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Proposed Regulation
Agency Background Document

Agency name	Board of Pharmacy, Department of Health Professions
Virginia Administrative Code (VAC) citation	18 VAC 110-50-10 et seq.
Regulation title	Regulations Governing the Wholesale Distributors, Manufacturers and Warehousers
Action title	Greater oversight of wholesale distributors
Document preparation date	April 14, 2005

This information is required for executive branch review and the Virginia Registrar of Regulations, pursuant to the Virginia Administrative Process Act (APA), Executive Orders 21 (2002) and 58 (1999), and the *Virginia Register Form, Style, and Procedure Manual.*

Brief summary

In a short paragraph, please summarize all substantive changes that are being proposed in this regulatory action.

Since regulations governing the practice of pharmacy have become so extensive and complex, the Board has proposed the adoption of a new chapter (Chapter 50) for the regulation of wholesale distributors and manufacturers and the amending of applicable sections of Chapter 20 to delete requirements for those entities in the regulations governing the practice of pharmacy.

For manufacturers, warehousers and wholesale distributors, the new chapter will include applicable definitions, fees, and policies for renewal and reinstatement. Requirements are set out for issuance of a license, including inspection of the facility and compliance with applicable laws relating to the business of distributing controlled substances. Safeguards against drug diversion or possession by unauthorized persons are established, along with requirements for storage that protects the safety and efficacy of the drugs.

For wholesale distributors, the new regulations set out the information verifying the legitimacy of the business and its owners that must be provided in order to obtain a license to distribute drugs in Virginia. There are also requirements for the minimum qualifications and

responsibilities for the person named as the responsible party and minimum requirements for storage, handling and transporting of drugs. Finally, to protect the integrity and safety of drugs in the wholesale distribution system, the regulations establish requirements for examination of drug shipments and documents, the handling of damaged or adulterated drugs, policies and procedures for the operation of the business, recordkeeping, and due diligence in regard to the purchase of drugs from another wholesale distributor not licensed in Virginia.

For manufacturers, the federal rule, entitled The Good Manufacturing Practice for Finished Pharmaceuticals, is adopted by reference.

Legal basis

Please identify the state and/or federal legal authority to promulgate this proposed regulation, including (1) the most relevant law and/or regulation, including Code of Virginia citation and General Assembly chapter number(s), if applicable, and (2) promulgating entity, i.e., the agency, board, or person. Describe the legal authority and the extent to which the authority is mandatory or discretionary.

18VAC110-20-10 et seq. Regulations Governing the Practice of Pharmacy is promulgated under the general authority of Title 54.1, Chapter 24 of the Code of Virginia. Chapter 24 establishes the general powers and duties of health regulatory boards including the responsibility to promulgate regulations in accordance with the Administrative Process Act.

> ***§ 54.1-2400 -General powers and duties of health regulatory boards***
> *The general powers and duties of health regulatory boards shall be:*
> *…*
> *6. To promulgate regulations in accordance with the Administrative Process Act (§ 9-6.14:1 et seq.) which are reasonable and necessary to administer effectively the regulatory system. Such regulations shall not conflict with the purposes and intent of this chapter or of Chapter 1 (§ 54.1-100 et seq.) and Chapter 25 (§ 54.1-2500 et seq.) of this title. …*

The specific statutory authority for the Board of Pharmacy to regulate the practice of pharmacy including the manufacturing and wholesale distribution of controlled substances is found in § 54.1-3307 of the Code of Virginia.

§ 54.1-3307. Specific powers and duties of Board.

The Board shall regulate the practice of pharmacy and the manufacturing, dispensing, selling, distributing, processing, compounding, or disposal of drugs and devices. The Board shall also control the character and standard of all drugs, cosmetics and devices within the Commonwealth, investigate all complaints as to the quality and strength of all drugs, cosmetics, and devices and take such action as may be necessary to prevent the manufacturing, dispensing, selling, distributing, processing, compounding and disposal of such drugs, cosmetics and devices which do not conform to the requirements of law. In so regulating the Board shall consider any of the following criteria as they are applicable:

1. Maintenance of the quality, quantity, integrity, safety and efficacy of drugs or devices distributed, dispensed or administered.

2. Compliance with the prescriber's instructions regarding the drug, its quantity, quality and directions for use.

3. Controls and safeguards against diversion of drugs or devices.

4. Maintenance of the integrity of, and public confidence in, the profession and improving the delivery of quality pharmaceutical services to the citizens of Virginia.

5. Maintenance of complete records of the nature, quantity or quality of drugs or substances distributed or dispensed, and of all transactions involving controlled substances or drugs or devices so as to provide adequate information to the patient, the practitioner or the Board.

6. Control of factors contributing to abuse of legitimately obtained drugs, devices, or controlled substances.

7. Promotion of scientific or technical advances in the practice of pharmacy and the manufacture and distribution of controlled drugs, devices or substances.

8. Impact on costs to the public and within the health care industry through the modification of mandatory practices and procedures not essential to meeting the criteria set out in subdivisions 1 through 7 of this section.

9. Such other factors as may be relevant to, and consistent with, the public health and safety and the cost of rendering pharmacy services.

The Board may collect and examine specimens of drugs, devices and cosmetics which are manufactured, stored or dispensed in this Commonwealth.

The specific authority for the Board to license wholesale distributors is found in the Drug Control Act in the following sections:

§ 54.1-3435. License to act as wholesale distributor; renewal; fee.

It shall be unlawful for any person to engage in the wholesale distribution of prescription drugs in this Commonwealth without a valid unrevoked license issued by the Board. The applicant for licensure as a wholesale distributor, as defined in § 54.1-3401, in this Commonwealth shall apply to the Board for a license, using such forms as the Board may furnish; renew such license using such forms as the Board may furnish, if granted, annually on or before January 1 of each year; notify the Board within thirty days of any substantive change in the information reported on the application form previously submitted to the Board; and remit a fee as determined by the Board.

The Board may promulgate such regulations relating to the storage, handling, and distribution of prescription drugs by wholesale distributors as it deems necessary to implement this section, to prevent diversion of prescription drugs, and to protect the public.

§ 54.1-3435.01. Registration of nonresident wholesale distributors; renewal; fee.

