# [***2016 VA Regulation Text 164673***](https://advance.lexis.com/api/document?collection=administrative-codes&id=urn:contentItem:5V0X-08V0-01WK-94S0-00000-00&context=)

18 VAC 110-16, -20, -25, -50

Proposed Rule, November 27, 2018

**Notice**

**Added:**Text highlighted in green
**Deleted:**~~Red text with a strikethrough~~

**Agency**

Department of Health Professions / Board of Pharmacy

**Digest**

 Titles of Regulations: 18VAC110-15. Regulations for Delegation to an Agency Subordinate (adding 18VAC110-15-10).

18VAC110-20. Regulations Governing the Practice of Pharmacy (amending 18VAC110-20-10, 18VAC110-20-20, 18VAC110-20-25, 18VAC110-20-110, 18VAC110-20-140, 18VAC110-20-150, 18VAC110-20-180, 18VAC110-20-200, 18VAC110-20-211, 18VAC110-20-220, 18VAC110-20-240, 18VAC110-20-270, 18VAC110-20-280, 18VAC110-20-290, 18VAC110-20-355, 18VAC110-20-390, 18VAC110-20-425, 18VAC110-20-470, 18VAC110-20-490, 18VAC110-20-530, 18VAC110-20-550, 18VAC110-20-580, 18VAC110-20-630, 18VAC110-20-680; adding 18VAC110-20-112; repealing 18VAC110-20-15, 18VAC110-20-21, 18VAC110-20-30 through 18VAC110-20-106).

18VAC110-21. Regulations Governing the Licensure of Pharmacists and Registration of Pharmacy Technicians (adding 18VAC110-21-10 through 18VAC110-21-180).

18VAC110-50. Regulations Governing Wholesale Distributors, Manufacturers, and Warehousers (amending 18VAC110-50-40, 18VAC110-50-60, 18VAC110-50-80).

Statutory Authority:

 [*Sections 54.1-2400*](https://advance.lexis.com/api/document?collection=statutes-legislation&id=urn:contentItem:5T53-0M50-004G-J2CG-00000-00&context=) and [*54.1-3307 of the Code of Virginia*](https://advance.lexis.com/api/document?collection=statutes-legislation&id=urn:contentItem:5T53-0KT0-004G-J024-00000-00&context=).

Public Hearing Information:

January 9, 2019 - 9:05 a.m. - Perimeter Center, Commonwealth Conference Center, 9960 Mayland Drive, Suite 201, Board Room 4, Henrico, VA 23233

Public Comment Deadline: February 22, 2019.

Agency Contact: Caroline Juran, RPh, Executive Director, Board of Pharmacy, 9960 Mayland Drive, Suite 300, Richmond, VA 23233-1463, telephone (804) 367-4456, FAX (804) 527-4472, or email *caroline.juran@dhp.virginia.gov*.

Basis: Chapter 24 (Section 54.1-2400 et seq.) of Title 54.1 of the Code of Virginia establishes the general powers and duties of health regulatory boards, including the responsibility to promulgate regulations and establish renewal schedules. The specific authority to control prescription drugs in the Commonwealth is found in Chapters 33 (Section 54.1-3300 et seq.) and 34 (Section 54.1-3400 et seq.) of Title 54.1 of the Code of Virginia.

Purpose: Regulation of the practice of pharmacy is both complex and essential to public health and safety. The Board of Pharmacy takes seriously its statutory responsibility to ensure the safety, integrity, and efficacy of prescription drugs in the Commonwealth. At the same time, the practice of pharmacy is constantly changing as new technologies become available. To incorporate efficiency and cost-effectiveness, rules for pharmacy practice must be changed while balancing the assurances that controlled substances are dispensed in a manner that protects from medication error and diversion that is harmful to the patient and the community.

Substance: As part of the periodic review, the board determined that provisions in 18VAC110-20 relating to the licensure of pharmacists and registration of pharmacy technicians should be re-promulgated into a separate chapter, 18VAC110-21, to reduce the size and complexity of this chapter. Some of Part I, General Provisions, will be included in a new chapter, and all of Parts II and III will be repealed and restated. Additionally, 18VAC110-20-15, Criteria for delegation of informal fact-finding proceedings to an agency subordinate, will be moved into a separate chapter, 18VAC110-15, because it applies to all types of licensees, registrants, and permit holders regulated by the board.

Issues: The primary advantage to the public may be stronger provisions defining unprofessional conduct, such as "performing any act likely to deceive, defraud, or harm the public." While the board may currently be able to establish grounds for disciplinary action, additional specificity strengthens the ability of the board to take action if there is harm to the public. There are no disadvantages to the public. With exception of clearer rules for licensees, there are no advantages or disadvantages to the agency.

Department of Planning and Budget's Economic Impact Analysis:

Summary of the Proposed Amendments to Regulation. As the result of a periodic review,¬1 the Board of Pharmacy (Board) proposes to mainly update and reformat the regulation to improve clarity and readability. The proposed regulation also contains a number of changes to address issues identified in practice or to streamline enforcement.

Result of Analysis. The benefits likely exceed the costs.

Estimated Economic Impact. The majority of the changes in this action are intended to improve clarity and readability of the regulation without introducing any new requirements or altering existing ones. However, there are proposals that represent a change in practice. One such change is the proposed update of the practices that constitute unprofessional conduct. Based on situations encountered in disciplinary cases and/or included in other chapters enacted by other health regulatory boards, the Board proposes to update what constitutes unprofessional conduct. For example, obtaining money or property of a patient by fraud or misrepresentation, providing false information to the compliance inspector, performing acts to deceive, defraud, or harm the public are now listed in this section. This change does not directly affect any particular person or entity at this time but may be the basis of a disciplinary action for someone in the future.

In another change, the Board proposes to specify that if the pharmacy is not operational within 90 days from issuance of a new permit, the permit is rescinded unless an extension is granted. Normally, controlled substances should not be left in a facility that is not operational. This change was prompted by a questionable pharmacy operation that came to the Board's attention, but the Board could not take action due to lack of authority to rescind such a permit. Under the proposed rule, the Board will allow 90 days from the date the permit is issued for last minute preparations to occur. This change is not expected to have any direct impact on any regulated entity at this time because the questionable pharmacy operation has already been ceased but will likely strengthen the Board's enforcement authority if and when needed.

Similarly, one of the medical equipment suppliers has challenged the Board's authority to request hours of its operation. Medical equipment suppliers are sometimes open for limited hours, complicating enforcement. Without such information, the Board could not effectively schedule an unannounced inspection of the facility. Thus, the Board proposes to require that a medical equipment supplier must designate the hours of operation when it is open to the public and to require notification to the Board and to the public if those hours change. These requirements are similar to those for pharmacies. With the requested information, the Board will know the hours of operation, when the facility is open, and when an inspection can occur.

The Board is also concerned with the adequacy of the current requirements to become a pharmacist-in-charge. There is no minimum experience requirement to become a pharmacist-in-charge, yet the position requires broad knowledge of pharmacy operations and significant responsibilities for the inventory and security of the pharmacy. Thus, the Board proposes to require a minimum of two years of experience before becoming a pharmacist-in-charge. This change will narrow the pool of eligible pharmacists to become a pharmacist-in-charge but will likely improve public safety and protect the pharmacists who might be assigned the job of pharmacist-in-charge before he/she was ready to assume such a responsibility.

The Board proposes to require a temperature record for cold storage units and for maintenance of such record for two years. The facilities are already required to have proper refrigeration equipment to protect the integrity and safety of certain drugs such as vaccines. According to the Department of Health Professions (DHP), inexpensive tools are available to measure and record temperatures in a cold storage. This change will make sure that information to check compliance will be available for review by inspectors. Regulants may also benefit from proper refrigeration by reducing waste of valuable drugs due to exposing drugs to improper temperatures.

The Board proposes to add language that the policy and procedure manual must include provisions for granting and terminating user access in settings where automated devices dispense and administer drugs. According to the Board, it is vital that only appropriately qualified users have access to automated devices that dispense drugs to prevent diversion for personal use or for sale.

The Board proposes to require that five of the required 15 hours of continuing education for annual renewal be obtained in courses or programs that are live or interactive. The Board also proposes to allow two new activities that may be used to fulfill required live or interactive continuing education, including one hour for attendance at a board meeting or hearing and one hour for serving as a preceptor for someone gaining practical experience. The Board believes pharmacists benefit from some interaction in an educational environment, so a portion of continuing hours is proposed to be live or interactive. DHP notes that it would not be necessary for a pharmacist to attend a course in person; participation in an interactive, real-time course would suffice. To the extent live or interactive continuing education is more effective than other settings, this change should be beneficial.

The Board proposes to give a pharmacist who is presented with a forged prescription the option of returning it to the customer or keeping it for law enforcement. Current regulation prohibits the return of a forged prescription, but DHP notes that pharmacists sometimes feel threatened by refusing to return it. The regulation is being amended to give the pharmacist the option depending on the situation. This change will likely help pharmacists to safely get themselves out of a dangerous situation in the case of a criminal attempt to obtain drugs from them by forged prescriptions.

In response to a petition for rulemaking,¬2 the Board proposes to allow sharing of prescriptions between a provider pharmacy for a long-term care facility and a back-up pharmacy for such a facility to dispense drugs up to a seven-day supply. Currently, the prescription must be transferred to the back-up facility to dispense any drugs. This change will facilitate coverage when the provider pharmacy experiences a temporary shortage in a medication that is needed at the facility.

Finally, the Board proposes to allow that a stat-drug box may include a substitution of liquid for solid dosage unit for each drug schedule. This change will provide more flexibility to the pharmacies that utilize stat-boxes.

Businesses and Entities Affected. There are 34,789 persons or entities that have been issued a license, registration, or permit by the Board. These entities include, but are not limited to, pharmacists, technicians, interns, pharmacies, manufacturers, wholesalers, warehouses, medical equipment suppliers, etc.

Localities Particularly Affected. The proposed regulation does not affect any particular locality more than others.

Projected Impact on Employment. No significant impact on employment is expected.

Effects on the Use and Value of Private Property. No significant impact on the use and value of private property is expected.

Real Estate Development Costs. No significant impact on real estate development costs is expected.

Small Businesses:

Definition. Pursuant to [*Section 2.2-4007.04 of the Code of Virginia*](https://advance.lexis.com/api/document?collection=statutes-legislation&id=urn:contentItem:5T53-0MR0-004G-J350-00000-00&context=), small business is defined as "a business entity, including its affiliates, that (i) is independently owned and operated and (ii) employs fewer than 500 full-time employees or has gross annual sales of less than $6 million."

Costs and Other Effects. There is no estimate of the number of small businesses. However, the majority of pharmacies are part of large national chains. The costs and other effects on any small business would be the same as discussed above.

Alternative Method that Minimizes Adverse Impact. The proposed changes are not likely to create a significant adverse impact on small businesses.

Adverse Impacts:

Businesses. The proposed changes are not likely to create a significant adverse impact on businesses.

Localities. The proposed regulation will not adversely affect localities.

Other Entities. The proposed regulation will not adversely affect other entities.

Agency's Response to Economic Impact Analysis: The Board of Pharmacy concurs with the economic impact analysis of the Department of Planning and Budget.

Summary:

Pursuant to a periodic review, the Board of Pharmacy proposes to (i) move the provisions relating to the licensure of pharmacists and registration of pharmacy technicians from Regulations Governing the Practice of Pharmacy (18VAC110-20) into a new regulatory chapter, Regulations Governing the Licensure of Pharmacists and Registration of Pharmacy Technicians (18VAC110-21); (ii) address current issues with practice, clarify requirements, and incorporate provisions currently found in guidance documents in 18VAC110-20 and Regulations Governing Wholesale Distributors, Manufacturers, and Warehousers (18VAC-110-50); and (iii) move the provision regarding the delegation of informal fact-finding proceedings from 18VAC110-20 into a new chapter, Regulations for Delegation to an Agency Subordinate (18VAC110-15).

¬1http://townhall.virginia.gov/l/View PReview.cfm?PRid=1466

¬2http://townhall.virginia.gov/L/View Petition.cfm?petition Id=233

**Text**

REGULATIONS FOR DELEGATION TO AN AGENCY SUBORDINATE

Criteria for delegation of informal fact-finding proceeding to an agency subordinate.

Decision to delegate. In accordance with subdivision 10 of [*Section 54.1-2400 of the Code of Virginia*](https://advance.lexis.com/api/document?collection=statutes-legislation&id=urn:contentItem:5T53-0M50-004G-J2CG-00000-00&context=), the board may delegate an informal fact-finding proceeding to an agency subordinate upon determination that probable cause exists that a practitioner or an entity may be subject to a disciplinary action.

Criteria for delegation. Cases that may not be delegated to an agency subordinate, except as may be approved by a committee of the board, include those that involve:

Intentional or negligent conduct that causes or is likely to cause injury to a patient;

Drug diversion;

Impairment with an inability to practice with skill and safety;

Indiscriminate dispensing; and

Medication error in administration or dispensing.

Criteria for an agency subordinate.

An agency subordinate authorized by the board to conduct an informal fact-finding proceeding may include board members and professional staff or other persons deemed knowledgeable by virtue of their training and experience in administrative proceedings involving the regulation and discipline of health professionals.

The executive director shall maintain a list of appropriately qualified persons to whom an informal fact-finding proceeding may be delegated.

The board may delegate to the executive director the selection of the agency subordinate who is deemed appropriately qualified to conduct a proceeding based on the qualifications of the subordinate and the type of case being heard.

General Provisions

Definitions.

In addition to words and terms defined in [*Sections 54.1-3300*](https://advance.lexis.com/api/document?collection=statutes-legislation&id=urn:contentItem:5T53-0MC0-004G-J1K5-00000-00&context=) and *54.1-3401 of the Code of Virginia*, the following words and terms when used in this chapter shall have the following meanings, unless the context clearly indicates otherwise:

~~"ACPE" means the Accreditation Council for Pharmacy Education.~~

"Acquisition" of an existing entity permitted, registered , or licensed by the board means (i) the purchase or transfer of all or substantially all of the assets of the entity or of any corporation that owns or controls the entity; (ii) the creation of a partnership by a sole proprietor or change in partnership composition; (iii) the acquiring of 50% or more of the outstanding shares of voting stock of a corporation owning the entity or of the parent corporation of a wholly owned subsidiary owning the entity, except that this shall not apply to any corporation the voting stock of which is actively traded on any securities exchange or in any over-the-counter market; or (iv) the merger of a corporation owning the entity  ~~,~~  or of the parent corporation of a wholly owned subsidiary owning the entity  ~~,~~  with another business or corporation.

"Actively reports" means reporting all dispensing errors and analyses of such errors to a patient safety organization as soon as practical or at least within 30 days of identifying the error.

"Alternate delivery site" means a location authorized in 18VAC110-20-275 to receive dispensed prescriptions on behalf of and for further delivery or administration to a patient.

"Analysis" means a review of the findings collected and documented on each dispensing error, assessment of the cause and any factors contributing to the dispensing error, and any recommendation for remedial action to improve pharmacy systems and workflow processes to prevent or reduce future errors.

"Authorized collector" means a narcotic treatment program, hospital  ~~,~~  or clinic with an on-site pharmacy, or pharmacy that is authorized by the U.S. Drug Enforcement Administration to receive drugs  ~~from an ultimate user, a person lawfully entitled to dispose of an ultimate user decedent's property, or a long-term care facility on behalf of an ultimate user who resides or has resided at that facility~~  for the purpose of destruction.

"Beyond-use date" means the date beyond which the integrity of a compounded, repackaged, or dispensed drug can no longer be assured and as such is deemed to be adulterated or misbranded as defined in [*Sections 54.1-3461*](https://advance.lexis.com/api/document?collection=statutes-legislation&id=urn:contentItem:5T53-0KT0-004G-J04R-00000-00&context=) and [*54.1-3462 of the Code of Virginia*](https://advance.lexis.com/api/document?collection=statutes-legislation&id=urn:contentItem:5T53-0KT0-004G-J04S-00000-00&context=).

"Board" means the Virginia Board of Pharmacy.

 ~~"CE" means continuing education as required for renewal of licensure by the Board of Pharmacy.~~

 ~~"CEU" means a continuing education unit awarded for credit as the equivalent of 10 contact hours.~~

"Chart order" means a lawful order for a drug or device entered on the chart or in a medical record of a patient by a prescriber or  ~~his~~  the prescriber's designated agent.

"Compliance packaging" means packaging for dispensed drugs that is comprised of a series of containers for solid oral dosage forms and designed to assist the user in administering or self-administering the drugs in accordance with directions for use.

 ~~"Contact hour" means the amount of credit awarded for 60 minutes of participation in and successful completion of a continuing education program.~~

"Correctional facility" means any prison, penitentiary, penal facility, jail, detention unit, or other facility in which persons are incarcerated by government officials.

"DEA" means the U.S. Drug Enforcement Administration.

"Dispensing error" means one or more of the following discovered after the final verification by the pharmacist, regardless of whether the patient received the drug:

Variation from the prescriber's prescription drug order, including  ~~but not limited to~~  :

Incorrect drug;

Incorrect drug strength;

Incorrect dosage form;

Incorrect patient; or

Inadequate or incorrect packaging, labeling, or directions.

Failure to exercise professional judgment in identifying and managing:

Known therapeutic duplication;

Known drug-disease contraindications;

Known drug-drug interactions;

Incorrect drug dosage or duration of drug treatment;

Known drug-allergy interactions;

A clinically significant, avoidable delay in therapy; or

Any other significant, actual, or potential problem with a patient's drug therapy.

Delivery of a drug to the incorrect patient.

Variation in bulk repackaging or filling of automated devices, including  ~~but not limited to~~  :

Incorrect drug;

Incorrect drug strength;

Incorrect dosage form; or

Inadequate or incorrect packaging or labeling.

"Drug donation site" means a permitted pharmacy that specifically registers with the board for the purpose of receiving or redispensing eligible donated prescription drugs pursuant to [*Section 54.1-3411.1 of the Code of Virginia*](https://advance.lexis.com/api/document?collection=statutes-legislation&id=urn:contentItem:5T53-0MK0-004G-J0DV-00000-00&context=).

"Electronic prescription" means a written prescription that is generated on an electronic application and is transmitted to a pharmacy as an electronic data file; Schedules II through V prescriptions shall be transmitted in accordance with 21 CFR Part 1300  ~~and is transmitted to a pharmacy as an electronic data file~~  .

"EMS" means emergency medical services.

"Expiration date" means that date placed on a drug package by the manufacturer or repacker beyond which the product may not be dispensed or used.

 ~~"Facsimile (FAX)~~  "Faxed prescription" means a written prescription or order  ~~which~~  that is transmitted by an electronic device over telephone lines  ~~which sends~~  that send the exact image to the receiver (pharmacy) in a hard copy form.

"FDA" means the U.S. Food and Drug Administration.

"Floor stock" means a supply of drugs that have been distributed for the purpose of general administration by a prescriber or other authorized person pursuant to a valid order of a prescriber.

 ~~"Foreign school of pharmacy" means a school outside the United States and its territories offering a course of study in basic sciences, pharmacology, and pharmacy of at least four years in duration resulting in a degree that qualifies a person to practice pharmacy in that country.~~

"Forgery" means a prescription that was falsely created, falsely signed, or altered.

