Virginia Regulatory Town Hall

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Final Regulation
Agency Background Document

Agency name	Board of Pharmacy, Department of Health Professions
Virginia Administrative Code (VAC) citation	18VAC110-50-10 et seq.
Regulation title	Regulations Governing the Wholesale Distributors, Manufacturers and Warehousers
Action title	Establishment of a pedigree system
Document preparation date	September 13, 2007

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

Please provide a brief summary (no more than 2 short paragraphs) of the proposed new regulation, proposed amendments to the existing regulation, or the regulation proposed to be repealed. Alert the reader to all substantive matters or changes. If applicable, generally describe the existing regulation.

Part IV (sections 160-190) and applicable definitions in section 10 are being added to comply with the statutory mandate for the "*establishment and implementation of a pedigree system.*" The Board is required by law to "*structure the implementation of the pedigree with limited application to certain schedules or certain drugs, upon finding that such drugs are more subject to counterfeiting* and to "*establish in regulation a process for amending such list that provides notice and opportunity for public comment.*" As required by law, the Board has limited the pedigree system "*to those drugs that have left the normal distribution channel as defined in subsection D.*" The Board has also provided for exceptions to the pedigree requirements of this section for emergency medical reasons as defined in regulation.

Statement of final agency action

Please provide a statement of the final action taken by the agency including (1) the date the action was taken, (2) the name of the agency taking the action, and (3) the title of the regulation.

On September 12, 2007, the Board of Pharmacy adopted final amendments to 18VAC110-50-10 et seq., Regulations Governing the Wholesale Distributors, Manufacturers and Warehousers for the establishment of a pedigree system.

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 numbers, if applicable, and (2) promulgating entity, i.e., agency, board, or person. Describe the legal authority and the extent to which the authority is mandatory or discretionary.

18VAC110-50-10 et seq. Regulations Governing Wholesale Distributors, Warehousers and Manufacturers 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 mandate to establish pedigree requirements is found in § 54.1-3307 of the Code of Virginia.

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

A. 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 that do not conform to the requirements of law.

The Board's regulations shall include criteria for:

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.

B. The Board's regulations to implement the criteria set forth in subsection A shall include, but shall not be limited to, the establishment and implementation of a pedigree system, as defined in subsection D. The Board shall structure the implementation of the pedigree with limited application to certain schedules or certain drugs, upon finding that such drugs are more subject to counterfeiting. In order to maintain a current and appropriate list of drugs susceptible to counterfeiting, the Board may amend such list in its regulations. Such amendments to the list shall be exempt from the requirements of Article 2 (§ 2.2-4006 et seq.) of the Administrative Process Act. The Board shall establish in regulation a process for amending such list that provides notice and opportunity for public comment. The Board shall limit the implementation of a pedigree system to those drugs that have left the normal distribution channel as defined in subsection D. The pedigree shall also satisfy the requirements of 21 U.S.C. § 353(e), regarding requirements for wholesale distributors of drugs in interstate commerce. The Board may provide for exceptions to the pedigree requirements of this section for emergency medical reasons as defined in regulation.

C. The Board may collect and examine specimens of drugs, devices and cosmetics that are manufactured, distributed, stored or dispensed in the Commonwealth.

D. For the purposes of this section:

"Normal distribution channel" means a chain of custody for a prescription drug from initial sale by a pharmaceutical manufacturer, through acquisition and sale by one wholesale distributor as defined in § 54.1-3401, that is not exempted pursuant to § 54.1-3401.1, until sale to a pharmacy or other person dispensing or administering the controlled substance; or a chain of custody for a prescription drug from initial sale by a pharmaceutical manufacturer, through acquisition and sale by one wholesale distributor as defined in § 54.1-3401, that is not exempted pursuant to § 54.1-3401.1, to a chain pharmacy warehouse to its intracompany pharmacies; or a chain of custody for a prescription drug from initial sale by a pharmaceutical manufacturer to a chain pharmacy warehouse to its intracompany pharmacies.

"Pedigree" means a paper document or electronic file recording each distribution of a controlled substance from sale by a pharmaceutical manufacturer through acquisition and sale by any wholesale distributor, as defined in § 54.1-3401 and not exempted pursuant to § 54.1-3401.1, until sale to a pharmacy or other person dispensing or administering the controlled substance. Returns from a pharmacy to the originating wholesale distributor or pharmaceutical manufacturer shall not be subject to the pedigree requirements of this section.

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.

