506 (10/01/09)

13 DE Reg. 1581 (06/01/10)

16 DE Reg. 998 (03/01/13)

17 DE Reg. 653 (12/01/13)

17 DE Reg. 990 (04/01/14)

2.0 Grounds for Disciplinary Proceeding

- 2.1 Conduct that may merit discipline pursuant to 24 **Del.C.** §2518(a) includes but is not limited to the following act(s):

- 2.1.1 Knowingly engaging in any activity which violates state and federal laws 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; and.

- 2.1.23 Using facsimile equipment to circumvent documentation, authenticity, verification or other standards of pharmacy or drug diversion.
- 2.2 Pharmacists may, in good faith and upon reasonable belief, withhold suspected forged prescriptions for release to law enforcement. When, in the judgment of the pharmacist, it is not prudent or possible to retain a suspected forged prescription, the pharmacist may exercise the option of making and retaining a copy of the prescription for release to law enforcement. Reporting the incident to law enforcement supports the personal responsibility of the dispensing pharmacist to be constantly vigilant against forged or altered prescriptions.

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

11 DE Reg. 222 (08/01/07)

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 and refusal to dispense pharmaceuticals based on the religious, moral, or ethical beliefs of the dispensing pharmacist. 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.
 - 3.1.2.7 Conducting an annual inspection of the pharmacy using the Board approved "pharmacist-in-charge self-inspection report" by February 1st of each year. The completed self-inspection report must be signed and dated by the pharmacist-in-charge and maintained on premises for three years in a form readily retrievable and available to Board inspectors.
 - 3.1.2.7.1 A new or incoming pharmacist-in-charge must complete the "pharmacist-in-charge self-inspection report" within thirty days of assuming the duties of pharmacist-in-charge and annually thereafter by February 1st.

- 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 appropriate to the individual pharmacy practice.
 - 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.
- 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 §2533(e).
 - 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, 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 Controlled Substances.
 - 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. The pharmacist-in-charge shall notify the Board within fifteen days after the completion of any remodeling.
- 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. §2533 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.
- 3.8 Technician Support. At all times that the pharmacy department is open for business, there shall be at least one technician immediately available in the facility to assist in the pharmacy at the pharmacist's request. A schedule of technician support shall be readily available to the pharmacists at all times.
- 3.9 A conspicuous sign with letters not less than three-quarter inches in height, reading "patients may request the lot numbers and expiration dating for their dispensed medication at the time of prescription drop-off" 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.

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)

11 DE Reg. 689 (11/01/07)

13 DE Reg. 506 (10/01/09)

15 DE Reg. 887 (12/01/11)

15 DE Reg. 1507 (04/01/12)

16 DE Reg. 654 (12/01/12)

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 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.

5.1.1 Receive oral prescriptions and reduce them immediately to writing.

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

5.1.3 The pharmacist, intern or student who dispenses the original prescription shall hand-sign or initial the prescription. Initials mechanically or electronically generated are acceptable.

5.1.4 Prior to dispensing a prescription to the patient or agent of the patient the pharmacist must verify that the medication in the container is as labeled. Pharmacies must include a description of their verification process in their policy and procedures manual.

5.1.5 Before dispensing or delivering a new medication to a patient or his or her agent, 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.

5.1.6 Compounding is the responsibility 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 a certified pharmacy technician under the direct supervision of a pharmacist if:

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

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

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

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

- 5.1.6.5 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.
- 5.1.7 Compounded medications for office use.
 - 5.1.7.1 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.
- 5.1.8 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 unless the information is stored electronically and readily retrievable. No drug can be added to the cell until the present supply is depleted unless the drug is of the same lot number and expiration date.
- 5.1.9 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.
- 5.1.10 Mandatory Patient Profile Record System
 - 5.1.10.1 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.
 - 5.1.10.2 The following information shall be recorded by a pharmacist or designee:
 - 5.1.10.2.1 The family name and first name of the person for whom the medication is intended (the patient);
 - 5.1.10.2.2 The address of the patient and phone number;
 - 5.1.10.2.3 The patient's age, or date of birth, and gender;
 - 5.1.10.2.4 The original date the medication is dispensed pursuant to the receipt of a prescriber's prescription;
 - 5.1.10.2.5 The number or designation identifying the prescription;
 - 5.1.10.2.6 The prescriber's name;
 - 5.1.10.2.7 The name, strength, quantity, directions and refill information of the drug dispensed;
 - 5.1.10.2.8 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;
 - 5.1.10.2.9 If the patient refuses to give all or part of the required information, the pharmacist shall so indicate and initial in the appropriate area.
 - 5.1.10.2.10 Pharmacist comments relevant to the patient's drug therapy, including any other information peculiar to the specific patient or drug.
 - 5.1.10.3 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.
 - 5.1.10.4 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 and shall, if necessary, consult with the prescriber.
 - 5.1.10.5 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.
- 5.1.11 Exchange of Valid Non-Controlled Prescriptions Between Pharmacies
 - 5.1.11.1 Verbal Exchange of Prescriptions - When a pharmacy receives a verbal request for a prescription transfer, it may be honored provided that:

- 5.1.11.1.1 The request comes from a registered pharmacist or pharmacy intern or student participating in an approved College of Pharmacy coordinated practical experience program under the direct supervision of a pharmacist.
- 5.1.11.1.2 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.
- 5.1.11.1.3 The prescription used for refills must be clearly identified as a copy.
- 5.1.11.1.4 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.
- 5.1.11.1.5 The copy shows the last date of dispensing.
- 5.1.11.1.6 Only the actual number of refills remaining are indicated.
- 5.1.11.1.7 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.
- 5.1.11.2 A copy prepared or transmitted that does not meet the requirements of this Regulation is deemed to be an invalid prescription.
- 5.1.11.3 Written copies of prescriptions are for information only and are not valid for refilling.
- 5.1.12 Automated Data Processing Systems (ADPS)
 - 5.1.12.1 Profiles. When ADP'S are used to maintain patient profile records, all the requirements of Delaware Pharmacy Regulation Section 5.0 must be met. In addition, there must be readily retrievable records that identify the responsible pharmacist(s) for each step in the dispensing and counseling processes; and a mechanism for tracking the prescription drug order during each step in the dispensing process and to identify all pharmacies involved in the dispensing of the and/or processing of the medication. The system must be adequately secured in order to protect the confidentiality and integrity of patient information.
 - 5.1.12.2 Prescription (Drug Order) Information. Prescription information (drug order) shall include, but not be limited to:
 - 5.1.12.2.1 Original dispensing date.
 - 5.1.12.2.2 Name and address of patient (patient location if in an institution).
 - 5.1.12.2.3 Name of prescriber.
 - 5.1.12.2.4 DEA number of prescriber in the case of a controlled substance.
 - 5.1.12.2.5 Name, strength, dosage form and quantity, (or Stop Date), and route of administration if other than oral form of drug prescribed.
 - 5.1.12.2.6 Renewals authorized.
 - 5.1.12.2.7 Directions of use for patient.
 - 5.1.12.3 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:
 - 5.1.12.3.1 Quantity dispensed.
 - 5.1.12.3.2 Date of dispensing.
 - 5.1.12.3.3 Serial Number (or equivalent if an institution).
 - 5.1.12.3.4 The identification of the pharmacist responsible for dispensing.
 - 5.1.12.3.5 Record of renewals to date.
 - 5.1.12.3.6 Name and strength of medicine.
 - 5.1.12.3.7 Records kept pursuant to this section may be maintained in an alternative data retention system, such as a direct digital imaging system, provided that: the records maintained in the alternative data retention system contain all of the information required in a manual record; the data processing system is capable of producing a hard copy of the electronic record on the request of the Board, its representative, or any law enforcement agency; and the digital images are recorded and stored only by means of a technology that does not allow subsequent revision or replacement of the images.

- 5.1.12.4 Record Retrieval (Documentation of Activity). Any such ADPS 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:
 - 5.1.12.4.1 Serial number of prescription (equivalent if an institution).
 - 5.1.12.4.2 Date of processing.
 - 5.1.12.4.3 Quantity dispensed.
 - 5.1.12.4.4 The identification of the pharmacist responsible for dispensing.
 - 5.1.12.4.5 Medication dispensed.
- 5.1.12.5 Auxiliary Recordkeeping System. An auxiliary recordkeeping system shall be established for the documentation of renewals if the ADPS 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 is not exceeded. When the ADPS is restored to operation, the information regarding prescriptions dispensed and renewed during the inoperative period shall be entered into the automated data processing system.
- 5.1.12.6 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.
- 5.1.12.7 Transfer of Prescriptions via Automated Data Processing (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. A pharmacist may transfer a prescription electronically (ADP) for non-controlled drug for renewal purposes in accordance with current State Regulations.
 - 5.1.12.7.1 Any pharmacy using ADP must comply with all applicable State and Federal regulations.
 - 5.1.12.7.2 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.
 - 5.1.12.7.3 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.
 - 5.1.12.7.4 The pharmacist receiving the transferred prescription drug order shall reduce it to writing with the following information:
 - 5.1.12.7.4.1 Write the word "TRANSFER" on the face of the transferred prescription unless the prescription is electronically transferred.
 - 5.1.12.7.4.2 Provide all information required to be on the prescription drug order pursuant to State and Federal laws and regulations.
 - 5.1.12.7.5 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.
- 5.1.13 Electronic Transmission of Prescriptions
 - 5.1.13.1 All Prescription Drug Orders communicated by way of Electronic Transmission shall:
 - 5.1.13.1.1 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;
 - 5.1.13.1.2 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;
 - 5.1.13.1.3 be transmitted by an authorized Practitioner or his designated agent; and
 - 5.1.13.1.4 be deemed the original Prescription Drug Order provided it meets the requirements of this subsection.
 - 5.1.13.2 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.

- 5.1.13.3 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.
- 5.1.13.4 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.
- 5.1.13.5 Persons other than those bound by a confidentiality agreement shall not have access to Pharmacy records containing Confidential Information or personally identifiable information concerning the Pharmacy's patients.
- 5.1.13.6 Controlled substance prescriptions may be electronically transmitted.
- 5.1.13.7 Facsimile prescriptions must meet the following requirements in addition to the above listed electronic Transmission requirements.
 - 5.1.13.7.1 The prescription order shall include the fax number of the transmitter, the number of transmitted pages, the name, phone number, and fax 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.
 - 5.1.13.7.2 Unless the prescription is written for a schedule II controlled substance, the prescriber should not issue the written prescription to the patient.
 - 5.1.13.7.3 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.
 - 5.1.13.7.4 The receiving facsimile machine must be in the prescription department to protect patient-pharmacist-authorized prescriber confidentiality and security.
 - 5.1.13.7.5 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.
- 5.1.14 Return and Disposal of Medications and Supply
 - 5.1.14.1 Except as provided in subsection 5.1.14.2, non-controlled substance prescriptions may not be returned to the pharmacy except for disposal.
 - 5.1.14.2 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, and which have been stored under USPNF (United States Pharmacopeia/National Formulary) conditions, may be redispensed in accordance with expiration dating. The pharmacist must examine the medication prior to re-dispensing for obvious signs of misbranding or adulteration. Partially used products may not be redispensed. Nothing in this regulation precludes the Federal laws and regulations.
 - 5.1.14.3 Dispensed medications returned by the public shall be properly disposed of in accordance with Delaware Controlled Substance laws and regulations and the federal Controlled Substance Act, 21 CFR 1300 to the end. Proposed disposal methods must be authorized by the Delaware Office of Controlled Substances and federal authority.
- 5.1.15 Centralized Prescription Processing
 - 5.1.15.1 A pharmacy may perform or outsource centralized prescription processing, services provided the parties:
 - 5.1.15.1.1 have the same owner; or
 - 5.1.15.1.2 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
 - 5.1.15.1.3 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.
 - 5.1.15.2 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:
 - 5.1.15.2.1 A description of how the parties will comply with federal and state laws and regulations;
 - 5.1.15.2.2 The maintenance of appropriate records to identify the responsible pharmacist(s) in each step of the dispensing and counseling processes;
 - 5.1.15.2.3 The maintenance of a mechanism for tracking the prescription drug order during each step in the dispensing process;

- 5.1.15.2.4 The maintenance of a mechanism to identify on the prescription label all pharmacies involved in dispensing the prescription drug, order;
- 5.1.15.2.5 The provision of adequate security to protect the confidentiality and integrity of patient information;
- 5.1.15.2.6 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.
- 5.1.15.3 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.
- 5.1.15.4 Any pharmacy where prescriptions are processed and/or dispensed via central fill must notify their patients using signage clearly visible to patients in the pharmacy department that part or parts of their prescription may be processed at a location other than where it is dispensed.
- 5.1.15.5 In addition to a QA program any pharmacy where prescriptions are processed and/or dispensed via central fill must record and track medication errors and potential errors and identify the system breakdown responsible for the errors and potential errors. Such records must be readily available for inspection.

5.2 Patient Counseling

- 5.2.1 Prior to dispensing a prescriptive medication to a new patient, a new medication to an existing patient or a medication that has had a change in the dose, strength, route of administration or directions for use, a pharmacist, or a registered intern or pharmacy student working under the direct supervision of a pharmacist, shall provide verbal counseling to the patient on pertinent medication information. The counseling may include, but not be limited to the following:
 - 5.2.1.1 the name and description of the prescribed drug;
 - 5.2.1.2 the dosage and the dosage form;
 - 5.2.1.3 the method and route of administration;
 - 5.2.1.4 the duration of the prescribed drug therapy;
 - 5.2.1.5 any special directions and precautions for preparation, administration, and use by the patient that the pharmacist determines are necessary;
 - 5.2.1.6 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;
 - 5.2.1.7 patient techniques for self-monitoring of the drug therapy;
 - 5.2.1.8 proper storage and appropriate disposal methods for unwanted or unused medications;
 - 5.2.1.9 prescription refill information;
 - 5.2.1.10 the action to be taken in the event of a missed dose; and
 - 5.2.1.11 current over-the-counter medication use.
- 5.2.2 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.
- 5.2.3 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 refuses the counseling. There must be a record in a uniform place that documents a patient's acceptance or refusal of counseling.
- 5.2.4 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), or if an agent is picking up the prescription for the patient, written or printed information shall be included with the prescription. The patient or his/her agent shall be provided with the pharmacist's contact information and informed that the pharmacist will be available for consultation.