 ~~"FPGEC certificate" means the certificate given by the Foreign Pharmacy Equivalency Committee of NABP that certifies that the holder of such certificate has passed the Foreign Pharmacy Equivalency Examination and a credential review of foreign training to establish educational equivalency to board approved schools of pharmacy, and has passed approved examinations establishing proficiency in English.~~

"Generic drug name" means the nonproprietary name listed in the United States Pharmacopeia-National Formulary (USP-NF) or in the United States Adopted Names (USAN) and the USP Dictionary of Drug Names.

"Hospital" or "nursing home" means those facilities as defined in Title 32.1 of the Code of Virginia or as defined in regulations by the Virginia Department of Health.

 ~~"Inactive license" means a license that is registered with the Commonwealth but does not entitle the licensee to practice, the holder of which is not required to submit documentation of CE necessary to hold an active license.~~

 "Initials" means the first letters of a person's name or other unique personal identifier.

"Long-term care facility" means a nursing home, retirement care, mental care, or other facility or institution that provides extended health care to resident patients.

"NABP" means the National Association of Boards of Pharmacy.

"Nuclear pharmacy" means a pharmacy providing radiopharmaceutical services.

"On duty" means that a pharmacist is on the premises at the address of the permitted pharmacy and is available as needed.

"On-hold prescription" means a valid prescription that is received and maintained at the pharmacy for initial dispensing on a future date.

"Patient safety organization" means an organization that has as its primary mission continuous quality improvement under the Patient Safety and Quality Improvement Act of 2005  ~~(Pub. L.~~  (P.L. 109-41) and is credentialed by the Agency for Healthcare Research and Quality.

"Permitted physician" means a physician who is licensed pursuant to [*Section 54.1-3304 of the Code of Virginia*](https://advance.lexis.com/api/document?collection=statutes-legislation&id=urn:contentItem:5T53-0KT0-004G-J020-00000-00&context=) to dispense drugs to persons to whom or for whom pharmacy services are not reasonably available.

"Perpetual inventory" means an ongoing system for recording quantities of drugs received, dispensed, or otherwise distributed by a pharmacy.

"Personal supervision" means the pharmacist must be physically present and render direct, personal control over the entire service being rendered or act being performed. Neither prior nor future instructions shall be sufficient nor shall supervision rendered by telephone, written instructions, or by any mechanical or electronic methods be sufficient.

"Pharmacy closing" means that the permitted pharmacy ceases pharmacy services or fails to provide for continuity of pharmacy services or lawful access to patient prescription records or other required patient records for the purpose of continued pharmacy services to patients.

 ~~"Pharmacy technician trainee" means a person who is currently enrolled in an approved pharmacy technician training program and is performing duties restricted to pharmacy technicians for the purpose of obtaining practical experience in accordance with Section 54.1-3321 D of the Code of Virginia.~~

"PIC" means the pharmacist-in-charge of a permitted pharmacy.

"Practice location" means any location in which a prescriber evaluates or treats a patient.

"Prescription department" means any contiguous or noncontiguous areas used for the compounding, dispensing , and storage of all  ~~Schedule~~  Schedules II through VI drugs and devices and any Schedule I investigational  ~~drugs~~  drug .

 ~~"PTCB" means the Pharmacy Technician Certification Board, co-founded by the American Pharmaceutical Association and the American Society of Health System Pharmacists, as the national organization for voluntary examination and certification of pharmacy technicians.~~

"Quality assurance plan" means a plan approved by the board for ongoing monitoring, measuring, evaluating, and, if necessary, improving the performance of a pharmacy function or system.

"Radiopharmaceutical" means any drug that exhibits spontaneous disintegration of unstable nuclei with the emission of nuclear particles or photons and includes any nonradioactive reagent kit or radionuclide generator that is intended to be used in the preparation of any such substance  ~~,~~  but does not include drugs such as carbon-containing compounds or potassium-containing salts that include trace quantities of naturally occurring radionuclides. The term also includes any biological product that is labeled with a radionuclide or intended solely to be labeled with a radionuclide.

"Repackaged drug" means any drug removed from the manufacturer's original package and placed in different packaging.

"Robotic pharmacy system" means a mechanical system controlled by a computer that performs operations or activities relative to the storage, packaging, compounding, labeling, dispensing, or distribution of medications  ~~,~~  and collects, controls, and maintains all transaction information.

"Safety closure container" means a container that meets the requirements of the federal Poison Prevention Packaging Act of 1970 [*(15 USC Sections 1471*](https://advance.lexis.com/api/document?collection=statutes-legislation&id=urn:contentItem:4YF7-GJN1-NRF4-42J4-00000-00&context=)-1476), that is, in testing such containers, that 85% of a test group of 200 children of ages 41-52 months are unable to open the container in a five-minute period and that 80% fail in another five minutes after a demonstration of how to open it and that 90% of a test group of 100 adults must be able to open and close the container.

"Satellite pharmacy" means a pharmacy that is noncontiguous to the centrally permitted pharmacy of a hospital but at the location designated on the pharmacy permit.

"Special packaging" means packaging that is designed or constructed to be significantly difficult for children younger than five years of age to open to obtain a toxic or harmful amount of the drug contained therein within a reasonable time and not difficult for normal adults to use properly  ~~,~~  but does not mean packaging that all such children cannot open or obtain a toxic or harmful amount within a reasonable time.

"Special use permit" means a permit issued to conduct a pharmacy of a special scope of service that varies in any way from the provisions of any board regulation.

"Storage temperature" means those specific directions stated in some monographs with respect to the temperatures at which pharmaceutical articles shall be stored, where it is considered that storage at a lower or higher temperature may produce undesirable results. The conditions are defined by the following terms:

"Cold" means any temperature not exceeding 8deg.C (46deg.F). A refrigerator is a cold place in which temperature is maintained thermostatically between 2deg. and 8deg.C (36deg. and 46deg.F). A freezer is a cold place in which the temperature is maintained thermostatically between -20deg. and -10deg.C (-4deg. and 14deg.F).

"Room temperature" means the temperature prevailing in a working area.

"Controlled room temperature" means a temperature maintained thermostatically that encompasses the usual and customary working environment of 20deg. to 25deg.C (68deg. to 77deg.F); that results in a mean kinetic temperature calculated to be not more than 25deg.C; and that allows for excursions between 15deg. and 30deg.C (59deg. and 86deg.F) that are experienced in pharmacies, hospitals, and warehouses.

"Warm" means any temperature between 30deg. and 40deg.C (86deg. and 104deg.F).

"Excessive heat" means any temperature above 40deg.C (104deg.F).

"Protection from freezing" means where, in addition to the risk of breakage of the container, freezing subjects a product to loss of strength or potency  ~~,~~  or to the destructive alteration of its characteristics, the container label bears an appropriate instruction to protect the product from freezing.

"Cool" means any temperature between 8deg. and 15deg.C (46deg. and 59deg.F).

"Terminally ill" means a patient with a terminal condition as defined in [*Section 54.1-2982 of the Code of Virginia*](https://advance.lexis.com/api/document?collection=statutes-legislation&id=urn:contentItem:5T53-0KS0-004G-J566-00000-00&context=).

"Ultimate user" means a person who has lawfully obtained, and who possesses, a controlled substance for his own use or for the use of a member of his household or for an animal owned by him or a member of his household.

"Unit dose container" means a container that is a single-unit container, as defined in United States Pharmacopeia-National Formulary, for articles intended for administration by other than the parenteral route as a single dose, direct from the container.

"Unit dose package" means a container that contains a particular dose ordered for a patient.

"Unit dose system" means a system in which multiple drugs in unit dose packaging are dispensed in a single container, such as a medication drawer or bin, labeled only with patient name and location. Directions for administration are not provided by the pharmacy on the drug packaging or container but are obtained by the person administering directly from a prescriber's order or medication administration record.

"USP-NF" means the United States Pharmacopeia-National Formulary.

"Well-closed container" means a container that protects the contents from extraneous solids and from loss of the drug under the ordinary or customary conditions of handling, shipment, storage, and distribution.

 ~~Criteria for delegation of informal fact-finding proceedings to an agency subordinate.~~  (Repealed.)

 ~~A. Decision to delegate. In accordance with~~ [*~~Section 54.1-2400 (10) of the Code of Virginia~~*](https://advance.lexis.com/api/document?collection=statutes-legislation&id=urn:contentItem:5T53-0M50-004G-J2CG-00000-00&context=)~~, the board may delegate an informal fact-finding proceeding to an agency subordinate upon determination that probable cause exists that a practitioner may be subject to a disciplinary action.~~

 ~~B. Criteria for delegation. Cases that may not be delegated to an agency subordinate, except as may be approved by a committee of the board, include those that involve:~~

 ~~1. Intentional or negligent conduct that causes or is likely to cause injury to a patient;~~

 ~~2. Drug diversion;~~

 ~~3. Impairment with an inability to practice with skill and safety;~~

 ~~4. Indiscriminate dispensing; and~~

 ~~5. Medication error in administration or dispensing.~~

 ~~C. Criteria for an agency subordinate.~~

 ~~1. An agency subordinate authorized by the board to conduct an informal fact-finding proceeding may include board members and professional staff or other persons deemed knowledgeable by virtue of their training and experience in administrative proceedings involving the regulation and discipline of health professionals.~~

 ~~2. The executive director shall maintain a list of appropriately qualified persons to whom an informal fact-finding proceeding may be delegated.~~

 ~~3. The board may delegate to the executive director the selection of the agency subordinate who is deemed appropriately qualified to conduct a proceeding based on the qualifications of the subordinate and the type of case being heard.~~

Fees.

Unless otherwise provided, fees listed in this section shall not be refundable.

 ~~B. Unless otherwise provided, any fees for taking required examinations shall be paid directly to the examination service as specified by the board.~~

Initial application fees.

 ~~1. Pharmacist license                    $180~~   ~~2. Pharmacy intern registration          $15~~   ~~3. Pharmacy technician                   $25~~   ~~registration~~   ~~4.~~  1. Pharmacy permit        $270  ~~5.~~  2. Permitted physician    $270 licensed to dispense drugs  ~~6.~~  3. Medical equipment      $180 supplier permit  ~~7. Humane society permit                 $20~~   ~~8.~~  4. Outsourcing facility $270 permit  ~~9.~~  5. Nonresident pharmacy $270 registration  ~~10.~~  6. Nonresident           $270 outsourcing facility registration  ~~11.~~  7. Controlled            $90 substances registrations  ~~12.~~  8. Innovative program    $250 approval. If the board determines that a technical consultant is required in order to make a decision on approval, any consultant fee, not to exceed the actual cost, shall also be paid by the applicant in addition to the application fee.  ~~13. Approval of a pharmacy               $150~~   ~~technician training program~~   ~~14. Approval of a continuing             $100~~   ~~education program~~   ~~15.~~  9. Approval of a         $50 repackaging training program

Annual renewal fees.

 ~~1. Pharmacist active license -          $90~~   ~~due no later than December 31~~   ~~2. Pharmacist inactive license -        $45~~   ~~due no later than December 31~~   ~~3. Pharmacy technician                  $25~~   ~~registration - due no later than~~   ~~December 31~~   ~~4.~~  1. Pharmacy permit -     $270 due no later than April 30  ~~5.~~  2. Physician permit to $270 practice pharmacy - due no later than February 28  ~~6.~~  3. Medical equipment     $180 supplier permit - due no later than February 28  ~~7. Humane society permit - due no       $20~~   ~~later than February 28~~   ~~8.~~  4. Outsourcing           $270 facility permit - due no later than April 30  ~~9.~~  5. Nonresident           $270 pharmacy registration - due no later than the date of initial registration  ~~10.~~  6. Nonresident          $270 outsourcing facility registration - due no later than the date of initial registration  ~~11.~~  7. Controlled           $90 substances registrations - due no later than February 28  ~~12.~~  8. Innovative program continued approval based on board order not to exceed $200 per approval period.  ~~13. Approval of a pharmacy              $75 every two years~~   ~~technician training program~~   ~~14. Approval of a repackaging~~        $30 every two years 9. Repackaging training program

Late fees. The following late fees shall be paid in addition to the current renewal fee to renew an expired  ~~license~~  permit or registration within one year of the expiration date  ~~or within two years in the case of a pharmacy technician training program~~  . In addition, engaging in activities requiring a  ~~license,~~  permit  ~~,~~  or registration after the expiration date of such  ~~license,~~  permit  ~~,~~  or registration shall be grounds for disciplinary action by the board.

 ~~1. Pharmacist license                    $30~~   ~~2. Pharmacist inactive license           $15~~   ~~3. Pharmacy technician                   $10~~   ~~registration~~   ~~4.~~  1. Pharmacy permit        $90  ~~5.~~  2. Physician permit to    $90 practice pharmacy  ~~6.~~  3. Medical equipment      $60 supplier permit  ~~7. Humane society permit                 $5~~   ~~8.~~  4. Outsourcing facility $90 permit  ~~9.~~  5. Nonresident pharmacy $90 registration  ~~10.~~  6. Nonresident           $90 outsourcing facility registration  ~~11.~~  7. Controlled            $30 substances registrations  ~~12. Approval of a pharmacy               $15~~   ~~technician training program~~   ~~13. Approval of a repackaging~~         $10 8. Repackaging training program

Reinstatement fees.

Any person or entity attempting to renew a  ~~license,~~  permit  ~~,~~  or registration more than one year after the expiration date  ~~, or more than two years after the expiration date in the case of a pharmacy technician training program,~~  shall submit an application for reinstatement with any required fees. Reinstatement is at the discretion of the board and, except for reinstatement following  ~~license~~  revocation or suspension, may be granted by the executive director of the board upon completion of an application and payment of any required fees.

 ~~1. Pharmacist license                $210~~   ~~2. Pharmacist license after          $500~~   ~~revocation or suspension~~   ~~3. Pharmacy technician               $35~~   ~~registration~~   ~~4. Pharmacy technician               $125~~   ~~registration after revocation~~   ~~or suspension~~

Facilities or entities that cease operation and wish to resume shall not be eligible for reinstatement but shall apply for a new permit or registration. Facilities or entities that failed to renew and continued to operate for more than one renewal cycle shall pay the current and all back renewal fees for the years in which they were operating plus the following reinstatement fees:

a. Pharmacy permit                          $240 b. Physician permit to practice pharmacy    $240 c. Medical equipment supplier permit        $210  ~~d. Humane society permit                $30~~   ~~e.~~  d. Outsourcing           $240 facility permit  ~~f.~~  e. Nonresident           $115 pharmacy registration  ~~g.~~  f. Nonresident           $240 outsourcing facility registration  ~~h.~~  g. Controlled            $180 substances registration  ~~i. Approval of a pharmacy               $75~~   ~~technician training program~~   ~~j. Approval of a repackaging~~         $50 h. Repackaging training program

Application for change or inspection fees for facilities or other entities.

1. Change of pharmacist-in-charge          $50 2. Change of ownership for any facility    $50 3. Inspection for remodeling or change     $150 of location for any facility 4. Reinspection of any facility            $150 5. Board-required inspection for a         $150 robotic pharmacy system 6. Board-required inspection of an         $150 innovative program location 7. Change of pharmacist responsible for    $25 an approved innovative program

Miscellaneous fees.

 ~~1. Duplicate wall certificate         $25~~   ~~2.~~  1. Returned check      $35  ~~3.~~  2. Duplicate           $10  ~~license~~  permit or registration  ~~4.~~  3. Verification of     $25  ~~licensure~~  permit or registration

 ~~Public address.~~  (Repealed.)

 ~~An individual licensed by or registered with the board who has provided the board with a public address that is different from the address of record shall notify the board in writing if there is a change in the address.~~

Unprofessional conduct.

The following practices shall constitute unprofessional conduct within the meaning of [*Section 54.1-3316 of the Code of Virginia*](https://advance.lexis.com/api/document?collection=statutes-legislation&id=urn:contentItem:5T53-0M50-004G-J2CT-00000-00&context=):

Failing to comply with provisions of [*Section 32.1-127.1:03 of the Code of Virginia*](https://advance.lexis.com/api/document?collection=statutes-legislation&id=urn:contentItem:5T53-0M80-004G-J4RS-00000-00&context=) related to the confidentiality and disclosure of patient records or related to provision of patient records to another practitioner or to the patient or  ~~his~~  the patient's personal representative;

Willfully or negligently breaching the confidentiality of a patient unless otherwise required or permitted by applicable law;

Failing to maintain confidentiality of information received from the ***Prescription Monitoring*** Program, obtaining such information for reasons other than to assist in determining the validity of a prescription to be filled, or misusing information received from the program;

 ~~4. Engaging in disruptive or abusive behavior in a pharmacy or other health care setting that interferes with patient care or could reasonably be expected to adversely impact the quality of care rendered to a patient;~~

 ~~5. Engaging or attempting to engage in a relationship with a patient that constitutes a professional boundary violation in which the practitioner uses his professional position to take advantage of the vulnerability of a patient or his family, including but not limited to sexual misconduct with a patient or a member of his family or other conduct that results or could result in personal gain at the expense of the patient;~~

Failing to maintain adequate safeguards against diversion of controlled substances;

Failing to appropriately respond to a known dispensing error in a manner that protects the health and safety of the patient;

Delegating a task within the practice of pharmacy to a person who is not adequately trained to perform such a task;

Failing by the PIC to ensure that pharmacy interns and pharmacy technicians working in the pharmacy are registered and that such registration is current;  ~~or~~

 ~~10. Failing to exercise professional judgment in determining whether a prescription meets requirements of law before dispensing~~

Obtaining money or property of a patient or client by fraud or misrepresentation;

Providing false information or failing to cooperate with an employee of the Department of Health Professions in the conduct on an investigation or inspection;

Violating any provision of this chapter or Chapter 33 (Section 54.1-3300 et seq.) or 34 (Section 54.1-3400 et seq.) of Title 54.1 of the Code of Virginia;

Performing any act likely to deceive, defraud, or harm the public; or

Having a restriction of a license, permit, or registration to practice in another jurisdiction in the United States .

 ~~Part II~~

 ~~Licensure Requirements for Pharmacists~~  (Repealed)

 ~~Requirements for pharmacy practical experience.~~  (Repealed.)

 ~~A. Each applicant for licensure as a pharmacist shall have gained practical experience in the practice of pharmacy as set forth in this section and 18VAC110-20-40.~~

 ~~B. An applicant for licensure as a pharmacist shall attain a minimum of 1,500 hours of practical experience.~~

 ~~C. Practical experience that is gained within an ACPE-accredited school of pharmacy, that conforms to the current ACPE standards, and that allows the student to gain at least 1,500 hours of practical experience, shall meet the board's practical experience requirements for licensure as a pharmacist.~~

 ~~D. All practical experience credit gained outside of an ACPE-accredited school of pharmacy program shall only be gained after successful completion of the equivalent of at least two semesters in an ACPE-accredited school of pharmacy. Credit shall not be given for more than 50 hours in one week and not less than an average of 20 hours per week averaged over a month. The board may grant an exception to the minimum number of hours for good cause shown.~~

 ~~E. In accordance with~~ [*~~Section 54.1-3312 of the Code of Virginia~~*](https://advance.lexis.com/api/document?collection=statutes-legislation&id=urn:contentItem:5T53-0M60-004G-J3HK-00000-00&context=)~~, all practical experience required by this section shall be gained within the United States.~~

 ~~Procedure for gaining practical experience.~~  (Repealed.)

