DEPARTMENT OF STATE

DIVISION OF PROFESSIONAL REGULATION

BOARD OF PHARMACY

Statutory Authority: 24 Delaware Code, Section 2506(a)(1) (24 **Del.C.** §2506(a)(1))
24 **DE Admin. Code** 2500

EMERGENCY

ORDER

2500 Board of Pharmacy

AUTHORITY

On July 1, 2025, the Board of Pharmacy ("Board") held an emergency meeting with less than 7 days' notice on the basis that the meeting was "necessary for the immediate preservation of the public peace, health, or safety." 29 **Del.C.** § 10004(e)(1). The purpose of the meeting was to consider the adoption of emergency regulatory amendments to 24 **DE Admin. Code** 2500. Further, 29 **Del.C.** § 10119 authorizes the Board to adopt emergency regulations where an agency determines that an imminent peril to the public health, safety or welfare requires amendment of a regulation with less than the notice required by 29 **Del.C.** § 10115.

REASON FOR THE EMERGENCY ORDER

The anticipated mass closure of Rite Aid pharmacies throughout Delaware threatens to disrupt access to essential medications for residents, particularly those managing chronic conditions. The sudden influx of prescription transfers and patient care responsibilities to remaining pharmacies may overwhelm existing pharmacy staff and infrastructure. The threat to public health created by Rite Aid pharmacy closures is imminent. SB 180 - SA 1, 153rd General Assembly, was signed by the Governor on June 30 and is effective immediately. This Bill amends 24 **Del.C.** § 2523 pertaining to licensure exemptions to provide that nothing in the chapter prevents "[a] pharmacist who is licensed in a jurisdiction or territory of the United States from providing pharmacy services in this State during emergency circumstances, as determined by the Board in coordination with the Secretary of State, or a declared local, jurisdictional, or national disaster. This exemption applies for a period as determined by the Board and the Secretary of State, so long as such person abides by Delaware laws, rules, and regulations relating to pharmacy. In order to be eligible for this exemption, the pharmacist must notify the Board of the pharmacist's intent to practice in this State pursuant to this paragraph." 24 **Del.C.** § 2523(10).

The anticipated mass closure of Rite Aid pharmacies in Delaware presents "emergency circumstances" warranting application of the licensure exemption set forth in 24 **Del.C.** § 2523(10). The emergency regulatory amendments adopted herein serve to implement the temporary practice of out-of-state pharmacists in Delaware. This Emergency Order also temporarily amends the regulation to facilitate the processing of prescriptions to ensure that Delaware residents are able to obtain essential medications in a timely manner. These temporary, emergency amendments to the regulation are adopted with the concurrence of the Secretary of State.

EFFECTIVE DATE OF ORDER

It is hereby ordered that 24 DE Admin. Code 2500 is temporarily modified as shown by underline as follows:

21. Temporary Authorization for the Use of Non-Delaware Licensed Pharmacists.

A pharmacy holding a permit issued by the Board may employ or otherwise use the services of pharmacists holding active, unrestricted licenses in good standing in other states or territories of the United States provided that the permit holder submits to the Board a Notification of Intent to Practice in Delaware with licensure verifications for each out-of-state licensed pharmacist. The permit holder will be responsible for the practice of the out-of-state pharmacist, who shall attest

to compliance with all applicable state and federal laws and regulations. The permit holder is responsible for uploading the Notification of Intent to Practice in Delaware to DELPROS, the licensing system used by the Board.

22. Expanded Role for Pharmacy Technicians.

22.1 Pharmacy technicians who are either certified or trained pursuant to subsection 19.1 are temporarily authorized to assist in the processing of prescription transfers, by obtaining and documenting necessary information, under the supervision of a licensed pharmacist.

22.2 Pharmacists remain responsible for verifying and approving all prescription transfers.

23. Faxed prescription transfers of non-controlled medications may be used as written transfers if all required information is included in the faxed prescription.

24. Pharmacists are authorized to dispense a one-time emergency refill of non-controlled medications if all of the following requirements are met:

24.1 The pharmacist obtains prescription information from: a prescription label, a prescription record within the pharmacy, a prescription record from another pharmacy, a common database, or other healthcare record, if unable to obtain refill authorization from the prescriber after reasonable effort.

24.2 The pharmacist notes on the prescription record the date, the quantity dispensed, and the pharmacist's name or initials.

24.3 In the pharmacist's professional judgment, the interruption of medication therapy may produce undesirable consequences or may be detrimental to the patient's health and welfare.

25. Offsite pharmacists are authorized to enter and verify patient data and conduct telehealth services from a remote location if the patient is on site at the pharmacy.

26. The Board shall expedite the following;

26.1 Licensure of new graduate pharmacists.

26.2 Approvals of renovation plans for existing pharmacies to expand their footprint to make more workstations and more room for pharmacy operations in existing pharmacies.

This Emergency Order shall take effect on July 1, 2025 and shall remain in effect for 120 days. At the expiration of 120 days, the Board, with the concurrence of the Secretary of State, may renew this Emergency Order once for a period not to exceed 60 days, consistent with 29 **Del.C.** §10119(3).

PETITION FOR RECOMMENDATIONS

Pursuant to 29 **Del. C.** § 10119(4), the Board will receive, consider, and respond to petitions by any interested person for recommendations or revisions of this Emergency Order. Petitions should be presented to the Delaware Board of Pharmacy, 861 Silver Lake Boulevard, Dover, Delaware 19904 or by or by email to ruthm.dixon@delaware.gov.