A. Any person located outside this Commonwealth who engages in the wholesale distribution of prescription drugs into this Commonwealth shall be registered with the Board. The applicant for registration as a nonresident wholesale distributor shall apply to the Board using such forms as the Board may furnish; renew such registration, if granted, using such forms as the Board may furnish, annually on or before January 1 of each year; notify the Board within thirty days of any substantive change in the information previously submitted to the Board; and remit a fee, which shall be the fee specified for wholesale distributors located within the Commonwealth.

B. The nonresident wholesale distributor shall at all times maintain a valid, unexpired license, permit, or registration in the state in which it is located and shall furnish proof of such upon application and at each renewal.

C. Records of prescription drugs distributed into this Commonwealth shall be maintained in such a manner that they are readily retrievable from records of distributions into other jurisdictions and shall be provided to the Board, its authorized agent, or any agent designated by the Superintendent of the Department of State Police upon request within seven days of receipt of such request.

D. This section shall not apply to persons who distribute prescription drugs directly to a licensed wholesale distributor located within this Commonwealth.

§ 54.1-3435.02. Certain permitted pharmacies and medical equipment suppliers exempted.

A. A permitted pharmacy may engage in wholesale distributions of small quantities of prescription drugs without being licensed as wholesale distributors when such wholesale distributions are in compliance with federal law as follows: such wholesale distributions of controlled substances do not exceed five percent of the gross annual sales of prescription drugs by the relevant permitted pharmacy or such wholesale distributions of Schedules II through V controlled substances do not exceed five percent of the total dosage units of the Schedule II through V controlled substances dispensed annually by the relevant permitted pharmacy.

B. A permitted medical equipment supplier may engage in wholesale distributions of small quantities of oxygen without being licensed as a wholesale distributor when such wholesale distributions are in compliance with federal law and such distributions do not exceed five percent of the gross annual sales of oxygen by the relevant permitted medical equipment supplier.

§ 54.1-3435.1. Denial, revocation, and suspension of license as wholesale distributor or of registration as a nonresident wholesale distributor.

A. The license as a wholesale distributor or registration as a nonresident wholesale distributor of prescription drugs may be denied, suspended, or revoked by the Board for any of the following:

1. Any conviction of the applicant or licensee under federal or state laws relating to controlled substances, including, but not limited to, drug samples and wholesale or retail prescription drug distribution;

2. Any felony conviction of the applicant or licensee;

3. Any misdemeanor conviction of the applicant or licensee for a crime involving moral turpitude;

4. Conduct in the manufacture or distribution of prescription drugs contrary to the protection of the health, safety, and welfare of the public;

5. Fraud or deceit in any application for licensure or permit under this chapter;

6. Denial, suspension, revocation, or restriction of any federal or state license previously or currently held by the applicant or licensee for the manufacture or distribution of any drug;

7. Violations of licensing requirements under previously held licenses;

8. Failure to maintain and make available to the Board or to federal regulatory officials those records required to be maintained by wholesale distributors of prescription drugs;

9. Violations of the minimum requirements for qualifications, personnel, storage, and handling of prescription drugs and maintenance of prescription drug records as set forth in the federal Prescription Drug Marketing Act of 1987 (21 U.S.C. §§ 333, 353 and 381) and Part 205 of Chapter 21 of the Code of Federal Regulations; or

10. Violations of any provision of this chapter or regulations of the Board governing wholesale distributors.

B. Wholesale drug distributors shall allow the Board or its authorized agents to enter and inspect, at reasonable times and in a reasonable manner, their premises and delivery vehicles, and to audit their records and written operating procedures. Such agents shall be required to show appropriate identification prior to being permitted access to wholesale drug distributors' premises and delivery vehicles.

The specific authority for the Board to issue permits to manufacturers is found in the Drug Control Act in the following sections:

§ 54.1-3437. Permit to manufacture drugs.

It shall be lawful to manufacture, make, produce, pack, package, repackage, relabel or prepare any drug not controlled by Schedule I after first obtaining the appropriate permit from the Board. Such permits shall be subject to the Board's regulations on sanitation, equipment, and safeguards against diversion. This provision shall not apply to manufacturers or packers of medicated feeds who manufacture or package no other drugs.

§ 54.1-3437.1. Limited permit for repackaging drugs.

The Board may issue a limited manufacturing permit for the purpose of repackaging drugs, upon such terms and conditions approved by the Board, to the pharmacy directly operated by the Department of Mental Health, Mental Retardation and Substance Abuse Services and which serves clients of the community services boards.

§ 54.1-3438. Manufacturing, etc., of drugs or proprietary medicines, to be supervised by pharmacist.

No drugs or proprietary medicines shall be manufactured, made, produced, packed, packaged, repackaged, relabeled or prepared within this Commonwealth, except under the personal and immediate supervision of a pharmacist or such other person as may be approved by the Board of Pharmacy after an investigation and a determination by the Board that they are qualified by scientific or technical training to perform such duties or supervision as may be necessary to protect the public health and safety. This provision shall not apply to manufacturers or packers of medicated feeds who manufacture or pack no other drugs. Medicated feeds are hereby defined as products obtained by mixing a commercial feed and a drug.

§ 54.1-3439. Application for nonrestricted manufacturing permit; fee.

Every person desiring to manufacture any drug or proprietary medicines shall annually apply to the Board for a nonrestricted manufacturing permit. The application shall be accompanied by the required fee. Separate applications shall be made and separate permits issued for each specific place of manufacturing. Each such permit shall expire on December 31.

§ 54.1-3440. Persons to whom nonrestricted permit is granted.

No person shall be granted a nonrestricted permit as a manufacturer unless he is of good moral character and properly equipped as to land, buildings, equipment and safeguards against diversion to carry out the functions of a manufacturer with due regard to the protection of the public safety.

§ 54.1-3441. Restricted manufacturing permit; application; fee; separate application and permit for each place of manufacturing.

Every person desiring to manufacture a proprietary medicine or to repackage medical gases shall apply to the Board for a restricted manufacturing permit. The application shall be accompanied by the required fee. Separate applications shall be made and separate permits issued for each separate place of manufacturing.