Effective Date: October 11, 1996

Effective Date: April 14, 1997 Section 5.4 revised

Effective Date: June 11, 1998

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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)
13 DE Reg. 506 (10/01/09)
13 DE Reg. 1581 (06/01/10)
15 DE Reg. 99 (07/01/11)
16 DE Reg. 654 (12/01/12)
17 DE Reg. 990 (04/01/14)
18 DE Reg. 707 (03/01/15)

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 repacked, the quantity repacked, 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”. The containers shall meet all of the requirements of the USP/NF standard entitled, “Customized Patient Medication Package.” Packaging of controlled substances in a “Customized Patient Medication Package” is prohibited.

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)
17 DE Reg. 653 (12/01/13)

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 Definitions. Words and terms defined in Title 24, Chapter 25 of the **Delaware Code** are applicable to these regulations. The following additional words and terms, when used within Section 8.0, shall have the following meaning unless the context clearly indicates otherwise:
 - “**Authorized agent**” means a pharmacist who is trained and qualified to inspect against the Board’s standards and has been designated by the Board to conduct inspections on its behalf.
 - “**Entity**” means corporations, companies, associations, firms, partnerships, societies and joint-stock companies, but does not include individuals.
- 8.1.1 Clarification of Statutory Exceptions from the Definition of Wholesale Distribution.
 - 8.1.1.1 “Common control,” as used in 24 **Del.C.** §2502(t)(3), means the power to direct or cause the direction of the management and policies of a person or an organization, whether by ownership of stock, voting rights, by contract, or otherwise.
 - 8.1.1.2 “Emergency medical distributions,” as provided for by 24 **Del.C.** §2502(t)(4), may include, but is not limited to: transfers of a drug between a wholesale distributor and pharmacy to alleviate a temporary shortage of the drug arising from delays in or interruption of distribution schedules arranged in the ordinary course of business; or transfers of drugs by a licensed pharmacy or limited services permit holder to another licensed pharmacy or limited services permit holder. In all cases, transfers conducted pursuant to emergency medical reasons may be reviewed by the Board. Such transfers shall not exceed 5.0% of the total drug sales revenue of either the transferor or transferee pharmacy during any 12 consecutive month period.
- 8.2 Permit Requirements. Wholesale distributors that operate within this state, whether or not the wholesale distributor is physically located within this state, must first be granted a permit 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 permittee, 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 permitted to purchase drugs in the state;
 - 8.2.1.2 Name of the owner or owners and operator or operators of the permittee (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 not publicly traded on a major stock exchange: 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 Assurance that a copy of the wholesale distributor's written policies and procedures, required by Regulation 8.6, will be available at the distributor's site for review prior to licensure and thereafter for inspection;

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 Regulation 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.

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

8.2.6 All out-of-state wholesale distributors must comply with all rules, regulations, and laws of the state in which they are physically located and of all states in which they hold permits, including this state.

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.

8.3 Minimum Qualifications. The Board will consider the following factors in determining eligibility for granting a permit to persons who engage in the wholesale distribution of drugs:

8.3.1 Any findings by the Board that the applicant has violated or been disciplined by a regulatory agency in any state violating Federal, State, or local laws relating to drug distribution;

8.3.2 Any criminal convictions of the applicant under Federal, State, or local laws;

8.3.2.1 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; if the applicant is a corporation and not publicly traded on a major stock exchange, key personnel also includes: key company officers, key management, principals, and key owners. 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.

8.3.3 The applicant's past experience in the manufacture or distribution of drugs, including controlled substances;

8.3.4 The furnishing by the applicant of false or fraudulent material in any application made in connection with drug manufacturing or distribution;

- 8.3.5 Suspension, sanction or revocation by Federal, State, or local government against any license or permit currently or previously held by the applicant or any of its owners for violations of any Federal, State or local laws relating to drugs;
 - 8.3.6 Compliance with the requirements of Delaware regulations under previously granted wholesale distribution permits, if any;
 - 8.3.7 Compliance with the requirements to maintain and/or make available to the Board authority or to Federal, State, or local law enforcement officials those records required to be maintained by wholesale distributors.
 - 8.3.8 Any other factors or qualifications the Board considers relevant to and consistent with the public health and safety.
- 8.4 Personnel. As a condition for receiving and retaining a wholesale drug distributor permit, the permittee shall:
- 8.4.1 Require each individual employed in any drug wholesale distribution activity to have any combination of education, training, and experience sufficient for that 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 Maintain records evidencing that each employee has been trained in accordance with the policy and procedure manual approved required by Regulation 8.6. These records shall be kept for 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 permitted 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 whom may be served all legal processes in any action or proceeding against such permitted wholesale distributor growing out of or arising from its activities in this state. A copy of any such service of process shall be mailed to the wholesale distributor by the Board via certified mail, return receipt requested, postage prepaid, at the address the permitted wholesale distributor has designated on its application for permit in Delaware. If a wholesale distributor is not permitted in Delaware, service on the Secretary of State only shall be sufficient service; and
 - 8.4.4 Ensure that all key personnel have at least an associate's degree from an accredited institution of higher education acceptable to the Board or a minimum of two (2) years of verifiable full-time managerial or supervisory experience acceptable to the Board in a licensed pharmacy or wholesale distributor where the individual's responsibilities included, but were not limited to, recordkeeping, storage, and shipment of drugs. 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; if the applicant is a corporation and not publicly traded on a major stock exchange, key personnel also includes: key company officers, key management, principals, and key owners.
- 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 permitted wholesale distributors and their officers, agents, representatives, and employees:
- 8.5.1 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 facility are maintained in accordance with each drug's product labeling or in compliance with the *United States Pharmacopeia/National Formulary (USP/NF)*;
 - 8.5.1.2 Be of suitable size and construction to allow for 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 drug, the drug may be held at "controlled" room temperature, as defined in the USP/NF, 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 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; and
 - 8.5.1.7 Be a commercial location and not a personal dwelling or residence.

8.5.2 Wholesale distributors shall:

- 8.5.2.1 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;
- 8.5.2.2 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;
- 8.5.2.3 Maintain records of all personnel and their training; and
- 8.5.2.4 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.

8.5.3 Wholesale distributors involved in the distribution of controlled substances shall be duly registered with Drug Enforcement Administration (DEA) and the appropriate state agency 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; or
- 8.6.1.2 Any volunteer action by the manufacturer to remove defective or potentially defective drugs from the market.

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 three (3) years after disposition of the outdated drugs.

8.6.4 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 the Office of Narcotics and Dangerous Drugs (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.

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 or its authorized agent. 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 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; and
- 8.8.5 May possess and maintain, in good working order, technology and equipment that allows the wholesale distributor to authenticate, track, and trace drugs. The technology and equipment shall satisfy standards set by the Board and shall only be used to conduct tracking, tracing, and authentication of drugs. Wholesale distributors shall employ, train, and document the training of personnel in the proper use of such technology and equipment.

10 DE Reg. 1628 (4/1/07)

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 Policies 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 requirements.
- 9.2.1.12 A policy and procedure outlining therapeutic drug selection.
- 9.2.1.13 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 Pharmacy Technicians. Pharmacy technicians may be utilized in assisting the pharmacist. Pharmacy technicians must be supervised by a registered pharmacist who is present within the hospital and is responsible for the activities of the pharmacy technicians.

9.2.4 Pharmacy technicians must meet the requirements of Regulation 19.

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 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 pharmacist or pharmacist's designee shall be notified within 24 hours, and the pharmacist or pharmacist's 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 Section 3.0 and Section 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 with the 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 Section 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 DE Reg. 85 (7/1/05)

10 DE Reg. 1629 (4/1/07)

13 DE Reg. 1581 (06/01/10)

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 information 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 Pharmacy Technicians: The pharmacist managing the section of the pharmacy providing sterile/anti-neoplastic product pharmacy services may be assisted by pharmacy technicians. These technicians must have specialized training in this field, and shall work under the supervision of a licensed pharmacist. The training provided to these technicians must be described in writing in a training manual. The duties and responsibilities of these technicians 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. In addition to the requirements specified in Regulations 10.2 through 10.5 the Manual shall include 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).

10.0 **Pharmaceutical Compounding**

10.1 Non-Sterile and Sterile Preparations

- 10.1.1 The Board requires all individuals and entities licensed by the Delaware Board of Pharmacy engaged in compounding to adhere to and comply with both the current edition of the United States Pharmacopeia Chapters 795 (USP 795) and 797 (USP 797) and this Regulation, as applicable to their specific practice setting. Chapters 795 and 797 shall be reviewed and followed by compounders prior to non-sterile or sterile pharmaceutical compounding. The purpose of this Regulation is to provide all compounders with the requirements for good compounding practices for the preparation of non-sterile and sterile compounded formulations for dispensing and/or administration to humans and animals. Compounding is an integral part of pharmacy practice and is essential to the provision of healthcare. These regulations apply to non-sterile and sterile compounding of medications that are prepared for a specific patient and that are prescribed or ordered subject to a valid practitioner order or practitioner-patient relationship. The Delaware licensee engaged in compounding is responsible for ensuring compliance the requirements of Section 10.0.

10.2 Definitions applicable to Section 10.0

"Active ingredients" means chemicals, substances, or other components of articles intended for use in the diagnosis, cure, mitigation, treatment, or prevention of diseases in humans or animals or for use as nutritional supplements.

"Added substances" means the ingredients necessary to prepare the drug product but are not intended or expected to cause human pharmacological response if administered alone in the amount or concentration contained in a single dose of the compounded preparation. The term "added substances" is used synonymously with the terms "inactive ingredients," "excipients," and "pharmaceutical ingredients."

“Beyond-use date” (“BUD”) means the date after which a compounded preparation should not to be used as determined from the date the preparation is compounded. For sterile compounding, see subsection 10.4.

“Component” means any ingredient used in the compounding of a drug preparation, including any active ingredient or added substance that is used in its preparation.

“Compounder” means an individual or entity licensed by the Delaware Board of Pharmacy and engaged in the performance of compounding pursuant to a prescription or medication order by a licensed prescriber.

“Compounding” means the preparation, mixing, assembling, altering, packaging, and labeling of a drug, drug-delivery device, or device in accordance with a licensed practitioner’s prescription, medication order, or initiative based on the practitioner/patient/pharmacist/compounder relationship in the course of professional practice. Compounding includes, but is not limited to, the following:

- Preparation of drug dosage forms for both human and animal patients.
- Preparation of drugs or devices in anticipation of prescription drug orders based on routine, regularly observed prescribing patterns.
- Reconstitution or manipulation of commercial products that may require the addition of one or more ingredients.
- Preparation of drugs or devices for the purposes of, or as an incident to, research (clinical or academic), teaching, or chemical analysis.

“CSPs” means Compounded Sterile Preparations.

“Hazardous drugs” means any drug in studies of animals or humans that have been classified as carcinogenic, toxic to development or reproduction, or toxic to organs.

“Manufacturing” means any compounding activity that is not pursuant to a valid prescription or an order to prepare for administration and for an individual patient. Manufacturing is the production, propagation, conversion, or processing of a drug or device, either directly or indirectly, by extraction of the drug from substances of natural origin or by means of chemical or biological synthesis. Manufacturing may also include any packaging or repackaging of the substance(s) or labeling or relabeling of containers for resale by pharmacies, practitioners, or other persons. Any person engaged in manufacturing must be licensed in accordance with 24 Del.C. §2541.

“Preparation” means a compounded drug dosage form or dietary supplement or a device to which a compounder has introduced a drug. This term will be used to describe compounded formulations.

“Product” means manufactured pharmaceutical dosage forms.

“Vehicle” means a component for internal or external use that is used as a carrier or diluent in which liquids, semisolids, or solids are dissolved or suspended. Examples include, but are not limited to, water, syrups, elixirs, oleaginous liquids, solid and semisolid carriers, and proprietary products.

10.3 Non-sterile Pharmaceutical Compounding

10.3.1 Categories of Compounding. In the three general categories of non-sterile compounding described in this Regulation, different levels of experience, training and physical facilities are associated with each category:

10.3.1.1 Simple Compounding

10.3.1.1.1 Reconstituting or manipulating a commercial product that may require the addition of one or more ingredients as directed by the manufacturer.

10.3.1.1.2 A preparation that has a USP compounding monograph or appears in a peer reviewed article that contains: specific quantities for all components; compounding procedures and equipment, stability data for that formulation with an appropriate BUD. Examples include solutions, suspensions and gels.

10.3.1.2 Moderate Compounding

10.3.1.2.1 Making a preparation that requires special calculation or procedures to determine quantities of components per preparation or per individualized dosage units.

10.3.1.2.2 Making a preparation for which stability data for that specific formulation is not available. Example: mixing two or more manufactured creams when the stability of the mixture is unknown.

10.3.1.3 Complex Compounding

10.3.1.3.1 Making a preparation that requires special training, environment, facilities, equipment, and procedures. Examples include transdermal dosage forms and modified-release preparations.