Purpose

Please explain the need for the new or amended regulation. Describe the rationale or justification of the proposed regulatory action. Detail the specific reasons it is essential to protect the health, safety or welfare of citizens. Discuss the goals of the proposal and the problems the proposal is intended to solve.

The Board of Pharmacy has proposed a pedigree system 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 by establishment of a pedigree system. "Pedigree" means "*a paper document or electronic file recording each distribution of a controlled substance from sale by a pharmaceutical*

manufacturer through acquisition and sale by any wholesale distributor, as defined in § 54.1-3401 and not exempted pursuant to § 54.1-3401.1, until sale to a pharmacy or other person dispensing or administering the controlled substance. Returns from a pharmacy to the originating wholesale distributor or pharmaceutical manufacturer shall not be subject to the pedigree requirements of this section."

Chapter 50 of the Board of Pharmacy regulations is being amended to comply with a statutory mandate to "regulate the practice of pharmacy and the manufacturing, dispensing, selling, distributing, processing, compounding, or disposal of drugs and devices" (§54.1-3307 A). To protect the supply of drugs distributed in the Commonwealth, the Board is charged by statute to establish and implement a pedigree system.

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 drugs that leave the normal distribution channel in order to prevent opportunities for counterfeiting of drugs and ensure the integrity, safety and efficacy of drugs or devices distributed in the Commonwealth.

Substance

Please identify and explain the new substantive provisions, the substantive changes to existing sections, or both where appropriate. A more detailed discussion is required under the "All changes made in this regulatory action" 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. The proposed action, as mandated by § 54.1-3307 of the Code of Virginia, will set out the susceptible drugs for which a pedigree must be required, to include those drugs that leave the normal distribution channel or do not fall under one of the variations of the normal distribution channel. In the regulation, the types of drug distribution or variations of the normal distribution channel that do not require a pedigree are listed and defined. There are also a time frame and notice requirements for amending the list of susceptible drugs.

For those distributions that do have to have an authenticated pedigree, the content requirements are set out; distributions are given one year from the effective date of the regulations to comply with the pedigree requirements. There are also requirements for authentication of a pedigree by any manufacturer or distributor listed on the pedigree and provisions of quarantining any drug for which a pedigree cannot be authenticated. Finally, there are requirements for recordkeeping of transactions and pedigree authentications for a period of not less than three years.

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 there are no disadvantages to the public or the Commonwealth, please 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 by establishing rules for a pedigree to follow the distribution of any drug that leaves the normal distribution channel or one of the variations of acceptable distribution. With

the adoption of new regulations for a pedigree system, 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 may be some increased effort and cost associated with expanded oversight requirements, but there is a broad interpretation of "normal distribution channel" so the number of pedigrees that will be required is limited.

Changes made since the proposed stage

Please describe all changes made to the text of the proposed regulation since the publication of the proposed stage. For the Registrar's office, please put an asterisk next to any substantive changes.

In response to public comment, the following amendments were made to regulations as proposed in order to clarify certain provisions.

1) A new subdivision 5 was added to subsection A of section 160 to include another variation considered to be within normal distribution channel, namely distribution from an authorized distributor of record to one other authorized distributor of record to an office-based healthcare practitioner authorized by law to dispense or administer such drug to a patient. The change was requested by the Healthcare Distribution Management Association.

2) A new subsection A was added to section 180 to specify that each person who is engaged in the wholesale distribution of a drug, who is provided a pedigree as specified in 18VAC110-50-160 and attempts to further distribute that drug, must affirmatively verify before any distribution of a prescription drug that each transaction listed on the pedigree has occurred. The change was requested by Cardinal Health, a wholesale distributor. The additional language makes it clear that each person who is engaged in the wholesale distribution of a drug and who is provided a pedigree has the responsibility to authenticate that pedigree before they further distribute the drug.

3) In subsection B, the phrase "only for those applicable transactions outside the normal chain of distribution conducted by that manufacturer or wholesale distributor" was added to ensure that buyers and sellers only have to undertake the process of authentication of a pedigree when they participate in transactions outside the normal chain of distribution. The change was requested by the Pharmaceutical Research and Manufacturers of America.

Public comment

Please summarize all comments received during the public comment period following the publication of the proposed stage, and provide the agency response. If no comment was received, please so indicate.

Proposed regulations were published in the Virginia Register of Regulations on June 11, 2007. Public comment was requested for a 60-day period ending August 10, 2007. The following written or electronic comment was received:

- From Elizabeth Gallenagh, Healthcare Distribution Management Association (HDMA).

1) Recommended the insertion in section 160 an additional transaction path allowing a drug to pass from a manufacturer to an Authorized Distributor of Record to one other Authorized Distributor of Record to an office-based healthcare practitioner authorized by law to dispense or administer such drug to a patient.