§ 54.1-3442. When permit not to be granted; regulations.

No person shall be granted a restricted manufacturing permit as a manufacturer unless such person is properly equipped as to buildings and equipment to carry out the functions of a manufacturer with due regard to the protection of the public health. The Board shall promulgate regulations in order to carry out the provisions of this section.

Purpose

Please explain the need for the new or amended regulation by (1) detailing the specific reasons why this regulatory action is essential to protect the health, safety, or welfare of citizens, and (2) discussing the goals of the proposal and the problems the proposal is intended to solve.

Counterfeiting of prescription drugs is a growing risk to the public health and safety and a potentially lucrative source of criminal activity. Over the past several years the incidences of counterfeit prescription drug products detected in the U.S. legitimate drug supply system has been increasing. In the 1990's, the average number of counterfeit drugs found in the supply system was approximately 5 per year. According to FDA, this number has jumped to over 20 a year since 2001.

Of the drugs which have found to be counterfeited, many are expensive injectable drugs used to treat our sickest population, patients undergoing cancer chemotherapy, AIDS patients, and patients with kidney disease undergoing renal dialysis. Under-treatment or non-treatment in these patients due to receiving counterfeit drug products would lead to exacerbation of the disease state or other symptoms, and possibly death. In at least one case, a counterfeit product purporting to be Procrit, was not only found to contain little to no active drug, but was also contaminated with acinetobacter and pseudomonas bacteria, which could easily lead to a deadly infection in a normal patient, and is much more dangerous to a patient who already has a compromised immune system.

Counterfeiting has become very sophisticated in that often the counterfeit products look almost identical to the real product. Much of the counterfeiting takes place in garage labs where there is no consideration of maintaining even sanitary conditions much less sterile conditions. The counterfeiting business is very lucrative. There is little overhead, and with the high cost of some prescription drugs, very profitable. In one Florida case, one company selling counterfeit drugs to

a Tennessee wholesaler received $17 million in wire transfers. It has become more lucrative than dealing in illegal street drugs and less risky in terms of penalties if caught.

Florida hosted the majority of these criminal enterprises up until about two years ago when it increased its oversight of the wholesale distributor business and began serious enforcement efforts. Now these businesses are looking for other states with less strict laws and regulations. It is important for Virginia to act now to strengthen and clarify its rules as a deterrent to counterfeiters.

The Board of Pharmacy is proposing amendments to increase its oversight of the wholesale distribution market in order to prevent opportunities for counterfeiting of drugs and ensure the integrity, safety and efficacy of drugs or devices distributed in the Commonwealth. While current regulations require persons engaged in the wholesale distribution of drugs to hold a permit issued by the Board and to adhere to certain rules for safeguarding drugs from diversion, additional requirements are needed to adequately protect the public from the distribution of counterfeited, adulterated, misbranded, or otherwise unfit drugs.

Substance

Please briefly identify and explain the new substantive provisions, the substantive changes to existing sections, or both where appropriate. (More detail about these changes is requested in the "Detail of changes" section.)

The Board has adopted requirements for the licensure and regulations of wholesale distributors and manufacturers as a new chapter – Chapter 50, Regulations Governing the Licensure of Wholesale Distributors, Manufacturers and Warehousers. In doing so, current rules for permits, fees, and security for wholesale distributors and manufacturers would be eliminated in Chapter 20 and moved to the new chapter. Rules for manufacturers are identical to those currently found in Chapter 20, but the rules for wholesale distributors include additional application and practice requirements.

The proposed action for wholesale distributors encompasses some of the Model Rules of the National Association of Boards of Pharmacy, includes some definitions for terms not currently defined in the Drug Control Act, specific criteria for an application for licensure to include detailed information about the distribution operation, provisions for inspections and requirements for personnel, security, anti-counterfeiting measures, recordkeeping, and quality control.

Issues

Please identify the issues associated with the proposed regulatory action, including:
1) the primary advantages and disadvantages to the public, such as individual private citizens or businesses, of implementing the new or amended provisions;
2) the primary advantages and disadvantages to the agency or the Commonwealth; and
3) other pertinent matters of interest to the regulated community, government officials, and the public.

If the regulatory action poses no disadvantages to the public or the Commonwealth, please so indicate.

1) The primary advantage to the public is additional protection from the consequences of misbranded, adulterated, or counterfeited prescription drugs. In an increasingly complex environment for the marketing and distribution of prescription drugs and devices, the Board of Pharmacy has an obligation to be proactive in ensuring the safety, integrity and quality of controlled substances that are distributed in the Commonwealth. In instances where due diligence has not been observed in other states, drugs that were adulterated or counterfeited have entered the consumer market and resulted in harm to the public. Harm may come from an adulterated or counterfeited drug or device to which a patient has an adverse reaction or which does not have the strength or quality to achieve the intended result from pharmacotherapy.

It is the Board's responsibility to set out rules that minimize opportunities for counterfeiting of the drug supply, to ensure that records are being adequately maintained, and ensure that there is sufficient oversight to deter adulteration or counterfeiting. With the adoption of new regulations for wholesale distributors, the Board intends to add rules that offer clear standards of practice that provide for both deterrence and enforcement.

2) There are no disadvantages to the public or the agency. There will be some increased effort and cost associated with expanded application and oversight requirements, but the board intends to issue limited-use permits to the majority of its currently-licensed wholesale distributors who only engage in the distribution of medical gases. The availability of a limited-use permit will allow the board to focus on a small number of entities that are actually distributing the full range of prescription drugs in Virginia.

Economic impact

Please identify the anticipated economic impact of the proposed regulation.