ORDER

It is hereby ordered this 1st day of July 2025 that the above referenced amendments to 24 DE Admin. Code 2500, a copy of which is hereby attached, is adopted, pursuant to 29 **Del. C.** § 10119, as referenced above, and supported by the evidence contained herein. The Board agency will submit a copy of this Emergency Order to the Registrar of Regulations for publication in the next issue of the Register of Regulations as required by 29 **Del. C.** § 10119(5).

DELAWARE BOARD OF PHARMACY

/s/ Joshua Coffield, PharmD
President

/s/ Cheri Briggs, PharmD
Vice President

/s/ Nicholas Juliano, PharmD

ABSENT
Solomon Ezembakwe, PharmD

/s/ Vincent Madaline, PharmD

/s/ Safwat Ibrahium, RPh

/s/ Lakeisha Cunningham

SECRETARY OF STATE
Charuni Patibanda-Sanchez

***Please note: Electronic signatures ("/s/") were accepted pursuant to 6 Del.C. §12A-107(d).**

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. Patient counseling may be provided through telehealth.

"**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.

"**Telehealth**" means the use of information and communications technologies consisting of telephones, remote patient monitoring devices or other electronic means which support clinical health care, provider consultation, patient and professional health-related education, public health, health administration, and other services as described in regulation. Telehealth may be used for patient counseling only.

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 (NAPB). For more information on this process, please refer to the Registration Bulletin at: http://www.napb.net.ftpfiles/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 45 days following the date of the failure with a limit of 3 attempts in a 12-month period. If an applicant has failed the examination 3 times, and 12 months have passed since the failure of the last examination, 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 6 months or has attended an accredited college of pharmacy as a registered student for a minimum of 1 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 31 days following the date of the failure. If an applicant has failed the examination 3 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 3 months or has completed a 1 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 2 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 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 Reg 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 1 registration period to another period is permitted. Each biennial licensure renewal period, the required 30 hours must include the following:

1.4.1.1 At least 2 hours of continuing education in the area of medication safety/errors and;

1.4.1.2 At least 2 hours of continuing education in: 1) the distribution, dispensing or delivery of controlled substances; or 2) the detection and recognition of symptoms, patterns of behavior, or other characteristics of impairment and dependency resulting from the abusive or illegal use of controlled substances.

1.4.2 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 Providers must be approved by ACPE.

1.5.3 A maximum of 2 credit hours will be awarded for First Aid, attendance at a Board of Pharmacy meeting and CPR/BCLS courses 1 time only per registration period.

1.5.4 Credit for Instructors of Continuing Education

1.5.4.1 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.

1.5.4.2 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.

1.5.4.3 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.)

1.5.4.4 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 Credit for On the Job Training:

1.5.5.1 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.

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

1.5.5.3 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.)

1.5.5.4 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 Audit of Continuing Education Hours

1.6.1 Audit. Each biennium, the Division of Professional Regulation shall randomly select from the list of renewed licensees a percentage of licensees, determined by the Board, to be audited. The Board may also audit based on complaints or charges against an individual license, relative to compliance with continuing education requirements or based on a finding of past non-compliance during prior audits.

1.6.2 Documentation. When a licensee is selected for audit, the licensee shall be required to submit documentation accounting for the continuing education hours claimed by the licensee. For ACPE-approved courses, the CPE log from NABP is acceptable documentation. For other courses, programs or activities, licensees selected for random audit are required to supplement the attestation with supporting materials which may include a syllabus, agenda, itinerary or brochure published by the sponsor of the activity and a document showing proof of attendance (i.e., certificate, a signed letter from the sponsor attesting to attendance, report of passing test score). The Board shall attempt to verify the continuing education shown on the documentation provided by the licensee. Upon completion of the review, the Board will decide whether the licensee's continuing education meets the requirements of these regulations.

1.6.2.1 Any continuing education not meeting all provisions of these regulations shall be rejected in part or in whole by the Board.

1.6.2.2 Any incomplete or inaccurate documentation of continuing education may be rejected in part or in whole by the Board.

1.6.3 Board Review and Hearing Process. The Board shall review all documentation requested of any licensee shown on the audit list. If the Board determines the licensee has met the requirements, the licensee's license shall remain in effect. If the Board initially determines the licensee has not met the requirements, the licensee shall be notified and a hearing may be held pursuant to the Administrative Procedures Act. This hearing will be conducted to determine if there are any extenuating circumstances justifying the apparent noncompliance with these requirements. Unjustified noncompliance of these regulations shall constitute a violation of 24 **Del.C.** §2512(b) and may subject the licensee to discipline pursuant to 24 **Del.C.** §2516.

1.6.4 Sanctions for Unjustified Noncompliance. The minimum penalty for the first finding of unjustified noncompliance shall be a $250 monetary penalty. However, the Board may impose any of the additional penalties specified in 24 **Del.C.** §2516. The minimum penalty for the second finding of unjustified noncompliance shall be a $500 monetary penalty. However, the Board may recommend to the Board imposing any of the additional penalties specified in 24 **Del.C.** §2516.