10.3.2 Responsibilities of the Compounder and General Principles of Compounding

- 10.3.2.1 The compounder shall compound preparations of accepted strength, quality, and purity in accordance with the prescription or medication order.
- 10.3.2.2 The compounder shall dispense the finished preparation, with appropriate packaging and labeling, and in compliance with the requirements established by the applicable state agencies, Delaware Board of Pharmacy, federal law, and other regulatory agencies where appropriate.
- 10.3.2.3 Individuals who are engaged in drug or dietary supplement compounding shall be proficient in compounding and should expand their knowledge annually.
- 10.3.3 To ensure the quality of compounded preparation, compounders shall adhere to the general principles listed in USP 795 guidelines, including but not limited to:
 - 10.3.3.1 Training of all personnel shall be current and documentation of such kept on site.
 - 10.3.3.2 Compounding ingredients shall be purchased from reliable sources and are properly stored.
 - 10.3.3.3 Bulk component containers shall be properly labeled and MSDS sheets available.
 - 10.3.3.4 Equipment used shall be clean, properly used and maintained.
 - 10.3.3.5 Environment shall be suitable to prevent cross contamination.
 - 10.3.3.6 Compounding personnel shall wear appropriate and clean clothing. Protective apparel such as lab coats, gowns, gloves, shoes, or masks shall be worn as necessary to protect personnel from chemical exposure and/or contamination.
 - 10.3.3.7 Only authorized personnel shall be allowed in the compounding area.
 - 10.3.3.8 Conditions and procedures shall be such to prevent errors.
 - 10.3.3.9 All aspects of compounding shall be properly documented.
 - 10.3.3.10 Procedures and records shall be maintained for investigating and correcting failures or problems in compounding and testing.
- 10.3.4 Compounding Process
 - 10.3.4.1 The compounder shall ensure that each individual incidence of compounding meets the criteria in USP 795.
- 10.3.5 Compounding Facilities
 - 10.3.5.1 The compounder shall ensure that the compounding area adheres to the general principles listed in USP 795 guidelines, including but not limited to:
 - 10.3.5.1.1 Shall have an adequate space specifically designated for compounding and storage of equipment and materials.
 - 10.3.5.1.2 Shall be clean, orderly, and properly maintained.
 - 10.3.5.1.3 Shall have easily accessible hand washing, hot and cold water, soap or detergent, and an air-drier or single-use towels.
- 10.3.6 Compounding Equipment
 - 10.3.6.1 All equipment and utensils used in compounding shall be of appropriate design and capacity, and shall be cleaned and stored in a manner to protect it from contamination.
 - 10.3.6.2 Automatic, mechanical, electronic, or other equipment used in compounding shall be routinely inspected, calibrated, or checked according to the manufacturer's recommendations to ensure proper performance.
 - 10.3.6.3 Equipment shall be stored to protect it from contamination. It shall be located in an area to facilitate its use, cleaning and maintenance.
 - 10.3.6.4 Extra care shall be used when cleaning equipment used in compounding preparations containing substances requiring special handling (e.g., antibiotics, cytotoxic, or other hazardous materials).
- 10.3.7 Component Selection, Handling and Storage
 - 10.3.7.1 A USP, NF, or FCC (Food Chemical Codex) substance is the recommended source of ingredients for compounding all preparations.
 - 10.3.7.2 If ingredients are from a non-FDA registered facility professional judgment shall be used and a Certificate of Analysis is required.
 - 10.3.7.3 There shall be recorded procedures for compounded products to include components, amount, order of procedure, and equipment to ensure that the finished products have the identity, strength, quality, and purity they purport or are represented to possess.
 - 10.3.7.4 Components for compounding shall be accurately weighed, measured or subdivided as appropriate. If a component is transferred from the original container to a new container, the new container shall be labeled with the component name, original supplier, lot or control number.

transfer date, and expiration date and shall provide integrity that it is equal to or better than the original container.

10.3.7.5 Written control procedures shall be established to monitor the output and to validate the performance of those compounding processes that may be responsible for causing variability in the final drug product. Such control procedures shall include, but are not limited to, the following (where appropriate):

10.3.7.5.1 Capsule weight variation

10.3.7.5.2 Adequacy of mixing to insure uniformity and homogeneity

10.3.7.5.3 Clarity, completeness, or pH of solutions

10.3.7.6 When compounding with manufactured drug products, the compounder shall consider all ingredients, including excipients, present in the drug product relative to the intended use of the compounded preparation and the effect of manipulating the drug product on the therapeutic appropriateness and stability of the components.

10.3.7.7 When compounding for food-producing animals, the compounder shall consult the list of components prohibited for use in food-producing animals and consider withdrawal times. For example, treating animals in the food chain with certain antibiotics.

10.3.7.8 All components used in compounding must be stored as directed by the manufacturer, or according to USP, NF, or FCC monograph requirements, in a clean, dry area under appropriate temperature conditions. All components shall be stored off the floor, handled and stored to prevent contamination, and rotated so that the oldest stock is used first. All containers shall be properly labeled.

10.3.8 Stability Criteria and Beyond-Use Dating

10.3.8.1 The BUD is the date after which a compounded preparation shall not be used and is determined from the date when the preparation is compounded. Because compounded preparations are intended for administration immediately or following short-term storage, their BUDs are assigned on the basis of criteria different from those applied to assigning expiration dates to manufactured drug products. Criteria used shall be assigned according to USP 795. Compounders shall consult and apply drug-specific and general stability documentation and literature when available.

10.3.8.2 General Guidelines for maximum BUD are recommended for non-sterile compounded drug preparations in the absence of stability information that is applicable to a specific drug or preparation. The BUD shall not exceed the expiration date of the API or any other component.

<u>Type of Formulation</u>	<u>Maximum BUD</u>
<u>Non-aqueous formulation</u>	<u>6 months</u>
<u>Water-containing oral formulation</u>	<u>14 days under refrigeration</u>
<u>Water-containing topical/dermal and mucosal liquid and semisolid formulation</u>	<u>30 days</u>

10.3.9 Packaging and Drug Preparation Containers

10.3.9.1 The compounder shall ensure that the containers and closures used in packaging compounded preparations meet USP requirements.

10.3.9.1.1 The containers and closures shall be made of suitable clean material in order not to alter the quality, strength, or purity of the compounded preparation.

10.3.9.1.2 Container-drug interaction should be considered for substances that have sorptive or leaching properties.

10.3.9.1.3 Containers and closures shall be handled and stored in such a way as to prevent contamination.

10.3.10 Required Compounding Documentation

10.3.10.1 Documentation, written or electronic, enables a compounder, whenever necessary, to systematically trace, evaluate, and replicate the steps included throughout the process of compounding and shall be kept for 3 years.

10.3.10.2 Documentation shall comply with state and federal laws.

10.3.10.3 Documentation is not required when preparing a compounded preparation according to the manufacturer's labeled instructions.

10.3.10.4 Requirements for Master Formulation Record

- 10.3.10.4.1 Official or assigned name, strength, and dosage form of the preparation.
- 10.3.10.4.2 Calculations needed to determine and verify quantities of components and doses of active pharmaceutical ingredients.
- 10.3.10.4.3 Description of all ingredients and their quantities.
- 10.3.10.4.4 Compatibility and stability information, including references when available.
- 10.3.10.4.5 Equipment needed.
- 10.3.10.4.6 Mixing instructions.
- 10.3.10.4.7 Order of mixing.
- 10.3.10.4.8 Mixing temperature or other controls.
- 10.3.10.4.9 Duration of mixing.
- 10.3.10.4.10 Any other pertinent instruction.
- 10.3.10.4.11 Labeling information, in addition to legally required information, should include: Name and quantity or concentration of each active ingredient, assigned BUD, storage conditions, prescription number.
- 10.3.10.4.12 Container used in dispensing.
- 10.3.10.4.13 Packaging and storage requirements.
- 10.3.10.4.14 Description of final preparation.
- 10.3.10.4.15 Results of quality control procedures and expected results (e.g., Weight range of filled capsules, pH record etc)

10.3.10.5 Requirements for Compounding Record

- 10.3.10.5.1 Official or assigned name, strength, and dosage of the preparation.
- 10.3.10.5.2 Master Formulation Record reference for the preparation.
- 10.3.10.5.3 Names and quantities of all components.
- 10.3.10.5.4 Sources, lot numbers, and expiration dates of components.
- 10.3.10.5.5 Total quantity compounded.
- 10.3.10.5.6 Name of the person who prepared the compound, who performed the quality control procedures, and approved the preparation.
- 10.3.10.5.7 Date of the preparation.
- 10.3.10.5.8 Assigned controlled or prescription number.
- 10.3.10.5.9 Assigned BUD.
- 10.3.10.5.10 Description of final preparation.
- 10.3.10.5.11 Results of quality control procedures (e.g., weight range of filled capsules, pH record, etc.).
- 10.3.10.5.12 Documentation of any QC issues and any ADRs reported by patient.

10.3.11 Quality Control

- 10.3.11.1 The safety, quality, and performance of compounded preparations depend on correct ingredients, proper calculations, and accurate and precise measurements, appropriate formulation conditions and procedures, and prudent pharmaceutical judgment. As a final check, the compounder shall review each procedure in the compounding process. To ensure accuracy and completeness, the compounder shall observe the finished preparation to ensure that it appears as expected and shall investigate any discrepancies and take appropriate corrective action before the prescription is dispensed to the patient.

10.3.11.1.1 Compounding Controls

- 10.3.11.1.1.1 The compounder shall ensure that there are written procedures for the compounding of drug preparations to ensure that the finished preparations have the identity, strength, quality, and purity that they purport to have. These procedures shall be available in either written form or electronically stored.
- 10.3.11.1.1.2 The written procedures shall be followed in execution of the compounding process.
- 10.3.11.1.1.3 The compounder shall check and document each weight and measurement. The identity of the person(s) actually performing the compounding and of the compounder shall be recorded. Records shall be maintained for at least 3 years.
- 10.3.11.1.1.4 The compounder shall have established written procedures that will describe quality assurance tests or examinations to be conducted on the compounded preparation to ensure uniformity and integrity.

10.3.11.1.1.5 Appropriate control procedures shall be established to monitor the output and to validate the performance of those compounding processes and equipment that may be responsible for causing variability in the final compounded preparation.

10.3.11.1.1.6 For further guidance on recommended quality control procedures, see USP chapter 1163.

10.3.12 Patient Counseling as required by subsection 5.2

10.3.12.1 At the time of dispensing, the patient or the patient's agent shall be counseled by the dispensing pharmacist about proper use, storage, handling, and disposal of the compounded preparation. The patient or the patient's agent shall also be instructed to observe and report to the compounder any changes in the physical characteristics of the compounded preparation. The compounding pharmacist shall investigate any reported problem with a compounded preparation and take corrective action.

10.3.13 Compounding for Animal Patients

10.3.13.1 All portions of this section apply to compounded preparations formulated for both human and animal patients. Intended use on any animal patient (e.g., companion, performance, food) shall be determined before compounding for that patient. Because humans can consume animals as food, care must be taken to prevent drug residue from entering the human food chain. All pharmacists compounding for animals shall possess a functional knowledge of drug regulation and disposition in animal patients.

10.3.13.2 The compounding pharmacist shall be knowledgeable about the individual species limitations in physiology and metabolic capacity that can result in toxicity when certain drugs or excipients are used in compounded preparations. For this reason, pharmacists compounding for animals should use, when possible, formulations developed specifically for animal patients. If such formulations are not available, the compounding pharmacist shall conduct a literature review to determine whether a specific component of the formula is toxic to the target species.

10.4 Sterile Pharmaceutical Compounding

10.4.1 Compliance with USP 797 for sterile pharmaceutical compounding

10.4.1.1 The Board requires all individuals and entities licensed by the Board of Pharmacy engaged in sterile compounding to adhere to and comply with the current edition of the United States Pharmacopeia Chapter 797 (USP 797) and with this Regulation, as applicable to their specific practice setting. USP Chapter 797 shall be reviewed and followed by compounders prior to sterile pharmaceutical compounding. The purpose of this Regulation is to provide all compounders with guidance on applying good compounding practices for the preparation of sterile compounded formulations for dispensing and/or administration to humans and animals. These Regulations apply to sterile compounding of medications that are prepared for an individual patient, prescribed or ordered subject to a valid practitioner order and/or practitioner-patient relationship.

10.4.1.2 The objective of USP 797 is to describe conditions and practices to prevent harm, including death, to patients that could result from (1) microbial contamination, (2) excessive bacterial endotoxins, (3) variability in the intended strength of correct ingredients that exceeds limits, (4) unintended chemical and physical contaminants and (5) ingredients of inappropriate quality in compounded sterile products (CSPs).

10.4.1.3 It is generally acknowledged that direct or physical contact of critical sites of CSPs with contaminants, especially microbial sources, poses the greatest probability of risk to patients. Therefore, compounding personnel must be meticulously conscientious in precluding contact contamination of CSPs both within and outside ISO Class 5 (see Table 1) areas.

Table 1. ISO Classification of Particulate Matter in Room Air (limits are in particles of 0.5 µm and larger per cubic meter [current ISO] and cubic feet [former Federal Standard No. 209E, FS 209E])

<u>Class Name</u>		<u>Particle Count</u>	
<u>ISO Class</u>	<u>US FS 209E</u>	<u>ISO, m3</u>	<u>FS 209E, ft3</u>
<u>3</u>	<u>Class 1</u>	<u>35.2</u>	<u>1</u>
<u>4</u>	<u>Class 10</u>	<u>352</u>	<u>10</u>
<u>5</u>	<u>Class 100</u>	<u>3,520</u>	<u>100</u>
<u>6</u>	<u>Class 1,000</u>	<u>35,200</u>	<u>1,000</u>
<u>7</u>	<u>Class 10,000</u>	<u>352,000</u>	<u>10,000</u>
<u>8</u>	<u>Class 100,000</u>	<u>3,520,000</u>	<u>100,000</u>

10.4.1.4 The standards in USP 797 and in this Regulation are intended to apply to all persons who prepare CSPs and all places where CSPs are prepared.

10.4.1.5 CSPs include any of the following:

- Compounded biologics, diagnostics, drugs, nutrients, and radiopharmaceuticals including the following dosage forms that must be sterile when administered to patients: aqueous bronchial and nasal inhalations, baths and soaks for live organs and tissues, injections, irrigations for wounds and body cavities, ophthalmic drops and ointments and tissue implants.
- Manufactured sterile products that are either prepared strictly according to manufacturer's instructions or prepared differently.

10.4.2 Definitions applicable to subsection 10.4:

"Ante-Area" means an ISO Class 8 (see table 1) or better area where personnel hand hygiene and garbing procedures, staging of components, order entry, CSP labeling, and other high-particulate-generating activities are performed.

"Aseptic Processing" means a mode of processing pharmaceutical and medical products that involves the separate sterilization of the product and the package; and the transfer of the product into the container and its closure under at least ISO Class 5 conditions.

"Beyond-Use-Date (BUD)" means the date or time after which a CSP shall not be used, stored, or transported. The date is determined from the date or time the preparation is compounded.

"Biological Safety Cabinet (BSC)" means a ventilated cabinet providing downward high-efficiency particulate air (HEPA) filtered airflow for CSPs, personnel, product, and environmental protection.

