18VAC110-50-10. Definitions.

In addition to words and terms defined in §§54.1-3300, 54.1-3307 and 54.1-3401 of the Code of Virginia, the following words and terms when used in this chapter shall have the following meanings, unless the context clearly indicates otherwise:

"Authorized distributor of record" means a wholesale distributor with whom a manufacturer has entered into a written agreement under which such wholesale distributor is either authorized to distribute all of that manufacturer's prescription drug products, or only those products listed in the agreement, for such a period of time or number of shipments as specified in the agreement.

"Control number" means the unique identifying customer number assigned by the Virginia Department of Motor Vehicles to an individual when issuing a driver's license, learner's permit, or official identification card. This number is displayed on the driver's license or ID card in lieu of the Social Security Number.

"DEA" means the United States Drug Enforcement Administration.

"Drop shipment" means the sale and distribution of a prescription drug in which a manufacturer, third party logistics provider, or the manufacturer's exclusive distributor directly ships the prescription drug to a pharmacy, chain drug warehouse, or other person authorized to dispense or administer the prescription drug, and the pharmacy, chain drug warehouse or other authorized person is invoiced by a wholesale distributor which took title to the prescription drug during the shipping, but did not take physical possession of the prescription drug.

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

"FDA" means the United States Food and Drug Administration.

"Manufacturer's exclusive distributor" means a distributor licensed by the board as a wholesale distributor or registered as a non-resident wholesale distributor who contracts with a manufacturer to provide or coordinate warehousing, distribution or other services on behalf of a manufacturer for a prescription drug and who takes title to that manufacturer's prescription drug, but who does not have general responsibility to direct the sale or disposition of the prescription drug.

"Third party logistics provider" means an entity licensed by the board as a wholesale distributor or registered as a non-resident wholesale distributor who contracts with a manufacturer to provide or coordinate warehousing, distribution, or other services on behalf of a manufacturer for a prescription drug, but does not take title to the prescription drug and who only sells, distributes, or otherwise disposes of the prescription drug at the direction of the manufacturer.

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

Part IV. Pedigree requirements

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;

2. Distribution by a third party logistics provider;

3. Drop shipments;

4. Distributions to a veterinarian for veterinary use; and

5. 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.

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.

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).

18VAC110-50-180. Authentication of a pedigree.

A. 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, 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.

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.