 ~~A. Each person desiring to gain practical pharmacy experience in Virginia shall first register with the board as a pharmacy intern on a form provided by the board prior to becoming so engaged as a pharmacy intern. This requirement shall apply to any person gaining practical experience within the Commonwealth whether for licensure in Virginia or in another state.~~

 ~~B. In order to be eligible to register as a pharmacy intern, an applicant shall meet at least one of the following criteria:~~

 ~~1. The applicant shall be enrolled in and have started course work in a professional degree program of a board-approved school of pharmacy. Such registration is only valid while the student is enrolled in the school of pharmacy and is satisfactorily progressing toward meeting the requirements for licensure as a pharmacist. An expiration date shall be assigned to the registration to cover the estimated time period for the student to complete the school program and pass the required examinations. If the student is no longer enrolled in the school program, takes a voluntary break from the program, or is otherwise not actively participating in the school program, except for regularly scheduled school breaks, the registration is no longer valid and shall be returned to the board immediately;~~

 ~~2. The applicant is a graduate of a board-approved school of pharmacy or a graduate of a foreign school of pharmacy, has established educational equivalency and proficiency in English by obtaining the FPGEC certificate, and desires to gain required practical experience required for licensure as a pharmacist. Such applicant shall provide documentation on a board-approved form of current employment or an employment start date within 90 days in a pharmacy in Virginia with approval by the supervising pharmacist. An expiration date shall be assigned to cover the estimated time period needed to obtain the required practical experience hours and take the required examinations to become licensed as a pharmacist;~~

 ~~3. The applicant has already gained the required practical experience, but is an otherwise qualified applicant awaiting examination for licensure. A three-month expiration date shall be assigned to allow the applicant time to take required examinations; or~~

 ~~4. The applicant is an applicant for reactivation or reinstatement of a previously issued pharmacist license and is meeting board requirements for relicensure. An expiration date shall be assigned to reasonably cover the period of time necessary to meet the board requirements.~~

 ~~C. For documented, good cause shown, the executive director of the board may extend the expiration date of the intern registration upon submission of an application form approved by the board and payment of the initial application fee.~~

 ~~D. A pharmacy intern shall be supervised by a pharmacist who holds a current, unrestricted license and assumes full responsibility for the training, supervision and conduct of the intern.~~

 ~~E. The intern registration of a pharmacy student shall be valid only while the student is enrolled in a school of pharmacy. The registration card issued by the board shall be returned to the board upon failure to be enrolled.~~

 ~~F. Practical experience gained within any other state must be registered with and certified by the board of that state in order to be accepted or certified by this board. In the event that a state relies on the pharmacy school to certify the hours of experience, an affidavit from the pharmacy school certifying the hours of experience gained in the United States may be accepted in lieu of board certification.~~

 ~~G. All practical experience of the pharmacy intern shall be evidenced by an affidavit approved by the board, which shall be filed prior to or with the application for examination for licensure.~~

 ~~H. An applicant for licensure by endorsement may provide verification acceptable to the board of practical experience hours worked as a pharmacist in another state within the United States in lieu of prelicensure intern hours in order to meet the practical experience requirement.~~

 ~~I. A pharmacy intern shall notify the board in writing of any change in address of record within 14 days of such change.~~

 ~~Curriculum and approved schools of pharmacy.~~  (Repealed.)

 ~~A. The following minimum educational requirements for the specified periods shall be recognized by the board for the purpose of licensure.~~

 ~~1. On and after June 1, 1936, but before June 1, 1964, the applicant for licensure shall have been graduated from a four-year course of study with a Bachelor of Science degree in pharmacy awarded.~~

 ~~2. On and after June 1, 1964, the applicant for licensure shall have been graduated from at least a five-year course of study with a Bachelor of Science degree in pharmacy or a Doctorate of Pharmacy degree awarded.~~

 ~~B. In order to be licensed as a pharmacist within this Commonwealth, the applicant shall have been granted the first professional degree from a program of a school of pharmacy which meets the requirements of~~ [*~~Section 54.1-3312 of the Code of Virginia~~*](https://advance.lexis.com/api/document?collection=statutes-legislation&id=urn:contentItem:5T53-0M60-004G-J3HK-00000-00&context=)~~.~~

 ~~Content of the examination and grades required; limitation on admittance to examination.~~  (Repealed.)

 ~~A. Prior to admission to any examination required for licensure, the applicant shall have met all other requirements to include education and practical experience requirements, but in no case shall the applicant be admitted if grounds exist to deny licensure under~~ [*~~Section 54.1-3316 of the Code of Virginia~~*](https://advance.lexis.com/api/document?collection=statutes-legislation&id=urn:contentItem:5T53-0M50-004G-J2CT-00000-00&context=)~~.~~

 ~~B. The applicant shall achieve a passing score as determined by the board on the licensure examination which is approved by the board and which shall consist of an integrated examination of pharmacy practice, pharmacology, pharmacy mathematics, and such other subjects as are necessary to assure that the candidate possesses the necessary knowledge and skills to practice pharmacy.~~

 ~~C. When an applicant for licensure by examination fails to meet the passing requirements of the board-approved integrated pharmacy examination on three occasions, he shall not be readmitted to the examination until he has completed an additional 1,000 hours of practical experience as a pharmacy intern as set forth in 18VAC110-20-40.~~

 ~~D. The applicant shall also achieve a passing score as determined by the board on an examination that tests the candidate's knowledge of federal and state laws related to pharmacy practice.~~

 ~~E. When an applicant fails to pass the law examination, he shall not be allowed to retake it for a period of 30 days.~~

 ~~F. If an applicant requests a testing accommodation for either examination based on a physical or mental impairment that substantially limits one or more major life activities, subject to the Americans with Disabilities Act, the board may approve a reasonable accommodation that does not compromise the security or integrity of the examination.~~

 ~~1. Supporting documentation shall be provided by the applicant to include the following to be considered for review:~~

 ~~a. A letter of request from the candidate that specifies the testing accommodation requested;~~

 ~~b. A written report of an evaluation (educational, psychological, or physical) within the preceding two years from a qualified professional that states a diagnosis of the disability, describes the disability, recommends specific accommodations, and provides justification that the accommodation is appropriate and necessary for the diagnosed disability. If the comprehensive evaluation was done more than two years ago and the condition is one that is not subject to change, the original evaluation report may be submitted along with a current letter from the qualified professional stating that there has been no change in the condition since the time of the evaluation; and~~

 ~~c. A written statement from the appropriate person at the applicant's school of pharmacy that describes any testing accommodations made while the student was enrolled, if applicable.~~

 ~~2. The applicant will be notified in writing of the decision. If the request for accommodation is granted, the approval information will be forwarded to the examination contractor and the form of the accommodation will be coordinated with the contractor.~~

 ~~Requirements for foreign-trained applicants.~~  (Repealed.)

 ~~A. Applicants for licensure who were trained in foreign schools of pharmacy shall obtain the FPGEC certificate prior to being allowed to register as a pharmacy intern and gain required practical experience in Virginia.~~

 ~~B. After obtaining the FPGEC certificate, the applicant may apply for a pharmacy intern registration and shall fulfill the requirements for practical experience set forth in 18VAC110-20-30 and 18VAC110-20-40 before being admitted to examinations required by 18VAC110-20-60.~~

 ~~C. Applicants for licensure who were trained in foreign schools of pharmacy shall also complete and achieve passing scores on the examinations set forth in 18VAC110-20-60 before being licensed as a pharmacist.~~

 ~~Registration for voluntary practice by out-of-state licensees.~~  (Repealed.)

 ~~Any pharmacist who seeks registration to practice on a voluntary basis pursuant to subdivision 12 of~~ [*~~Section 54.1-3301 of the Code of Virginia~~*](https://advance.lexis.com/api/document?collection=statutes-legislation&id=urn:contentItem:5T53-0KT0-004G-J01W-00000-00&context=) ~~under the auspices of a publicly supported, all volunteer, nonprofit organization that sponsors the provision of health care to populations of underserved people shall:~~

 ~~1. File a complete application for registration on a form provided by the board at least five business days prior to engaging in such practice;~~

 ~~2. Provide a complete list of each state in which he has held a pharmacist license and a copy of any current license;~~

 ~~3. Provide the name of the nonprofit organization and the dates and location of the voluntary provision of services;~~

 ~~4. Pay a registration fee of $10; and~~

 ~~5. Provide a notarized statement from a representative of the nonprofit organization attesting to its compliance with the provisions of subdivision 12 of~~ [*~~Section 54.1-3301 of the Code of Virginia~~*](https://advance.lexis.com/api/document?collection=statutes-legislation&id=urn:contentItem:5T53-0KT0-004G-J01W-00000-00&context=)~~.~~

 ~~Renewal and reinstatement of license.~~  (Repealed.)

 ~~A. Pharmacist licenses expire on December 31 and shall be renewed annually prior to that date by the submission of a renewal fee, renewal form, and statement of compliance with continuing education requirements.~~

 ~~B. A pharmacist newly licensed on or after October 1 shall not be required to renew that license until December 31 of the following year.~~

 ~~C. A pharmacist who fails to renew his license by the expiration date may renew his license at any time within one year of its expiration by submission of the renewal fee and late fee, renewal form, and statement of compliance with continuing education requirements.~~

 ~~D. A pharmacist who fails to renew his license for more than one year following expiration and who wishes to reinstate such license shall submit an application for reinstatement, pay the current renewal fee and a reinstatement fee, and submit documentation showing compliance with continuing education requirements. Reinstatement is at the discretion of the board and may be granted by the executive director of the board provided no grounds exist to deny said reinstatement.~~

 ~~E. A pharmacist who has been registered as inactive for more than one year must apply for reinstatement, submit documentation showing compliance with continuing education requirements, and pay the current year active renewal fee in order to resume active licensure.~~

 ~~F. In order to reactivate or reinstate a license to active status, a pharmacist who holds an inactive license, who has allowed his license to lapse, or who has had his license suspended or revoked must submit evidence of completion of CEU's or hours equal to the requirements for the number of years in which his license has not been active, not to exceed a total of 60 hours of CE.~~

 ~~G. A pharmacist whose license has been lapsed, in inactive status, or suspended or revoked for more than five years shall, as a condition of reinstatement in addition to 60 hours CE, take and receive a passing score on the board-approved law examination and furnish acceptable documentation of one of the following:~~

 ~~1. Active pharmacy practice within the past five years as a properly licensed pharmacist in another state; or~~

 ~~2. Practical experience as a pharmacy intern registered with the board of at least 160 hours within six months immediately prior to being reinstated.~~

 ~~H. The practice of pharmacy without a current, active pharmacist license is unlawful and shall constitute grounds for disciplinary action by the board.~~

 ~~I. It shall be the duty and responsibility of each licensee to inform the board of his current address. A licensee shall notify the board within 14 days in writing or electronically of any change of an address of record. Properly updating address of record directly through the board's web-based application or other approved means shall constitute lawful notification. All notices required by law or by these rules and regulations are deemed to be legally given when mailed to the address of record and shall not relieve the licensee of the obligation to comply.~~

 ~~Requirements for continuing education.~~  (Repealed.)

 ~~A. A pharmacist shall be required to have completed a minimum of 1.5 CEUs or 15 contact hours of continuing pharmacy education in an approved program for each annual renewal of licensure. CEUs or hours in excess of the number required for renewal may not be transferred or credited to another year.~~

 ~~B. A pharmacy education program approved for continuing pharmacy education is:~~

 ~~1. One that is approved by the Accreditation Council for Pharmacy Education (ACPE);~~

 ~~2. One that is approved as a Category I Continuing Medical Education (CME) course, the primary focus of which is pharmacy, pharmacology, or drug therapy; or~~

 ~~3. One that is approved by the board in accordance with the provisions of 18VAC110-20-100.~~

 ~~C. The board may grant an extension pursuant to Section 54.1-3314.1 E of the Code of Virginia. Any subsequent extension shall be granted only for good cause shown.~~

 ~~D. Up to two hours of the 15 hours required for annual renewal may be satisfied through delivery of pharmacy services as a pharmacist, without compensation, to low-income individuals receiving health services through a local health department or a free clinic organized in whole or primarily for the delivery of those services. One hour of continuing education may be credited for three hours of providing such volunteer services, as documented by the health department or free clinic.~~

 ~~E. Pharmacists are required to attest to compliance with CE requirements in a manner approved by the board at the time of their annual license renewal. Following each renewal period, the board may conduct an audit of the immediate past two years' CE documents to verify compliance with requirements. Pharmacists are required to maintain, for two years following renewal, the original certificates documenting successful completion of CE, showing date and title of the CE program or activity, the number of CEUs or contact hours awarded, and a certifying signature or other certification of the approved provider. Pharmacists selected for audit must provide these original documents to the board by the deadline date specified by the board in the audit notice.~~

 ~~Approval of continuing education programs.~~  (Repealed.)

 ~~A. The board will approve without application or further review any program offered by an ACPE-approved provider and will accept for credit certificates bearing the official ACPE logo and program number.~~

 ~~B. The board may approve an individual CE program under the following provisions:~~

 ~~1. An approved individual program is a course, activity, or lecture which includes subject matter related to the competency of the practice of pharmacy and which has been approved for CE credit by the board.~~

 ~~2. In order to receive approval for an individual program, the sponsor or provider must apply prior to the program offering on a form provided by the board. The information which must be provided shall include but not be limited to: name of provider, location, date and time of program, charges to participants, description of program content and objectives, credentials of speaker or author, method of delivery, evaluation procedure, evidence of a post assessment, credits requested, mechanism for recordkeeping, and any such information as the board deems necessary to assure quality and compliance.~~

 ~~3. The sponsor applying for board approval of an individual program must pay a fee as required in 18VAC110-20-20 C 12.~~

 ~~4. The board shall notify the provider or sponsor within 60 days following the receipt of a completed application of approval or disapproval of a program and the number of credits which may be awarded. The board shall also assign an expiration date for approval of the program not to exceed two years from the date of approval.~~

 ~~5. The provider of an approved program shall provide to each participant who completes the required hours and passes the post test a certification with the name of the provider, name of the participant, description of course and method of delivery, number of hours credited, date of completion, and program identification number.~~

 ~~6. The provider of an approved program shall maintain all records on that program, its participants, and hours awarded for a period of five years and shall make those records available to the board upon request.~~

 ~~7. The board shall periodically review and monitor programs. The provider of a CE program shall waive registration fees for a representative of the board for that purpose.~~

 ~~8. Any changes in the information previously provided about an approved program or provider must be submitted or the board may withdraw its approval. If a provider wants to give a live program more than once, all program dates must either be submitted on the original application or provided to the board in subsequent correspondence at least five days prior to giving the program.~~

 ~~Part III~~

 ~~Requirements for Pharmacy Technician Registration~~  (Repealed)

 ~~Application for registration as a pharmacy technician.~~  (Repealed.)

 ~~A. Any person wishing to apply for registration as a pharmacy technician shall submit the application fee and an application on a form approved by the board.~~

 ~~B. In order to be registered as a pharmacy technician, an applicant shall provide evidence of the following:~~

 ~~1. Satisfactory completion of an approved training program; and~~

 ~~2. A passing score on a board-approved examination.~~

 ~~C. In lieu of the requirements of subsection B of this section, an applicant may provide evidence of current PTCB certification.~~

 ~~D. A pharmacy technician trainee may perform tasks restricted to pharmacy technicians for no more than nine months without becoming registered as a pharmacy technician.~~

 ~~Criteria for approval for training programs.~~  (Repealed.)

 ~~A. Any person wishing to apply for approval of a pharmacy technician training program shall submit the application fee and an application on a form approved by the board and meet the criteria established in this section.~~

 ~~B. The curriculum of a training program for pharmacy technicians shall include instruction in applicable, current laws and regulations and in the tasks that may be performed by a pharmacy technician to include the following or any other task restricted to pharmacy technicians in regulation:~~

 ~~1. The entry of prescription information and drug history into a data system or other recordkeeping system;~~

 ~~2. The preparation of prescription labels or patient information;~~

 ~~3. The removal of the drug to be dispensed from inventory;~~

 ~~4. The counting, measuring, or compounding of the drug to be dispensed;~~

 ~~5. The packaging and labeling of the drug to be dispensed and the repackaging thereof;~~

 ~~6. The stocking or loading of automated dispensing devices or other devices used in the dispensing process; and~~

 ~~7. The acceptance of refill authorization from a prescriber or his authorized agent provided there is no change to the original prescription.~~

 ~~C. Each program shall have a program director who shall be either (i) a pharmacist with a current license in any jurisdiction and who is not currently suspended or revoked in any jurisdiction in the United States; (ii) a pharmacy technician with at least one year of experience performing technician tasks who holds a current registration in Virginia or current PTCB certification and who is not currently suspended or revoked as a pharmacy technician in any jurisdiction; or (iii) other person approved and deemed qualified by the board to be a program director.~~

 ~~D. Instructors for the core components listed in subsection B of this section shall meet the requirements for the program director listed in subsection C of this section. The program director may serve as an instructor.~~

 ~~E. The length of the program shall be sufficient to prepare a program participant to sit for the board-approved examination and demonstrate entry-level competency.~~

 ~~F. The program shall maintain records of program participants either on-site or at another location where the records are readily retrievable upon request for inspection. A program shall provide a certificate of completion to participants who successfully complete the program and provide verification of completion of the program for a participant upon request by the board. Records shall be maintained for two years from date of completion or termination of program.~~

 ~~G. The program shall report within 14 days any substantive change in the program to include a change in program name, program director, instructors, name of institution or business if applicable, address, program content, length of program, or location of records.~~

 ~~H. A pharmacy technician training program approval expires after two years, after which the program may apply for renewal. For continued approval, the program shall submit the renewal application, renewal fee, and a self-evaluation report on a form provided by the board at the time of renewal notification. Renewal of a program's approval is at the discretion of the board, and the decision to renew shall be based on documentation of continued compliance with the criteria set forth in this section.~~

 ~~Examination.~~  (Repealed.)

 ~~A. The board shall approve one or more examinations to test entry-level competency for pharmacy technicians. In order to be approved, a competency examination shall be developed in accordance with and meet the recognized acceptable test measurement standards of the Joint Technical Standards for Education and Psychological Testing (American Psychological Association, current edition), and shall be administered by an independent third party.~~

 ~~B. The board may contract with an examination service for the development and administration of a competency examination.~~

 ~~C. The board shall determine the minimum passing standard on the competency examination.~~

 ~~D. Any requests for testing accommodations under the Americans with Disabilities Act shall be in accordance with the provisions of 18VAC110-20-60 F.~~

 ~~Address of record; maintenance of certificate.~~  (Repealed.)

 ~~A. It shall be the duty and responsibility of each pharmacy technician to inform the board of his current address. A pharmacy technician shall notify the board in writing or electronically of any change of an address of record within 14 days. Properly updating address of record directly through the board's web-based application or other approved means shall constitute lawful notification. All notices required by law or by these rules and regulations are deemed to be legally given when mailed to the address of record and shall not relieve the registrant of the obligation to comply.~~

 ~~B. A pharmacy technician shall maintain his current registration certificate at his principal place of practice available for inspection upon request. A pharmacy technician who does not have a principal place of practice may maintain it at any pharmacy in which he practices or his address of record.~~

 ~~Renewal and reinstatement of registration.~~  (Repealed.)