"Buffer Area" means an area where the primary engineering control (PEC) is physically located and where preparation and staging of components used to compound CSPs is done.

"Clean Room" means a room in which the concentration of airborne particles is controlled to meet a specific class.

"Compounding Aseptic Containment Isolator (CACI)" means an aseptic isolator designed to provide worker protection from drug exposure during compounding.

"Compounding Aseptic Isolator (CAI)" means an isolator designed to maintain an aseptic environment for compounding pharmaceutical ingredients or preparations.

"Critical Site" means a location that includes any component or fluid pathway surfaces or openings at risk of contamination. (e.g., vial septa, open vials, injection ports, beakers, ampuls, needle hubs, syringe tips)

"Disinfectant" means an agent applied to inanimate objects that destroys disease-causing pathogens or other harmful micro-organisms.

"Media-Fill Test" means a test used to qualify aseptic technique of compounding personnel.

"Multiple-Dose Container" means a multiple-unit container for preservative-containing preparations intended for parenteral administration only. The beyond-use date for an open or entered container containing preservatives is 28 days unless otherwise specified by the manufacturer.

"Primary Engineering Control (PEC)" means a device or room that provides an ISO Class 5 environment for the exposure of critical sites when compounding CSPs. (Laminar Air Flow Workbenches, Biological Safety Cabinet, Compounding Aseptic Isolators, Compounding Aseptic Containment Isolators).

"Single-Use Container" means a single-unit container for preparations intended for parenteral administration intended for single-use only.

"Segregated Compounding Area" means a designated space, demarcated area or room, that is restricted to preparing low-risk level CSPs with a BUD of 12 hours or less. Such area shall contain a device that provides an ISO Class 5 air quality and shall be void of activities and materials that are extraneous to sterile compounding.

"Sterilization by Filtration" means a passage of a solution through a sterilizing grade membrane.

"Terminal Sterilization" means the application of a lethal process (e.g. autoclaving) to sealed containers for the purpose of achieving sterility.

10.4.3 Abbreviations and acronyms

ACD automated compounding device

ACPH air changes per hour

ALARA as low as reasonably achievable

<u>ASHRAE</u>	<u>American Society of Heating, Refrigerating and Air-Conditioning Engineers</u>
<u>BI</u>	<u>biological indicator</u>
<u>BSC</u>	<u>biological safety cabinet</u>
<u>BUD</u>	<u>beyond-use date</u>
<u>CACI</u>	<u>compounding aseptic containment isolator</u>
<u>CAI</u>	<u>compounding aseptic isolator</u>
<u>CDC</u>	<u>Centers for Disease Control and Prevention</u>
<u>CETA</u>	<u>Controlled Environment Testing Association</u>
<u>CFU</u>	<u>colony-forming unit</u>
<u>CSP</u>	<u>compounded sterile product</u>
<u>CSTD</u>	<u>closed-system vial-transfer device</u>
<u>DCA</u>	<u>direct compounding area</u>
<u>ECV</u>	<u>endotoxin challenge vial</u>
<u>EU</u>	<u>endotoxin Unit</u>
<u>FDA</u>	<u>Food and Drug Administration</u>
<u>HEPA</u>	<u>high efficiency particulate air</u>
<u>HICPAC</u>	<u>Healthcare Infection Control Practices Advisory Committee</u>
<u>HVAC</u>	<u>heating, ventilation, and air conditioning</u>
<u>IPA</u>	<u>isopropyl alcohol</u>
<u>ISO</u>	<u>International Organization for Standardization</u>
<u>LAFW</u>	<u>laminar air flow workbench</u>
<u>MDVs</u>	<u>multidose-dose vials</u>
<u>MMWR</u>	<u>Morbidity and Mortality Weekly Report</u>
<u>NIOSH</u>	<u>National Institute for Occupational Safety and Health</u>
<u>NIST</u>	<u>National Institute of Standards and Technology</u>
<u>PEC</u>	<u>primary engineering control</u>
<u>PET</u>	<u>positron emission tomography</u>
<u>PPE</u>	<u>personnel protective equipment</u>
<u>psi</u>	<u>pounds per square inch</u>
<u>QA</u>	<u>quality assurance</u>
<u>SOP</u>	<u>standard operating procedure</u>
<u>SVI</u>	<u>sterile vial for injection</u>
<u>TSA</u>	<u>trypticase soy agar</u>
<u>USP</u>	<u>United States Pharmacopeia</u>

10.4.4 Responsibilities of compounding personnel

10.4.4.1 USP 797 emphasizes the need to maintain high standards for the quality and control of processes, components, and environments and for the skill and knowledge of personnel who prepare CSPs. Individuals and entities licensed by the Delaware Board of Pharmacy and engaged in compounding are responsible for compounding personnel, who ensure that CSPs are accurately identified, measured, diluted, and mixed and are correctly purified, sterilized, packaged, sealed, labeled, stored, dispensed, and distributed. Compounding personnel's performance responsibilities include:

10.4.4.1.1 Maintaining appropriate cleanliness conditions and providing labeling and supplementary instructions for the proper clinical administration of CSPs.

10.4.4.1.2 Compounding supervisors shall ensure, through either direct measurement or appropriate information sources, that specific CSPs maintain their labeled strength within monograph limits for USP articles, or within 10% if not specified until their BUDs.

10.4.4.1.3 A written quality assurance procedure shall be established and shall include the following:

10.4.4.1.3.1 Accuracy and precision of measuring and weighing;

10.4.4.1.3.2 The requirement for sterility; methods of sterilization and purification;

10.4.4.1.3.3 Safe limits and ranges for strength of ingredients, bacterial endotoxins, and particulate matter, pH;

10.4.4.1.3.4 Labeling accuracy and completeness;

- 10.4.4.1.3.5 BUD assignment and packaging and storage requirements.
- 10.4.4.1.3.6 The dispenser shall, when obtainable and practicable, obtain and evaluate results of testing for identity, strength, purity, and sterility before a CSP is dispensed.
- 10.4.4.1.4 Qualified licensed healthcare professionals who supervise compounding and dispensing of CSPs shall ensure that the following objectives are achieved:
 - 10.4.4.1.4.1 Compounding personnel are adequately skilled, educated, instructed, and trained to correctly perform and document the following activities in their sterile compounding duties:
 - 10.4.4.1.4.1.1 Perform aseptic hand cleansing and disinfection of non-sterile compounding surfaces;
 - 10.4.4.1.4.1.2 Select and appropriately don protective garb;
 - 10.4.4.1.4.1.3 Maintain or achieve sterility of CSPs in ISO Class 5 environment and protect personnel and environment from contamination;
 - 10.4.4.1.4.1.4 Identify, weigh, and measure ingredients;
 - 10.4.4.1.4.1.5 Manipulate sterile products aseptically, sterilize high-risk CSPs, and label and quality inspect CSPs.
 - 10.4.4.1.4.2 Ingredients have their correct identity, quality, and purity.
 - 10.4.4.1.4.3 Water-containing CSPs that are non-sterile during any phase of the compounding procedure are sterilized within 6 hours of completing the preparation.
 - 10.4.4.1.4.4 Packaging selected for CSPs is appropriate to preserve sterility and strength until the BUD.
 - 10.4.4.1.4.5 Labels on CSPs list the names and amounts or concentration of active ingredients. Prior to dispensing or administration, the clarity of solutions is visually confirmed; the identity and amounts of ingredients, procedures to prepare and sterilize CSPs, and specific release criteria are reviewed to ensure their accuracy and completeness.
 - 10.4.4.1.4.6 BUDs are assigned on the bases of direct testing or extrapolation from reliable sources.
- 10.4.5 Requirements for CSP Microbial Contamination Risk Levels
 - 10.4.5.1 The three contamination categories, low-risk, medium-risk, and high-risk, are assigned according to the potential for microbial contamination during compounding.
 - 10.4.5.1.1 Low-Risk Level CSPs
 - 10.4.5.1.1.1 All CSPs shall be compounded with aseptic manipulation entirely within ISO Class 5 or better air quality using only sterile ingredients, products, components, and devices.
 - 10.4.5.1.1.2 Compounding shall involve only transfer, measuring and mixing of not more than three commercially manufactured packages of sterile products and not more than two entries into any one sterile container or package.
 - 10.4.5.1.1.3 Manipulations shall be limited to aseptically opening ampuls, penetrating disinfected stoppers with sterile needles and syringes, and transferring sterile liquids from one sterile package to another.
 - 10.4.5.1.1.4 In the absence of passing a sterility test, storage of low-level CSPs shall not exceed 48 hours at room temperature or 14 days at a cold temperature or 45 days in a solid frozen state.
 - 10.4.5.2 Medium-Risk Level CSPs
 - 10.4.5.2.1 Multiple individual or small doses of sterile products are combined to prepare a CSP that will be administered to either multiple patients or a single patient multiple times.
 - 10.4.5.2.2 The compounding procedure contains complex aseptic manipulations.
 - 10.4.5.2.3 The process requires unusually long duration for mixing or dissolution.
 - 10.4.5.2.4 In the absence of a sterility test of medium-risk CSPs shall not exceed 30 hours at controlled room temperature or 9 days at cold temperature or 45 days in a solid frozen state.
 - 10.4.5.3 High-Risk Level CSPs
 - 10.4.5.3.1 Non-sterile ingredients are incorporated or a non-sterile device is used prior to terminal sterilization.
 - 10.4.5.3.2 Any ingredient, device, environment or surface is exposed to air quality less than ISO Class 5 for more than 1 hour.
 - 10.4.5.3.3 Compounding personnel are improperly garbed and gloved.
 - 10.4.5.3.4 Non-sterile, water-containing preparations are stored for more than 6 hours before sterilization.
 - 10.4.5.3.5 Chemical purity and ingredient strength has not been verified by compounding personnel.

10.4.5.3.6 In the absence of a sterility test of high-risk CSPs must not exceed 24 hours at controlled room temperature or 3 days at cold temperature or 45 days in a solid frozen state.

10.4.6 Quality Assurance Requirements.

10.4.6.1 Quality assurance practices include but are not limited to:

10.4.6.1 Routine disinfection and air quality testing of the direct compounding environment.

10.4.6.2 Visual confirmation that compounding personnel are properly garbed and gloved.

10.4.6.3 Review of all orders and ingredients to ensure correct identity and amounts were used in CSP.

10.4.6.4 Visual inspection of CSPs for the absence of particulate in solutions, absence of leakage from vials and bags, and accuracy of labeling.

10.4.6.5 Perform Media-Fill Test pursuant to level of sterile compounding being performed.

10.4.6.5.1 Media-Fill Test Procedure: Refer to USP 797 for instruction relative to risk level of CSPs being prepared.

10.4.6.6 The Media-Fill Test shall be performed at least annually for each person authorized to compound in a low-risk or medium-risk environment

10.4.6.7 The Media-Fill Test shall be performed semi-annually by those authorized to compound high-risk level CSPs.

10.4.6.8 The Media-Fill Test shall be completed without interruption and should be designed to simulate the most stressful and challenging conditions encountered during compounding.

10.4.6.9 The Media-Fill Test shall be performed in an ISO Class 5 or better environment.

10.4.7 Personnel Training and Evaluation in Aseptic Manipulation Skills

10.4.7.1 Personnel who prepare CSPs shall be trained conscientiously and skillfully by expert personnel and through instructional sources and professional publications in the theoretical principles and practical skills of aseptic manipulations and in achieving and maintaining ISO Class 5 environmental conditions before they begin to prepare CSPs.

10.4.7.2 Compounding personnel shall perform didactic review and pass written and media-fill testing initially and annually for low and medium-risk compounding of CSPs and semi-annually for high-risk.

10.4.8 Immediate-Use CSPs

10.4.8.1 The immediate-use provision is intended only for those situations where there is a need for emergency or immediate patient administration of a CSP. Immediate-use CSPs are not intended for storage for anticipated needs or batch compounding. Refer to USP 797 for requirement exemption criteria for immediate-use CSPs.

10.4.9 Single-dose and Multiple-dose Containers

10.4.9.1 Opened or needle-punctured single-dose containers, such as bags, bottles, syringes and vials of sterile products and CSPs shall be used within 1 hour if opened in worse than ISO Class 5 environment and remaining contents discarded.

10.4.9.2 Single-dose containers exposed to ISO Class 5 environment or cleaner air may be used for up to 6 hours after initial needle puncture.

10.4.9.3 Opened single-use containers shall not be stored for any time period.

10.4.9.4 Multiple-dose containers contain antimicrobial preservatives and therefore have a BUD of 28 days after initially entering or opening unless otherwise specified by the manufacturer.

10.4.10 Hazardous Drugs as CSPs

10.4.10.1 Hazardous drugs shall be prepared for administration only under conditions that protect the healthcare workers and other personnel in the preparation and storage areas.

10.4.10.1.1 Hazardous drugs shall be stored separately from other inventory in a manner to prevent contamination and personnel exposure.

10.4.10.1.2 Access shall be limited to areas where drugs are stored and prepared to protect persons not involved in drug preparation.

10.4.10.1.3 All hazardous drugs shall be prepared in a BSC or CACI that meets or exceeds the standards outlined in USP 797 for CACI. The ISO Class 5 BSC or CACI shall be placed in an ISO Class 7 area that is physically separated from other preparation areas. In facilities that prepare a low volume of hazardous drugs, the use of two tiers of containment (e.g., CSTD within a BSC or CACI that is located in a non-negative pressure room) is acceptable.