Projected cost to the state to implement and enforce the proposed regulation, including (a) fund source / fund detail, and (b) a delineation of one-time versus on-going expenditures	As a special fund agency, the Board must generate sufficient revenue to cover its expenditures from non-general funds, specifically the renewal and application fees it charges to practitioners or entities for necessary functions of regulation. There would be a one-time expense of approximately $3,000 for promulgation of the amended rule, including meetings of the Regulation Committee at which this regulation has been developed. A public hearing would be heard in conjunction with a regularly scheduled board meeting, and to the extent possible, all notifications would be done electronically to minimize the cost. On-going expenditures for the agency are related to inspections of wholesale distributors which are not currently conducted but will be required for licensure under the proposed regulations. There are 125 current active wholesale distributors; 50 are

	probably suppliers of only medical gases. The remaining 75 probably supply prescription drugs. DHP estimates the inspection time, including travel, for the gas only suppliers to be 2.5 hours and the average inspection time for suppliers of prescription drugs to be 4 hours (there are several large wholesale distributors that may take 8 hours or more hours to complete). Based on an hourly rate of $71, the estimated cost of inspecting all wholesale distributors to be: 50 * 2.5 hours * $71 = $8,875 75 * 4 hours * $71 = $21,300 Total = $30,175 Based on a two year inspection cycle, the annual cost would be one half the total or $15,078.50. The Board has estimated that the additional expenditures could be offset by fees charged to licensees, but costs related to regulation of wholesale distributors will have to be re-evaluated after the next biennium to determine whether fees are sufficient to support their regulation.
Projected cost of the regulation on localities	None
Description of the individuals, businesses or other entities likely to be affected by the regulation	The businesses affected would be wholesale distributors, manufacturers and warehousers.
Agency's best estimate of the number of such entities that will be affected	There are currently: Wholesale distributors 153 Non-resident wholesale distributors 553 Manufacturers 21 Warehousers 29
Projected cost of the regulation for affected individuals, businesses, or other entities	Manufacturers and warehousers will not incur additional costs since requirements for fees, inspections, storage and security are consistent with current rules. Additional cost to existing wholesale distributors should be minimal, because the requirements were either already required by VA in the current rules (alarm, etc), or required by the federal regulations. Minimum facility requirements, records, policy and procedures are essentially the same as current requirements. When the Department begins to inspect wholesale distributors, some existing facilities may be found to be out of compliance, and bringing facilities into compliance may represent a cost that would be incurred if they were currently being inspected. Some requirements for information on the initial application and the specific requirements for responsible party are new and will require

	additional effort and costs. It is likely that existing wholesale distributors would already have a person on staff that meets the requirements, but for new applicants, there may be the cost of having to provide the additional requested information. The three major national distributors are already licensed in Virginia and would meet the proposed requirements.

Alternatives

Please describe any viable alternatives to the proposal considered and the rationale used by the agency to select the least burdensome or intrusive alternative that meets the essential purpose of the action.

In order to set out rules that are enforceable through inspections and disciplinary proceedings conducted by the Board, it is necessary to adopt regulations. While the Board could issue a guidance document that expresses its intent regarding the practices of wholesale distributors, it would not have legal standing to enforce the guidance as requirements of law and regulation. In recognition of the need to address actual and potential problems with distribution of drugs that do that meet standards for purity, quality and safety, the National Association of Boards of Pharmacy (NABP) has recently issued Model Rules for the Licensure of Wholesale Distributors. Effective February 20, 2004, the Model Rules establish definitions used in regulation, requirements for licensure, minimum qualifications for persons who engage in wholesale distribution of drugs or devices, minimum requirements for storage, handling, transport and shipment and for maintenance of records, requirements for security and anti-counterfeiting, storage of drugs and devices, returned, damaged or outdated drugs, and recordkeeping. Model Rules also require the development of policies and procedures and sets out prohibited acts that are unlawful for a person to perform or to aid in the performance.

Rather than adopting the NABP Model Rules by reference or incorporating them wholly into its regulation, the Board used them as a guideline in developing regulations. The Board also received recommended rules from Pfizer, Inc. and "Recommended Guidelines for Pharmaceutical Distribution System Integrity" from the Healthcare Distribution Management Association (HDMA). In addition, the Board looked at regulations in other states for wholesale distribution of drugs and devices and involved advisors who have familiarity with the wholesale distribution business in the development of rules that will achieve the goal of protecting the integrity and safety of prescription drugs and devices but avoid requirements that may be onerous and without justification. The Board of Pharmacy convened a workgroup of stakeholders to review regulations of wholesale distributors with the intent of strengthening the ability of the Board to detect problems and enforce rules aimed at protection of the drug supply. Advisors from Pfizer, HDMA, the Virginia Pharmacists Association, and others participated with a committee of board members to consider all recommendations and model regulations.

After extensive discussion and review of all recommended requirements, the Committee adopted many of the Model Rules from NABP, with the exception of requirements for a $100,000 surety bond and a pedigree system for all prescription drugs through the distribution system. The Board

felt that the surety bond was unnecessary and overly burdensome for some wholesalers who do business in a number of states. While the requirement of a paper pedigree was seriously considered, the Board determined that the cost and burden of such a pedigree system was not warranted at this time. Counterfeiters who produce a look-alike prescription drug and packaging could also easily counterfeit the pedigree, so the Board was not convinced that such a regulation was a sufficient deterrent to warrant the cost and effort.

Subsequent to the adoption of a proposed regulation, advocates for a pedigree system (Pfizer) requested introduction of legislation to mandate promulgation of such a regulation. As introduced, SB1326 (Sen. Ruff) was inclusive of model rules that Pfizer had provided in its comment to the Board. The amendment in the nature of a substitute adopted by the Assembly does give the Board some discretion in the adoption of a regulation and implementation of a pedigree system to address primarily those schedules of drugs more subject to counterfeiting. The Board will be addressing the new statutory requirement for a pedigree in a separate rulemaking process once the statute takes effect. The Board did not want to delay the effective date of these regulations as it considers these changes essential in deterring the establishment of criminal enterprises in the wholesale distributor business in Virginia.

Public comment

Please summarize all comments received during public comment period following the publication of the NOIRA, and provide the agency response.

Commenter	Comment	Agency response
Gary Bolick, Director of Government Affairs, Pfizer, Inc.	Believe preventing counterfeit, misbranded or adulterated medications from entering the drug distribution system is a critical initiative. Pfizer provided model rules that included the following key elements: 1) Licensure that would ensure that only legitimate suppliers are involved in the distribution system, including criminal and business background information and a surety bond; 2) restrictions of the sale, distribution and transfer of prescription drugs; and 3) a paper or electronic pedigree that authenticates the drug as it moves through the distribution system.	The Board accepted many of the recommendations of Pfizer in its requirements for licensure, but did not adopt the suggested rules for a surety bond, the 5% limitation on sales that leave the normal chain of distribution, or the pedigree requirements.