 ~~A. Pharmacy technician registrations expire on December 31 and shall be renewed annually prior to that date by the submission of a renewal fee and renewal form. A pharmacy technician newly registered on or after July 1 shall not be required to renew that registration until December 31 of the following year. Failure to receive the application for renewal shall not relieve the pharmacy technician of the responsibility for renewing the registration by the expiration date.~~

 ~~B. A pharmacy technician who fails to renew his registration by the expiration date may renew his registration at any time within one year of its expiration by submission of the renewal fee and late fee, renewal form, and attestation of having obtained required continuing education.~~

 ~~C. A pharmacy technician who fails to renew his registration for more than one year following expiration and who wishes to reinstate such registration shall submit an application for reinstatement, pay the current renewal fee and a reinstatement fee, and submit documentation showing compliance with continuing education requirements. Reinstatement is at the discretion of the board and may be granted by the executive director of the board provided no grounds exist to deny said reinstatement. Conducting tasks associated with a pharmacy technician with a lapsed registration shall be illegal and may subject the registrant to disciplinary action by the board.~~

 ~~D. A person who fails to reinstate a pharmacy technician registration within five years of expiration, shall not be eligible for reinstatement and shall repeat an approved training program and repeat and pass the examination, or hold current PTCB certification, before applying to be reregistered.~~

 ~~Requirements for continued competency.~~  (Repealed.)

 ~~A. A pharmacy technician shall be required to have completed a minimum of 0.5 CEUs or five contact hours of approved continuing education for each annual renewal of registration. Hours in excess of the number required for renewal may not be transferred or credited to another year.~~

 ~~B. An approved continuing education program shall meet the requirements as set forth in subsection B of 18VAC110-20-90 or subsection B of 18VAC110-20-100.~~

 ~~C. Upon written request of a pharmacy technician, the board may grant an extension of up to one year in order for the pharmacy technician to fulfill the continuing education requirements for the period of time in question. The granting of an extension shall not relieve the pharmacy technician from complying with current year requirements. Any subsequent extension shall be granted for good cause shown.~~

 ~~D. Up to one hour of the five hours required for annual renewal may be satisfied through delivery of pharmacy services as a pharmacy technician, without compensation, to low-income individuals receiving health services through a local health department or a free clinic organized in whole or primarily for the delivery of those services. One hour of continuing education may be credited for three hours of providing such volunteer services, as documented by the health department or free clinic.~~

 ~~E. Original certificates showing successful completion of continuing education programs shall be maintained by the pharmacy technician for a period of two years following the renewal of his registration. The pharmacy technician shall provide such original certificates to the board upon request in a manner to be determined by the board.~~

Pharmacies

Pharmacy permits generally.

A pharmacy permit shall not be issued to a pharmacist to be simultaneously in charge of more than two pharmacies.

Except in an emergency, a permit holder shall not require a pharmacist to work longer than 12 continuous hours in any work day and shall allow at least six hours of off-time between consecutive shifts. A pharmacist working longer than six continuous hours shall be allowed to take a 30-minute break.

The  ~~pharmacist-in-charge (PIC)~~  PIC or the pharmacist on duty shall control all aspects of the practice of pharmacy. Any decision overriding such control of the PIC or other pharmacist on duty shall be deemed the practice of pharmacy and may be grounds for disciplinary action against the pharmacy permit.

A pharmacist shall not be eligible to serve as PIC until after having obtained a minimum of two years of experience practicing as a pharmacist in Virginia or another jurisdiction in the United States. The board may grant an exception to the minimum number of years of experience for good cause shown.

When the PIC ceases practice at a pharmacy or no longer wishes to be designated as PIC, he shall immediately return the pharmacy permit to the board indicating the effective date on which he ceased to be the PIC.

Although not required by law or regulation, an outgoing PIC shall have the opportunity to take a complete and accurate inventory of all  ~~Schedule~~  Schedules II through V controlled substances on hand on the date he ceases to be the PIC, unless the owner submits written notice to the board showing good cause as to why this opportunity should not be allowed.

A PIC who is absent from practice for more than 30 consecutive days shall be deemed to no longer be the PIC. Pharmacists-in-charge having knowledge of upcoming absences for longer than 30 days shall be responsible for notifying the board and returning the permit. For unanticipated absences by the PIC, which exceed 15 days with no known return date within the next 15 days, the owner shall immediately notify the board and shall obtain a new PIC.

An application for a permit designating the new PIC shall be filed with the required fee within 14 days of the original date of resignation or termination of the PIC on a form provided by the board. It shall be unlawful for a pharmacy to operate without a new permit past the 14-day deadline unless the board receives a request for an extension prior to the deadline. The executive director for the board may grant an extension for up to an additional 14 days for good cause shown.

Only one pharmacy permit shall be issued to conduct a pharmacy occupying the same designated prescription department space. A pharmacy shall not engage in any other activity requiring a license or permit from the board, such as manufacturing or wholesale-distributing, out of the same designated prescription department space.

Before any permit is issued, the applicant shall attest to compliance with all federal, state , and local laws and ordinances. A pharmacy permit shall not be issued to any person to operate from a private dwelling or residence after September 2, 2009.

Supervision of pharmacy technicians.

A pharmacist shall determine the number of pharmacy interns, pharmacy technicians, and pharmacy technician trainees he can safely and competently supervise at one time; however, no pharmacist shall supervise more than four persons performing the duties of a pharmacy technician at one time.

In addition to the acts restricted to a pharmacist in Section 54.1-3320 A of the Code of Virginia, a pharmacist shall provide personal supervision of compounding of extemporaneous preparations by pharmacy technicians.

New pharmacies, acquisitions , and changes to existing pharmacies.

Any person wishing to open a new pharmacy, engage in the acquisition of an existing pharmacy, change the location of an existing pharmacy, move the location or make structural changes to an existing prescription department, or make changes to a previously approved security system shall file an application with the board.

In the acquisition of an existing pharmacy, if prescription records are to be accessible to anyone for purposes other than for continuity of pharmacy services at substantially the same level offered by the previous owner or for the necessary transfer of prescription records, the owner of the pharmacy acquiring the records shall disclose such information in writing to each patient 14 days prior to the acquisition. Such release of prescription records shall be allowed only to the extent authorized by [*Section 32.1-127.1:03 of the Code of Virginia*](https://advance.lexis.com/api/document?collection=statutes-legislation&id=urn:contentItem:5T53-0M80-004G-J4RS-00000-00&context=).

Although a closing inventory is not required, a complete and accurate inventory shall be taken of all Schedules II through V controlled substances on hand in accordance with [*Section 54.1-3404 of the Code of Virginia*](https://advance.lexis.com/api/document?collection=statutes-legislation&id=urn:contentItem:5T53-0KT0-004G-J02N-00000-00&context=) on the date the pharmacist first engages in business under the new ownership. Inventories associated with any change in PIC shall also be performed in accordance with 18VAC110-20-110.

The proposed location or structural changes shall be inspected by an authorized agent of the board prior to issuance of a permit.

Pharmacy permit applications  ~~which~~  that indicate a requested inspection date  ~~,~~  or requests  ~~which~~  that are received after the application is filed  ~~,~~  shall be honored provided a 14-day notice is allowed prior to the requested inspection date.

Requested inspection dates  ~~which~~  that do not allow a 14-day notice to the board may be adjusted by the board to provide 14 days for the scheduling of the inspection.

At the time of the inspection, the dispensing area shall comply with 18VAC110-20-150, 18VAC110-20-160, 18VAC110-20-170, 18VAC110-20-180, and 18VAC110-20-190.

If an applicant substantially fails to meet the requirements for issuance of a permit and a reinspection is required  ~~,~~  or if the applicant is not ready for the inspection on the established date and fails to notify the inspector or the board at least 24 hours prior to the inspection, the applicant shall pay a reinspection fee as specified in 18VAC110-20-20 prior to a reinspection being conducted.

Drugs shall not be stocked within the proposed pharmacy or moved to a new location until approval is granted by the inspector or board staff.

Once the permit is issued, prescription drugs may not be stocked earlier than two weeks prior to the designated opening date. Once prescription drugs have been placed in the pharmacy, a pharmacist shall be present on a daily basis to ensure the safety and integrity of the drugs. If there is a change in the designated opening date, the pharmacy shall notify the board office, and a pharmacist shall continue to be on site on a daily basis.

If the pharmacy is not operational within 90 days from the date the permit is issued, the board shall rescind the pharmacy permit unless an extension is granted for good cause shown.

Physical standards for all pharmacies.

The prescription department shall not be less than 240 square feet. The patient waiting area or the area used for counseling, devices, cosmetics, and proprietary medicines shall not be considered a part of the minimum 240 square feet. The total area shall be consistent with the size and scope of the services provided.

Access to stock rooms, rest rooms, and other areas other than an office that is exclusively used by the pharmacist shall not be through the prescription department. A rest room in the prescription department, used exclusively by pharmacists and personnel assisting with dispensing functions, may be allowed provided there is another rest room outside the prescription department available to other employees and the public. This subsection shall not apply to prescription departments in existence prior to November 4, 1993.

The pharmacy shall be constructed of permanent and secure materials. Trailers or other moveable facilities or temporary construction shall not be permitted.

The entire area of the location of the pharmacy practice, including all areas where drugs are stored , shall be well lighted and well ventilated; the proper storage temperature shall be maintained to meet USP-NF specifications for drug storage.

The prescription department counter work space shall be used only for the compounding and dispensing of drugs and necessary  ~~record keeping~~  recordkeeping .

A sink with hot and cold running water shall be within the prescription department. A pharmacy issued a limited-use permit that does not stock prescription drugs as part of its operation is exempt from this requirement.

Adequate refrigeration facilities equipped with a monitoring thermometer for the storage of drugs requiring cold storage temperature shall be maintained within the prescription department  ~~,~~  if the pharmacy stocks such drugs.

A pharmacy stocking drugs requiring cold storage temperature shall record the temperature daily and adjust the thermostat as necessary to ensure an appropriate temperature range. The record shall be maintained manually or electronically for a period of two years.

Security system.

A device for the detection of breaking shall be installed in each prescription department of each pharmacy. The installation and the device shall be based on accepted alarm industry standards  ~~,~~  and shall be subject to the following conditions:

The device shall be a sound, microwave, photoelectric, ultrasonic, or any other generally accepted and suitable device.

The device shall have at least one hard-wired communication method, be monitored in accordance with accepted industry standards, maintained in operating order, have an auxiliary source of power, and be capable of sending an alarm signal to the monitoring entity when breached if the communication line is not operational.

The device shall fully protect the prescription department and shall be capable of detecting breaking by any means when activated.

Access to the alarm system for the prescription department area of the pharmacy shall be restricted to the pharmacists working at the pharmacy, except for access by other persons in accordance with 18VAC110-20-190 B 2, and the system shall be activated whenever the prescription department is closed for business.

The alarm system shall include a feature by which any breach in the alarm shall be communicated by the monitoring entity to the PIC or a pharmacist working at the pharmacy.

Exceptions to provisions in this section:

Alarm systems approved prior to November 4, 1993, will be deemed to meet the requirements of subdivisions A 1, A 2, and A 3 of this section, provided that no structural changes are made in the prescription department, that no changes are made in the security system, that the prescription department is not closed while the rest of the business remains open, and that a breaking and loss of drugs does not occur. If a breaking with a loss of drugs occurs, the pharmacy shall upgrade the alarm to meet the current standards and shall file an application with the board in accordance with 18VAC110-20-140 A within 14 days of the breaking.

If the prescription department was located in a business with extended hours prior to November 4, 1993, and had met the special security requirements by having a floor to ceiling enclosure, a separately activated alarm system shall not be required.

This section shall not apply to pharmacies  ~~which~~  that are open and staffed by pharmacists 24 hours a day. If the pharmacy changes its hours or if it must be closed for any reason, the PIC or owner must immediately notify the board, file an application in accordance with 18VAC110-20-140 A, and have installed prior to closing  ~~,~~  a security system that meets the requirements of subdivisions A 1 through A 4 of this section.

Storage of drugs, devices, and controlled paraphernalia; expired drugs.

Prescriptions awaiting delivery. Prescriptions prepared for delivery to the patient may be placed in a secured area outside of the prescription department, not accessible to the public, where access to the prescriptions is restricted to individuals designated by the pharmacist. With the permission of the pharmacist, the prepared prescriptions may be transferred to the patient at a time when the pharmacist is not on duty. If a prescription is delivered at a time when the pharmacist is not on duty, written procedures shall be established and followed by the pharmacy  ~~which~~  that detail security of the dispensed prescriptions and a method of compliance with counseling requirements of [*Section 54.1-3319 of the Code of Virginia*](https://advance.lexis.com/api/document?collection=statutes-legislation&id=urn:contentItem:5T53-0M50-004G-J2CV-00000-00&context=). Additionally, a log shall be made and maintained of all prescriptions delivered to a patient when a pharmacist is not present to include the patient's name, prescription  ~~number(s)~~  number , date of delivery, and  ~~the~~  signature of the person receiving the prescription. Such log shall be maintained for a period of one year.

Dispersion of Schedule II drugs. Schedule II drugs shall either be dispersed with other schedules of drugs or shall be maintained within a securely locked cabinet, drawer, or safe or maintained in a manner that combines the two methods for storage . The cabinet, drawer, or safe may remain unlocked during hours that the prescription department is open and a pharmacist is on duty.

Safeguards for controlled paraphernalia and Schedule VI medical devices. Controlled paraphernalia and Schedule VI medical devices shall not be placed in an area completely removed from the prescription department whereby patrons will have free access to such items or where the pharmacist cannot exercise reasonable supervision and control.

Expired, or otherwise adulterated or misbranded drugs; security. Any drug  ~~which~~  that has exceeded the expiration date  ~~,~~  or is otherwise adulterated or misbranded  ~~,~~  shall not be dispensed or sold; it shall be separated from the stock used for dispensing. Expired prescription drugs shall be maintained in a designated area within the prescription department until proper disposal.

Disposal of drugs by authorized collectors.

Any narcotic treatment program, hospital  ~~,~~  or clinic with an on-site pharmacy, or pharmacy  ~~wishing to accept for return~~  that accepts a previously dispensed drug for the purpose of destruction shall first be authorized by the DEA as a collector. A collector so authorized may receive drugs from an ultimate user, a person lawfully entitled to dispose of an ultimate user decedent's property, or a long-term care facility on behalf of an ultimate user who resides or has resided at that facility  ~~shall first be authorized by the DEA as a collector~~  . The process used to collect and destroy drugs, along with any required recordkeeping, shall comply with applicable federal and state law.

Prior to collecting drugs, an authorized collector shall submit in writing to the board:

The name, address, and license number, if applicable, of the facility;

The intended method or methods of collection (i.e., collection receptacle or mail-back program); and

Signature of PIC or medical director of a narcotic treatment program.

If an authorized collector chooses to cease acting as a collector, the PIC or medical director shall notify the board within 30 days.

A narcotic treatment program that does not have an in-house pharmacy shall obtain a controlled substance registration.

Nuclear Pharmacies

General requirements for pharmacies providing radiopharmaceutical services.

Nuclear pharmacies shall comply with standards and requirements of the Nuclear Regulatory Commission  ~~(NRC)~~  and the Virginia Department of Health related to the staffing and operation of the facility.

Radiopharmaceuticals are to be dispensed only upon an order from a prescriber authorized to possess, use , and administer radiopharmaceuticals.

Orders shall originate at an institution or  ~~healthcare~~  health care facility licensed to receive and possess radiopharmaceuticals  ~~,~~  and must contain all necessary information relative to the radiopharmaceutical, activity, time of calibration, and any special preparation or delivery instructions.

Orders for radiopharmaceuticals may be transmitted orally, by  ~~fax~~  facsimile (fax) , or by electronic transmission by an authorized agent of the prescriber. If the fax or electronic transmission of the authorized agent is pursuant to an oral order from the prescriber, the transmitted document need not include the prescriber's signature  ~~,~~  but must include the name of the agent.

The immediate outside container of a radioactive drug to be dispensed shall also be labeled in accordance with requirements of Section 54.1-3410.1 B of the Code of Virginia.

The immediate inner container shall be labeled with  ~~:~~  (i) the standard radiation symbol  ~~;~~  , (ii) the words "Caution--Radioactive Material , "  ~~;~~  and (iii) the serial number assigned to the order.

Nuclear pharmacies may redistribute approved radioactive drugs if the pharmacy does not process the radioactive drugs in any manner nor violate the product packaging.

Drug Inventory and Records

Manner of maintaining records, prescriptions, inventory records.

Each pharmacy shall perform and maintain the inventories and records of drugs as follows:

Inventories and records of all drugs listed in Schedules I and II shall be maintained separately from all other records of the pharmacy. Inventories of drugs in Schedules I and II shall be performed by physically counting the drugs. Each pharmacy shall maintain a perpetual inventory of all Schedule II drugs received and dispensed  ~~, with~~  that accurately indicates the physical count of each Schedule II drug "on-hand" at the time of performing the inventory. The perpetual inventory shall include a reconciliation of each Schedule II drug at least monthly with a written explanation for any difference between the physical count and the theoretical count . Electronic monitoring at the pharmacy or by another entity that provides alerts for discrepancies between drugs received and drugs dispensed is acceptable provided such alerts are reviewed at least monthly.

Inventories and records of drugs listed in Schedules III, IV, and V may be maintained separately or with records of Schedule VI drugs but shall not be maintained with other records of the pharmacy. Inventories of drugs in Schedules III, IV, and V may be performed by estimating the count of drugs in Schedules III, IV, and V unless the container contains greater than 1,000 tablets or capsules or there has been a theft or any other unusual loss of drug and the exact kind and quantity of the drug loss is unknown.

All executed order forms, prescriptions, and inventories of  ~~Schedule~~  Schedules II through V drugs shall be maintained at the same address as the stock of drugs to which the records pertain. If authorized by DEA, other records pertaining to  ~~Schedule~~  Schedules II through V drugs, such as invoices, may be maintained in an off-site database or in secured storage. All records in off-site storage shall be retrieved and made available for inspection or audit within 48 hours of a request by the board or an authorized agent.

All inventories required by [*Section 54.1-3404 of the Code of Virginia*](https://advance.lexis.com/api/document?collection=statutes-legislation&id=urn:contentItem:5T53-0KT0-004G-J02N-00000-00&context=) shall be signed and dated by the person taking the inventory and shall indicate whether the inventory was taken prior to the opening of business or after close of business. A 24-hour pharmacy with no opening or closing of business shall clearly document whether the receipt or distribution of drugs on the inventory date occurred before or after the inventory was taken.

Invoices or other records showing receipts of Schedule VI drugs shall be maintained  ~~,~~  but may be stored in an electronic database or record as an electronic image that provides an exact, clearly legible  ~~,~~  image of the document or in secured storage either on site or off site. All records in off-site storage or database shall be retrieved and made available for inspection or audit within 48 hours of a request by the board or an authorized agent.

All records required by this section shall be filed chronologically and maintained for a period of not less than two years from the date of transaction.

Prescriptions.

A hard copy prescription shall be placed on file for every initial prescription dispensed and be maintained for two years from the date of last refill. All prescriptions shall be filed chronologically by date of initial dispensing or by date of initial entry into the automated data processing system in compliance with 18VAC110-20-250 if such a system is employed by the pharmacy.

Schedule II drugs. Prescriptions for Schedule II drugs shall be maintained in a separate prescription file.