1.6.5 Requests for Extension- Extenuating Circumstances. A licensee applying for renewal may request an extension and be given up to an additional 12 months to make up all outstanding required continuing education providing he/she can show good cause why he/she was unable to comply with such requirements at the same time he/she applies for renewal. The licensee must state the reason for such extension along with whatever documentation he/she feels is relevant. The Board shall consider requests such as extensive travel outside the United States, military service, extended illness of the licensee or his/her immediate family, or a death in the immediate family of the licensee. The written request for extension must be received by the Board prior to the licensure renewal. The Board shall issue an extension when it determines that 1 or more of these criteria have been met or if circumstances beyond the control of the licensee have rendered it impossible for the licensee to obtain the required continuing education. A licensee who has successfully applied for an extension under this paragraph shall make up all outstanding hours of continuing education within the extension period approved by the Board. Make-up credits may not be used in the next renewal period.

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. While a pharmacist may renew his or her license within 60 days immediately following expiration of the license, all CE requirements must be met by the renewal deadline, which is September 30 of even years.

1.9 Duty to Update Address - Licensees must provide the Division of Professional Regulation with his/her current home mailing address. Any change in home mailing address must be reported to the Division within 10 days of such change. All notifications and correspondence pertaining to a pharmacist's license that are sent through the mail will be sent only to the most recent address provided by the licensee. The failure to provide the Division with a current home mailing address will not operate to excuse any duty or responsibility of the licensee and confirmed delivery to the most recent address provided by the licensee will be considered proper notice.

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

1 DE Reg. 1965 (06/01/98)
2 DE Reg. 683 (10/01/98)
4 DE Reg. 163 (07/01/00)

4 DE Reg. 1501 (03/01/01)
6 DE Reg. 488 (10/01/02)
7 DE Reg. 309 (09/01/03)
9 DE Reg. 85 (07/01/05)
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)
20 DE Reg. 995 (06/01/17)
21 DE Reg. 989 (06/01/18)
26 DE Reg. 768 (03/01/23)

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 (07/01/00)

3.0 Pharmacy Requirements

3.1 Pharmacist in Charge

3.1.1 Application for permit to operate a pharmacy in the State of Delaware must be on a form approved by the Board. The form shall include the statement to be signed by the pharmacist in charge, "I understand that I am responsible for conducting and managing the prescription department in compliance with applicable State and Federal laws."

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

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

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

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

3.1.2.4 Establish procedures within operation that maintain standard of practice as it relates to the dispensing of pharmaceuticals 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 3 years in a form readily retrievable and available to Board inspectors. A new or incoming pharmacist-in-charge must complete the “pharmacist-in-charge self-inspection report” within 30 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 15 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 5 feet high measured from the floor. A conspicuous sign with letters not less than 3 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 90 days after assuming the position.

3.8 Technician Support. The pharmacy permit holder shall ensure that, at all times that the pharmacy department is open for business, there shall be at least 1 fully trained 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 3/4 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.

2 DE Reg. 683 (10/01/98)
6 DE Reg. 488 (10/01/02)
7 DE Reg. 309 (09/01/03)
7 DE Reg. 1666 (06/01/04)
9 DE Reg. 85 (07/01/05)
9 DE Reg. 1253 (02/01/06)
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)
19 DE Reg. 660 (01/01/16)

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 2-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 1 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.

5.1.5.1 Effective 6 months after the effective date of this regulation, a pharmacy, 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, shall not deliver, or cause to be delivered, dispensed drugs to a patient's residence where such drugs are intended to be subsequently transported by the patient or patient's agent to a hospital, medical clinic, prescriber's office, or pharmacy for administration and that require special storage, reconstitution or compounding prior to administration. An exception to this subsection may be made for patients with inherited bleeding disorders who may require therapy to prevent or treat bleeding episodes.

5.1.5.2 Effective 6 months after the effective date of this regulation, a patient-specific compounded preparation may not be delivered by a pharmacy to the office of a practitioner or an infusion center for administration unless there is a written contract or agreement between the dispensing pharmacy and the ordering physician or facility determining that this delivery arrangement is in the best interest of that specific patient. The written contract or agreement must describe the procedures for such a delivery system and the responsibilities of each party.

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, or a pharmacy technician who has completed a Board-approved program for sterile compounding, 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 Compounded nonsterile or sterile preparations for human use provided by a Delaware licensed pharmacy without a patient specific prescription. Only an FDA-registered outsourcing facility properly licensed in Delaware may distribute to a practitioner for office use human compounded preparations without a patient-specific prescription.

5.1.7.2 Compounded nonsterile or sterile preparations for animal use without a patient specific prescription.

5.1.7.2.1 A Delaware licensed pharmacy may provide a compounded nonsterile or sterile preparation without a patient-specific prescription to a Delaware licensed veterinarian who intends to administer to the animal patient in his or her care or to dispense to the patient's owner or caretaker only if the pharmacy:

5.1.7.2.1.1 Complies with USP 795 or USP 797, or any updated versions, as applicable;

5.1.7.2.1.2 Complies with applicable federal law; and

5.1.7.2.1.3 Labels compounded nonsterile or sterile preparations with:

5.1.7.2.1.3.1 The name and strength of the preparation; or a list of the active ingredients and the strength of the active ingredients in the preparation;

5.1.7.2.1.3.2 An appropriate beyond-use date as determined by the pharmacist in accordance with USP-NF standards for pharmacy compounding;

5.1.7.2.1.3.3 The quantity of the preparation; and

5.1.7.2.1.3.4 The name, address and license number of the pharmacy.

5.1.7.2.2 A Delaware licensed pharmacy may not provide compounded nonsterile or sterile preparations without a patient-specific prescription to Delaware licensed veterinarians:

5.1.7.2.2.1 In an amount greater than 10% of the total amount of non-patient specific compounded preparations sold by the pharmacy in a rolling year; or

5.1.7.2.2.2 If the compounded nonsterile or sterile preparations are copies or close approximations to products approved by the FDA.