- 10.4.10.1.4 Appropriate personnel protective equipment (PPE) shall be worn. PPE shall include gowns, face masks, eye protection, hair covers, shoe covers or dedicated shoes, and double gloving with sterile chemo-type gloves.
- 10.4.10.1.5 All personnel who compound hazardous drugs shall be fully trained in the storage, handling, and disposal of these drugs. The training shall include at least the following:
 - 10.4.10.1.5.1 Safe aseptic manipulation practices.
 - 10.4.10.1.5.2 Negative pressure techniques when utilizing a BSC or CACI.
 - 10.4.10.1.5.3 Correct use of CSTD devices.
 - 10.4.10.1.5.4 Containment, cleanup, and disposal procedures for spills.
 - 10.4.10.1.5.5 Treatment of personnel contact and inhalation exposure.
- 10.4.10.1.6 Compounding personnel of reproductive capability shall confirm in writing that they understand the risks of handling hazardous drugs.
- 10.4.10.1.7 Disposal of all hazardous drug wastes shall comply with all applicable federal and state regulations.
- 10.4.10.1.8 All personnel who perform routine custodial waste removal and cleaning activities shall be trained in appropriate procedures to protect themselves and prevent contamination.
- 10.4.11 Radiopharmaceuticals as CSPs
 - 10.4.11.1 Compounding personnel shall refer to and adhere to USP 797 and Regulation 13 prior to compounding radiopharmaceuticals.
 - 10.4.11.2 Radiopharmaceuticals compounded from sterile components in closed sterile containers and with a volume of 100 ml or less for a single-dose injection or not more than 30 ml taken from a multiple-dose container shall be designated as, and conform to, the standards for Low-Risk CSPs. These radiopharmaceuticals shall be compounded using appropriately shielded vials and syringes in a properly functioning and certified ISO Class 5 PEC located in an ISO Class 8 or cleaner air environment to permit compliance with special handling, shielding and negative air flow requirements.
 - 10.4.11.3 Radiopharmaceuticals prepared as CSPs shall be prepared in a segregated compounding area with a defining line of demarcation.
- 10.4.12 Allergen Extracts as CSPs
 - 10.4.12.1 Allergen extracts as CSPs are single-dose and multiple-dose intradermal or subcutaneous injections that are prepared by specially trained physicians and personnel under their direct supervision.
 - 10.4.12.2 See USP 797 for complete criteria regarding regulation exemption requirements.
 - 10.4.12.3 Personnel who compound allergen extracts as CSPs shall be aware of greater potential risk for microbial and foreign material contamination when allergen extracts as CSPs are compounded in compliance with exemption criteria instead of the more rigorous standards contained elsewhere in USP 797.
- 10.4.13 Verification of Compounding Accuracy and Sterility
 - 10.4.13.1 Packaged and labeled CSPs shall be visually inspected for physical integrity and expected appearance, including final fill amount. The accuracy of identities, concentrations, amounts, and purities of ingredients in CSPs shall be confirmed by reviewing labels on packages, observing and documenting correctly standardized devices, and reviewing information in labeling certificates of analysis provided by suppliers.
 - 10.4.13.1.1 Sterilization Methods
 - 10.4.13.1.1.1 The licensed healthcare professionals who supervise compounding personnel shall be responsible for determining that the selected sterilization method both sterilizes and maintains the strength, purity, quality, and packaging integrity of CSPs. Requirements for matching CSPs and components to appropriate sterilization methods include, but are not limited to, the following:
 - 10.4.13.1.1.2 CSPs have been ascertained to remain physically and chemically stable when subjected to the selected sterilization method.
 - 10.4.13.1.1.3 Glass and metal devices may be covered tightly with aluminum foil, then exposed to dry heat in an oven at a mean temperature of 250°C for 30 minutes to achieve sterility and depyrogenation. Such items are either used immediately or stored in an environment suitable for compounding Low-Risk and Medium Risk CSPs.

10.4.13.1.1.4 Personnel shall ascertain from appropriate information sources that the sterile microporous membrane filter used to sterilize CSP solutions, during either compounding or administration, is chemically and physically compatible with CSP.

10.4.13.2 Sterilization of High-Risk Level CSPs by Filtration

10.4.13.2.1 Sterile filters used to sterilize CSPs shall be pyrogen free and have a nominal pore size of 0.2 or 0.22 µm. They shall be certified by the manufacturer to meet USP 797 standards.

10.4.13.2.2 The compounding supervisor shall ensure, directly or from appropriate documentation, that the filters are chemically and physically stable at the pressure and temperature conditions to be used, that they have enough capacity to filter the required volumes, and that they will achieve sterility and maintain pre-filtration pharmaceutical quality, including strength of ingredients of the specific CSP.

10.4.13.2.3 Filter units used to sterilize CSPs shall also be subjected to manufacturers' recommended integrity test, such as the bubble point test.

10.4.13.3 Sterilization of High-Risk Levels CSPs by Steam

10.4.13.3.1 To achieve sterility all materials shall be exposed to steam at 121°C under a pressure of about 15 psi for the duration verified by testing to achieve sterility of the items, which is usually 20 to 60 minutes for CSPs. Not exposing items to pressurized steam may result in survival of microbial organisms and spores.

10.4.13.3.2 Before their sterilization, plastic, glass, and metal devices shall be tightly wrapped in low-particle-shedding paper or fabrics or sealed in envelopes that prevent post-sterilization microbial penetration.

10.4.13.3.3 The effectiveness of steam sterilization shall be verified using appropriate Biological Indicators and other confirmation methods such as temperature-sensing devices.

10.4.13.4 Sterilization of High-Risk Level CSPs by Dry Heat

10.4.13.4.1 Dry heat sterilization is usually done in an oven designed for sterilization. Heated filtered air shall be evenly distributed throughout the chamber by a blower device.

10.4.13.4.2 Dry heat shall be used only for those materials that cannot be sterilized by steam, when either the moisture would damage the material or the material is impermeable.

10.4.13.4.3 The effectiveness of dry heat sterilization shall be verified by using appropriate Biological Indicators.

10.4.13.5 Depyrogenation by Dry Heat

10.4.13.5.1 Dry heat pyrogenation shall be used to render glassware or containers such as vials free from pyrogens as well as viable microbes.

10.4.13.5.2 A typical cycle would be 30 minutes at 250°C.

10.4.13.5.3 Dry heat depyrogenation shall be verified by using endotoxin challenge vials as described in USP 797.

10.4.14 Environmental Quality and Control

10.4.14.1 Exposure of Critical Sites

10.4.14.1.1 Maintaining the sterility and cleanliness of critical sites is a primary safeguard for CSPs. Critical sites are locations that include any component or fluid pathway surface (e.g., vial septa, injection ports, beakers) or openings (e.g., opened ampuls, needle hubs) exposed and at risk of direct contact with air, moisture, or touch contamination. The nature of the critical site affects the risk of contamination. Protection of critical sites by precluding physical contact and airborne contamination shall be given the highest priority in sterile compounding practice.

10.4.14.2 Facility Design and Environmental Controls

10.4.14.2.1 Compounding facilities shall be physically designed and environmentally controlled to minimize airborne contamination from contacting critical sites.

10.4.14.2.2 Facilities shall provide a comfortable and well-lit working environment which typically includes a temperature of 20°C or cooler, to maintain comfortable compounding conditions for compounding personnel to perform flawlessly when attired in the required aseptic compounding garb.

10.4.14.2.3 PECs shall maintain ISO Class 5 or better conditions for 0.5 µm particles while compounding CSPs.

10.4.14.2.4 Buffer areas are designed to maintain at least ISO Class 7.

- 10.4.14.2.5 In-situ, air pattern analysis via smoke studies shall be conducted at the critical area to demonstrate unidirectional airflow and sweeping action over and away from the product under dynamic conditions.
- 10.4.14.2.6 The principles of HEPA-filtered unidirectional airflow in the work environment shall be understood and practiced in the compounding process in order to achieve the desired environmental conditions.
- 10.4.14.2.7 Policies and procedures for working in the PEC area shall be written and followed.
- 10.4.14.2.8 Activities and tasks carried out within the buffer area shall be limited to only those necessary when working within a controlled environment.
- 10.4.14.2.9 Only the furniture, equipment, supplies, and other material required for the compounding activities to be performed shall be brought into the area, and they shall be non-permeable, non-shedding, cleanable, and resistant to disinfectants. Whenever such items are brought into the area, they shall first be cleaned and disinfected. Whenever possible, equipment and other items used in the buffer area shall not be taken out of the area except for calibration, servicing, or other activities associated with the proper maintenance of the item.
- 10.4.14.2.10 The surfaces of ceilings, walls, floors, fixtures, shelving counter, and cabinets in the buffer area shall be smooth impervious, free from cracks and crevices, and non-shedding, thereby promoting cleanability and minimizing spaces in which microorganisms and other contaminants may accumulate. The surfaces shall be resistant to damage by disinfectant agents.
- 10.4.14.2.11 Carts shall be of stainless steel wire, nonporous plastic, or sheet metal construction with good quality, cleanable casters to promote mobility.
- 10.4.14.2.12 Storage shelving, counters, and cabinets shall be smooth, impervious, free from cracks and crevices, non-shedding, cleanable, and disinfectable; their number, design and manner of installation shall promote effective cleaning and disinfection.
- 10.4.14.3 Placement of Primary Engineering Controls
- 10.4.14.3.1 Only authorized personnel and materials required for compounding and cleaning shall be permitted in the buffer area.
- 10.4.14.3.2 Pre-sterilization procedures for High-Risk level CSPs, such as weighing and mixing, shall be completed in no worse than an ISO Class 8 environment.
- 10.4.14.3.3 PECs shall be located out of traffic patterns and away from room air currents.
- 10.4.14.4 Viable and Non-Viable Environmental Sampling (ES) Testing
- 10.4.14.4.1 Environmental sampling shall occur as a part of a comprehensive quality management program and shall occur minimally under any of the following conditions:
- 10.4.14.4.1.1 As part of the commissioning and certification of new facilities and equipment.
- 10.4.14.4.1.2 Following any servicing of facilities and equipment.
- 10.4.14.4.1.3 As part of the re-certification of facilities and equipment (i.e. every 6 months)
- 10.4.14.4.1.4 In response to identified problems with end products or staff technique.
- 10.4.14.4.1.5 In response to issues with CSPs, observed compounding personnel work practices, or patient-related infections.
- 10.4.14.5 Environmental Non-Viable Particle Testing Program
- 10.4.14.5.1 Total Particle Counts—Certification that each ISO classified area is within established guidelines shall be performed no less than every 6 months and whenever the LAFW, BSC, CAI, or CACI is relocated or the physical structure of the buffer area or ante-area has been altered.
- 10.4.14.5.2 Testing shall be performed by qualified operators using current, state-of-the-art electronic equipment.
- 10.4.14.6 Environmental Viable Airborne Particle Testing Program
- 10.4.14.6.1 Sampling Plan—An appropriate environmental sampling plan shall be developed for airborne viable particles based on risk assessment of compounding activities performed.
- 10.4.14.6.2 Growth Medium—A general microbiological growth medium such as Soybean Casein Digest Medium shall be used to support the growth of bacteria. Malt extract agar or some other media that supports the growth of fungi shall be used in High-Risk level compounding environments.
- 10.4.14.6.3 Viable Air Sampling—Evaluation of airborne microorganisms shall be performed by properly trained individuals for all compounding risk levels.

10.4.14.6.4 Air Sampling Frequency and Process—Air sampling shall be performed at least semiannually.

10.4.14.6.5 Action Levels, Documentation, and Data Evaluation—Sampling data shall be collected and reviewed on a periodic basis as a means of evaluation the overall control of the compounding environment. See USP 797 for specific recommended action levels.

10.4.15 Additional Personnel Requirements

10.4.15.1 Food, drinks, and materials exposed in patient care and treatment areas shall not enter ante-areas, buffer areas, or segregated compounding areas where compounding and ingredients of CSPs are present.

10.4.15.2 When compounding activities require the manipulation of a patient's blood-derived or other biological material, the manipulation shall be clearly separated from routine material-handling procedures and equipment used in CSP preparation activities, and they shall be controlled by specific SOPs in order to avoid any cross-contamination.

10.4.15.3 Packaged compounding supplies and components, such as needles, syringes, tubing sets, and small and large-volume parenteral, should be taken from cartons and wiped down with a disinfectant that does not leave a residue, when possible in an ante-area of ISO Class 8 air quality, before being passed into the buffer areas.

10.4.15.4 Personnel hand hygiene and garbing procedures shall also be performed in the ante-area.

10.4.15.5 There shall be some demarcation designation that separates the ante-area from the buffer area.

10.4.15.6 Adequate provision for performing antiseptic hand cleansing using an alcohol-based surgical hand scrub with persistent activity followed by the donning of sterile gloves shall be provided after entry into the buffer area.

10.4.16 Cleaning and Disinfecting the Compounding Area

10.4.16.1 All cleaning and disinfecting practices and policies for the compounding of CSPs shall be included in written SOPs and shall be followed by all compounding personnel.

10.4.16.2 Cleaning and disinfecting shall occur before compounding is performed.

10.4.16.3 Cleaning and disinfecting surfaces in the LAFW, BSCs, CAIs and CACIs are the most critical practices before the preparation of CSPs. Consequently, such surfaces shall be cleaned and disinfected frequently, including at the beginning of each work shift, before each batch preparation is started, every 30 minutes during continuous compounding periods, when there are spills, and when surface contamination is known or suspected from procedural breaches.

10.4.16.4 Work surfaces in the ISO Class 7 buffer areas and ISO Class 8 ante-areas as well as segregated compounding areas shall be cleaned and disinfected at least daily, and dust and debris shall be removed when necessary from storage sites for compounding ingredients and supplies using a method that does not degrade the ISO Class 7 or 8 air quality.

Table 2: Minimum Frequency of Cleaning and Disinfecting Compounding Areas

<u>SITE</u>	<u>MINIMUM FREQUENCY</u>
<u>ISO Class 5 Primary Engineering Controls (e.g. LAFW, BSC, CAI, CACI)</u>	<u>At the beginning of each shift, before each batch, every 30 minutes of continuous compounding, after spills, and when contamination is known or suspected.</u>
<u>Counters and easily cleanable work surfaces</u>	<u>Daily</u>
<u>Floors</u>	<u>Daily</u>
<u>Walls</u>	<u>Monthly</u>
<u>Ceilings</u>	<u>Monthly</u>
<u>Storage Shelving</u>	<u>Monthly</u>

10.4.16.5 All cleaning materials shall be non-shedding and dedicated to use in the buffer or clean area, ante-area, and segregated compounding areas and shall not be removed from these areas except for disposal.

10.4.16.6 Supplies and equipment removed from shipping cartons shall be wiped with a suitable disinfectant agent (e.g., sterile IPA 70% alcohol) delivered from a spray bottle or other suitable delivery method.