 ~~Schedule~~  Schedules III  ~~through~~  , IV, and V drugs. Prescriptions for  ~~Schedule~~  Schedules III  ~~through~~  , IV, and V drugs shall be maintained either in a separate prescription file for drugs listed in Schedules III, IV, and V only or in such form that they are readily retrievable from the other prescriptions of the pharmacy. Prescriptions will be deemed readily retrievable if, at the time they are initially filed, the face of the prescription is stamped in red ink in the lower right corner with the letter "C" no less than one inch high and filed in the prescription file for drugs listed in the usual consecutively numbered prescription file for Schedule VI drugs. However, if a pharmacy employs an automated data processing system or other electronic recordkeeping system for prescriptions  ~~which~~  that permits identification by prescription number and retrieval of original documents by prescriber's name, patient's name, drug dispensed, and date filled, then the requirement to mark the hard copy prescription with a red "C" is waived.

Chart orders.

A chart order written for a patient in a hospital or long-term care facility, a patient receiving home infusion services, or a hospice patient pursuant to Section 54.1-3408.01 A of the Code of Virginia shall be exempt from having to contain all required information of a written prescription provided:

This information is contained in other readily retrievable records of the pharmacy; and

The pharmacy maintains and complies with a current policy and procedure manual that sets out where this information is maintained  ~~and~~  , how to retrieve it , and the minimum requirements for chart orders consistent with state and federal law and accepted standard of care.

A chart order may serve as the hard copy prescription for those patients listed in subdivision 1 of this subsection. When a chart order is intended for out-patient dispensing, it shall comply with requirements for a prescription in 18VAC110-20-286.

Requirements for filing of chart orders.

Chart orders shall be filed chronologically by date of initial dispensing with the following exception: If dispensing data can be produced showing a complete audit trail for any requested drug for a specified time period and each chart order is readily retrievable upon request, chart orders may be filed using another method. Such alternate method shall be clearly documented in a current policy and procedure manual.

If a single chart order contains both an order for a Schedule II drug and one or more orders for a drug in another schedule, where the Schedule II drug is not floor stocked  ~~,~~  but is dispensed from the pharmacy pursuant to this order for the specific patient, the original order must be filed with records of dispensing of Schedule II drugs and a copy of the order placed in the file for other schedules.

Prescription Order and Dispensing Standards

Dispensing of prescriptions; certification of completed prescriptions  ~~; supervision of pharmacy technicians~~  .

In addition to the  ~~acts restricted to a pharmacist in Section 54.1-3320 A of the Code of Virginia, a pharmacist shall provide personal supervision of compounding of extemporaneous preparations by pharmacy technicians. B. A pharmacist shall determine the number of pharmacy interns, pharmacy technicians, and pharmacy technician trainees he can safely and competently supervise at one time; however, no pharmacist shall supervise more than four persons acting as pharmacy technicians at one time~~  requirements in [*Section 54.1-3408.01 of the Code of Virginia*](https://advance.lexis.com/api/document?collection=statutes-legislation&id=urn:contentItem:5T53-0MC0-004G-J1V9-00000-00&context=) for an oral prescription or written prescription, including those transmitted via facsimile or electronically, a prescription shall include a quantity or duration of the order by which the pharmacist can calculate the authorized quantity using directions for use. Except for prescriptions transmitted electronically in compliance with 18VAC110-20-285, written prescriptions shall also include the prescriber's manual signature .

After the prescription has been prepared and prior to the delivery of the order, a pharmacist shall inspect the prescription product to verify its accuracy in all respects  ~~,~~  and place his initials on the record of dispensing as a certification of the accuracy of  ~~,~~  and the responsibility for  ~~,~~  the entire transaction. If more than one pharmacist is involved in verifying the accuracy of the prescription product, a record shall be maintained identifying the date of dispensing, each pharmacist involved in the process, and the individual task for which  ~~he~~  each pharmacist is responsible for verifying the accuracy. Such record showing verification of accuracy shall be maintained on a pharmacy record and, if necessary, an alternate record consistent with 18VAC110-20-255 for the required time period of two years  ~~,~~  unless otherwise specified in regulation. If the dispensing involves central or remote processing, records of pharmacist verification shall be maintained in a manner consistent with 18VAC110-20-276 and 18VAC110-20-515.

If a pharmacist declines to fill a prescription for any reason other than the unavailability of the drug prescribed, he shall record on the back of the prescription the word "declined"; the name, address, and telephone number of the pharmacy; the date filling of the prescription was declined; and the signature of the pharmacist.

If a pharmacist determines from a prescriber or by other means, including the use of his professional judgment, that a prescription presented for dispensing is a forgery, the pharmacist  ~~shall not~~  may refuse to return the forged prescription to the person presenting it. The forged prescription may be given to a law-enforcement official investigating the forgery  ~~;~~  , or it shall be retained for a minimum of 30 days before destroying it  ~~,~~  in the event it is needed for an investigative or other legitimate purpose.

An on-hold prescription shall be entered into the automated data processing system if such system is employed by the pharmacy, and the pharmacist on-duty shall verify the accuracy of the data entry at that time. The pharmacist subsequently dispensing the on-hold prescription on a future date shall, at a minimum, conduct a prospective drug review consistent with Section 54.1-3319 A of the Code of Virginia. If an on-hold prescription is returned to a patient prior to the initial dispensing of the drug, the pharmacist shall delete the entry in the automated data processing system.

A pharmacy may use a drop box for the collection of written prescriptions and refill requests. The drop box shall be located in a visible area within the permitted facility and shall be locked at all times with access to the items placed in the drop box restricted to pharmacists practicing at the pharmacy or an authorized pharmacy technician practicing at the pharmacy when a pharmacist is on duty. The drop box shall be constructed in a manner to prevent the theft or loss of a written prescription or confidential information and shall be bolted to the floor or a fixed structure. Pharmacists shall in some manner inform the public that containers left in a drop box for refill should not contain unused drugs.

Transmission of a prescription order by facsimile  ~~machine~~  device .

Unless otherwise prohibited by federal law, prescription orders for  ~~Schedule~~  Schedules III through VI drugs may be transmitted to pharmacies by facsimile (fax) device  ~~(FAX)~~  upon the following conditions:

The prescription shall be faxed only to the pharmacy of the patient's choice.

A valid faxed prescription shall contain all required information for a prescription. A written prescription shall include the prescriber's signature.

An authorized agent, as defined in Section 54.1-3408.01 C of the Code of Virginia, may transmit an oral prescription by facsimile and shall record on the faxed prescription the agent's full name and wording that clearly indicates that the prescription being transmitted is an oral prescription.

A faxed prescription shall be valid only if faxed from the prescriber's practice location, except in the following situations:

Forwarding a faxed chart order from a long-term care facility or from a hospice, including a home hospice;

Faxing an oral prescription by authorized agent under the conditions set forth in subdivision 3 of this subsection; or

Forwarding a written prescription by an authorized agent from a long-term care facility, provided the provider pharmacy maintains written procedures for such transactions  ~~,~~  and provided the original prescription is obtained by the provider pharmacy within seven days of dispensing. The original prescription shall be attached to the faxed copy.

The following additional information shall be recorded on the faxed prescription:

The date that the prescription was faxed;

The printed name, address, phone number, and fax number of the authorized prescriber; and

The institution, if applicable, from which the prescription was faxed, including address, phone number , and fax number.

Prescription orders for Schedule II drugs may only be faxed for information purposes and may not serve as the original written prescription authorizing dispensing, except for orders to be administered to long-term care facility and home infusion patients in accordance with Section 54.1-3408.01 B of the Code of Virginia and except for prescriptions written for a Schedule II narcotic substance for patients residing in a hospice certified by Medicare under Title XVIII or licensed by the state, which may include home hospice. The prescriber shall note on the prescription if the patient is a hospice patient, and the prescription shall meet all requirements for a written prescription, including the prescriber's manual signature.

If the faxed prescription is of such quality that the print will fade and not remain legible for the required retention period, the receiving pharmacist shall copy or transcribe the faxed prescription on paper of permanent quality.

Authorizations for refills may be faxed by the prescriber to the pharmacy provided the authorization includes patient name, address, drug name and strength, quantity, directions for use, prescriber's name, prescriber's manual signature or agent's name, and date of authorization.

Dispensing of Schedule II drugs.

A prescription for a Schedule II drug shall be dispensed in good faith but in no case shall it be dispensed more than six months after the date on which the prescription was issued.

A prescription for a Schedule II drug shall not be refilled except as authorized under the conditions for partial dispensing as set forth in 18VAC110-20-310.

In case of an emergency situation, a pharmacist may dispense a drug listed in Schedule II upon receiving oral authorization of a prescribing practitioner  ~~,~~  provided that:

The quantity prescribed and dispensed is limited to the amount adequate to treat the patient during the emergency period;

The prescription shall be immediately reduced to writing by the pharmacist and shall contain all information required in Section 54.1-3410 of the Drug Control Act, except for the signature of the prescribing practitioner;

If the pharmacist does not know the practitioner,  ~~he~~  the pharmacist shall make a reasonable effort to determine that the oral authorization came from a practitioner using  ~~his~~  the practitioner's phone number as listed in the telephone directory or other good-faith efforts to ensure the practitioner's identity; and

Within seven days after authorizing an emergency oral prescription, the prescribing practitioner shall cause a written prescription for the emergency quantity prescribed to be delivered to the dispensing pharmacist. In addition to conforming to the requirements of Section 54.1-3410 of the Drug Control Act, the prescription shall have written on its face "Authorization for Emergency Dispensing" and the date of the oral order. The written prescription may be delivered to the pharmacist in person or by mail postmarked within the seven-day period  ~~,~~  or transmitted as an electronic prescription in accordance with federal law and regulation to include annotation of the electronic prescription with the original authorization and date of the oral order. Upon receipt, the dispensing pharmacist shall attach the paper prescription to the oral emergency prescription , which had earlier been reduced to writing. The pharmacist shall notify the nearest office of the Drug Enforcement Administration and the board if the prescribing practitioner fails to deliver a written prescription to  ~~him~~  the pharmacist . Failure of the pharmacist to do so shall void the authority conferred by this subdivision to dispense without a written prescription of a prescribing practitioner.

When presented a prescription written for a Schedule II controlled substance, a pharmacist may add or correct the patient's address upon verification, correct the patient's name upon verification, or add the prescriber's DEA registration number to the prescription. The pharmacist may add or change the dosage form, drug strength, directions for use, drug quantity, or issue date only after oral consultation directly with and agreement of the prescriber. Such consultations and corresponding changes shall be noted by the pharmacist on the prescription. The pharmacist shall not add or change the prescriber's signature or make changes to the controlled substance prescribed, except for dispensing therapeutically equivalent drugs as permitted by law.

Pharmacy repackaging of drug; records required; labeling requirements.

Pharmacies in which bulk reconstitution of injectable, bulk compounding , or the repackaging or prepackaging of drugs is performed shall maintain adequate control records for a period of one year or until the expiration, whichever is greater. The records shall show the name of the  ~~drug(s)~~  drugs used; strength, if any; date repackaged; quantity prepared; initials of the pharmacist verifying the process; the assigned lot or control number; the manufacturer's or distributor's name and lot or control number; and an expiration date.

The drug name; strength, if any; the assigned lot or control number or the manufacturer's or distributor's name and lot or control number; and an appropriate expiration date determined by the pharmacist in accordance with USP guidelines shall appear on any subsequently repackaged or reconstituted units.

Repackaging of drugs shall be performed in compliance with USP-NF standards.

Pharmacies using automated counting devices or dispensers in which drugs are removed from manufacturer's original packaging and placed in bulk bins shall comply with the following requirements:

A bin filling record shall be maintained  ~~,~~  manually or in a computerized record for a period of one year from date of filling from which information can be readily retrieved  ~~,~~  for each bin including:

The drug name and strength, if any;

The name of the manufacturer or distributor;

Manufacturer's control or lot  ~~number(s)~~  numbers and expiration date for all lots placed into the bin at the time of filling;

Any assigned lot number;

An expiration date determined according to USP guidelines for repackaging;

The date of filling; and

The pharmacist's initials verifying the accuracy of the process.

If more than one lot is added to a bin at the same time, the lot  ~~which~~  that expires first shall be used to determine the expiration date if shorter than a calculated date based on USP guidelines.

Each bin shall be labeled in such a manner as to cross-reference the information on the filling record with the correct expiration date.

If only one lot is added to a bin at one time, but a subsequent lot may be added before the first has cleared, the automated device shall be constructed to reasonably dispense the first lot before the second lot is dispensed , and the expiration date on the bin's label shall reflect the expiration date assigned to the earlier lot.

In the event of a drug recall involving one of multiple lots placed in a bin of an automated counting device in the last three months or if a recalled drug is known to remain in the bin, all drugs shall be removed from the bin and not used for patient care. The removal of drugs from the bin is not required if:

The technology of the automated counting device can ensure drugs in a particular lot have been cleared; or

The bin has been "run dry," with a record made of the "run dry" date, since the addition of the recalled lot number in which all drugs were completely removed prior to filling with a subsequent lot number.

An automated counting device shall be cleaned and maintained in accordance with recommended manufacturer guidelines and specifications.

A pharmacy may return a dispensed drug to stock for redispensing that has never left the pharmacy premises or the control of the pharmacy delivery agent pursuant to Section 54.1-3411.[*1 A 3*](https://advance.lexis.com/api/document?collection=cases&id=urn:contentItem:3VH0-JMJ0-0039-4054-00000-00&context=) of the Code of Virginia under the following conditions:

An expiration date shall be placed on the label prior to returning the drug to stock. In the absence of stability data to the contrary, the date on the label may not exceed the expiration date on the manufacturer's container or one year from the date the drug was originally dispensed and placed in the prescription vial, whichever date is earlier.

The restocked drug shall be used to fill the next prescription received for that product. In the event that the drug is not dispensed prior to the new assigned expiration date, it shall be removed from working stock as expired  ~~,~~  and disposed of in accordance with 18VAC110-20-210.

If there is no lot number on the label of a drug returned to stock or on the prescription records that can be cross-referenced from the prescription label, the drug shall be removed from stock upon any recall of that drug product and returned to the manufacturer or otherwise disposed of in accordance with 18VAC110-20-210.

Kickbacks, fee-splitting, interference with supplier.

A  ~~pharmacist~~  pharmacy shall not solicit or foster prescription practice with a prescriber of drugs or any other person providing for rebates,  ~~"~~  kickbacks,  ~~"~~  fee-splitting, or special charges in exchange for prescription orders  ~~unless fully disclosed in writing to the patient and any third party payor~~  .

A  ~~pharmacist~~  pharmacy shall not interfere with the patient's right to choose his supplier of medication or cooperate with any person  ~~or persons~~  in denying a patient the opportunity to select his supplier of prescribed medications.

Robotic pharmacy systems.

Consistent with 18VAC110-20-420, a pharmacy providing services to a hospital or a long-term care facility and operating a robotic pharmacy system that dispenses drugs in  ~~bar-coded~~  barcoded unit dose or compliance packaging is exempted from 18VAC110-20-270 C, provided the accuracy of the final dispensed prescription product complies with a written quality assurance plan and requirements of this chapter. The following requirements for operation of a robotic pharmacy system shall apply:

Pharmacists shall review for accuracy and appropriateness of therapy all data entry of prescription orders into the computer operating the system.

The packaging, repackaging, stocking , and restocking of the robotic pharmacy system shall be performed by pharmacy technicians or pharmacists.

Pharmacists shall verify and check for the accuracy of all drugs packaged or repackaged for use by the robot by a visual check of both labeling and contents prior to stocking the drugs in the robotic pharmacy system. A repackaging record shall be maintained in accordance with 18VAC110-20-355 A, and the verifying pharmacist shall initial the record. Packaging and labeling, including the appropriate beyond-use date, shall conform to requirements of this chapter and current USP-NF standards.

A written policy and procedure must be maintained and complied with and shall include at a minimum  ~~,~~  procedures for ensuring:

Accurate packaging and repackaging of all drugs for use in the robotic pharmacy system, to include properly labeled barcodes, and method for ensuring pharmacist verification of all packaged and repacked drugs compliant with this chapter and assigned barcodes ;

Accurate stocking and restocking of the robotic pharmacy system;

Removing expired drugs;

Proper handling of drugs that may be dropped by the robotic pharmacy system;

Performing routine maintenance of robotic pharmacy system as indicated by manufacturer's schedules and recommendations;

Accurate dispensing of drugs via robotic pharmacy system for cart fills, first doses, and cart fill updates during normal operation and during any scheduled or unscheduled downtime;

Accurate recording of any scheduled or unanticipated downtime with an explanation of the problem to include the time span of the downtime and the resolution;

Appropriately  ~~investigating, identifying and correcting~~  performing a root cause analysis to investigate, identify, and correct sources of discrepancies or errors associated with the robotic pharmacy system; and

Maintaining quality assurance reports.

 ~~5. Pharmacists shall perform a daily random check of medications or compliance packaging picked by the robot for 5.0% of all patients' bins and 5.0% of all first doses or cart updates. Documentation of this check shall include the pharmacist's initials for each medication checked and a description of all discrepancies found.~~

All manual picks shall be checked by pharmacists.

If the robot picks an incorrect medication, the pharmacy shall immediately institute a 100% check of all affected doses or compliance packages and  ~~shall immediately report the error to the board. The 100% check procedure shall continue until such time as the pharmacy provides documentation to the board showing that the cause of the error has been determined and addressed and that the robot is no longer making errors, and the board allows the pharmacy to return to a reduction in checking~~  perform a root cause analysis to investigate, identify, and correct the source of discrepancy or error in compliance with the pharmacy's policies and procedures prior to resuming full operations of the robot .

Quarterly quality assurance reports demonstrating the accuracy of the robot shall be maintained. At a minimum, these reports shall include  ~~: a. A~~  a summary indicating the date and description of all discrepancies that include  ~~but are not limited to~~  discrepancies involving the packaging, repackaging , and dispensing of drugs via the robotic pharmacy system found during that quarter plus a cumulative summary since initiation of the robotic pharmacy system.

 ~~b. The total number of doses packaged or compliance packages prepared for the robotic pharmacy system and total number of doses or compliance packages picked by the robot during the quarter.~~

 ~~c. The total number of doses or compliance packages picked by the robot that were checked in conducting the 5.0% checks.~~

 ~~d. Dates and time associated with any scheduled or unanticipated downtime with an explanation of the problem to include the time span of the downtime and the resolution.~~

 ~~9. All unanticipated downtime shall be immediately reported to the board.~~

All records required by this section shall be maintained at the address of the pharmacy for a minimum of two years. Records may be maintained in offsite storage or as an electronic image that provides an exact image of the document that is clearly legible provided such offsite or electronic storage is retrievable and made available for inspection or audit within 48 hours of a request by the board or an authorized agent.

Intravenous admixture robotics may be utilized to compound drugs in compliance with [*Section 54.1-3410.2 of the Code of Virginia*](https://advance.lexis.com/api/document?collection=statutes-legislation&id=urn:contentItem:5T53-0MM0-004G-J0Y8-00000-00&context=) and 18VAC110-20-321; however, a pharmacist shall verify the accuracy of all compounded drugs pursuant to 18VAVC110-20-270 B.

Emergency room.

All drugs in the emergency department shall be under the control and supervision of the PIC and shall be subject to the following additional requirements:

All drugs kept in the emergency room shall be in a secure place from which unauthorized personnel and the general public are excluded.