Family impact

Please assess the impact of the proposed regulatory action on the institution of the family and family stability.

There is no impact of the proposed regulatory action on the institution of the family and family stability.

Detail of changes

Please detail all changes that are being proposed and the consequences of the proposed changes. Detail all new provisions and/or all changes to existing sections.

Current section number	Proposed new section number, if applicable	Current requirement	Proposed change and rationale
18VAC110-20-20	n/a	Fees for applications, renewal, inspection, etc	Deletes those fees related to regulation of manufacturers, wholesale distributors, and warehousers – all regulated in a new chapter (50)
18VAC110-20-630	n/a	Requirement for license or permit to operate as a manufacturer, wholesale distributor, and warehouser	Deleted – requirement in Chapter 50
18VAC110-20-640	n/a	Safeguards against diversion of drugs requirements	Deleted – requirement in Chapter 50
18VAC110-20-660	n/a	Requirements for manufacturing	Deleted – requirement in Chapter 50
18VAC110-20-670	n/a	Compliance with Prescription Drug Marketing Act	Deleted – requirement in Chapter 50 *Currently, the Board incorporates the federal Prescription Drug Marketing Act to establish regulations for wholesale distributors. However, the federal government mandates that those facilities be licensed and inspected by state boards, so having requirements set out in the Virginia Administrative Code is clearer for compliance and enforcement purposes.*
n/a	18VAC110-50-10	n/a	**Sections 10-50 are applicable to wholesale distributors, manufacturers and warehousers** Section 10 establishes definitions for certain terms and acronyms used in regulation
n/a	20	n/a	Sets fees for applications, renewal, late renewal, reinstatement, inspections, and miscellaneous actions. Also sets policies for renewal and reinstatement. *The fees and policies are identical to those currently required.*
n/a	30	n/a	**Application; Location of business; inspection required** A. Any person or entity desiring to obtain a license as a wholesale distributor, registration as a non-resident wholesale distributor, or permit as a manufacturer or warehouser shall file an application with the board on a form approved by the board. An application shall be filed for

			a new license, registration, or permit, or for acquisition of an existing wholesale distributor, manufacturer, or warehouser. B. A licensee or permit holder proposing to change the location of an existing license or permit, or make structural or security system 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. *Requirements for an application and inspection of a newly or structural altered location prior to being granted a license to operate and stock prescription drugs are consistent with those for pharmacies.* C. A license or permit shall not be issued to any wholesale distributor, manufacturer, or warehouser 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. *Currently, a wholesale distributor, manufacturer or warehouser is allowed to operate from a private dwelling if there is a separate business entrance and it is open for inspection at all time during normal business hours. From experiences with counterfeit operations in other states, it is apparent that a prohibition on allowing a wholesaler to operate out of a private dwelling is necessary; counterfeiters must often operate from a garage and do not maintain a legitimate business address. If a licensee's business is limited to medical gases or over-the-counter drugs, an applicant could apply for a limited-use license that could waive this requirement of the regulation.* D. If a wholesale distributor, manufacturer, or warehouser engages in receiving, possessing, storing, using, manufacturing, distributing, or otherwise disposing of any Schedule II – V controlled substances, it shall also obtain a controlled substances registration from the board in accordance with § 54.1-3422 of the Code of Virginia, and shall also be duly registered with DEA and in compliance with all applicable laws and rules for the storage, distribution, shipping, handling, and transporting of controlled substances. *It is currently required for a business dealing in scheduled drugs to obtain a DEA registration.* E. Prior to issuance of a license or permit by the board, a proposed location shall be inspected by an authorized agent of the board. 1. Applications which indicate a requested inspection date, or requests which are received after the application is filed, shall be honored provided a 14-day notice is allowed prior to the requested inspection date. 2. Requested inspection dates which do not allow a 14-day notice to the board may be adjusted by the board to provide 14 days prior to conducting a scheduled inspection. 3. At the time of the inspection, the proposed prescription drug storage area shall be in compliance with 18 VAC 110-50-40 and 18 VAC 110-50-50, and wholesale distributors shall meet the requirements of 18 VAC 110-50-90. 4. 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 18 VAC 110-50-20 prior to a reinspection being conducted.

			5. Prescription drugs shall not be stocked within the proposed location or moved to a new location until approval is granted by the inspector or board staff. *Requirements for an inspection, notification to the board and compliance prior to being granted a license to operate and stock prescription drugs are consistent with those for pharmacies.*
n/a	40	n/a	**Safeguards against diversion of drugs.** A. The holder of the license or permit 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. B. The holder of the license or permit, except for those distributors of only medical gases other than nitrous oxide, shall install an operable device for the detection of breaking subject to the following conditions: 1. The device shall be a sound, microwave, photoelectric, ultrasonic, or any other generally accepted and suitable device. 2. The installation shall be hard-wired and both the installation and device shall be based on accepted burglar alarm industry standards. 3. The device shall be operable, centrally-monitored, and have an auxiliary source of power. 4. The device shall fully protect all areas where prescription drugs are stored and shall be reasonably capable of detecting breaking by any means when activated. 5. 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. 6. The system shall be activated whenever the drug storage areas are closed for business. *Requirements for security and detection of breaking are the same as those currently found in 18VAC110-20-640.* C. Distribution or delivery of prescription drugs shall be accomplished in a manner to prevent diversion or possession of drugs by unauthorized persons. 1. The holder of the license or permit 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. 2. The holder of the license or permit shall affirmatively verify that the person to whom prescription drugs are delivered is authorized by law to receive such drugs. 3. Prescriptions 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, or warehouser, 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. *The rule for delivery of drugs is similar to section 640 in Chapter 20, but the provision for transfer of drug to an authorized agent is added to allow a dispenser to meet the immediate needs of a patient. A*