5.1.7.3 Compounded nonsterile or sterile preparations for animal use provided by an FDA-registered outsourcing facility properly licensed in Delaware with or without a patient specific prescription.

5.1.7.3.1 An FDA-registered outsourcing facility properly licensed in Delaware may provide compounded nonsterile or sterile preparations:

5.1.7.3.1.1 Pursuant to a patient-specific prescription, or

5.1.7.3.1.2 In response to an order from a Delaware licensed veterinarian that is not for an identified animal patient where the veterinarian intends to administer the prescription to the animal patient in his or her care or to dispense to the animal patient's owner or caretaker.

5.1.7.3.2 Delaware licensed veterinarians must follow federal laws and regulations when administering or dispensing preparations obtained from an outsourcing facility.

5.1.7.3.3 Subsection 5.1.7.2.2.1 does not apply to subsection 5.1.7.3.

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 1 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 1 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 Section 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 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 Address and phone number of office where prescriber was located at the time prescription was issued.

5.1.12.2.5 DEA number of prescriber in the case of a controlled substance.

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

5.1.12.2.7 Renewals authorized.

5.1.12.2.8 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 3 years. Information must be immediately accessible for a period of

not less than 1 year from the date of last entry. Information beyond 1 year but up to 3 years from the date of last entry may be maintained off-line but must be produced no later than 5 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 Section 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 patents 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 counseling to the patient on pertinent medication information. The counseling may be provided verbally or electronically, whichever method the patient prefers. 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.

5.2.5 Patient counseling may be conducted through telehealth subject to the following requirements:

5.2.5.1 During the telehealth treatment session, the patient shall be located within the borders of the State of Delaware.

5.2.5.2 Informed consent: Before services are provided through telehealth, the pharmacist, or a registered intern or pharmacy student working under the direct supervision of a pharmacist, shall obtain verbal informed consent from the patient, or other appropriate person with authority to make health care treatment decisions for the patient.

5.2.5.3 Confidentiality: The pharmacist, or a registered intern or pharmacy student working under the direct supervision of a pharmacist, shall ensure that their electronic transmission is secure to maintain confidentiality of the patient's medical information as required by the Health Insurance Portability and Accountability Act (HIPAA) and other applicable Federal and State laws.

5.2.5.4 Competence and scope of practice: the pharmacist, or a registered intern or pharmacy student working under the direct supervision of a pharmacist, shall be responsible for determining and documenting that telehealth is an appropriate level of care for the patient; shall comply with the Board's law and rules and regulations and all current standards of care requirements applicable to onsite care; and shall limit the practice of telehealth to the area of competence in which proficiency has been gained through education, training and experience.

Effective Date: October 11, 1996
Effective Date: April 14, 1997 Section 5.4 revised
Effective Date: June 11, 1998
Amended Effective September 11, 1999
1 DE Reg. 1965 (06/01/98)
3 DE Reg. 431 (09/01/99)
4 DE Reg. 163 (07/01/00)
4 DE Reg. 682 (10/01/00)
9 DE Reg. 85 (07/01/05)
9 DE Reg. 1253 (02/01/06)
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)
19 DE Reg. 860 (03/01/16)
20 DE Reg. 995 (06/01/17)
21 DE Reg. 989 (06/01/18)
26 DE Reg. 768 (03/01/23)
27 DE Reg. 258 (10/01/23)
27 DE Reg. 980 (06/01/24)

6.0 Pure Drug Regulations

6.1 Definition

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

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

6.3 Anyone who repacks and labels drugs in convenient quantities for their own subsequent use must maintain a log on the premises showing the date prepacked, the quantity prepacked, the control number, expiration date and name and strength of the drug. Prepacking must be done under the supervision of a registered pharmacist or any other person authorized to dispense under 24 **Del.C.** §2513. Each container must have a label containing the name of the drug, its strength, the manufacturer's control number, the expiration date if applicable, the name of the manufacturer, or the name and strength of the drug and a conference code number which would enable the control number, manufacturer and expiration date to be retrieved from the log. Nothing in this regulation precludes the Federal laws and regulations.

6.3.1 Beyond use date for single unit and unit dose containers. The beyond use date for these products shall be 1 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 (03/01/01)
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 2 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 as a Wholesaler, Manufacturer, Outsourcing Facility or Third-Party Logistics Provider

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 a wholesaler, manufacturer, outsourcing facility or third-party logistics provider, whether corporations, companies, associations, firms, partnerships, societies and joint-stock companies, but does not include individuals.

"**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 they report to and the pharmacists-in-charge; 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.

"**Manufacturer**" means a person engaged in the production, preparation, propagation, conversion, or processing of a drug or device, either directly or indirectly, by extraction from a substance of natural origin or independently by a chemical or biological synthesis. The term includes packaging or repackaging a substance or labeling or relabeling a container and promoting and marketing the drug or device and preparing and promoting a commercially available product from a bulk compound for resale by a person, including a pharmacy or practitioner. The term does not include compounding.