Oral orders for medications shall be reduced to writing and shall be signed by the  ~~practitioner~~  prescriber .

A medical practitioner may dispense drugs to his patients if in a bona fide medical emergency or when pharmaceutical services are not readily available and if permitted to do so by the hospital; the drug container and the labeling shall comply with the requirements of this chapter and the Drug Control Act.

A record shall be maintained of all drugs administered in the emergency room.

A separate record shall be maintained on all drugs, including drug samples, dispensed in the emergency room. The records shall be maintained for a period of two years showing:

Date and time dispensed;

Patient's name;

Prescriber's name;

Name of drug dispensed, strength, dosage form, quantity dispensed, and dose.

Automated devices for dispensing and administration of drugs.

A hospital may use automated devices for the dispensing and administration of drugs pursuant to [*Section 54.1-3301 of the Code of Virginia*](https://advance.lexis.com/api/document?collection=statutes-legislation&id=urn:contentItem:5T53-0KT0-004G-J01W-00000-00&context=) and Sections 54.1-3401 and 54.1-3434.02 of the Drug Control Act and in accordance with 18VAC110-20-270, 18VAC110-20-420, or 18VAC110-20-460 as applicable.

Policy and procedure manual; access codes.

Proper use of the automated dispensing devices and means of compliance with requirements shall be set forth in the pharmacy's policy and procedure manual , which shall include provisions for granting and terminating user access .

Personnel allowed access to an automated dispensing device shall have a specific access code that records the identity of the person accessing the device. The device may verify access codes using biometric identification or other coded identification after the initial log-on in order to eliminate sharing or theft of access codes.

Distribution of drugs from the pharmacy.

Prior to removal of drugs from the pharmacy, a delivery record shall be generated for all drugs to be placed in an automated dispensing device  ~~which~~  . The delivery record shall include the date; drug name, dosage form, and strength; quantity; hospital unit and a unique identifier for the specific device receiving the drug; initials of the person loading the automated dispensing device; and initials of the pharmacist checking the drugs to be removed from the pharmacy and the delivery record for accuracy.

At the time of loading any  ~~Schedule~~  Schedules II through V drug, the person loading will verify that the count of that drug in the automated dispensing device is correct. Any discrepancy noted shall be recorded on the delivery record and immediately reported to the pharmacist in charge, who shall be responsible for ensuring reconciliation of the discrepancy or properly reporting of a loss.

Distribution of drugs from the device.

Automated dispensing devices in hospitals shall be capable of producing a hard-copy record of distribution  ~~which~~  that shall show patient name, drug name and strength, dose withdrawn, date and time of withdrawal from the device, and identity of person withdrawing the drug. The record shall be filed in chronological order from date of issue or maintained electronically .

If an automated dispensing device is used to obtain drugs for dispensing from an emergency room, a separate dispensing record is not required provided the automated record distinguishes dispensing from administration and records the identity of the physician who is dispensing.

Discrepancy reports. A discrepancy report for all Schedules II through V drugs and any drugs of concern, as defined in [*Section 54.1-3456.1 of the Code of Virginia*](https://advance.lexis.com/api/document?collection=statutes-legislation&id=urn:contentItem:5T53-0N10-004G-J426-00000-00&context=), shall be generated for each discrepancy in the count of a drug on hand in the device. Each such report shall be initiated or resolved by the PIC or his designee within 72 hours of the time the discrepancy was discovered or, if determined to be a theft or an unusual loss of drugs, shall be immediately reported to the board in accordance with Section 54.1-3404 E of the Drug Control Act.

Reviews and audits.

The PIC or his designee shall conduct at least a monthly review for compliance with written policy and procedures that are consistent with Section 54.1-3434.02 A of the Drug Control Act for security and use of the automated dispensing devices, to include procedures for timely termination of access codes when applicable, accuracy of distribution from the device, and proper recordkeeping.

The PIC or his designee shall conduct at least a monthly audit to review distribution of  ~~Schedule~~  Schedules II through V drugs from each automated dispensing device as follows:

The audit shall reconcile records of all quantities of  ~~Schedule~~  Schedules II through V drugs dispensed from the pharmacy with records of all quantities loaded into each device to detect whether any  ~~drugs~~  drug recorded as removed from the pharmacy  ~~were~~  was diverted rather than  ~~being~~  placed in the proper device.

If a pharmacy has an ongoing method for perpetually monitoring drugs in  ~~Schedule~~  Schedules II through V to ensure drugs dispensed from the pharmacy have been loaded into the device and not diverted, such as with the use of perpetual inventory management software, then the audit required in this subsection may be limited to the discrepancies or exceptions as identified by the method for perpetually monitoring the drugs.

The PIC or his designee shall conduct at least a monthly audit to review the dispensing and administration records of  ~~Schedule~~  Schedules II through V drugs from each automated dispensing device as follows:

The audit shall include a review of administration records  ~~from~~  for each device per month for possible diversion by fraudulent charting. The review shall include all  ~~Schedule~~  Schedules II through V drugs administered for a time period of not less than 24 consecutive hours during the audit period.

The hard-copy distribution and administration records printed out and reviewed in the audit shall be initialed and dated by the person conducting the audit. If nonpharmacist personnel conduct the audit, a pharmacist shall review the record and shall initial and date the record.

The PIC or his designee shall be exempt from requirements of this audit if reconciliation software that provides a statistical analysis is used to generate reports at least monthly. The statistical analysis shall be based on:

Peer-to-peer comparisons of use for that unit or department; and

Monitoring of overrides and unresolved discrepancies.

The report shall be used to identify suspicious activity, which includes  ~~, but is not limited to,~~  usage beyond three standard deviations in peer-to-peer comparisons. A focused audit of the suspicious activity and individuals associated with the activity shall be performed whenever suspicious activity is identified from the reports.

The PIC or his designee shall maintain a record of compliance with the reviews and audits in accordance with subsection H of this section.

Inspections. Automated dispensing devices shall be inspected monthly by pharmacy personnel to verify proper storage, proper location of drugs within the device, expiration dates, the security of drugs , and validity of access codes. The PIC or his designee shall maintain documentation of the inspection in accordance with subsection H of this section. With the exception of a monthly physical review of look-alike and sound-alike drugs stored within matrix drawers or open access areas within the device, such monthly inspection shall not require physical inspection of the device if the device is capable of and performs the following:

At least daily monitoring of refrigerator or freezer storage with documented temperature ranges, variances, and resolutions;

Automatic identification and isolation of the location of each drug within the device using a machine readable product identifier, such as barcode technology, and generation of a report verifying the applicable settings;

Electronic tracking of drug expiration dates and generation of proactive reports allowing for the replacement of drugs prior to their expiration date; and

Electronic detection of the opening of the device, identification of the person accessing the device, automatic denial of access to the device during malfunctions and mechanical errors, and generation of reports of any malfunction and mechanical error.

Records.

All records required by this section shall be maintained for a period of not less than two years. Records shall be maintained at the address of the pharmacy providing services to the hospital except manual Schedule VI distribution records, reports auditing for indications of suspicious activity, and focused audits, all of which may be maintained in offsite storage or electronically as an electronic image that provides an exact image of the document that is clearly legible provided such offsite or electronic records are retrievable and made available for inspection or audit within 48 hours of a request by the board or an authorized agent.

Distribution and delivery records and required initials may be generated or maintained electronically provided:

The system being used has the capability of recording an electronic signature that is a unique identifier and restricted to the individual required to initial or sign the record.

The records are maintained in a read-only format that cannot be altered after the information is recorded.

The system used is capable of producing a hard-copy printout of the records upon request.

 ~~Schedule~~  Schedules II through V distribution and delivery records may also be stored  ~~offsite~~  off site or electronically in compliance with requirements of subdivision 1 of this subsection and if authorized by DEA or in federal law or regulation.

Hard-copy distribution and administration records that are printed and reviewed in conducting required audits may be maintained at an off-site location or electronically provided they can be readily retrieved upon request; provided they are maintained in a read-only format that does not allow alteration of the records; and provided a separate log is maintained for a period of two years showing dates of audit and review, the identity of the automated dispensing device being audited, the time period covered by the audit and review, and the initials of all reviewers.

Pharmacy's responsibilities to long-term care facilities.

The pharmacy serving a long-term care facility shall:

Receive a valid order prior to the dispensing of any drug.

Ensure that personnel administering the drugs are trained in using the dispensing system provided by the pharmacy.

Ensure that the drugs for each patient are kept and stored in the originally received containers and that the medication of one patient shall not be transferred to another patient.

Ensure that each cabinet, cart , or other area utilized for the storage of drugs is locked and accessible only to authorized personnel.

Ensure that the storage area for patients' drugs is well lighted, of sufficient size to permit storage without crowding, and is maintained at appropriate temperature.

Ensure that poison and drugs for "external use only" are kept in a cabinet and separate from other medications.

Provide for the disposition of discontinued drugs under the following conditions:

Discontinued drugs may be returned to the pharmacy for resale or transferred to another pharmacy for redispensing to the indigent if authorized by Section 54.1-3411.1 of the Code of Virginia and 18VAC110-20-400, or disposed of by appropriate means in compliance with 18VAC110-20-210 and with any applicable local, state, and federal laws and regulations.

Drug destruction at the pharmacy shall be witnessed by the PIC and by another pharmacy employee. The pharmacy may transfer the drugs for destruction to an entity appropriately licensed to accept returns for destruction. Drug destruction at the facility shall be witnessed by the director of nursing or  ~~,~~  if there is no director, then by the facility administrator and by a pharmacist providing pharmacy services to the facility or by another employee authorized to administer medication.

A complete and accurate record of the drugs returned or destroyed or both shall be made. The original of the record of destruction shall be signed and dated by the persons witnessing the destruction and maintained at the long-term care facility for a period of two years. A copy of the destruction record shall be maintained at the provider pharmacy for a period of two years.

Long-term care facilities shall destroy discontinued or unused drugs or return them to the pharmacy within 30 days of the date the drug was discontinued.

Ensure that appropriate drug reference materials are available in the facility units.

Ensure that a monthly review of drug therapy by a pharmacist is conducted for each patient in long-term care facilities except those licensed under Title 63.2 of the Code of Virginia. Such review shall be used to determine any irregularities, which may include  ~~but not be limited to~~  drug therapy, drug interactions, drug administration , or transcription errors. The pharmacist shall sign and date the notation of the review. All significant irregularities shall be brought to the attention of the attending practitioner or other party having authority to correct the potential problem.

The pharmacy providing services to the long-term care facility may share a copy of a Schedule VI prescription or order with another pharmacy for the purpose of dispensing an immediate supply of drugs, not to exceed a seven-day supply, without transferring the prescription pursuant to 18VAC110-20-360 if the following conditions are satisfied:

The pharmacy providing services to the long-term care facility has a written contract with the other pharmacy outlining services to be provided, the recordkeeping associated with the dispensing, and the responsibilities of each pharmacy; and

The pharmacy providing services to the long-term care facility provides a valid oral or written prescription or order to the other pharmacy.

Stat-drug box.

An additional drug box called a stat-drug box may be prepared by a pharmacy to provide for initiating therapy prior to the receipt of ordered drugs from the pharmacy. Access to the stat-drug box is restricted to a licensed nurse, pharmacist, or prescriber and only these licensed individuals may administer a drug taken from the stat-drug box. Additionally, a valid prescription or lawful order of a prescriber must exist prior to the removal of any drug from the stat-drug box. A stat-drug box shall be subject to the following conditions:

The box is sealed in such a manner that will preclude the loss of drugs.

The dispensing pharmacy must have a method of sealing such boxes so that once the seal is broken, it cannot be reasonably resealed without the breach being detected.

If a seal is used, it shall have a unique numeric or alphanumeric identifier to preclude replication or resealing, or both. The pharmacy shall maintain a record of the seal identifiers when placed on a box and maintain the record until such time as the seal is replaced.

In lieu of seals, a box with a built-in mechanism preventing resealing or relocking once opened except by the provider pharmacy is also acceptable.

The box shall have a form to be filled out upon opening the box and removing contents to write the name of the person opening the box, the date, the time, and the name and quantity of items removed. When the stat-drug box has been opened, it is returned to the pharmacy.

There shall be a listing of the contents of the box maintained in the pharmacy and also attached to the box in the facility. This same listing shall become a part of the policy and procedure manual of the facility served by the pharmacy.

The drug listing on the box shall bear an expiration date for the box. The expiration date shall be the day on which the first drug in the box will expire.

The contents of the box shall be limited to those drugs in which a delay in initiating therapy may result in harm to the patient.

The listing of drugs contained in the stat-drug box shall be determined by the provider pharmacist in consultation with the medical and nursing staff of the long-term care facility.

The stat-drug box shall contain no more than 20 solid dosage units per schedule of Schedules II through V drugs except that one unit of liquid, not to exceed 30 ml, may be substituted for a solid dosage unit in each drug schedule . If the unit of a liquid that may contain more than one dose is removed from the stat-drug box pursuant to a patient order, the remainder shall be stored with that patient's other drugs, may be used for subsequent doses administered to that patient, and shall not be administered to any other patient.

Drugs that would be stocked in a stat-drug box, pursuant to this section, may be stocked in an automated drug dispensing system in a nursing home in accordance with 18VAC110-20-555, except that the quantity of drugs in Schedules II through V stocked in the system shall be determined by the provider pharmacist in consultation with the medical and nursing staff of the nursing home.

The pharmacy may provide more than one stat-drug box to a long-term care facility. Contents of the multiple boxes are not required to be uniform.

 ~~Humane societies and animal~~  Animal shelters.

 ~~A humane society or~~  An animal shelter, after having obtained the proper registrations pursuant to state and federal laws, may purchase, possess and administer controlled substances in accordance with provisions of [*Section 54.1-3423 of the Code of Virginia*](https://advance.lexis.com/api/document?collection=statutes-legislation&id=urn:contentItem:5T53-0KT0-004G-J03C-00000-00&context=) provided that these procedures are followed:

Drugs ordered by a  ~~humane society~~  public or private animal shelter , as defined in [*Section 3.2-6500 of the Code of Virginia*](https://advance.lexis.com/api/document?collection=statutes-legislation&id=urn:contentItem:5T53-0MT0-004G-J504-00000-00&context=), shall only be stored and administered at the address of the  ~~humane society or~~  shelter.

A veterinarian shall provide general supervision for the facility and shall provide and certify training in accordance with guidelines set forth by the State Veterinarian to the  ~~person(s)~~  persons responsible for administration of the drugs. Certification of training signed by the veterinarian providing the training shall be maintained at the facility for each person administering drugs and must be retained for not less than two years after the person ceases administering.

The person in charge of administration of drugs for the facility shall obtain the required permit and controlled substances registration from the board and shall be responsible for maintaining proper security and required records of all controlled substances obtained and administered.

If that person ceases employment with the facility or relinquishes his position, he shall immediately return the registration to the board and shall take a complete and accurate inventory of all drugs in stock.

An application for a new registration shall be filed with the required fee within 14 days on a form provided by the board. At that time, the new responsible person shall take a complete and accurate inventory of all drugs in stock.

Drugs shall be stored in a secure, locked place and only the  ~~person(s)~~  person responsible for administering may have access to the drugs.

All invoices and order forms shall be maintained for a period of two years.

Complete and accurate records shall be maintained for two years on the administration of the drug. The record shall show the name and strength of the drug, date of administration, the species of the animal, the weight of animal, the amount of drug administered and the signature of the person administering the drug.

Medical Equipment Suppliers

Issuance of a permit as a medical equipment supplier.

Any person or entity desiring to obtain a permit as a medical equipment supplier shall file an application with the board on a form approved by the board. An application shall be filed for a new permit or for acquisition of an existing medical equipment supplier. The application shall designate the hours of operation the location will be open to service the public and shall be signed by a person who works at the location address on the application and will act as a responsible party for that location.

Any change in the hours of operation expected to last for more than one week shall be reported to the board in writing and a notice posted, at least 14 days prior to the anticipated change, in a conspicuous place to the public.

Such notification of a change in hours of operation is not required when the change is necessitated by emergency circumstances beyond the control of the owner or responsible party or when the change will result in an expansion of the current hours of operation.

If the medical equipment supplier is unable to post the change in hours 14 days in advance, the responsible party or owner shall ensure the board is notified as soon as he knows of the change and disclose the emergency circumstances preventing the required notification.

Within 14 days of a change in the responsible party assigned to the permit, the outgoing responsible party shall inform the board, and a new application shall be submitted indicating the name of the new responsible party.

A permit holder proposing to change the location of an existing license or permit or make structural changes to an existing location shall file an application for approval of the changes following an inspection conducted by an authorized agent of the board.

A permit shall not be issued to any medical equipment supplier to operate from a private dwelling or residence or to operate without meeting the applicable facility requirements for proper storage and distribution of drugs or devices. Before any license or permit is issued, the applicant shall demonstrate compliance with all federal, state and local laws and ordinances.

Medical equipment suppliers.

A medical equipment supplier's location shall be inspected by the board prior to engaging in business. The location shall be clean and sanitary and shall have a system of temperature control to provide for specified storage conditions for any Schedule VI drug or device.

Hypodermic needles and syringes and Schedule VI drugs shall not be placed on open display or in an open area where patrons will have access to such items. No Schedule VI devices shall be placed in an area where responsible parties cannot exercise reasonable supervision and control.

A medical equipment supplier shall receive a valid order from a practitioner prior to dispensing and shall maintain this order on file on the premises for a period of two years from date of last dispensing. The original order may be kept at a centralized office as long as it is readily retrievable within 48 hours and a copy of the order is kept on the premises of the dispensing supplier. In lieu of a hard copy, an electronic image of an order may be maintained in an electronic database provided it preserves and provides an exact image of the order that is clearly legible and made available within 48 hours of a request by a person authorized by law to have access to prescription information.

Medical equipment suppliers shall make a record at the time of dispensing. This record shall be maintained on the premises for two years from date of dispensing and shall include:

Name and address of patient;

Item dispensed and quantity, if applicable; and

Date of dispensing.

A valid order authorizing the dispensing of drugs or devices may be transferred from one medical equipment supplier to another medical equipment supplier provided the order can be filled or refilled. The transfer shall be communicated either orally by direct communication between an individual at the transferring medical equipment supplier and the receiving medical equipment supplier, by facsimile machine, or by electronic transmission.

The transferring medical equipment supplier shall:

Record the word "VOID" on the face of the invali - dated order;

Record on the reverse side of the invalidated order the name and address of the medical equipment supplier to which it was trans - ferred, the date of the transfer, and for an oral transfer, the name of the individual receiving the prescription information and the name of the individual transferring the information.

The receiving medical equipment supplier shall:

Write the word "TRANSFER" on the face of the trans - ferred pre - scription;

Provide all information required to be on a valid order to include:

Date of issuance of original order;

Original number of refills authorized on the original order;

Date of original dispensing if applicable;

Number of valid refills remaining and date of last dispensing;

Medical equipment supplier name and address from which the order information was transferred; and

Name of transferring individual if transferred orally.

Both the original and transferred order shall be main - tained for a period of two years from the date of last refill. In lieu of recording the required information on the hard copy of a valid order, a medical equipment supplier may record all required information in an automated data processing system used for the storage and retrieval of dispensing information.