			pharmacy or another wholesaler may need an emergency supply of a drug and may need to send an agent to pick up the drug from the location of the business.
n/a	50	n/a	**Storage** A. All prescription drugs and devices shall be stored at appropriate temperatures and under appropriate conditions in accordance with requirements, if any, in the labeling of such drugs, or with requirements of USP-NF. B. If no specific storage requirements are established for a drug or a device, it may be held at controlled room temperature, as defined in USP-NF, to help ensure that its identity, strength, quality, and purity are not adversely affected. C. Appropriate manual, electromechanical, or electronic temperature and humidity recording equipment, and/or logs shall be utilized to document proper storage of prescription drugs. D. Packaging of the prescription drugs should be in accordance with USP-NF standards. E. Schedule II – V controlled substances shall be separated from Schedule VI prescription drugs and stored in a secure area in accordance with DEA security requirements and standards. F. Any facility shall be of adequate size and construction and have the proper equipment necessary for the proper storage of prescription drugs and devices as set forth in this section. *The requirements for storage of prescription drugs are similar to those currently required in the federal Prescription Drug Marketing Act of 1987 (21 USC §321; 21 CFR 205) – See section 205.50 "Minimum requirements for the storage and handling of prescription drugs"*
n/a	60	n/a	**Part II. Sections 60-140 are only applicable to wholesale distributors.** **Special or limited-use licenses** The regulation will allow the board to issue a limited-use wholesale distributor license to entities that do not engage in the wholesale distribution of prescription drugs except medical gases and may waive certain requirements of regulation based on the limited nature of such distribution. *If a wholesale distributor does not include the distribution of prescription drugs, except for medical gases (which are schedule VI drugs), there would be no need for some of the due diligence and other requirements intended to prevent or deter counterfeiting. In order to reduce the burden of meeting unnecessary requirements, the board could grant a limited-use license to these facilities. Limited-use licenses are currently granted to certain pharmacies that have a specialized practice which does not necessitate all requirements for space, counseling, etc.*
n/a	70	n/a	Section 70 sets **minimum required information.** A. The application form for a new license or for registration as a non-resident wholesale distributor, or any change of ownership shall include at least the following information: 1. The name, full business address, and telephone number of the applicant or licensee and name and telephone number of a designated contact person; 2. All trade or business names used by the applicant or licensee; 3. The federal employer identification number of the applicant or licensee;

			4. The type of ownership and name(s) of the owner of the entity, including: a. If an individual: the name, address, social security number or control number; b. If a partnership: the name, address, and social security number or control number of each partner, and the name of the partnership and federal employer identification number; c. If a corporation: (1) The name and address of the corporation, federal employer identification number, state of incorporation, the name and address of the resident agent of the corporation; (2) The name, address, social security number or control number, and title of each corporate officer and director; (3) For non-publicly held corporations, the name and address of each shareholder that owns ten (10) percent or more of the outstanding stock of the corporation. (4) The name, federal employer identification number, and state of incorporation of the parent company. d. If a sole proprietorship: the full name, address, and social security number or control number of the sole proprietor and the name and federal employer identification number of the business entity; e. If a limited liability company, the name and address of each member, the name and address of each manager, the name of the limited liability company and federal employer identification number, the name and address of the resident agent of the limited liability company, and the name of the state in which the limited liability company was organized; 5. Name, business address and telephone number, and social security number or control number, and documentation of required qualifications as stated in 18VAC110-50-80 of the person who will serve as the responsible party; 6. A list of all states in which the entity is licensed to purchase, possess and distribute prescription drugs, and into which it ships prescription drugs; 7. A list of all disciplinary actions, to include date of action and parties to the action, imposed against the entity by state or federal regulatory bodies, including any such actions against the responsible party, principals, owners, directors, or officers over the last seven years; 8. A full description, for non-resident wholesale distributors, including the address, square footage, security and alarm system description, temperature and humidity control, and other relevant information of the facility or warehouse space used for prescription drug storage and distribution; and 9. An attestation providing a complete disclosure of any past criminal convictions and violations of the state and federal laws regarding drugs or devices or an affirmation and attestation that the applicant has not been involved in, or convicted of, any criminal or prohibited acts. Such attestation shall include the responsible party, principals, directors, officers, or any shareholder who owns 10% or more of outstanding stock in any non-publicly held corporation. B. An applicant or licensee shall notify the board of any changes to the information required in this section within 30 days of such change. *The requirements for licensure are similar to those currently required in the federal Prescription Drug Marketing Act of 1987 (21 USC §321; 21 CFR 205) – See section 205.5 "Minimum required information for*

			licensure" The proposed requirements in section 70 are taken from Section 1 of the "Model Rules for the Licensure of Wholesale Distributors" issued by the National Association of Boards of Pharmacy, with the exception that the Model Rules suggest a surety bond of not less than $100,000 for each license. The Board determined that a surety bond was overly burdensome and did not adopt that regulation.
n/a	80	n/a	**Minimum qualifications, eligibility, and responsible party.** A. The board shall use the following factors in determining the eligibility for licensure of wholesale distributors: 1. The existence of grounds to deny an application as set forth in §54.1-3435.1 of the Code of Virginia; 2. The applicant's past experience in the manufacture or distribution of drugs or devices; 3. Compliance with the recordkeeping requirements; 4. 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 5. The responsible party's credentials as set forth in subsection B of this section. B. Requirements for the person named as the responsible party: 1. The responsible party shall be the primary contact person for the board as designated by the wholesale distributor, who shall be responsible for managing the wholesale distribution operations at that location; 2. The responsible party shall have a minimum of two years of verifiable experience in a pharmacy or wholesale distributor licensed 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; 3. A person may only serve as the responsible party for one wholesale distributor license at any one time; 4. The responsible party shall be employed full time in a managerial position and actively engaged in daily operations of the wholesale distributor; 5. The responsible party shall be present on a full-time basis at the location of the wholesale distributor during normal business hours, except for time periods when absent due to illness, family illness or death, vacation, or other authorized absence; and 6. The responsible party shall be aware of, and knowledgeable about, all policies and procedures pertaining to the operations of the wholesale distributor and all applicable state and federal laws related to wholesale distribution of prescription drugs. C. The person named as the responsible party on the application shall submit the following with the application: 1. A passport size and quality photograph taken within 30 days of submission of the application; 2. A resume listing employment, occupations, or offices held for the past seven years including names, addresses, and telephone numbers of the places listed; 3. A sworn statement or affirmation disclosing whether the person has a criminal conviction or is the subject of any pending criminal charges within or outside the Commonwealth; 4. A criminal history record check through the Central Criminal