"**Outsourcing facility**" means a facility that is located within the United States of America at 1 address that is engaged in the compounding of sterile drugs and nonsterile drugs; has registered as an outsourcing facility with the federal Food and Drug Administration under Section 503B of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. Sec. 353b); and is doing business within or into Delaware.

"**Third-party logistics provider**" means an entity that provides or coordinates warehousing or other logistics services for a dangerous drug or dangerous device in intrastate or interstate commerce on behalf of a manufacturer, wholesaler, or dispenser of the dangerous drug or dangerous device, but does not take ownership of the dangerous drug or dangerous device, nor have responsibility to direct its sale or disposition

"**Wholesaler**" means a person engaged in the wholesale distribution of drugs, including, but not limited to, a manufacturer's or distributor's warehouse, a chain drug warehouse or wholesale drug warehouse, an independent wholesale drug trader, and a pharmacy that engages in the wholesale distribution of drugs.

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% of the total drug sales revenue of either the transferor or transferee pharmacy during any 12 consecutive month period.

8.2 Permit Requirements. Wholesalers, manufacturers, outsourcing facilities and third-party logistics providers that operate within this state, whether or not physically located within this state, must first be granted a permit by the Board.

8.2.1 The applicant for a permit shall provide information required by a Board-approved application, including but not limited to:

8.2.1.1 All trade or business names used, e.g. "doing business as" or "formerly known as." Trade or business names cannot be identical to the name used by another, unrelated entity permitted to purchase drugs in the state;

8.2.1.2 Name of the owner or owners and operator or operators and the pharmacist-in-charge of the applicant (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 applicant's written policies and procedures, required by subsection 8.6, will be available on-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 applicant to purchase, possess, and distribute drugs;

8.2.1.5 A list of all disciplinary actions by state and federal agencies against the applicant, as well as any actions against principals, owners, directors, officers and pharmacists, including the pharmacist-in-charge;

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 establishment is located. If leased, the lease must be for an original term of not less than 1 calendar year.

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

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

8.2.4 Applicant 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 After receipt of a permit, the permittee 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 permittees 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 applicants:

8.3.1 Any findings by the Board that the key personnel of 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 key personnel of the applicant deemed substantially related to the practice of pharmacy as set forth in Section 17.0;

8.3.2.1 The Board shall consider the results of a criminal background check of the key personnel of the applicant to determine whether such individuals have been convicted of a crime substantially related to the practice of pharmacy as set forth in Section 17.0. The background check shall include all key personnel involved in the operations of the applicant. 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.

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 key personnel 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 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 wholesalers, manufacturers, outsourcing facilities and third-party logistics providers.

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 permit, the permittee shall:

8.4.1 Require each employee 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 subsection 8.6. These records shall be kept for 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 permittee 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 permittee growing out of or arising from its activities in this state. A copy of any such service of

process shall be mailed to the permittee by the Board via certified mail, return receipt requested, postage prepaid, at the address the permittee has designated on its application for permit in Delaware. If an entity 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 2 years of verifiable full-time managerial or supervisory experience acceptable to the Board in a licensed pharmacy or related business where the individual's responsibilities included, but were not limited to, recordkeeping, storage, and shipment of drugs.

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 records by permittees 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 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 Wholesalers, manufacturers, outsourcing facilities and third-party logistics providers 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 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 2 working days of a request by an authorized official of a federal, state, or local law enforcement agency.

8.5.3 Permittees 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. Permittees shall establish, maintain, and adhere to written policies and procedures for the receipt, security, storage, inventory, transport, shipping, and distribution of drugs. Permittees 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. Written policies and procedures shall include 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 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 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 3 business days.

8.7 Salvaging and Reprocessing. Permittees 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 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. Permittees shall employ, train, and document the training of personnel in the proper use of such technology and equipment.

10 DE Reg. 1628 (04/01/07)
21 DE Reg. 989 (06/01/18)

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 Section 19.0.

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 2 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 48 hours.

9.7 Equipment and Texts. Each hospital pharmacy shall have the equipment and texts required by 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 Section 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 (07/01/05)
10 DE Reg. 1629 (04/01/07)
13 DE Reg. 1581 (06/01/10)
21 DE Reg. 989 (06/01/18)

10.0 Pharmaceutical Compounding

All individuals and entities licensed by the Delaware Board of Pharmacy engaged in compounding shall adhere to and comply with both the current edition of the United States Pharmacopeia Chapters 795 (USP 795) and 797 (USP 797) and any updates published by USP. By December 1, 2019, all licensees engaged in compounding shall either be in compliance with USP 800, or shall submit a plan for coming into compliance to be reviewed and approved by the Board.

9 DE Reg. 85 (07/01/05)
13 DE Reg. 1581 (06/01/10)
19 DE Reg. 661 (01/01/16)
21 DE Reg. 989 (06/01/18)

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 2 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 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 2 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 10 days of starting as a consultant in the State. 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 90 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 throughout 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 2 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 2 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.

"**Radiopharmaceuticals**" are radioactive drugs as defined by the FDA.

"**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.

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 (02/01/06)

14.0 Administration of Injectable Medications, Biologicals and Adult Immunizations

14.1 Purpose. The purpose of this section 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. Certified pharmacy

technicians may only administer adult immunizations pursuant to the training, administration and documentation requirements set forth in subsection 19.2.3.