10.4.16.7 Entry points of bags and vials shall be disinfected with small, disposable, sterile 70% IPA swabs that are commercially available in individual packages. Use 1 swab per entry point and allow 70% IPA to dry before piercing stoppers with sterile needles and breaking necks of ampuls.

10.4.17 Personnel Cleansing and Garbing

10.4.17.1 The careful cleansing of hands and arms and the correct donning of PPE by compounding personnel constitute the first major step in preventing microbial contamination in CSPs. Personnel shall also be thoroughly competent and highly motivated to perform flawless aseptic manipulation with ingredients, devices, and components of CSPs.

10.4.17.2 Before entering the buffer area or segregated compounding area compounding personnel shall remove personal outer garments, all cosmetics, all hand and wrist or other visible jewelry that can interfere with effectiveness of PPE. The wearing of artificial nails is prohibited while working in the sterile compounding area. Natural nails shall be kept neat and trimmed.

10.4.17.3 Personnel shall don the following PPE in an order that proceeds from those activities considered to be the dirtiest to the cleanest. Garbing activities considered the dirtiest include donning of dedicated shoes or shoe covers, head and facial hair covers, and face masks/eye shields. Eye shields are optional except when working with irritants such as germicidal disinfecting agents or when preparing hazardous drugs.

10.4.17.4 A hand-cleansing procedure shall be performed by removing debris from underneath fingernails using a cleaner under running water followed by vigorous hand washing. Hands and forearms shall be washed to the elbows for at least 30 seconds with soap and water while in the ante-area. Hands and forearms shall be completely dried using either a lint-free cloth or an electric hand dryer.

10.4.17.5 After hand cleansing, a non-shedding gown, preferably disposable, with sleeves that fit snugly around the wrists and enclosed at the neck shall be donned.

10.4.17.6 Routine application of sterile 70% IPA shall occur throughout the compounding process and whenever non-sterile surfaces are touched.

10.4.17.7 Compounding personnel shall be trained and evaluated in the avoidance of touching critical sites.

10.4.17.8 During high-risk compounding activities that precede terminal sterilization, such as weighing and mixing non-sterile ingredients, compounding personnel shall be garbed and gloved the same as when performing compounding in an ISO Class 5 environment.

10.4.18 Personnel Training and Competency Evaluation of Garbing, Aseptic Work Practices and Cleaning/Disinfectant Procedures

10.4.18.1 Personnel Training

10.4.18.1.1 Personnel who prepare CSPs shall be trained conscientiously and skillfully by expert personnel in the theoretical principles and practical skills of garbing procedures, aseptic work practices, achieving and maintaining ISO Class 5 work environments, and cleaning and disinfection procedures.

10.4.18.1.1.1 This training shall be completed and documented before any compounding personnel begin to prepare CSPs.

10.4.18.1.1.2 Compounding personnel shall complete didactic training, pass written competence assessments, undergo skill assessment using observational audit tools, and media-fill testing.

10.4.18.1.1.3 Media-fill testing of aseptic work skills shall be performed initially before beginning to prepare CSPs:

10.4.18.1.1.3.1 Annually thereafter for low-risk and medium-risk level compounding

10.4.18.1.1.3.2 Semi-annually for high-risk level compounding.

10.4.18.2 Competency Evaluation of Garbing and Aseptic Work Practice

10.4.18.2.1 Compounding personnel shall be evaluated prior to beginning compounding CSPs and whenever media-fill testing is performed.

10.4.18.3 Aseptic Work Practice Assessment and Evaluation via Personnel Glove Fingertip Sampling

10.4.18.3.1 Sampling of compounding personnel glove fingertips shall be performed for all CSP risk level compounding. Touch contamination is the most likely source of introducing microorganisms into CSPs prepared by humans.

10.4.18.3.2 Glove fingertip sampling using sterile agar plates shall be used to evaluate the competency of personnel in performing hand hygiene and garbing procedures in addition to educating compounding personnel on proper work practices.

- 10.4.18.3.3 All compounding personnel shall successfully complete an initial competency evaluation and gloved fingertip/thumb sampling procedure (zero cfu) no less than three times before initially being allow to compound CSPs for human use.
- 10.4.18.4 Garbing And Gloving Competency Evaluation
 - 10.4.18.4.1 Compounding personnel shall be visually observed during the process of performing hand hygiene. The visual observation shall be documented and maintained for long-term assessment of compounding personnel.
- 10.4.18.5 Incubation Period
 - 10.4.18.5.1 Samples for personnel and environment shall be incubated at 30°C to 35°C for 48 to 72 hours. Results shall be documented and kept on file.
- 10.4.18.6 Aseptic Manipulation Competency Evaluation
 - 10.4.18.6.1 All compounding personnel shall have their aseptic technique and related practice competency evaluated initially during the media-fill test procedure and subsequent annual and/or semi-annual Media-Fill Test procedures.
- 10.4.18.7 Surface Cleaning and Disinfecting Sampling and Assessment
 - 10.4.18.7.1 Surface sampling shall be performed in all ISO classified areas on a periodic basis. See USP 797 for method and details.
- 10.4.18.8 Cleaning and Disinfecting Competency Evaluation
 - 10.4.18.8.1 Compounding personnel and other personnel responsible for cleaning shall be visually observed during the process of cleaning and disinfecting during initial training on cleaning procedures, during changes in staff, and at the completion of any Media-Fill Test procedure. Observation shall be documented.
- 10.4.18.9 Surface Collection Method—See USP 797 for complete instruction.
- 10.4.18.10 Action Levels, Documentation and Data Evaluation
 - 10.4.18.10.1 Sampling data shall be collected and reviewed on a routing basis as a means of evaluating the overall control of the compounding environment. See USP 797 for complete corrective actions, documentation, and data evaluation regulations.
- 10.4.19 Standard Operating Procedures (SOPs)
 - 10.4.19.1 The compounding facility shall have written, properly approved SOPs designed to ensure the quality of the environment in which a CSP is prepared. See USP 797 for a list of recommended procedures.
- 10.4.20 Elements of Quality Control
 - 10.4.20.1 A written description of specific training and performance evaluation program for individuals involved in the use of aseptic techniques for the preparation of sterile products shall be developed for each site.
 - 10.4.20.2 Sterile Ingredients and devices
 - 10.4.20.2.1 Commercially available sterile drug products, sterile ready-to use containers and devices are examples of sterile components. A written procedure for unit-by-unit physical inspection preparatory to use shall be followed to ensure that these components are sterile, free from defects, and otherwise suitable for their intended use.
 - 10.4.20.3 Non-Sterile Ingredients and Devices
 - 10.4.20.3.1 If any non-sterile components, including containers and ingredients, are used to make a CSP, such CSPs must be high risk.
 - 10.4.20.3.2 Non-sterile active ingredients and added substances or excipients for CSPs should preferably be official USP or NF articles.
 - 10.4.20.3.3 When nonofficial ingredients are used, they shall be accompanied by certificates of analysis from their suppliers to aid compounding personnel in judging the identity, quality, and purity in relation to the intended use in a particular CSP.
 - 10.4.20.3.4 Physical inspection of a package of ingredients is required.
 - 10.4.20.3.5 Bulk or unformulated drug substances and excipients shall be stored in tightly closed containers under temperature, humidity and lighting conditions consistent with monographs or approved by suppliers.
 - 10.4.20.3.6 The date of receipt by the compounding facility shall be clearly and indelibly marked on each container. Packages that lack a suppliers' expiration date cannot be used after 1 year unless

either appropriate inspection or testing indicates that the ingredient has retained its purity and quality for use in CSPs.

10.4.20.4 Equipment

10.4.20.4.1 Equipment, apparatus, and devices used to compound a CSP shall be consistently capable of operating properly and within acceptable tolerance levels.

10.4.20.4.2 Written procedures (SOP) outlining required equipment calibration, annual maintenance, monitoring for proper function, and controlled procedures for use of the equipment and specified time frames for these activities shall be established and followed. Results shall be documented and kept on file for the life of the machine.

10.4.20.4.3 Verification of Automated Compounding Devices (ACDs) for Parenteral Nutrition Compounding ACDs for the preparation of parenteral nutrition admixtures are widely used by pharmacists in hospitals and other healthcare settings. Refer to USP 797 for complete regulations regarding compounding with ACDs.

10.4.21 Finished Preparation Release Checks and Tests

10.4.21.1 The following quality metrics shall be performed for all CSPs before they are dispensed or administered.

10.4.21.1.1 Inspection of solutions dosage forms and review of Compounding Procedures

10.4.21.1.1.1 All CSPs that are intended to be solutions shall be visually inspected for the presence of particulate matter. The prescription orders, written compounding procedure, preparation records, and expended materials used to make CSPs at all contamination risk levels shall be inspected for correctness, aseptic mixing and sterilization, packaging, labeling, and expected physical appearance before they are administered or dispensed.

10.4.21.1.2 Physical Inspection

10.4.21.1.2.1 Finished CSPs are individually inspected in accordance with written procedures after compounding. Immediately after compounding and as a condition of release, each CSP unit, where possible, shall be inspected against lighted white or black background or both for evidence of visible particulates or other foreign matter. Pre-release inspection also includes container integrity.

10.4.21.1.3 Compounding Accuracy Check

10.4.21.1.3.1 Written procedures for double-checking compounding accuracy shall be followed for every CSP during preparation and immediately prior to release. Refer to Section 5.0.

10.4.21.1.4 Sterility Testing

10.4.21.1.4.1 All high-risk level CSPs that are prepared in groups of more than 25 identical individual single-dose packages or in multiple-dose vials (MDVs) for administration to multiple patients or that are exposed longer than 12 hours at 2°C to 8°C and longer than 6 hours in warmer than 8°C before they are sterilized shall pass sterility testing before they are dispensed or administered.

10.4.21.1.5 Bacterial Endotoxin (Pyrogen) Testing

10.4.21.1.5.1 All high-risk level CSPs, except those for inhalation and ophthalmic administration, that are prepared in groups of more than 25 identical individual single-dose packages or in MDVs for administration to multiple patients or that are exposed longer than 12 hours at 2°C to 8°C and longer than 6 hours at warmer than 8°C before they are sterilized shall be tested to ensure that they do not contain excessive bacterial endotoxins.

10.4.21.1.6 Identity and Strength Verification of Ingredients

10.4.21.1.6.1 Compounding facilities shall have at least the following written procedures for verifying the correct identity and quality of CSPs before they are dispensed and administered:

10.4.21.1.6.1.1 That labels of CSPs bear correct names and amounts or concentrations of ingredients, the total volume, the BUD, the appropriate route(s) of administration, the storage conditions, and other information for safe use.

10.4.21.1.6.1.2 That there are correct identities, purities, and amounts of ingredients by comparing the original written order with the written compounding record for the CSP.

10.4.21.1.6.1.3 That correct fill volumes in CSPs and correct quantities of filled units of the CSPs were obtained. When the strength of finished CSPs cannot be confirmed to be accurate, based on the above three inspections, the CSPs shall be assayed by methods that are specific for the active ingredients.

10.4.22 Storage and Beyond-Use-Dating

10.4.22.1 Personnel who prepare, dispense, and administer CSPs shall store them strictly in accordance with the conditions stated on the label of ingredient products and finished CSPs.

10.4.22.2 Determining Beyond-Use Dating (BUDs)

10.4.22.2.1 BUDs and expiration dates are not the same. BUDs for CSPs that are prepared strictly in accordance with manufacturers' product labeling shall be those specified in that labeling or from appropriate literature sources or direct testing.

10.4.22.3 Compounding personnel may refer to applicable publications to obtain relevant stability, compatibility, and degradation information regarding the drug or its congeners.

10.4.22.4 Compounding personnel who assign BUDs to CSPs when lacking direct chemical assay results shall critically interpret and evaluate the most appropriate available information sources to determine a conservative and safe BUD.

10.4.22.5 The SOP manual of the compounding facility and each specific CSP formula record shall describe the general basis used to assign the BUD and storage conditions.

10.4.22.6 Proprietary Bag and Vial system - Follow manufacturers' instructions for handling and storage.

10.4.22.7 Monitoring controlled storage areas

10.4.22.7.1 Compounding personnel shall monitor the drug storage areas within the compounding facility. Controlled temperature areas in compounding facilities include controlled room temperature of 20°C to 25°C, controlled cold temperature of 2°C to 8°C and freezing temperature of -25°C to -10°C.

10.4.22.7.2 A controlled temperature area shall be monitored at least once daily and the results documented on a temperature log.

10.4.22.7.3 The temperature-sensing mechanisms shall be suitably placed in the controlled temperature storage space to reflect accurately its true temperature.

10.4.23 Maintaining Sterility, Purity and Stability of Dispensed and Distributed CSPs

10.4.23.1 Compounding personnel shall ensure proper storage and security of CSPs prepared by or dispensed from the compounding facility until either their BUDs are reached or they are administered to patients. In fulfilling this general responsibility, the compounding facility is responsible for the proper packaging, handling, transport, and storage of CSPs prepared by or dispensed from it, including the appropriate education, training, and supervision of compounding personnel assigned to these functions. The compounding facility shall assist in the education and training of non-compounding personnel for carrying out any aspect of these functions. Refer to USP 797 for further regulation regarding packaging, handling, transport, use and storage, and administration of CSPs.

10.4.23.2 Education and Training

10.4.23.2.1 Compounding personnel shall design, implement, and maintain a formal education, training, and competency assessment program that encompasses all the functions and tasks addressed and all personnel to whom such functions and tasks are assigned.

10.4.23.3 Packing and Transporting CSPs

10.4.23.3.1 Compounding personnel shall select packing containers and materials that are expected to maintain physical integrity, sterility, and stability of CSPs during transit.

10.4.23.3.2 Compounding facilities that ship CSPs to locations outside their own premises shall select modes of transport that are expected to deliver properly packed CSPs in un-damaged, sterile, and stable condition to recipients

10.4.23.3.3 Compounding personnel shall include specific handling and exposure instructions on the exteriors of containers packed with CSPs to be transported and obtain reasonable assurance of compliance therewith from transporters.