Board response: *The Board accepted the request of the commenter and inserted the language in section 160.*

2) Requested consideration of an alternative to the definition of "drop shipment" in proposed section 10 to more clearly reflect the practice of drop shipping prescription drugs and to clarify what transactions and entities are involved in the process:

"Drop shipment" means the sale of a prescription drug to a wholesale distributor by the manufacturer of the prescription drug (or by that manufacturer's co-licensed product partner, that manufacturer's third party logistics provider, that manufacturer's exclusive distributor, or by an authorized distributor of record that purchased the product directly from the manufacturer or from one of these entities) whereby:

(i) the wholesale distributor takes title to but not physical possession of such prescription drug;

(ii) the wholesale distributor invoices the pharmacy, pharmacy warehouse, or other person authorized by law to dispense or administer such drug; and

(iii) the pharmacy, pharmacy warehouse, or other person authorized by law to dispense or administer such drug receives delivery of the prescription drug directly from the manufacturer (or from that manufacturer's co-licensed product partner, that manufacturer's third party logistics provider, that manufacturer's exclusive distributor, or from an authorized distributor of record that purchased the product directly from the manufacturer or from one of these entities).

Board response: *The Board did not amend the definition of "drop shipment." The primary difference between the definition suggested by HDMA and that proposed by the Board was the inclusion of a "co-licensed product partner." Such an entity would be a manufacturer and would already be covered by the current definition. The other elements of a drop shipment listed in the commenter's definition are included in the definition as proposed.*

- Michelle Cope, National Association of Chain Drug Stores

Believes the proposed regulations will effectively secure the prescription drug distribution chain in Virginia and urges the Board to adopt the final regulations without changes.

Board response: *The Board considered the comment and made only those changes that were necessary for further clarity of the requirements. Comments from Cardinal, HDMA and PhRMA were provided to NACDS in advance of the Board meeting. In response, NACDS concurred with the changes that were made in final adoption of regulations.*

- Anne Leigh Kerr, Pharmaceutical Research and Manufacturers of America (PhRMA), requested clarification of section 180 so manufacturers or wholesale distributors would not be required to provide information on the authentication of a pedigree for any transaction other than one in which that manufacturer or wholesale distributor participated but so a pedigree would apply only to those applicable transactions outside the normal chain of distribution conducted by that manufacturer or wholesale distributor.

Board response: *The Board accepted the request of the commenter and inserted the language in paragraph B of section 180.*

- Martha Russell, Cardinal Health

1) Recommended the addition of definitions for "authentication" and "co-licensed partner." The term "co-licensed partner" would be included in the definition of a drop shipment as an entity that has the right to engage in the manufacturing and/or marketing of a prescription drug along with another entity.

Board response: *The Board accepted the request of the commenter to add a subsection to the authentication requirements in section 180. Included in the language in new subsection A was the description of "authentication," so the Board determined that an additional definition was unnecessary. The Board also did not add a definition for "co-licensed partner" because such an entity would be a manufacturer and would already be covered by the current definition. In a subsequent email from the commenter, she concurred that, with that explanation, an amendment was not necessary.*

2) Recommended alternative language for the section on returns to clarify confusion about when a pedigree must be generated. The Code requires a pedigree when drugs or sold or returned to another wholesale distributor before or at the time the drug is shipped to such wholesale distributor, but the suggested regulation would exempt certain returns of pharmaceutical products.

Board response: *The Board determined that the applicability of returns of pharmaceutical products was already specified in the statute, and an expansion of allowable returns without a pedigree could be in conflict with law.*

3) Recommended the addition of a paragraph to the authentication section to clarify that each person who is engaged in the wholesale distribution of a drug and who is provided a pedigree has the responsibility to authenticate that pedigree before they further distribute that drug.

Board response: *The Board accepted the request of the commenter and inserted the language as a new subsection A of section 180.*

A Public Hearing before the Board was held on June 12, 2007, at which the following comment was received:

Anne Leigh Kerr, on behalf of Pharmaceutical Research and Manufacturers of America (PhRMA), presented the same comment that was sent by letter and summarized above.