14.2 Educational Requirements

14.2.1 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 must be obtained through a CPR course for health care providers and the course must have a hands-on, skills check component.

14.2.1.1 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.

14.2.1.2 Pharmacists successfully completing the above education and practical training shall notify the Board. The Board will record the successful training in Board database systems. The pharmacist's license shall include the notation that such licensee has completed the training for the administration of injectable medications, biologicals and adult immunizations.

14.2.2 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.

14.2.3 Continued competency shall be maintained and available for Board inspection.

14.2.3.1 A minimum of 2 hours (0.2 C.E.U.) of the 30 hour requirement for continuing education for licensed pharmacists, every licensure period, must be dedicated to this area of practice. To be relieved of this requirement, the licensee must notify the Board, in writing, that he or she is no longer administering injectable medications, biological and adult immunizations.

14.2.3.2 A minimum of 2 hours of continuing education every 2 years for registered interns and pharmacy students must be dedicated to this area of practice.

14.2.4 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.

14.3 Practice Requirements

14.3.1 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.

14.3.2 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.

14.3.3 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.

14.3.4 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:

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

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

14.3.4.3 Date of original order and the date of administration.

14.3.4.4 The name of the prescribing practitioner and the pharmacist, registered intern, or pharmacy student administering the dose.

14.3.5 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.

14.3.6 The pharmacist, registered intern, or pharmacy student shall provide documentation to each person receiving immunizations and shall report to the Immunization Vaccination Registry.

14.3.7 All documentation and records required by this Regulation must be maintained for a period of not less than 3 years and available for inspection by the Board of Pharmacy.

14.4 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 (09/01/99)
17 DE Reg. 653 (12/01/13)
18 DE Reg. 707 (03/01/15)
21 DE Reg. 989 (06/01/18)

26 DE Reg. 64 (07/01/22)
26 DE Reg. 768 (03/01/23)

15.0 Automated Pharmacy Systems

15.1 Purpose and Scope. 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;

15.4.1.4.4 Policies and procedures for accessibility and quality assurance.

15.5 Record Keeping Requirements. Records and/or electronic data kept by Automated Pharmacy Systems shall meet the following requirements:

15.5.1 All events involving the filling/restocking, dispensing and maintenance of the Automated Pharmacy System must be recorded; and

15.5.2 Records must be maintained by the pharmacy and must be readily available to the Board for a 3 years and shall include:

15.5.2.1 Type of transaction including filling/restocking, dispensing and maintenance;

15.5.2.2 Identification of the individual accessing the system;

15.5.2.3 Name, strength, dosage form, and quantity of the drug removed or added;

15.5.2.4 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 subsection 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 subsection 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)
21 DE Reg. 989 (06/01/18)

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 Section 16.0, shall have the following meaning, unless the context clearly indicates otherwise:

"**Authorized agent**" is as defined in subsection 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 subsection 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 subsection 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 3 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)

21 DE Reg. 989 (06/01/18)

17.0 Crimes substantially related to the practice of pharmacy.

17.1 For the purposes of this section the following definitions shall apply:

"**Conviction**" means a verdict of guilty entered by a judge or jury, or a plea of guilty or a plea of *nolo contendere*.

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 Unlawful sexual contact in the second degree; class F felony. 11 **Del.C.** §768

17.2.4 Unlawful sexual contact in the first degree; class D felony. 11 **Del.C.** §769

17.2.5 Rape in the fourth degree; class C felony. 11 **Del.C.** §770

17.2.6 Rape in the third degree; class B felony 11 **Del.C.** §771

17.2.7 Rape in the second degree; class B felony. 11 **Del.C.** §772

17.2.8 Rape in the first degree; class A felony. 11 **Del.C.** §773

17.2.9 Sexual extortion; class E felony. 11 **Del.C.** §774

17.2.10 Continuous sexual abuse of a child; class B felony. 11 **Del.C.** §776

17.2.11 Dangerous crime against a child, definitions, sentences. 11 **Del.C.** §777

17.2.12 Sex offender unlawful sexual conduct against a child. 11 **Del.C.** §777A

17.2.13 Sexual abuse of a child by a person in a position of trust, authority or supervision in the first degree. 11 **Del.C.** §778

17.2.14 Sexual abuse of a child by a person in a position of trust, authority or supervision in the second degree 11 **Del.C.** §778A