10.4.23.3.4 Compounding personnel shall periodically review the delivery performance of couriers to ascertain that CSPs are being efficiently and properly transported.

10.4.23.4 Storage in locations outside compounding facilities

10.4.23.4.1 Compounding facilities that ship CSPs to patients and other recipients outside their own premises shall ascertain or provide whichever is appropriate, the following assurances:

10.4.23.4.2 Labels and accessory labeling for CSPs include clearly readable BUDs, storage instructions, and disposal instruction for out-of-date units.

10.4.23.4.3 Each patient or other recipient is able to store the CSPs properly, including the use of a properly functioning refrigerator and freezer if CSPs are labeled for such storage.

10.4.24 Patient or Caregiver Training

- 10.4.24.1 A formal training program shall provided as a means to ensure understanding and compliance with the many special and complex responsibilities placed on the patient or caregiver for the storage, handling, and administration of CSPs. The instructional objectives for the training program include all home care responsibilities expected of the patient or caregiver and specified in terms of patient or caregiver competencies. Upon conclusion of the training program, the patient or caregiver shall, correctly and consistently, be able to do the following:
- 10.4.24.1.1 Describe the therapy involved, including the disease or condition for which the CSPs are prescribed, goals of therapy, expected therapeutic outcome, and potential side effects of the CSPs.
- 10.4.24.1.2 Inspect all drug products, CSPs, devices, equipment, and supplies on receipt to ensure that proper temperatures were maintained during transport and that goods received show no evidence of deterioration or defects.
- 10.4.24.1.3 Handle, store, and monitor all drug products, CSPs, and related supplies and equipment in the home, including all special requirements related.
- 10.4.24.1.4 Visually inspect all drug products, CSPs, devices, and other items the patient or caregiver is required to use immediately prior to administration in a manner to ensure that all items are acceptable for use.
- 10.4.24.1.5 Check labels immediately prior to administration to ensure the right drug, dose, patient, and time of administration.
- 10.4.24.1.6 Clean the in-home preparation area, scrub hands, use proper aseptic technique, and manipulate all containers, equipment, apparatus, devices, and supplies used in conjunction with administration.
- 10.4.24.1.7 Employ all techniques and precautions associated with CSP administration; for example, preparing supplies and equipment, handling of devices, priming the tubing, and discontinuing infusion.
- 10.4.24.1.8 Care for catheters, change dressing, and maintain site patency as indicated.
- 10.4.24.1.9 Monitor for and detect occurrences of therapeutic complications such as infection, phlebitis, electrolyte imbalance, and catheter misplacement.
- 10.4.24.1.10 Respond immediately to emergency or critical situations such as catheter breakage or displacement, tubing disconnection, clot formation, flow blockage, and equipment malfunction.
- 10.4.24.1.11 Know when to seek and how to obtain professional emergency services or professional advice.
- 10.4.24.1.12 Handle, contain, and dispose of wastes, such as needles, syringes, devices, bio-hazardous spills or residuals, and infectious substances.
- 10.4.24.2 Training programs include a hands-on demonstration and practice with actual items that the patient or caregiver is expected to use, such as CSP containers, devices and equipment.
- 10.4.24.3 The compounding facility, in conjunction with nursing or medical personnel, is responsible for ensuring initially and on an on-going basis that the patient or caregiver understands, has mastered, and is capable of and willing to comply with all of these home care responsibilities.
- 10.4.25 Patient Monitoring and Adverse Events Reporting
- 10.4.25.1 Compounding facilities shall clinically monitor patients treated with CSPs according to these Regulations and accepted standards of practice.
- 10.4.25.2 The SOP manuals of compounding facilities shall describe specific instructions for receiving, acknowledging, and dating receipts, and for recording, or filing, and evaluating reports of adverse events and of the quality of preparation claimed to be associated with CSPs.
- 10.4.26 Quality Assurance (QA) Program
- 10.4.26.1 A provider of CSPs shall have in place a format QA program intended to provide a mechanism for monitoring, evaluating, correcting, and improving the activities and processes described in USP 797. Characteristics of a QA program include:
- 10.4.26.1.1 Formalization in writing.
- 10.4.26.1.2 Consideration of all aspects of the preparations and dispensing of products as described in USP 797, including environmental testing and verification results.
- 10.4.26.1.3 Description of specific monitoring and evaluation activities.
- 10.4.26.1.4 Specification of how results are to be reported and evaluated.
- 10.4.26.1.5 Identification of appropriate follow-up mechanisms when action limits or thresholds are exceeded.

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

13 DE Reg. 1581 (06/01/10)

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.
 - 11.2.8 A pharmacy that provides a "Customized Patient Medication Package" system can supply a maximum of 72 hours supply of medication per patient.
- 11.3 Emergency Use Medications
 - 11.3.1 Emergency use medications for the purposes of this Regulation shall be those injectable medications 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 Interim use medications for the purposes of this Regulation shall be those non-injectable medications 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.
 - 11.3.3 It is the responsibility of the facility and provider pharmacy to determine the supply of emergency use medication and interim use medication that are to be stocked as well as documenting the number of boxes and location(s) within the facility. Stock supply of interim use medication shall not exceed sixty (60) medications without the prior review and approval of the Board or its designee. Emergency use and interim use medications lists of current contents must be attached to the medication supply.
 - 11.3.4 Accountability for emergency use medications and interim use medications.
 - 11.3.4.1 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.
 - 11.3.4.2 The provider pharmacy is responsible for the accuracy of all emergency use and interim 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 or interim medication must be kept for a minimum of 2 years at the provider pharmacy with a copy at the facility and must be readily available for inspection by the Board.
 - 11.3.4.3 Failure to comply with these procedures can result in the suspension or denial of the use of emergency use and/or interim use medications.

11.3.4.4 Violations of accountability procedures for emergency use and/or interim use medications may result in review proceedings before the Board.

11.3.5 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)

13 DE Reg. 506 (10/01/09)

13 DE Reg. 1581 (06/01/10)

17 DE Reg. 653 (12/01/13)

12.0 Pharmaceutical Services in Health Care Facilities/Programs

12.1 Definition of Health Care Facilities/Programs:

A health care facility/program 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 component. These facilities/programs include, but are not limited to:

- 12.1.1 Assisted Living Facilities (16 **DE Admin. Code** 3225)
- 12.1.2 Group Homes (AIDS)
- 12.1.3 Group Homes (Mental Health)
- 12.1.4 Neighborhood Homes (DD)

- 12.1.5 Rest Residential
- 12.1.6 Intensive Behavioral Support and Educational Residence
- 12.1.7 Clinics
- 12.1.8 Residential Child Care Facilities and Day Treatment Programs
- 12.1.9 End Stage Renal Disease Treatment Centers
- 12.2 Requirements. Any health care facility/program in which pharmaceutical services are provided 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.
 - 12.2.1 Any pharmacist providing contractual pharmaceutical services to the Health Care Facilities/Programs will be responsible for providing information to the staff as may be appropriate or required to ensure safety, understanding and compliance with policies and procedures pertaining to pharmacy-related activities and concerns. The written policies and procedures which shall be provided include, but are not limited to:
 - 12.2.1.1 Policies and procedures that pertain to the pharmacy services provided for the contracted health care facility/program.
 - 12.2.1.2 Policies governing appropriate security and storage of medications.
 - 12.2.1.3 Policies and procedures necessary to insure the safe use, administration, control and accountability of all drugs throughout the Health Care Facility/Program in compliance with State and Federal laws.
 - 12.2.1.4 Policies and procedures outlining the destruction of wastage for all medications.
 - 12.2.1.5 Procedures to follow if a pharmacy dispensing error has occurred.
 - 12.2.2 The pharmacist shall make inspections of each Health Care Facility/ Program and related drug storage areas at least annually. The inspections may be more frequent if required by other state laws or depending on the contractual agreement with health care facilities/programs. At the discretion of the pharmacist a pharmacy support person may assist with the inspection under the direct supervision of a pharmacist.
 - 12.2.2.1 Inspections must include, but are not limited to, documentation of the following:
 - 12.2.2.1.1 Medication storage area(s) (59 to 86 degrees Fahrenheit) and refrigerator temperatures (36 to 46 degrees Fahrenheit);
 - 12.2.2.1.2 Security of all drugs/devices meeting all the requirements of State and Federal laws and regulations;
 - 12.2.2.1.3 Proper labeling, including any accessory or cautionary instructions;
 - 12.2.2.1.4 Proper expiration dating;
 - 12.2.2.1.5 Cleanliness;
 - 12.2.2.2 Copies of these inspection reports must be maintained at the facility and the pharmacy provider for two years.

17 DE Reg. 990 (04/01/14)

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

“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, Biologicals and Adult Immunizations

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, registered interns and pharmacy students 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, a registered intern or a pharmacy student shall complete a Board approved academic and hands-on practical curriculum and maintain a current Cardio-Pulmonary Resuscitation (CPR) certificate acceptable to the Board of Pharmacy. CPR certification cannot be obtained through an on-line course.
 - 14.1.1.1 An approved academic and practical curriculum includes, but is not limited to, disease epidemiology, vaccine characteristics, injection technique, emergency response to adverse events, and related topics.
 - 14.1.1.2 Pharmacists successfully completing the above education and practical training shall notify the Board. The Board will record the successful training in Board database systems.
- 14.1.2 A licensed pharmacist, registered intern or pharmacy student 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 and available for Board inspection.
 - 14.1.3.1 A minimum of two hours (0.2 C.E.U.) of the thirty hour requirement for continuing education for licensed pharmacists, every licensure period, must be dedicated to this area of practice.

14.1.3.2 A minimum of two hours of continuing education every two years for registered interns and pharmacy students 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 documentation shall be the responsibility of the pharmacist-in-charge.

14.2 Practice Requirements

14.2.1 The pharmacist-in-charge 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 The administration of injectable medications, biologicals and adult immunizations by registered interns and pharmacy students must be directly supervised by a licensed pharmacist who is approved for injectable administration.

14.2.3 The pharmacist, registered intern, or pharmacy student, 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, registered intern, or pharmacy student 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, registered intern, or pharmacy student administering the dose.

14.2.5 The pharmacist, registered intern, or pharmacy student 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, registered intern, or pharmacy student shall provide documentation to each person receiving immunizations and shall report to the Immunization 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 and available for inspection by the Board of Pharmacy.

14.3 Administration of medications includes injectable medications, biologicals and adult immunizations pursuant to a valid prescription or approved protocol approved by a physician duly licensed in this State.

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

17 DE Reg. 653 (12/01/13)

18 DE Reg. 707 (03/01/15)

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, hospital/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 under the jurisdiction of the Board of Pharmacy can be utilized in licensed pharmacies, remote locations, 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 including the make and model.
- 15.3.4 To ensure that changes in automation technology are reflected the Board will be notified of any updates, a repeat presentation shall 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 shall prior written notice of the installation or substantive changes of automated pharmacy systems. This written notification shall be readily retrievable upon inspection. 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 accessibility and quality assurance unless already on file with the Board.
- 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 in writing prior to the installation or removal of an approved Automated Pharmacy System.
 - 15.4.1.2 Developing and implementing an ongoing quality assurance program that monitors performance of the Automated Pharmacy System.
 - 15.4.1.3 Developing written policies and procedures for accessibility and quality assurance.
 - 15.4.1.4 Maintaining documentation readily available at the location where the system is used of at least the following:
 - 15.4.1.4.1 Board approved documentation.
 - 15.4.1.4.2 Name and address of the pharmacy and/or licensed health care facility where the automated pharmacy system is being used;
 - 15.4.1.4.3 Manufacturer's name and model;
 - 15.4.1.5.4 Policies and procedures for accessibility and quality assurance.
- 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 filling/restocking, dispensing and maintenance of the Automated Pharmacy System must be recorded; and
 - 15.5.1.2 Records must be maintained by the pharmacy and must be readily available to the Board for a three(3) years and shall include:
 - 15.5.1.2.1 Type of transaction including filling/restocking, dispensing and maintenance;
 - 15.5.1.2.2 Identification of the individual accessing the system;
 - 15.5.1.2.3 Name, strength, dosage form, and quantity of the drug removed or added;
 - 15.5.1.2.4 Name of the patient for whom the drug was ordered; and
- 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.
 - 15.6.3 Hospital/Institution. Unit based or centralized dispensing requires the same level of supervision required in Regulation 9.2.3 which states: pharmacy technicians 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 Long Term Care Pharmacy. The filling/restocking of automated pharmacy systems in long term care settings may be performed by a licensed pharmacist, physician, physician assistant, advanced practice

nurse, and registered nurse who is authorized by their Act to handle such medications subject to accountability provisions of regulation 11.3.4.

- 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.

13 DE Reg. 506 (10/01/09)

16.0 Automated Delivery Devices

- 16.1 Definitions – Words and terms defined in Title 24, Section 2502 of the **Delaware Code** are applicable to these regulations. The following additional words and terms, when used within regulation 16.0, shall have the following meaning, unless the context clearly indicates otherwise:
 - “**Authorized agent**” is as defined in regulation 8.1.
 - “**Automated delivery device**” or “**device**” means a mechanical device used exclusively for the storage and delivery to patients of prescriptions that have been processed and verified by a licensed pharmacist.
 - “**Delivery**” is defined in regulation 5.1.
- 16.2 Automated delivery devices may be utilized by licensed pharmacies and shall comply with the following provisions:
 - 16.2.1 Devices may only include refilled prescription medication for which counseling is not required under regulation 5.3.
 - 16.2.2 Devices may include all prescriptive medication except schedule II controlled substances.
 - 16.2.3 Devices shall include Board-approved means of patient identification, identification of persons authorized to pick up medication other than the patient, and identification of pharmacy personnel who place medication into the device.
 - 16.2.4 Devices shall electronically record all delivery transactions and such records shall be readily available for inspection for at least three years. Such records shall include, but are not limited to, the following for all transactions: the identity of pharmacy personnel who place medication into the device; the identity of the patient or authorized person who picks up the medication; the type, date, and time of the transaction; and the name, strength, dosage, form, and quantity of the drug delivered. The Board and pharmacist-in-charge may require additional information at their discretion.
 - 16.2.5 Devices may operate during any store hours at the pharmacy’s discretion.
 - 16.2.6 A Delaware-licensed pharmacist shall be immediately available in-person for consultation when the device is in service and the pharmacy is open. A Delaware-licensed pharmacist shall be immediately available telephonically via a toll-free number when the device is in service and the pharmacy is closed. Pharmacists providing telephonic consultation shall have access to the same patient information as would be available to a pharmacist conducting an in-person consultation.
 - 16.2.7 The following information shall be posted in the vicinity of the device:
 - 16.2.7.1 Pharmacy hours of operation,
 - 16.2.7.2 Device hours of operation, and
 - 16.2.7.3 Consultation availability, i.e. in-person during pharmacy hours and telephonically after-hours, including the toll-free number for after-hours consultation.
 - 16.2.8 The device shall be attached to the pharmacy department area in a manner acceptable to the Board.
 - 16.2.9 All delivery devices shall be reviewed, inspected, and approved by the Board or its authorized agent prior to installation.
 - 16.2.10 Patients using the device must have opted to use the device and signed a written consent form demonstrating their informed consent and intention to do so.
 - 16.2.11 Written policies and procedures shall be maintained and available for inspection. Written policies and procedures shall be acceptable to the Board and shall include, but are not limited to, the following topics:
 - 16.2.11.1 Maintaining the security of the device and the medications it contains.