			Records Exchange; and 5. 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 wholesale distribution of prescription drugs in which such businesses were named as a party. E. Responsibilities of the responsible party. 1. The responsible party shall ensure that any employee engaged in operations is adequately trained in the requirements for the lawful and appropriate wholesale distribution of prescription drugs. 2. The responsible party shall require that any employee who has access to prescription drugs attest that he has not been convicted of any federal or state drug law or any law relating to the manufacture, distribution or dispensing of prescription drugs. 3. The responsible party shall be responsible for maintaining current working knowledge of requirements for wholesale distributors and assuring continued training for employees. 4. The responsible party shall be responsible for maintaining proper security, storage and shipping conditions for all prescription drugs. 5. The responsible party shall be responsible for maintaining all required records. F. Each non-resident wholesale distributor shall designate a registered agent in Virginia for service of any notice or other legal document. Any non-resident 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 may be served all legal process in any action or proceeding against such non-resident wholesale distributor. A copy of any such service of legal documents shall be mailed to the non-resident wholesale distributor by the board by certified mail at the address of record. *The requirements for minimum qualifications for personnel are similar to those currently required in the federal Prescription Drug Marketing Act of 1987 (21 USC §321; 21 CFR 205) – See section 205.6, "Minimum qualification" The proposed requirements in section 80 are taken from Sections 2 and 3 of the "Model Rules for the Licensure of Wholesale Distributors" issued by the National Association of Boards of Pharmacy. With the complexity of prescription drugs and the business of wholesale distribution, it is necessary to have a responsible party that has the knowledge and experience with controlled substances to ascertain whether there may be problems before a shipment is delivered for dispensing to the consumer.*
n/a	90	n/a	**Minimum requirements for the storage, handling, transport, and shipment of prescription drugs** A. All locations where prescription drugs are received, stored, warehoused, handled, held, offered, marketed, displayed, or transported from shall: 1. Be of suitable construction to ensure that all drugs and devices in the facilities are maintained in accordance with the labeling of such drugs and devices or with official USP-NF compendium standards; 2. Be of suitable size and construction to facilitate cleaning, maintenance, and proper wholesale distribution operations;

			3. Have adequate storage areas to provide adequate lighting, ventilation, temperature, sanitation, humidity, space, equipment, and security conditions; 4. Have a quarantine area for storage of drugs and devices that are outdated, damaged, deteriorated, misbranded, adulterated, counterfeit, or suspected of being counterfeit, otherwise unfit for distribution, or that are in immediate or sealed secondary containers that have been opened; 5. Be maintained in a clean and orderly condition; and 6. Be free from infestation of any kind. B. The facility shall provide for the secure and confidential storage of information with restricted access and policies and procedures to protect the integrity and confidentiality of the information. C. The facility shall provide and maintain appropriate inventory controls in order to detect and document any theft, counterfeiting, or diversion of prescription drugs. *The requirements for licensure are similar to those currently required in the federal Prescription Drug Marketing Act of 1987 (21 USC §321; 21 CFR 205) – See section 205.50 "Minimum requirements for the storage and handling of prescription drugs and for the establishment and maintenance of prescription drug distribution records" The proposed requirements in section 90 are taken from Section 4 of the "Model Rules for the Licensure of Wholesale Distributors," with the exception of a requirement for a pedigree for the wholesale distribution of drugs.*
n/a	100	n/a	**Examination of drug shipments and accompanying documents.** A. Upon receipt, each shipping container shall be visually examined for identity to determine if it may contain contaminated, contraband, counterfeit, suspected of being counterfeit, or damaged drugs, or drugs or devices that are otherwise unfit for distribution. This examination shall be adequate to reveal container damage that would suggest possible contamination, adulteration, misbranding, counterfeiting, suspected counterfeiting, or other damage to the contents. B. Upon receipt of drugs, a wholesale distributor must review records for accuracy, completeness, and the integrity of the drugs considering the total facts and circumstances surrounding the transactions and the wholesale distributors involved. C. Each outgoing shipment shall be carefully inspected for identity of the drugs and to ensure that there is no delivery of drugs that have been damaged in storage or held under improper conditions. *The requirements for licensure are similar to those currently required in the federal Prescription Drug Marketing Act of 1987 – See section 205.50 (d) on Examination of materials in "Minimum requirements for the storage and handling of prescription drugs and for the establishment and maintenance of prescription drug distribution records" The proposed requirements in section 100 are taken from Section 7 of the "Model Rules for the Licensure of Wholesale Distributors"*
n/a	110	n/a	**Returned, damaged and counterfeit drugs; investigations** A. Any drug or device returned to a manufacturer or another wholesale distributor shall be kept under the proper conditions and documentation showing that proper conditions were maintained shall be provided to the manufacturer or wholesale distributor to which the drugs are returned.