17.2.15 Female genital mutilation. 11 **Del.C.** §780

17.2.16 Use of illegitimate retail sales receipt or Universal Product Code Label. 11 **Del.C.** §840A.

17.2.17 Theft. Felony. 11 **Del.C.** §841.

17.2.18 Forgery. 11 **Del.C.** §861.

17.2.19 Possession of forgery devices. 11 **Del.C.** §862.

17.2.20 Falsifying business records. 11 **Del.C.** §871.

17.2.21 Deceptive business practices. 11 **Del.C.** §906.

17.2.22 Insurance fraud. 11 **Del.C.** §913.

17.2.23 Health care fraud. 11 **Del.C.** §913A.

17.2.24 Unauthorized access to computer systems. 11 **Del.C.** §932.

17.2.25 Theft of computer services. 11 **Del.C.** §933.

17.2.26 Interruption of computer services. 11 **Del.C.** §934.

17.2.27 Misuse of computer system information. 11 **Del.C.** §935.

17.2.28 Possession or theft of a prescription form or a pad. 11 **Del.C.** §841C

17.2.29 Dealing in children. 11 **Del.C.** §1100

17.2.30 Sexual exploitation of a child. 11 **Del.C.** §1108

17.2.31 Dealing in child pornography. 11 **Del.C.** §1109

17.2.32 Possession of child pornography. 11 **Del.C.** §1111
17.2.33 Sexual offenders; prohibitions from school zones. 11 **Del.C.** §1112
17.2.34 Sexual solicitation of a child. 11 **Del.C.** §1112A
17.2.35 Prohibited acts A. Former 16 **Del.C.** §4751
17.2.36 Prohibited acts B. Former 16 **Del.C.** §4752
17.2.37 Unlawful delivery of noncontrolled substance. Former 16 **Del.C.** §4752A
17.2.38 Prohibited acts C. Former 16 **Del.C.** §4753
17.2.39 Trafficking in marijuana, cocaine, illegal drugs, methamphetamines, L.S.D., or designer drugs. Former 16 **Del.C.** §4753A
17.2.40 Prohibited acts D. Former 16 **Del.C.** §4754
17.2.41 Possession and delivery of noncontrolled prescription drug. Former 16 **Del.C.** §4754A
17.2.42 Prohibited acts E. Former 11 **Del.C.** §4755
17.2.43 Prohibited acts. Former 11 **Del.C.** §4756
17.2.44 Hypodermic syringe or needle; delivering or possessing; disposal; exceptions. Former 16 **Del.C.** §4757
17.2.45 Keeping drugs in original containers. Former 16 **Del.C.** §4758
17.2.46 Distribution to persons under 21 years of age. Former 16 **Del.C.** §4761
17.2.47 Purchase of drugs from minors. Former 16 **Del.C.** §4761A
17.2.48 Distribution, delivery, or possession of controlled substance within 1,000 feet of school property. Former 16 **Del.C.** §4767
17.2.49 Distribution, delivery or possession of controlled substance in or within 300 feet of park, recreation area, church, synagogue or other place of worship. Former 16 **Del.C.** §4768
17.2.50 Drug dealing-Aggravated possession; class B felony. 16 **Del.C.** §4752
17.2.51 Drug dealing-Aggravated possession; class C felony. 16 **Del.C.** §4753
17.2.52 Drug dealing-Aggravated possession; class D felony. 16 **Del.C.** §4754
17.2.53 Aggravated possession; class E felony. 16 **Del.C.** §4755
17.2.54 Aggravated possession; class F felony. 16 **Del.C.** §4756
17.2.55 Miscellaneous drug crimes; class B, C and F felony. 16 **Del.C.** §4757
17.2.56 Unlawful dealing in a counterfeit or purported controlled substance; class E felony. 16 **Del.C.** §4758
17.2.57 Registrant crimes. 16 **Del.C.** §4759
17.2.58 Maintaining a drug property; class F felony. 16 **Del.C.** §4760
17.2.59 Operating or attempting to operate clandestine laboratories; cleanup; penalties. 16 **Del.C.** §4760A
17.2.60 Illegal possession and delivery of noncontrolled prescription drugs. 16 **Del.C.** §4761
17.2.61 Hypodermic syringe or needle; delivering or possessing; disposal; exceptions; penalties. 16 **Del.C.** §4762
17.2.62 Possession of controlled substances or counterfeit controlled substances; class A or B misdemeanor. 16 **Del.C.** §4763

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)
20 DE Reg. 995 (06/01/17)

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. 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. Verbal orders:

18.3.1 Verbal orders shall be reduced to writing.

18.3.2 Verbal orders are only valid for oxygen and no other medical gases.

18.3.3 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.

18.3.4 The order is valid for the length of time authorized by the prescriber. If the duration is not specified the order is valid for 1 year.

18.4 Policy and Procedure Requirements. Written policy and procedures must be available for review and shall include but not be limited to the following areas:

18.4.1 Storage and handling

18.4.2 Oxygen Safety

18.4.3 Orders

18.4.4 Labeling

18.4.5 Record keeping

18.4.6 Patient education

18.4.7 Security

18.4.8 Recall

18.4.9 Quarantine

18.4.10 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 3 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 3 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. 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 permit holder shall ensure that pharmacy technicians successfully complete a training program. Once training has commenced, the technician in training may work in the pharmacy under the direct supervision of a pharmacist. For the purposes of this subsection, "direct supervision" means that a pharmacist is present in the pharmacy at all times.

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 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 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 subsection 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 except for the administration of adult immunizations as set forth in subsection 19.2.3. 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).

19.2.3 A certified pharmacy technician, who is certified by the Pharmacy Technician Certification Board (PTCB), the National Healthcareer Association (NHA), or other national entity approved by the Board, may administer adult immunizations under the direct supervision of a licensed pharmacist who is approved for injectable administration as set forth in Section 14.0. For the purposes of this subsection, "direct supervision" means oversight and control by a licensed pharmacist who remains on the premises and is responsible for the work performed by the certified pharmacy technician.

19.2.3.1 Educational Requirements

19.2.3.1.1 In order to administer adult immunizations, a certified pharmacy technician must 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 must be obtained through a CPR course for health care providers and the course must have a hands-on, skills check component.