A nonresident medical equipment supplier shall register and practice in accordance with [*Section 54.1-3435.3:1 of the Code of Virginia*](https://advance.lexis.com/api/document?collection=statutes-legislation&id=urn:contentItem:5T53-0N40-004G-J1BD-00000-00&context=).

REGULATIONS GOVERNING THE LICENSURE OF PHARMACISTS AND REGISTRATION OF PHARMACY TECHNICIANS

General

 Provisions

Definitions.

 In addition to words and terms defined in [*Sections 54.1-3300*](https://advance.lexis.com/api/document?collection=statutes-legislation&id=urn:contentItem:5T53-0MC0-004G-J1K5-00000-00&context=) and *54.1-3401 of the Code of Virginia*, the following words and terms when used in this chapter shall have the following meanings, unless the context clearly indicates otherwise:

 "ACPE" means the Accreditation Council for Pharmacy Education.

 "Board" means the Virginia Board of Pharmacy.

 "CE" means continuing education as required for renewal of licensure by the board.

 "CEU" means a continuing education unit awarded for credit as the equivalent of 10 contact hours.

 "Contact hour" means the amount of credit awarded for 60 minutes of participation in and successful completion of a continuing education program.

 "Foreign school of pharmacy" means a school outside the United States and its territories offering a course of study in basic sciences, pharmacology, and pharmacy of at least four years in duration resulting in a degree that qualifies a person to practice pharmacy in that country.

 "FPGEC certificate" means the certificate given by the Foreign Pharmacy Equivalency Committee of NABP that certifies that the holder of such certificate has passed the Foreign Pharmacy Equivalency Examination and a credential review of foreign training to establish educational equivalency to board approved schools of pharmacy and has passed approved examinations establishing proficiency in English.

 "Inactive license" means a license that is registered with the Commonwealth but does not entitle the licensee to practice, and the holder of which is not required to submit documentation of CE necessary to hold an active license.

 "NABP" means the National Association of Boards of Pharmacy.

 "Pharmacy technician trainee" means a person who is currently enrolled in an approved pharmacy technician training program and is performing duties restricted to pharmacy technicians for the purpose of obtaining practical experience in accordance with Section 54.1-3321 D of the Code of Virginia.

 "PTCB" means the Pharmacy Technician Certification Board, co-founded by the American Pharmaceutical Association and the American Society of Health System Pharmacists, as the national organization for the voluntary examination and certification of pharmacy technicians.

Fees.

Unless otherwise provided, fees listed in this section shall not be refundable.

Unless otherwise provided, any fees for taking required examinations shall be paid directly to the examination service as specified by the board.

Initial application fees.

 1. Pharmacist license                 $180 2. Pharmacy intern registration       $15 3. Pharmacy technician                $25 registration 4. Approval of a pharmacy             $150 technician training program 5. Approval of a continuing           $100 education program

Annual renewal fees.

 1. Pharmacist active license -       $90 due no later than December 31 2. Pharmacist inactive license       $45 - due no later than December 31 3. Pharmacy technician               $25 registration - due no later than December 31 4. Pharmacy technician               $75 every two years training program

Late fees. The following late fees shall be paid in addition to the current renewal fee to renew an expired license or registration within one year of the expiration date or within two years in the case of a pharmacy technician training program. In addition, engaging in activities requiring a license or registration after the expiration date of such license or registration shall be grounds for disciplinary action by the board.

 1. Pharmacist license                 $30 2. Pharmacist inactive license        $15 3. Pharmacy technician                $10 registration 4. Pharmacy technician training       $15 program

Reinstatement fees. Any person or entity attempting to renew a license or registration more than one year after the expiration date, or more than two years after the expiration date in the case of a pharmacy technician training program, shall submit an application for reinstatement with any required fees. Reinstatement is at the discretion of the board and, except for reinstatement following revocation or suspension, may be granted by the executive director of the board upon completion of an application and payment of any required fees.

 1. Pharmacist license                 $210 2. Pharmacist license after           $500 revocation or suspension 3. Pharmacy technician                $35 registration 4. Pharmacy technician                $125 registration after revocation or suspension 5. A pharmacy technician training program that failed to renew and continued to operate for more than one renewal cycle shall pay the current and all back renewal fees for the years in which they were operating plus a reinstatement fee of $75. A pharmacy technician training program that ceases operation and wishes to resume shall not be eligible for reinstatement but shall apply for a new registration.

Miscellaneous fees.

 1. Duplicate wall certificate         $25 2. Returned check                     $35 3. Duplicate license or               $10 registration 4. Verification of licensure or       $25 registration

Current name and address.

It shall be the duty and responsibility of each licensee and registrant to inform the board of his current name and address. A licensee or registrant shall notify the board within 14 days in writing or electronically of a name change or a change of an address of record. Properly updating a name or an address of record directly through the board's web-based application or other approved means shall constitute lawful notification.

All notices required by law or by this chapter are deemed to be received by the licensee or registrant when sent to the address of record and shall not relieve the licensee or registrant of the obligation to comply.

An individual licensed by or registered with the board who has provided the board with a public address that is different from the address of record shall notify the board in writing if there is a change in the address.

Unprofessional conduct.

 The following practices shall constitute unprofessional conduct within the meaning of [*Section 54.1-3316 of the Code of Virginia*](https://advance.lexis.com/api/document?collection=statutes-legislation&id=urn:contentItem:5T53-0M50-004G-J2CT-00000-00&context=):

Failing to comply with provisions of [*Section 32.1-127.1:03 of the Code of Virginia*](https://advance.lexis.com/api/document?collection=statutes-legislation&id=urn:contentItem:5T53-0M80-004G-J4RS-00000-00&context=) related to the confidentiality and disclosure of patient records or related to providing patient records to another practitioner or to the patient or the patient's personal representative;

Willfully or negligently breaching the confidentiality of a patient unless otherwise required or permitted by applicable law;

Failing to maintain the confidentiality of information received from the ***Prescription Monitoring*** Program, obtaining such information for reasons other than to assist in determining the validity of a prescription to be filled, or misusing information received from the program;

Engaging in disruptive or abusive behavior in a pharmacy or other health care setting that interferes with patient care or could reasonably be expected to adversely impact the quality of care rendered to a patient;

Engaging or attempting to engage in a relationship with a patient that constitutes a professional boundary violation in which the practitioner uses his professional position to take advantage of the vulnerability of a patient or the patient's family, including sexual misconduct with a patient or a member of the patient's family or other conduct that results or could result in personal gain at the expense of the patient;

Failing to maintain adequate safeguards against the diversion of controlled substances;

Failing to appropriately respond to a known dispensing error in a manner that protects the health and safety of the patient;

Delegating a task within the practice of pharmacy to a person who is not adequately trained to perform such a task;

Failing by the pharmacist in charge to ensure that pharmacy interns and pharmacy technicians working in the pharmacy are registered and that such registration is current;

Failing to exercise professional judgment in determining whether a prescription meets the requirements of law before dispensing;

Obtaining money or property of a patient or client by fraud or misrepresentation;

Providing false information or failing to cooperate with an employee of the Department of Health Professions in the conduct on an investigation or inspection;

Violating any provision of this chapter, 18VAC110-20, or Chapter 33 (Section 54.1-3300 et seq.) or 34 (Section 54.1-3400 et seq.) of Title 54.1 of the Code of Virginia;

Performing any act likely to deceive, defraud, or harm the public; or

Having a restriction of a license to practice pharmacy or a registration as a pharmacy technician in another jurisdiction in the United States.

Kickbacks, fee-splitting, interference with supplier.

A pharmacist shall not solicit or foster prescription practice with a prescriber of drugs or any other person providing for rebates, kickbacks, fee-splitting, or special charges in exchange for prescription orders.

A pharmacist shall not interfere with the patient's right to choose his supplier of medication or cooperate with any person or persons in denying a patient the opportunity to select his supplier of prescribed medications.

Licensure Requirement for Pharmacists

Requirements for pharmacy practical experience.

Each applicant for licensure as a pharmacist shall have gained practical experience in the practice of pharmacy as set forth in this section and 18VAC110-21-60.

An applicant for licensure as a pharmacist shall attain a minimum of 1,500 hours of practical experience.

Practical experience that is gained within an ACPE-accredited school of pharmacy, that conforms to the current ACPE standards, and that allows the student to gain at least 1,500 hours of practical experience shall meet the board's practical experience requirements for licensure as a pharmacist.

All practical experience credit gained outside of an ACPE-accredited school of pharmacy program shall only be gained after successful completion of the equivalent of at least two semesters in an ACPE-accredited school of pharmacy. Credit shall not be given for more than 50 hours in one week and not less than an average of 20 hours per week averaged over a month. The board may grant an exception to the minimum number of hours for good cause shown.

In accordance with [*Section 54.1-3312 of the Code of Virginia*](https://advance.lexis.com/api/document?collection=statutes-legislation&id=urn:contentItem:5T53-0M60-004G-J3HK-00000-00&context=), all practical experience required by this section shall be gained within the United States.

Procedure for gaining practical experience.

Each person desiring to gain practical pharmacy experience in Virginia shall first register with the board as a pharmacy intern on a form provided by the board prior to becoming so engaged as a pharmacy intern. This requirement shall apply to any person gaining practical experience within the Commonwealth whether for licensure in Virginia or in another state.

In order to be eligible to register as a pharmacy intern, an applicant shall meet at least one of the following criteria:

The applicant shall be enrolled in and have started course work in a professional degree program of a board-approved school of pharmacy. Such registration is only valid while the student is enrolled in the school of pharmacy and is satisfactorily progressing toward meeting the requirements for licensure as a pharmacist. An expiration date shall be assigned to the registration to cover the estimated time period for the student to complete the school program and pass the required examinations. If the student is no longer enrolled in the school program, takes a voluntary break from the program, or is otherwise not actively participating in the school program, except for regularly scheduled school breaks, the registration is no longer valid and shall be returned to the board immediately;

The applicant is a graduate of a board-approved school of pharmacy or a graduate of a foreign school of pharmacy, has established educational equivalency and proficiency in English by obtaining the FPGEC certificate, and desires to gain required practical experience required for licensure as a pharmacist. Such applicant shall provide documentation on a board-approved form of current employment or an employment start date within 90 days in a pharmacy in Virginia with approval by the supervising pharmacist. An expiration date shall be assigned to cover the estimated time period needed to obtain the required practical experience hours and take the required examinations to become licensed as a pharmacist;

The applicant has already gained the required practical experience but is an otherwise qualified applicant awaiting examination for licensure. A three-month expiration date shall be assigned to allow the applicant time to take required examinations; or

The applicant is an applicant for reactivation or reinstatement of a previously issued pharmacist license and is meeting board requirements for relicensure. An expiration date shall be assigned to reasonably cover the period of time necessary to meet the board requirements.

For documented good cause shown, the executive director of the board may extend the expiration date of the intern registration upon submission of an application form approved by the board and payment of the initial application fee.

A pharmacy intern shall be supervised by a pharmacist who holds a current, unrestricted license and assumes full responsibility for the training, supervision, and conduct of the intern.

The intern registration of a pharmacy student shall be valid only while the student is enrolled in a school of pharmacy. The registration card issued by the board shall be returned to the board upon failure to be enrolled.

Practical experience gained within any other state must be registered with and certified by the board of that state in order to be accepted or certified by the board. In the event that a state relies on the pharmacy school to certify the hours of experience, an affidavit from the pharmacy school certifying the hours of experience gained in the United States may be accepted in lieu of board certification.

All practical experience of the pharmacy intern shall be evidenced by an affidavit approved by the board, which shall be filed prior to or with the application for examination for licensure.

An applicant for licensure by endorsement may provide verification acceptable to the board of practical experience hours worked as a pharmacist in another state within the United States in lieu of prelicensure intern hours in order to meet the practical experience requirement.

A pharmacy intern shall notify the board in writing of any change in address of record within 14 days of such change .

Curriculum and approved schools of pharmacy.

The following minimum educational requirements for the specified periods shall be recognized by the board for the purpose of licensure.

On and after June 1, 1936, but before June 1, 1964, the applicant for licensure shall have been graduated from a four-year course of study with a Bachelor of Science degree in pharmacy awarded.

On and after June 1, 1964, the applicant for licensure shall have been graduated from at least a five-year course of study with a Bachelor of Science degree in pharmacy or a Doctorate of Pharmacy degree awarded.

In order to be licensed as a pharmacist within this Commonwealth, the applicant shall have been granted the first professional degree from a program of a school of pharmacy that meets the requirements of [*Section 54.1-3312 of the Code of Virginia*](https://advance.lexis.com/api/document?collection=statutes-legislation&id=urn:contentItem:5T53-0M60-004G-J3HK-00000-00&context=) or shall satisfy the requirements of 18VAC110-21-90.

Content of the examination and grades required; limitation on admittance to examination.

Prior to admission to any examination required for licensure, the applicant shall have met all other requirements to include education and practical experience requirements, but in no case shall the applicant be admitted if grounds exist to deny licensure under [*Section 54.1-3316 of the Code of Virginia*](https://advance.lexis.com/api/document?collection=statutes-legislation&id=urn:contentItem:5T53-0M50-004G-J2CT-00000-00&context=).

The applicant shall achieve a passing score as determined by the board on the licensure examination that is approved by the board and that shall consist of an integrated examination of pharmacy practice, pharmacology, pharmacy mathematics, and such other subjects as are necessary to assure that the candidate possesses the necessary knowledge and skills to practice pharmacy.

When an applicant for licensure by examination fails to meet the passing requirements of the board-approved integrated pharmacy examination on three occasions, the applicant shall not be readmitted to the examination until he has completed an additional 1,000 hours of practical experience as a pharmacy intern as set forth in 18VAC110-21-60.

The applicant shall also achieve a passing score as determined by the board on an examination that tests the candidate's knowledge of federal and state laws related to pharmacy practice. If an applicant has not subsequently been issued a license by any jurisdiction in the United States within three years of achieving a passing score, the applicant shall retake the examination in order to be licensed in Virginia.

When an applicant fails to pass the law examination, the applicant shall not be allowed to retake it for a period of 30 days.

If an applicant requests a testing accommodation for either examination based on a physical or mental impairment that substantially limits one or more major life activities, subject to the Americans with Disabilities Act, the board may approve a reasonable accommodation that does not compromise the security or integrity of the examination.

Supporting documentation shall be provided by the applicant to include the following to be considered for review:

A letter of request from the candidate that specifies the testing accommodation requested;

A written report of an evaluation (educational, psychological, or physical) within the preceding two years from a qualified professional that states a diagnosis of the disability, describes the disability, recommends specific accommodations, and provides justification that the accommodation is appropriate and necessary for the diagnosed disability. If the comprehensive evaluation was done more than two years ago and the condition is one that is not subject to change, the original evaluation report may be submitted along with a current letter from the qualified professional stating that there has been no change in the condition since the time of the evaluation; and

A written statement from the appropriate person at the applicant's school of pharmacy that describes any testing accommodations made while the student was enrolled, if applicable.

The applicant will be notified in writing of the decision. If the request for accommodation is granted, the approval information will be forwarded to the examination contractor and the form of the accommodation will be coordinated with the contractor.

Requirements for foreign-trained applicants.

Applicants for licensure who were trained in foreign schools of pharmacy shall obtain the FPGEC certificate prior to being allowed to register as a pharmacy intern and gain the required practical experience in Virginia.

After obtaining the FPGEC certificate, the applicant may apply for a pharmacy intern registration and shall fulfill the requirements for practical experience set forth in 18VAC110-21-50 and 18VAC110-21-60 before being admitted to examinations required by 18VAC110-21-80.

Applicants for licensure who were trained in foreign schools of pharmacy shall also complete and achieve passing scores on the examinations set forth in 18VAC110-21-80 before being licensed as a pharmacist.

Applicants for licensure who were trained in foreign schools of pharmacy, but who subsequently have been granted a professional degree from a program of a school of pharmacy that meets the requirements of [*Section 54.1-3312 of the Code of Virginia*](https://advance.lexis.com/api/document?collection=statutes-legislation&id=urn:contentItem:5T53-0M60-004G-J3HK-00000-00&context=), as specified in18VAC110-21-70, shall be exempt from the requirement for a FPGEC certificate but shall fulfill the requirements for practical experience set forth in 18VAC110-21-50 and 18VAC110-21-60 before being admitted to examinations required by 18VAC110-21-80.

Registration for voluntary practice by out-of-state licensees.

 Any pharmacist who seeks registration to practice on a voluntary basis pursuant to subdivision 12 of [*Section 54.1-3301 of the Code of Virginia*](https://advance.lexis.com/api/document?collection=statutes-legislation&id=urn:contentItem:5T53-0KT0-004G-J01W-00000-00&context=) under the auspices of a publicly supported, all volunteer, nonprofit organization that sponsors the provision of health care to populations of underserved people shall:

File a complete application for registration on a form provided by the board at least five business days prior to engaging in such practice;

Provide a complete list of each state in which the pharmacist has held a pharmacist license and a copy of any current license;

Provide the name of the nonprofit organization and the dates and location of the voluntary provision of services;

Pay a registration fee of $10; and

Provide a notarized statement from a representative of the nonprofit organization attesting to its compliance with the provisions of subdivision 12 of [*Section 54.1-3301 of the Code of Virginia*](https://advance.lexis.com/api/document?collection=statutes-legislation&id=urn:contentItem:5T53-0KT0-004G-J01W-00000-00&context=).

Requirements for Renewal or Reinstatement of Licensure

Renewal and reinstatement of license.

Pharmacist licenses expire on December 31 and shall be renewed annually prior to that date by the submission of a renewal fee, renewal form, and statement of compliance with continuing education requirements.

A pharmacist newly licensed on or after October 1 shall not be required to renew that license until December 31 of the following year.

A pharmacist who fails to renew his license by the expiration date may renew his license at any time within one year of its expiration by submission of the renewal fee and late fee, renewal form, and statement of compliance with continuing education requirements.

A pharmacist who fails to renew his license for more than one year following expiration and who wishes to reinstate such license shall submit an application for reinstatement, pay the current renewal fee and a reinstatement fee, and submit documentation showing compliance with continuing education requirements. Reinstatement is at the discretion of the board and may be granted by the executive director of the board provided no grounds exist to deny said reinstatement.

A pharmacist who has been registered as inactive for more than one year must apply for reactivation, submit documentation showing compliance with continuing education requirements, and pay the difference between the inactive fee and the current year active renewal fee in order to resume active licensure.

In order to reactivate or reinstate a license to active status, a pharmacist who holds an inactive license, who has allowed his license to lapse, or who has had his license suspended or revoked must submit evidence of completion of CEUs or hours equal to the requirements for the number of years in which his license has not been active, not to exceed a total of 60 hours of CE.

A pharmacist whose license has been lapsed, is in inactive status, or has been suspended or revoked for more than five years shall, as a condition of reinstatement or reactivation in addition to 60 hours CE, take and receive a passing score on the board-approved law examination and furnish acceptable documentation of one of the following:

Active pharmacy practice within the past five years as a properly licensed pharmacist in another state; or

Practical experience as a pharmacy intern registered with the board of at least 160 hours within six months immediately prior to being reinstated or reactivated.

The practice of pharmacy without a current, active pharmacist license is unlawful and shall constitute grounds for disciplinary action by the board.

Requirements for continuing education.

A pharmacist shall be required to have completed a minimum of 1.5 CEUs or 15 contact hours of continuing pharmacy education in an approved program for each annual renewal of licensure. CEUs or hours in excess of the number required for renewal may not be transferred or credited to another year.