All changes made in this regulatory action

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

Current section number	Proposed new section number, if applicable	Current requirement	Proposed change and rationale
10	n/a	Sets forth definitions for words and terms used in the regulation	Adds definitions for the following terms as necessary for understanding and interpretation of the regulations: "Authorized distributor of record" "Drop shipment" "Manufacturer's exclusive distributor" "Third party logistics provider" *It is necessary to define the exceptions in order to interpret section 160 which sets out the distributions for which a pedigree is not required, to include those prescription drugs that do not leave the normal distribution channel or those that include one or more of the following additional distributions or variations to the normal distribution channel. The terms "normal distribution channel" and "pedigree" are defined in 54.1-3307, so those definitions are applicable to this chapter.*
n/a	160	n/a	**18VAC110-50-160. Susceptible drugs.** A. The list of drugs susceptible to counterfeiting for which a pedigree is required shall be all prescription drugs in Schedules II through VI, except that a pedigree is not required for those prescription drugs that do not leave the normal distribution channel or those that include one or more of the following additional distributions or variations to the normal distribution channel: 1. Distribution by a manufacturer's exclusive distributor *(Defined in section 10)*;

			2. Distribution by a third party logistics provider *(Defined in section 10)*; 3. Drop shipments *(Defined in section 10)*; 4. Distributions to a veterinarian for veterinary use; and *The law requires that the Board structure the implementation of the pedigree with limited application to "certain schedules or certain drugs, upon finding that such drugs are more subject to counterfeiting". At the time the law was drafted, the model rules and regulations adopted by other states used a listing of susceptible drugs to determine the applicability of a pedigree. Subsequently, that concept has been supplanted by the idea of a normal distribution channel or an authorized distributor of record. A listing of specific drugs is constantly subject to change as circumstances in the marketplace dictate, so the concept of a pedigree for drugs that leave the usual channels of distribution seemed to be a more reasonable and effective means of implementing a pedigree system. Therefore, the Board has defined the "susceptible drugs" as those that leave the normal distribution channel or a variation thereof, rather than a listing of specific drug names or schedules.* 5. Distribution from an authorized distributor of record to one other authorized distributor of record to an office-based healthcare practitioner authorized by law to dispense or administer such drug to a patient; 6. Distributions for emergency medical reasons, defined as those in which (i) a state of emergency has been declared by the Governor in accordance with § 54.1-3307.3 of the Code of Virginia, or (ii) there is a documented shortage of a drug, where the failure to acquire and dispense a prescription drug could result in imminent danger to patient health, and the wholesale distributor, in lieu of a pedigree, complies with the following requirements: a. Obtains and maintains documentation from the manufacturer attesting to a shortage of the prescription drug and its non-availability through normal distribution channels; b. Purchases the prescription drug only through an authorized distributor of record and maintains the name of such distributor; c. Maintains a list of pharmacies or other authorized entities to which the prescription drug was distributed; and d. Notifies the board within 24 hours of such a distribution. *The law allows the Board to provide for exceptions for medical reasons, so defined in regulation as a state of emergency declared by the Governor or a documented shortage, such as drugs for flu immunization where there has been an outbreak in one area of the state and drugs need to be shipped in to cover the emergency. To ensure the a "documented shortage" is intend "documented", the regulations provide for compliance with certain requirements for*

			tracking the distribution and notifying the board. ***Change in final adoption: A new subdivision 5 was added to include another variation considered to be within normal distribution channel, namely distribution from an authorized distributor of record to one other authorized distributor of record to an office-based healthcare practitioner authorized by law to dispense or administer such drug to a patient.*** B. Not less than annually, the board shall evaluate whether the list of susceptible drugs in subsection A of this section should be amended. The board may modify the list under its authority to adopt exempt regulations, pursuant to § 2.2-4006 of the Administrative Process Act, in accordance with the following process: 1. The board shall conduct a public hearing on any proposed amendments to subsection A of this section. Thirty days prior to conducting such hearing, the board shall give written notice of the date, time, and place of the hearing to all persons requesting to be notified of the hearings and publish proposed amendments to the list in the Virginia Register of Regulations. 2. During the public hearing, interested parties shall be given reasonable opportunity to be heard and present information prior to final adoption of any amendments. Final amendments of the list shall also be published, pursuant to § 2.2-4031, in the Virginia Register of Regulations. 3. Final amendments to the list of susceptible drugs shall become effective upon filing with the Registrar of Regulations. *The law provides that In order to maintain a current and appropriate list of drugs susceptible to counterfeiting, the Board may amend the "list" in its regulations. Such amendments to the list are exempt from the requirements of Article 2 (§ 2.2-4006 et seq.) of the Administrative Process Act, but the Board must establish in regulation a process for amending such list that provides notice and opportunity for public comment.*
n/a	170	n/a	**18VAC110-50-170. Requirements of a pedigree.** A. For distributions of prescription drugs that require a pedigree in accordance with § 54.1.3307 of the Code of Virginia and 18VAC110-50-160 of this chapter, the pedigree shall list all distributions starting with the sale by a manufacturer through acquisition and sale by any wholesale distributor until final sale to a pharmacy or other person authorized to administer or dispense the prescription drug. B. When required by law and regulation to provide a pedigree, a wholesale distributor shall provide an authenticated pedigree for drugs sold or returned to another wholesale distributor before or at the time the drug is shipped to such wholesale distributor. C. The pedigree shall minimally include the following information on a prescription drug for which a pedigree is required: 1. The trade or generic name of the drug;