19.2.3.1.2 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.

19.2.3.2 A certified pharmacy technician may only administer adult immunizations consistent with public health and safety and in a competent manner consistent with the academic curriculum and training completed.

19.2.3.3 Continued competency shall be maintained and available for Board inspection. A minimum of 2 hours of continuing education every 2 years for certified pharmacy technicians must be dedicated to this area of practice.

19.2.3.4 Practice Requirements

19.2.3.4.1 The certified pharmacy technician, before administering an adult immunization, may assist the patient with pre-immunization paperwork.

19.2.3.4.2 The certified pharmacy technician must verify documentation for all adult immunizations administered and such documentation shall be available for inspection by the Board of Pharmacy. Documentation shall include:

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

19.2.3.4.2.2 Adult vaccine administered, expiration date, lot number, method of administration, dose administered.

19.2.3.4.2.3 Date of original order and the date of administration.

19.2.3.4.2.4 The name of the prescribing practitioner, where applicable, and the certified pharmacy technician administering the dose.

19.2.3.5 The certified pharmacy technician must provide documentation to each person receiving adult immunizations and must report to the Immunization Vaccination Registry.

13 DE Reg. 506 (10/01/09)
13 DE Reg. 1581 (06/01/10)
21 DE Reg. 989 (06/01/18)
26 DE Reg. 64 (07/01/22)
26 DE Reg. 768 (03/01/23)

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 subsections 9.9 through 9.13.

13 DE Reg. 506 (10/01/09)
21 DE Reg. 989 (06/01/18)

21.0 Temporary Authorization for the Use of Non-Delaware Licensed Pharmacists.

A pharmacy holding a permit issued by the Board may employ or otherwise use the services of pharmacists holding active, unrestricted licenses in good standing in other states or territories of the United States provided that the permit holder submits to the Board a Notification of Intent to Practice in Delaware with licensure verifications for each out-of-state licensed pharmacist. The permit holder will be responsible for the practice of the out-of-state pharmacist, who shall attest to compliance with all applicable state and federal laws and regulations. The permit holder is responsible for uploading the Notification of Intent to Practice in Delaware to DELPROS, the licensing system used by the Board.

22.0 Expanded Role for Pharmacy Technicians.

22.1 Pharmacy technicians who are either certified or trained pursuant to subsection 19.1 are temporarily authorized to assist in the processing of prescription transfers, by obtaining and documenting necessary information, under the supervision of a licensed pharmacist.

22.2 Pharmacists remain responsible for verifying and approving all prescription transfers.

23.0 Faxed prescription transfers of non-controlled medications may be used as written transfers if all required information is included in the faxed prescription.

24.0 Pharmacists are authorized to dispense a one-time emergency refill of non-controlled medications if all of the following requirements are met:

24.1 The pharmacist obtains prescription information from: a prescription label, a prescription record within the pharmacy, a prescription record from another pharmacy, a common database, or other healthcare record, if unable to obtain refill authorization from the prescriber after reasonable effort.

24.2 The pharmacist notes on the prescription record the date, the quantity dispensed, and the pharmacist's name or initials.

24.3 In the pharmacist's professional judgment, the interruption of medication therapy may produce undesirable consequences or may be detrimental to the patient's health and welfare.

25.0 Offsite pharmacists are authorized to enter and verify patient data and conduct telehealth services from a remote location if the patient is on site at the pharmacy.

26.0 The Board shall expedite the following;

26.1 Licensure of new graduate pharmacists.

26.2 Approvals of renovation plans for existing pharmacies to expand their footprint to make more workstations and more room for pharmacy operations in existing pharmacies.

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1 DE Reg. 1965 (06/01/98)
2 DE Reg. 683 (10/01/98)
3 DE Reg. 431 (09/01/99)
4 DE Reg. 163 (07/01/00)
4 DE Reg. 682 (10/01/00)
4 DE Reg. 1501 (03/01/01)
6 DE Reg. 488 (10/01/02)
7 DE Reg. 309 (09/01/03)
7 DE Reg. 914 (01/01/04)
7 DE Reg. 1666 (06/01/04)
8 DE Reg. 879 (12/01/04)
9 DE Reg. 85 (07/01/05)
9 DE Reg. 1253 (02/01/06)
9 DE Reg. 1984 (06/01/06)
10 DE Reg. 1628 (04/01/07)
11 DE Reg. 222 (08/01/07)
11 DE Reg. 689 (11/01/07)
11 DE Reg. 1065 (02/01/08)
13 DE Reg. 506 (10/01/09)
13 DE Reg. 1581 (06/01/10)
15 DE Reg. 99 (07/01/11)
15 DE Reg. 887 (12/01/11)
15 DE Reg. 1507 (04/01/12)
16 DE Reg. 654 (12/01/12)
16 DE Reg. 998 (03/01/13)
17 DE Reg. 653 (12/01/13)
17 DE Reg. 990 (04/01/14)
18 DE Reg. 707 (03/01/15)
19 DE Reg. 660 (01/01/16)
19 DE Reg. 860 (03/01/16)
20 DE Reg. 995 (06/01/17)
21 DE Reg. 989 (06/01/18)
26 DE Reg. 64 (07/01/22)
26 DE Reg. 768 (03/01/23)
27 DE Reg. 258 (10/01/23)
27 DE Reg. 980 (06/01/24)