			B. Any drug or device that, or any drug whose immediate or sealed outer or secondary container or labeling, is outdated, damaged, deteriorated, misbranded, adulterated, counterfeited, suspected of being counterfeited or adulterated, or otherwise deemed unfit for human consumption shall be quarantined and physically separated from other drugs and devices until its appropriate disposition. C. When a drug or device is adulterated, misbranded, counterfeited, or suspected of being counterfeit or when the immediate or sealed outer or secondary container or labeling of any drug or device is adulterated, misbranded other than misbranding identified by the manufacturer through a recall or withdrawal, counterfeited, or suspected of being counterfeit, the wholesale distributor shall: 1. Provide notice to the board and the manufacturer, and to the other wholesale distributor if applicable, from which such drug or device was acquired within three business days of that determination. 2. Maintain any such drug or device, its containers and labeling, and its accompanying documentation or any evidence of criminal activity until its disposition by the appropriate state and federal government authorities. D. The wholesale distributor shall fully cooperate with authorities conducting any investigation of counterfeiting or suspected counterfeiting to include the provision of any records related to receipt or distribution of the suspect drug or device. *The requirements for licensure are similar to those currently required in the federal Prescription Drug Marketing Act of 1987 – See section 205.50 (e) on Returned, damaged and outdated prescription drugs in "Minimum requirements for the storage and handling of prescription drugs and for the establishment and maintenance of prescription drug distribution records" The proposed requirements in section 100 are taken from Section 8 of the "Model Rules for the Licensure of Wholesale Distributors"*
n/a	120	n/a	**Policies and procedures** All wholesale distributors shall establish, maintain, and adhere to written policies and procedures for the proper receipt, security, storage, inventory, and distribution of prescription drugs. Wholesale distributors shall include in their policies and procedures at least the following: 1.A procedure for reporting thefts or losses of prescription drugs to the board and other appropriate persons; 2. A procedure whereby the oldest approved stock of a prescription drug is distributed first. The procedure may permit deviation from this process provided the deviation is temporary and appropriate for the distribution; 3. A procedure for handling recalls and withdrawals of prescription drugs and devices; 4. Procedures for preparing for, protecting against, and handling emergency situations that affect the security and integrity of drugs or the operations of the wholesale distributor; 5. A procedure to ensure that outdated drugs are segregated from other drugs to include the disposition of such drugs; 6. A procedure to ensure initial and ongoing training of all employees; 7. A procedure for ensuring, both initially and on an ongoing basis, that persons with access to prescription drugs have not been convicted of a drug law or any law related to the manufacture, distribution, or dispensing of prescription drugs; and

			8. A procedure for reporting counterfeit or suspected counterfeit prescription drugs or counterfeiting or suspected counterfeiting activities to the board and other appropriate law enforcement or regulatory agencies. *The requirements for licensure are similar to those currently required in the federal Prescription Drug Marketing Act of 1987 – See section 205.50 (g) on Written policies and procedures in "Minimum requirements for the storage and handling of prescription drugs and for the establishment and maintenance of prescription drug distribution records" The proposed requirements in section 120 are taken from Section 13 of the "Model Rules for the Licensure of Wholesale Distributors"*
n/a	130	n/a	**Recordkeeping** A. All records and documentation required in this subsection shall be maintained and made available for inspection and photocopying by an authorized agent of the board for a period of three years following the date the record was created or received by the wholesale distributor. A wholesale distributor shall establish and maintain the following: 1. Inventories and records of all transactions regarding the receipt and distribution, or other disposition of all prescription drugs, including the dates of receipt and distribution or other disposition; 2. Records documenting monitoring of environmental conditions to ensure compliance with the storage requirements as required in 18VAC110-50-50; 3. Documentation of visual inspection of drugs and accompanying documents required in 18VAC110-50-100, including the date of such inspection and the identity of the person conducting the inspection; 4. Documentation of quarantine of any product and steps taken for the proper reporting and disposition of the product shall be maintained, including the handling and disposition of all outdated, damaged, deteriorated, misbranded, or adulterated drugs; 5. An ongoing list of persons or entities from whom it receives prescription drugs and persons or entities to whom it distributes prescription drugs; 6. Copies of the mandated report of thefts or unusual losses of Schedule II-V controlled substances in compliance with the requirements of §54.1-3404 of the Code of Virginia; and 7. A copy of any written report to the board of any significant shortages or losses of prescription drugs. B. Records shall be either: a) be kept at the inspection site or immediately retrievable by computer or other electronic means and made readily available at the time of inspection; or b) if kept at a central location and not electronically retrievable at the inspection site, be made available for inspection within 48 hours of a request by an authorized agent of the board. C. All facilities shall have adequate backup systems to protect against the inadvertent loss or deliberate destruction of data. *The requirements for licensure are similar to those currently required in the federal Prescription Drug Marketing Act of 1987 – See section 205.50 (f) on Recordkeeping in "Minimum requirements for the storage and handling of prescription drugs and for the establishment and maintenance of prescription drug distribution records" The proposed requirements in section 130 are taken from Section 10 of the "Model Rules for the Licensure of Wholesale Distributors"*

n/a	140	n/a	**Due diligence.** A. Prior to the initial purchase of prescription drugs from another wholesale distributor not residing and licensed in Virginia, a wholesale distributor shall obtain, and update annually, the following information from the selling wholesale distributor: 1. A copy of the license to wholesale distribute from the resident state; 2. The most recent facility inspection report from the resident board or licensing agency; 3. A list of other names under which the wholesale distributor is doing business, or was formerly known as; 4. A list of corporate officers; 5. A list of all disciplinary actions by state and federal agencies; 6. A description, including the address, dimensions, and other relevant information, of each facility or warehouse used for drug storage and distribution; 7. A statement as to whether and for whom the wholesale distributor is an authorized distributor of record. B. If the selling wholesale distributor's facility has not been inspected by the resident board or the board's agent within three years of the contemplated purchase, the purchasing wholesale distributor may conduct an inspection of the wholesale distributor's facility prior to the first purchase of drugs or devices from another wholesale distributor, to ensure compliance with applicable laws and regulations relating to the storage and handling of drugs or devices. A third party may be engaged to conduct the site inspection on behalf of the purchasing wholesale distributor. C. Prior to the first purchase of drugs from another wholesale distributor not residing in and licensed in Virginia, the purchasing wholesale distributor shall secure a national criminal background check of all of the wholesale distributor's owners, corporate officers, and the person named as the responsible party with the resident board or licensing agency. *Due diligence is necessary if a wholesale distributor is buying drugs from another distributor not licensed in Virginia. Without assurances that the other distributor is a legitimate business operating within the law and in accordance with basic standards for sanitation, security and safety, the protection of the drug supply in Virginia could be jeopardized. The proposed requirements in section 140 are taken from Section 9 of the "Model Rules for the Licensure of Wholesale Distributors," except the requirements related to authentications of a drug's pedigree were not adopted.*
n/a	150	n/a	**Section 150 only pertains to manufacturers.** A. The Good Manufacturing Practice for Finished Pharmaceuticals regulations set forth in 21 CFR 211 are adopted by reference. B. Each manufacturer of drugs shall comply with the requirements set forth in the federal regulations referred to in subsection A of this section. *The requirements and incorporation by reference are identical to section 660 currently found in Chapter 20.*