			2. The dosage form and strength, the container size, number of containers, and lot number; 3. The name of the manufacturer of the finished drug product; 4. Each transaction in which the drug is shipped or received by a manufacturer or wholesale distributor showing the following: a. The business name and address of each entity involved in the chain of the drug's physical custody; b. Telephone number and other contact information needed to authenticate the pedigree. c. Sales invoice number or other unique shipping document number that identify each transaction; and d. The dates of the transactions to include shipping dates when a seller ships the product and the receiving dates when a purchaser receives the product. 5. A statement of certification that the information contained in the pedigree is true and accurate and the name and signature of the individual certifying the authenticity of the pedigree at the time of shipment of the drug. D. The requirement for a pedigree shall be effective beginning (one year from the effective date of a final regulation). *Requirements for the pedigree are consistent with federal standards. At the suggestion of wholesale distributors who have experience with pedigrees, the Board added information necessary to authenticate the pedigree, such as a telephone number or other contact information. The unique shipping number and transaction dates are necessary for tracking a particular drug through the distribution process in order to authenticate the pedigree.*
n/a	180	n/a	**18VAC110-50-180. Authentication of a pedigree.** A. Each person who is engaged in the wholesale distribution of a drug, who is provided a pedigree as specified in 18VAC110-50-160 and attempts to further distribute that drug, shall affirmatively verify before any distribution of a prescription drug that each transaction listed on the pedigree has occurred. B. Upon request of a wholesale distributor who is attempting to authenticate a pedigree for a drug as specified in 18VAC110-50-160, any manufacturer or wholesale distributor listed on the pedigree shall provide requested information in a timely manner, only for those applicable transactions outside the normal chain of distribution conducted by that manufacturer or wholesale distributor to include the following: 1. Dates of receipt or shipment of the drug as well as the name, address, and other contact information of those entities from whom they received the drug or to whom they shipped the drug;

			2. Lot number; 3. Sales invoice number or other unique shipping document numbers that identify each transaction; and 4. Name of the person who is providing the requested information. B. The wholesale distributor shall record the above information and maintain the information in accordance with 18VAC110-20-190. C. If a wholesale distributor that is attempting to authenticate the distribution of a drug back to a manufacturer is unable to authenticate each distribution, the wholesale distributor shall quarantine the drug and report to the board and the FDA within three business days after completing the attempted authentication. *In order for the wholesale distributor to authenticate the paper pedigree that accompanied the drug distributed with due diligence, he must verify the required information with the manufacturer or wholesale distributor who provided the pedigree. Subsection C provides the requirement for a quarantine and report to the Board if the authentication of the pedigree fails.* ***Changes in final adoption:*** ***A new subsection A was added to specify that each person who is engaged in the wholesale distribution of a drug, who is provided a pedigree as specified in 18VAC110-50-160 and attempts to further distribute that drug, must affirmatively verify before any distribution of a prescription drug that each transaction listed on the pedigree has occurred.*** ***In subsection B, the phrase "only for those applicable transactions outside the normal chain of distribution conducted by that manufacturer or wholesale distributor" was added to ensure that buyers and sellers only have to undertake the process of authentication of a pedigree when they participate in transactions outside the normal chain of distribution.***
n/a	190	n/a	**18VAC110-50-190. Recordkeeping.** A. Wholesale distributors shall establish and maintain inventories and records of all transactions relating to the receipt and distribution or other disposition of drugs as specified in 18VAC110-50-160, to include records of authentication of pedigrees, for a period of not less than three years. B. All records shall be made available to the board or its authorized agent upon request. If records are not kept on premises at the address of record, they shall be made available within 48 hours of such request. *Requirements for recordkeeping are consistent with those for pharmacies that maintain inventory and dispensing records off-premises (see 18VAC110-240). Wholesale distributors are required to maintain pedigree information for 3 years both for enforcement and*

			public safety, in case of an incidence relating to the integrity and validity of a controlled substance.

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.