- 16.2.11.2 A list of medications appropriate and approved for storage in the device; a list of the criteria used to determine the appropriate medications, with explanations when necessary; and a list of patient qualifications for device usage.
 - 16.2.11.3 Patient orientation of device usage, including being informed of which medications may and may not be delivered via the device.
 - 16.2.11.4 Pharmacy personnel training and responsibilities pertaining to device operations and maintenance.
- 16.3 The Pharmacist-in-Charge shall have the sole responsibility to:
- 16.3.1 assign, discontinue, or change access to the system; and
 - 16.3.2 ensure that access to the medications comply with state and federal regulations.

11 DE Reg. 689 (11/01/07)

17.0 Crimes substantially related to the practice of pharmacy.

- 17.1 For the purposes of this section the following definitions shall apply:
- 17.1.1 **"Conviction"** means a verdict of guilty entered by a judge or jury, or a plea of guilty or a plea of *nolo contendere* or other similar plea such as a **"Robinson"** or **"Alford"** plea unless the individual has been discharged under 11 **Del.C.** §4218 (probation before judgment) or under 10 **Del.C.** §1024 (domestic violence diversion program) or under 16 **Del.C.** §4764 (first offenders controlled substances diversion program).
- 17.2 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:
- 17.2.1 Unlawfully administering drugs. 11 **Del.C.** §625.
 - 17.2.2 Unlawfully administering a controlled substance or counterfeit substance or narcotic drugs. 11 **Del.C.** §626.
 - 17.2.3 Prohibited acts as to substances releasing vapors or fumes; unclassified misdemeanor. 11 **Del.C.** §627.
 - 17.2.4 Use of illegitimate retail sales receipt or UPC. 11 **Del.C.** §840A.
 - 17.2.5 Theft. 11 **Del.C.** §841.
 - 17.2.6 Forgery. 11 **Del.C.** §861.
 - 17.2.7 Possession of forgery devices. 11 **Del.C.** §862.
 - 17.2.8 Falsifying business records. 11 **Del.C.** §871.
 - 17.2.9 Deceptive business practices. 11 **Del.C.** §906.
 - 17.2.10 Insurance fraud. 11 **Del.C.** §913.
 - 17.2.11 Health care fraud. 11 **Del.C.** §913A.
 - 17.2.12 Unauthorized access to computer systems. 11 **Del.C.** §932.
 - 17.2.13 Theft of computer services. 11 **Del.C.** §933.
 - 17.2.14 Interruption of computer services. 11 **Del.C.** §934.
 - 17.2.15 Misuse of computer system information. 11 **Del.C.** §935.
 - 17.2.16 Unlawful delivery of noncontrolled substance. 16 **Del.C.** §4752A.
 - 17.2.17 Trafficking in marijuana, cocaine, illegal drugs, methamphetamines, L.S.D., or designer drugs. 16 **Del.C.** §4753A.
 - 17.2.18 Failure to keep drugs in original containers 16 **Del.C.** §4758.
 - 17.2.19 Sexual harassment; unclassified misdemeanor. 11 **Del.C.** §763
 - 17.2.20 Indecent exposure in the second degree; unclassified misdemeanor. 11 **Del.C.** §764
 - 17.2.21 Indecent exposure in the first degree; class A misdemeanor. 11 **Del.C.** §765
 - 17.2.22 Incest; class A misdemeanor. 11 **Del.C.** §766
 - 17.2.23 Unlawful sexual contact in the third degree; class A misdemeanor. 11 **Del.C.** §767
 - 17.2.24 Unlawful sexual contact in the second degree; class G felony. 11 **Del.C.** §768
 - 17.2.25 Unlawful sexual contact in the first degree; class F felony. 11 **Del.C.** §769
 - 17.2.26 Rape in the fourth degree; class C felony. 11 **Del.C.** §770
 - 17.2.27 Rape in the third degree; class B felony 11 **Del.C.** §771
 - 17.2.28 Rape in the second degree; class B felony. 11 **Del.C.** §772
 - 17.2.29 Rape in the first degree; class A felony. 11 **Del.C.** §773

- 17.2.30 Sexual extortion; class E felony. 11 **Del.C.** §774
- 17.2.31 Bestiality. 11 **Del.C.** §775
- 17.2.32 Continuous sexual abuse of a child; class B felony. 11 **Del.C.** §776
- 17.2.33 Dangerous crime against a child, definitions, sentences. 11 **Del.C.** §777
- 17.2.34 Sex offender unlawful sexual conduct against a child. 11 **Del.C.** §777A
- 17.2.35 Sexual abuse of a child by a person in a position of trust, authority or supervision in the first degree. 11 **Del.C.** §778, 778A
- 17.2.36 Female genital mutilation. 11 **Del.C.** §780
- 17.2.37 Dealing in children. 11 **Del.C.** §1100
- 17.2.38 Sexual exploitation of a child. 11 **Del.C.** §1108
- 17.2.39 Unlawful dealing in child pornography. 11 **Del.C.** §1109
- 17.2.40 Possession of child pornography. 11 **Del.C.** §1111
- 17.2.41 Sexual offenders; prohibitions from school zones. 11 **Del.C.** §1112
- 17.2.42 Sexual solicitation of a child. 11 **Del.C.** §1112A
- 17.2.43 Any conviction under Title 18 or Title 21 of the United States Code Annotated including, but not limited to Federal Health Care offenses.
- 17.3 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 (03/01/01)
- 7 DE Reg. 1666 (06/01/04)
- 8 DE Reg. 879 (12/01/04)
- 11 DE Reg. 689 (11/01/07)
- 16 DE Reg. 654 (12/01/12)
- 16 DE Reg. 998 (03/01/13)
- 17 DE Reg. 990 (04/01/14)

18.0 Storage and Dispensing of Medical Gases

- 18.1 The following rules are included to address those areas specific to the medical gases specialty practice.
 - "Medical gas"** means those gases and liquid oxygen intended for human consumption as per the standards of the U.S.P.
 - "Medical gas dispenser"** A person or entity who sells medical gases directly to a patient in Delaware.
 - "Medical gas distributor"** A person or entity who is licensed to distribute medical gases to another facility that is authorized to possess medical gases.
 - "Order"** means an order issued by a licensed practitioner legally authorized to order medicinal gases.
- 18.2 Licensure and Registration
 - 18.2.1 Any person that dispenses medical gas directly to patients by sale shall register with the Board of Pharmacy pursuant to 24 **Del.C.** §2523. Applications for registration under this Regulation shall be on a form supplied by the Board and accompanied by a fee determined by the Board. The registration shall be renewed bi-biennially as determined by the Board.
 - 18.2.1.1 A medical gas dispenser may refill cylinders for a patient provided that the licensee is registered by the FDA.
 - 18.2.2 Distributors of medical gas who distribute to non-patient entities shall obtain a distributor license from the Board of Pharmacy pursuant to 24 **Del.C.** §2540.
- 18.3 Order Requirements
 - 18.3.1 Verbal orders:
 - 18.3.1.1 Verbal orders shall be reduced to writing.
 - 18.3.1.2 Verbal orders are only valid for oxygen and no other medical gases.
 - 18.3.1.3 Verbal orders shall be reviewed by a licensed healthcare professional authorized to administer oxygen to a patient. This review shall be performed within 72 hours.
 - 18.3.1.4 The order is valid for the length of time authorized by the prescriber. If the duration is not specified the order is valid for one year.
- 18.4 Policy and Procedure Requirements

18.4.1 Written policy and procedures must be available for review and shall include but not be limited to the following areas:

- 18.4.1.1 Storage and handling
- 18.4.1.2 Oxygen Safety
- 18.4.1.3 Orders
- 18.4.1.4 Labeling
- 18.4.1.5 Record keeping
- 18.4.1.6 Patient education
- 18.4.1.7 Security
- 18.4.1.8 Recall
- 18.4.1.9 Quarantine
- 18.4.1.10 Loss/theft

18.5 Training Requirements

18.5.1 Personnel shall be trained in areas to comply with standards dictated by the United States Pharmacopoeia, the Food Drug Administration, the Department of Transportation, the Occupational Safety and Health Administration, the Board of Pharmacy, any other applicable requirement under State and Federal law and any implementing rules or regulations regarding storage, packaging, labeling, shipping, dispensing, transfilling, distributing and repackaging of medical gas.

18.5.2 Documentation of training required by this Regulation shall be readily available for inspection. The documentation shall be kept for three years from the date of last employment.

18.6 Storage and Handling Requirements

18.6.1 Storage and handling of medical gas shall follow the manufacturer's labeling requirements.

18.6.2 Labeling shall include the manufacturer's label and a lot number on the cylinder in accordance with the Federal Food Drug and Cosmetic Act under Title 21 of the Code of Federal Regulation.

18.7 Record Keeping Requirements

18.7.1 The original order shall be kept and be readily retrievable for a minimum of three years after the date of the last dispensing.

18.7.2 Records shall include but not be limited to:

- 18.7.2.1 Name, address and telephone number of the patient
- 18.7.2.2 Name, address and telephone number of licensed practitioner
- 18.7.2.3 Item and quantity dispensed
- 18.7.2.4 Date of dispensing

18.8 Inspections

18.8.1 Inspections are conducted unannounced, during normal business hours, in accordance with 24 Del.C. §2534.

13 DE Reg. 506 (10/01/09)

19.0 Technicians: Qualifications, Training, and Duties

19.1 Qualifications and Training

19.1.1 Pharmacy Technicians shall successfully complete a training program. Training shall begin immediately upon initiation of employment and be completed within 90 days. Once training is commenced the technician in training may work in the pharmacy under the direct supervision of a pharmacist or a trained technician.

19.1.1.1 The pharmacist-in-charge is responsible for ensuring proper training of all pharmacy technicians. The actual training may be delegated to a pharmacist or other trained pharmacy technicians.

19.1.1.2 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 technicians. Training should be a minimum of 10 hours of didactic training in the following areas:

- 19.1.1.2.1 general drug and dosage form knowledge
- 19.1.1.2.2 medical terminology
- 19.1.1.2.3 pharmaceutical calculations
- 19.1.1.2.4 prescription labeling requirements
- 19.1.1.2.5 general filling/dispensing responsibilities
- 19.1.1.2.6 patient profile record system requirements

- 19.1.1.2.7 requirements for patient counseling
- 19.1.1.2.8 confidentiality
- 19.1.1.2.9 safety practices
- 19.1.1.2.10 inventory functions
- 19.1.1.2.11 knowledge of applicable State and Federal Statutes and Regulations
- 19.1.1.2.12 other site-specific parameters

- 19.1.1.3 The general content of the training program must be maintained in the policy and procedure manual.
- 19.1.1.4 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.
- 19.1.1.5 Supervision. Pharmacy technicians must be supervised by a registered pharmacist who will be responsible for the activities of the pharmacy technicians.

19.1.2 Certified pharmacy technicians must be at least 18 years of age, and successfully pass the PTCB Exam or other national technician certification exam approved by the Board of Pharmacy. Only certified pharmacy technicians or those individuals approved pursuant to Regulations 19.1.2.1 may assist the pharmacist by reconstituting oral solutions and contacting the prescriber or their agent to obtain refill authorization or other patient or prescription information of a non-clinical nature, or assisting the pharmacist with compounding.

- 19.1.2.1 A pharmacy technician completing a training program approved by the Board in lieu of passing the PTCB exam or passing a national certification program may perform the functions of a certified technician. However, approval to perform the functions of the certified technician is limited to the approved setting and is not transferable to any other facility.

19.2 Allowed Activities

- 19.2.1 Except in emergency situations for short periods where staff is unavailable only pharmacy technicians and certified pharmacy technicians may assist the pharmacist or deliver prescriptions in the pharmacy to a patient or the patient's agent.
- 19.2.2 Pharmacy technicians and certified pharmacy technicians may carry out any pharmacy-related duty assigned to them by their supervising pharmacist except for those activities specifically excluded by 24 Del.C. §§2507(b) and 2502(19).

13 DE Reg. 506 (10/01/09)

13 DE Reg. 1581 (06/01/10)

20.0 Specialty Institutional Pharmacy Licenses.

- 20.1 Specialty institutional pharmacies are those institutional pharmacies which provide specialized pharmacy services restricted in scope of practice and designed to provide certain health care pharmacy services that are not generally obtainable from other pharmacy permittees. Specialty institutional pharmacies include but are not limited to short term or primary care treatment modalities that have pharmacies on site such as outpatient chemotherapy centers, primary treatment centers, free standing emergency rooms, rapid in/out surgical centers and certain county health programs.

20.2 Labeling and record keeping requirements shall be kept in accordance with Regulation 9.9 through 9.13.

13 DE Reg. 506 (10/01/09)

15 DE Reg. 887 (12/01/11)

16 DE Reg. 654 (12/01/12)

16 DE Reg. 998 (03/01/13)

19 DE Reg. 661 (01/01/16) (Final)