A pharmacy education program approved for continuing pharmacy education is:

One that is approved by the ACPE;

One that is approved as a Category I continuing medical education course, the primary focus of which is pharmacy, pharmacology, or drug therapy; or

One that is approved by the board in accordance with the provisions of 18VAC110-21-130.

Of the 15 contact hours required for annual renewal, at least five hours shall be obtained in courses or programs that are live or real-time interactive. Included in the five hours, the following may be credited:

A maximum of one hour for attendance at a board meeting or formal hearing; or

A maximum of one hour for serving as a preceptor for a pharmacy student or resident in an accredited school or program or for a foreign-trained student obtaining hours of practical experience.

The board may grant an extension pursuant to Section 54.1-3314.1 E of the Code of Virginia. Any subsequent extension shall be granted only for good cause shown.

Pharmacists are required to attest to compliance with the CE requirements in a manner approved by the board at the time of their annual license renewal. Following each renewal period, the board may conduct an audit of the immediate past two years CE documents to verify compli - ance with the requirements. Pharmacists are required to maintain for two years following renewal the original certificates documenting successful completion of CE, showing the date and title of the CE program or activity, the number of CEUs or contact hours awarded, and a certifying signature or other certification of the approved provider. Pharmacists selected for audit must provide these original documents to the board by the deadline date specified by the board in the audit notice.

Approval of continuing education programs.

The board will approve without application or further review any program offered by an ACPE-approved provider and will accept for credit certificates bearing the official ACPE logo and program number.

The board may approve an individual CE program under the following provisions:

An approved individual program is a course, activity, or lecture that includes subject matter related to the competency of the practice of pharmacy and that has been approved for CE credit by the board.

In order to receive approval for an individual program, the sponsor or provider must apply prior to offering the program on a form provided by the board. The information that must be provided shall include:

Name of provider;

Location;

Date and time of program;

Charges to participants;

Description of program content and objectives;

Credentials of speaker or author;

Method of delivery;

Evaluation procedure;

Evidence of a post assessment;

Credits requested;

Mechanism for recordkeeping; and

Any such information as the board deems necessary to assure quality and compliance.

The sponsor applying for board approval of an individual program shall pay a fee as required in 18VAC110-21-20 C 5.

The board shall notify the provider or sponsor within 60 days following the receipt of a completed application of approval or disapproval of a program and the number of credits that may be awarded. The board shall also assign an expiration date for approval of the program not to exceed two years from the date of approval.

The provider of an approved program shall provide to each participant who completes the required hours and passes the post-test a certification with the name of the provider, name of the participant, description of course and method of delivery, number of hours credited, date of completion, and program identification number.

The provider of an approved program shall maintain all records on that program, program participants, and hours awarded for a period of five years and shall make those records available to the board upon request.

The board shall periodically review and monitor programs. The provider of a CE program shall waive registration fees for a representative of the board for that purpose.

Any changes in the information previously provided about an approved program or provider shall be submitted, or the board may withdraw its approval. If a provider wants to give a live program more than once, all program dates shall either be submitted on the original application or provided to the board in subsequent correspondence at least five days prior to giving the program.

Requirements for Pharmacy Technician Registration

Application for registration as a pharmacy technician.

Any person wishing to apply for registration as a pharmacy technician shall submit the application fee and an application on a form approved by the board.

To be registered as a pharmacy technician, an applicant shall provide evidence of the following:

Satisfactory completion of a board-approved training program; and

A passing score on a board-approved examination.

In lieu of the requirements of subsection B of this section, an applicant may provide evidence of current PTCB certification.

A pharmacy technician trainee enrolled in an approved pharmacy technician training program pursuant to Section 54.1-3321 D of the Code of Virginia may perform tasks restricted to pharmacy technicians for no more than nine consecutive months from the date the trainee begins performing duties restricted to a pharmacy technician without becoming registered as a pharmacy technician.

Criteria for approval for training programs.

Any person wishing to apply for approval of a pharmacy technician training program shall submit the application fee, a sample certificate, and an application on a form approved by the board and meet the criteria established in this section.

The curriculum of a training program for pharmacy technicians shall include instruction in applicable current laws and regulations and in the tasks that may be performed by a pharmacy technician to include the following or any other task restricted to pharmacy technicians in regulation:

The entry of prescription information and drug history into a data system or other recordkeeping system;

The preparation of prescription labels or patient information;

The removal of the drug to be dispensed from inventory;

The counting, measuring, or compounding of the drug to be dispensed;

The packaging and labeling of the drug to be dispensed and the repackaging thereof;

The stocking or loading of automated dispensing devices or other devices used in the dispensing process; and

The acceptance of refill authorization from a prescriber or the prescriber's authorized agent provided there is no change to the original prescription.

Each program shall have a program director who shall be either (i) a pharmacist with a current license in any jurisdiction and who is not currently suspended or revoked in any jurisdiction in the United States; (ii) a pharmacy technician with at least one year of experience performing technician tasks who holds a current registration in Virginia or current PTCB certification and who is not currently suspended or revoked as a pharmacy technician in any jurisdiction; or (iii) other person approved and deemed qualified by the board to be a program director.

Instructors for the core components listed in subsection B of this section shall meet the requirements for the program director listed in subsection C of this section. The program director may serve as an instructor.

The length of the program shall be sufficient to prepare a program participant to sit for the board-approved examination and demonstrate entry-level competency.

The program shall maintain records of program participants either on site or at another location where the records are readily retrievable upon request for inspection. A program shall provide a certificate of completion, including the program approval number, to participants who successfully complete the program and provide verification of completion of the program for a participant upon request by the board. Records shall be maintained for two years from date of completion or termination of program.

The program shall report within 14 days any substantive change in the program to include a change in program name, program certificate, program director, instructors, name of institution or business if applicable, address, program content, length of program, or location of records.

A pharmacy technician training program approval expires after two years, after which the program may apply for renewal. For continued approval, the program shall submit the renewal application, renewal fee, and a self-evaluation report on a form provided by the board at the time of renewal notification. Renewal of a program's approval is at the discretion of the board, and the decision to renew shall be based on documentation of continued compliance with the criteria set forth in this section.

Examination.

The board shall approve one or more examinations to test entry-level competency for pharmacy technicians. In order to be approved, a competency examination shall be developed in accordance with and meet the recognized acceptable test measurement standards of the Joint Technical Standards for Education and Psychological Testing (American Psychological Association, current edition), and shall be administered by an independent third party.

The board may contract with an examination service for the development and administration of a competency examination.

The board shall determine the minimum passing standard on the competency examination.

Any requests for testing accommodations under the Americans with Disabilities Act shall be in accordance with the provisions of 18VAC110-21-80 F.

Renewal and reinstatement of registration.

Pharmacy technician registrations expire on December 31 and shall be renewed annually prior to that date by the submission of a renewal fee and renewal form. A pharmacy technician newly registered on or after July 1 shall not be required to renew that registration until December 31 of the following year. Failure to receive the application for renewal shall not relieve the pharmacy technician of the responsibility for renewing the registration by the expiration date.

A pharmacy technician who fails to renew his registration by the expiration date may renew his registration at any time within one year of its expiration by submission of the renewal fee and late fee, renewal form, and attestation of having met the continuing education requirements.

A pharmacy technician who fails to renew his registration for more than one year following expiration and who wishes to reinstate such registration shall submit an application for reinstatement, pay the current renewal fee and a reinstatement fee, and submit documentation showing compliance with continuing education requirements. Reinstatement is at the discretion of the board and may be granted by the executive director of the board provided no grounds exist to deny said reinstatement. Practicing as a pharmacy technician with a lapsed registration shall be illegal and may subject the registrant to disciplinary action by the board.

A person who fails to reinstate a pharmacy technician registration within five years of expiration shall not be eligible for reinstatement and shall repeat an approved training program and repeat and pass the examination or hold current PTCB certification before applying to be reregistered.

Requirements for continued competency.

A pharmacy technician shall be required to have completed a minimum of 0.5 CEUs or five contact hours of approved continuing education for each annual renewal of registration. Hours in excess of the number required for renewal may not be transferred or credited to another year.

An approved continuing education program shall meet the requirements as set forth in 18VAC110-21-120 B or 18VAC110-21-130 B.

Upon written request of a pharmacy technician, the board may grant an extension of up to one year in order for the pharmacy technician to fulfill the continuing education requirements for the period of time in question. The granting of an extension shall not relieve the pharmacy technician from complying with current year requirements. Any subsequent extension shall be granted for good cause shown.

Original documentation showing successful completion of continuing education programs shall be maintained by the pharmacy technician for a period of two years following the renewal of his registration. The pharmacy technician shall provide such documentation to the board upon request in a manner to be determined by the board.

REGULATIONS GOVERNING WHOLESALE DISTRIBUTORS, MANUFACTURERS, THIRD-PARTY LOGISTICS PROVIDERS, AND WAREHOUSERS

Safeguards against diversion of drugs.

The holder of the license as a wholesale distributor or permit as a manufacturer, warehouser, or third-party logistics provider, or registration as a nonresident wholesale distributor or nonresident manufacturer shall restrict all areas in which prescription drugs are stored or kept for sale to only those persons specifically designated as necessary for the manufacture, receipt, storage, distribution, or quality control of the controlled substance inventory and shall provide reasonable security measures to include appropriate locking devices on all access doors to these areas and adequate lighting both inside and outside the facility to deter unauthorized entry and diversion.

The holder of the license, permit, or registration, except for those distributors of only medical gases other than nitrous oxide, shall install a device for the detection of breaking subject to the following conditions:

The device shall be a sound, microwave, photoelectric, ultrasonic, or any other generally accepted and suitable device.

 ~~The~~  One communication line installation shall be hardwired and both the installation and device shall be based on accepted burglar alarm industry standards to include wireless motion sensors .

The device shall be maintained in operating order  ~~and~~  , shall have an auxiliary source of power , and shall be capable of sending an alarm signal to the monitoring entity when breached if the communication line is not operational .

The device shall fully protect all areas where prescription drugs are stored and shall be capable of detecting breaking by any means when activated.

Access to the alarm system shall be restricted to the person named on the application as the responsible party or to persons specifically designated in writing in a policy and procedure manual.

The system shall be activated whenever the drug storage areas are closed for business.

Distribution or delivery of prescription drugs shall be accomplished in a manner to prevent diversion or possession of drugs by unauthorized persons.

The holder of the license, permit, or registration shall only deliver prescription drugs to a person authorized to possess such drugs at a location where the person is authorized to possess such drugs  ~~,~~  and only at a time when someone authorized to possess such drugs is in attendance.

The holder of the license, permit, or registration shall affirmatively verify that the person to whom prescription drugs are delivered is authorized by law to receive such drugs.

Prescription drugs may be transferred to an authorized agent of a person who may lawfully possess prescription drugs, provided the transfer occurs on the premises of the wholesale distributor, manufacturer, warehouser, third-party logistics provider, nonresident wholesale distributor, or nonresident manufacturer and provided the identity and authorization of the agent is verified, and such transfer is only used to meet the immediate needs of a patient  ~~or patients~~  .

Wholesale Distributors and Third-Party Logistics Providers

Special or limited-use licenses.

The board may issue a limited-use wholesale distributor license  ~~,~~  ; limited-use nonresident wholesale distributor registration  ~~,~~  ; or limited-use manufacturer, limited-use nonresident manufacturer, or limited-use third-party logistics provider permit to entities that do not engage in the wholesale distribution of prescription drugs or in the acts of a third-party logistics provider except medical gases and may waive certain requirements of regulation based on the limited nature of such distribution. The issuance of such a license shall be subject to continuing compliance with the conditions set forth by the board.

Minimum qualifications, eligibility, and responsible party.

The board shall use the following factors in determining the eligibility for licensure of wholesale distributors, registration of nonresident wholesale distributors, and permitting of third-party logistics providers:

The existence of grounds to deny an application as set forth in [*Section 54.1-3435.1 of the Code of Virginia*](https://advance.lexis.com/api/document?collection=statutes-legislation&id=urn:contentItem:5T53-0M50-004G-J2CY-00000-00&context=);

The applicant's past experience in the manufacture or distribution of drugs or devices;

Compliance with the recordkeeping requirements;

Prior disciplinary action by a regulatory authority, prior criminal convictions, or ongoing investigations related to the manufacturing, distribution, prescribing, or dispensing of drugs by the responsible party or immediate family members of the responsible party, and owners, directors, or officers; and

The responsible party's credentials as set forth in subsection B of this section.

Requirements for the person named as the responsible party.

The responsible party shall be the primary contact person for the board as designated by the wholesale distributor, nonresident wholesale distributor, or third-party logistics provider, who shall be responsible for managing the wholesale distribution operations at that location;

The responsible party shall have a minimum of two years of verifiable experience in a pharmacy or wholesale distributor or third-party logistics provider licensed, registered, or permitted in Virginia or another state where the person's responsibilities included  ~~, but were not limited to,~~  managing or supervising the recordkeeping, storage, and shipment for drugs or devices;

A person may only serve as the responsible party for one wholesale distributor license, nonresident wholesale distributor registration, or third-party logistics provider permit at any one time;

The responsible party shall be employed full time in a managerial position and actively engaged in daily operations of the wholesale distributor, nonresident wholesale distributor, or third-party logistics provider;

The responsible party shall be present on a full-time basis at the location of the wholesale distributor, nonresident wholesale distributor, or third-party logistics provider during normal business hours, except for time periods when absent due to illness, family illness or death, vacation, or other authorized absence; and

The responsible party shall be aware of  ~~,~~  and knowledgeable about  ~~,~~  all policies and procedures pertaining to the operations of the wholesale distributor, nonresident wholesale distributor, or third-party logistics provider and all applicable state and federal laws related to wholesale distribution of prescription drugs or the legal acts of a third-party logistics provider.

The person named as the responsible party on the application shall submit the following with the application:

A passport size and quality photograph taken within 30 days of submission of the application;

A resume listing employment, occupations, or offices held for the past seven years including names, addresses, and telephone numbers of the places listed;

An attestation disclosing whether the person has a criminal conviction or is the subject of any pending criminal charges within or outside the Commonwealth;

A federal criminal history record check  ~~through the Central Criminal Records Exchange~~  ; and

A description of any involvement by the person with any business, including any investments, other than the ownership of stock in publicly traded company or mutual fund, during the past seven years, which manufactured, administered, prescribed, distributed, or stored drugs and devices and any lawsuits, regulatory actions, or criminal convictions related to drug laws or laws concerning third-party logistics providers or wholesale distribution of prescription drugs in which such businesses were named as a party.

Responsibilities of the responsible party.

Ensuring that any employee engaged in operations is adequately trained in the requirements for the lawful and appropriate wholesale distribution of prescription drugs or the legal acts of a third-party logistics provider;

Requiring any employee who has access to prescription drugs to attest that  ~~he~~  the employer has not been convicted of any federal or state drug law or any law relating to third-party logistics providers or to the manufacture, distribution, or dispensing of prescription drugs;

Maintaining current working knowledge of requirements for wholesale distributors or third-party logistics providers and assuring continued training for employees;

Maintaining proper security, storage , and shipping conditions for all prescription drugs; and

Maintaining all required records.

Each nonresident wholesale distributor shall designate a registered agent in Virginia for service of any notice or other legal document. Any nonresident wholesale distributor that does not so designate a registered agent shall be deemed to have designated the Secretary of the Commonwealth to be its true and lawful agent, upon  ~~who~~  whom may be served all legal process in any action or proceeding against such nonresident wholesale distributor. A copy of any such service of legal documents shall be mailed to the nonresident wholesale distributor by the board by certified mail at the address of record.

NOTICE: Forms used in administering the regulation have been filed by the agency. The forms are not being published; however, online users of this issue of the Virginia Register of Regulations may click on the name of a form with a hyperlink to access it. The forms are also available from the agency contact or may be viewed at the Office of the Registrar of Regulations, 900 East Main Street, 11th Floor, Richmond, Virginia 23219.

FORMS (18VAC110-50)

Application for a Permit as a Restricted Manufacturer (rev.  ~~3/09).~~  3/2009)

Application for a Permit as a Nonrestricted Manufacturer (rev.  ~~3/09).~~  3/2009)

Application for a Permit as a Warehouser (rev.  ~~3/09).~~  3/2009)

Application for a License as a Wholesale Distributor (rev.  ~~3/09).~~  3/2009)

Application for a Nonresident Wholesale Distributor Registration (rev.  ~~9/08).~~  9/2008)

Application for a License as a Wholesale Distributor - Limited Use for Distribution of Medical Gases Only (rev. 3/2010)  ~~.~~

 Application for a Permit as a Third-Party Logistics Provider (eff. 9/2017)

VA.R. Doc. No. R16-4673; Filed November 27, 2018, 8:49 a.m.

**History**

BOARD OF PHARMACY

Proposed Regulation

**Classification**

**Subject:** AGENCY RULEMAKING (99%); MISCONDUCT (93%); WHOLESALERS (93%); PRESCRIPTION DRUGS (93%); TECHNICIANS & TECHNOLOGICAL WORKERS (92%); PHARMACISTS (92%); REAL ESTATE (91%); NEGATIVE PERSONAL NEWS (90%); PROFESSIONAL CONTINUING EDUCATION (90%); BUSINESS OPERATIONS (90%); FALSE STATEMENTS (90%); REAL ESTATE DEVELOPMENT (90%); TALKS & MEETINGS (90%); CONTROLLED SUBSTANCES CRIME (90%); HEALTH CARE PROFESSIONALS (90%); ENVIRONMENTAL PERMITS (90%); SMALL BUSINESS (90%); PHARMACIES & DRUG STORES (90%); PUBLIC HEALTH ADMINISTRATION (90%); HEALTH DEPARTMENTS (90%); CONTROLLED SUBSTANCES (90%); DRUG SAFETY (90%); PUBLIC HEALTH (90%); SALES FIGURES (90%); MEDICAL DEVICES (90%); BUDGETS (90%); PHARMACIES (90%); HVAC SYSTEMS (90%); MEDICAL EQUIPMENT & SUPPLIES MFG (90%); PROFESSIONAL WORKERS (90%); LAW ENFORCEMENT (90%); COUNTERFEITING & FORGERY (90%); FRAUD & FINANCIAL CRIME (90%); PUBLIC HEARINGS (90%); ECONOMICS (90%); NURSING & RESIDENTIAL CARE FACILITIES (90%); RETAIL PHARMACEUTICALS (89%); DRUG INTERACTIONS & SIDE EFFECTS (89%); ACCREDITATION (59%); COMMON STOCK (59%); PRISONS (59%); SPECIAL INVESTIGATIVE FORCES (59%); PHARMACEUTICALS ASSOCIATIONS (59%); NURSING HOMES (59%); EXECUTIVES (59%); APPRENTICESHIPS & INTERNSHIPS (59%); PRESCRIPTION FORMULARIES (59%); PARENT COMPANIES (59%); LONG TERM HEALTH CARE (59%); COMPANY STRUCTURES & OWNERSHIP (59%); MEDICAL RECORDS (59%); PETITIONS (59%); CONTINUING EDUCATION (59%); ASSOCIATIONS & ORGANIZATIONS (59%); PRODUCT PACKAGING (59%)

**State:** VIRGINIA, USA (97%)

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Virginia Regulation Full Text

**End of Document**