FINAL/APPROVED (09/27/2006)

VIRGINIA BOARD OF PHARMACY
MINUTES OF AD-HOC PEDIGREE COMMITTEE

July 13, 2006
Fifth Floor
Conference Room 3

Department of Health Professions
6603 West Broad Street
Richmond, Virginia 23230

CALL TO ORDER: A meeting of the ad hoc committee appointed by the Board of Pharmacy to draft regulations to implement a pedigree system was called to order at 9AM.

PRESIDING: John Beckner, Board Vice-Chairman

COMMITTEE MEMBERS PRESENT: Bobby Ison
Michael J. Ayotte

STAFF PRESENT: Elizabeth Scott Russell, Executive Director
Caroline Juran, Deputy Executive Director
Elaine J. Yeatts, Senior Regulatory Analyst
Howard M. Casway, Senior Assistant Attorney General

DISCUSSION: Mr. Beckner called for public comment. There was no comment initially, but Mr. Beckner took public comment throughout the meeting. Cardinal Health had submitted written comments which were distributed and discussed throughout the meeting.

The committee discussed the impact of the recent announcement by FDA to remove the stay on implementation of federal regulations relating to the pedigree requirement, and reviewed a copy of the FDA announcement and related compliance policy guide. One difference between the federal requirements and state law is that federal law does not limit the pedigree to a list of susceptible products. It also defines "authorized distributor of record" (ADR), and does not require that a pedigree be implemented unless a distribution is made by an entity that is not an ADR, whereas Virginia law defines "normal distribution channel" and does not require that a pedigree be implemented unless a distribution is made outside the normal distribution channel. There was consensus that the Board should adopt regulations based on the current state law, and where there were differences, regulates parties would structure business practices to comply with the strictest provision.

The committee completed work on the last revision of draft regulations from the November 9, 2005 meeting. It eliminated the draft specific list of susceptible products based on the fact that federal regulations now applies to all products, and that any such list would be very quickly outdated. It instead recommended

language that exempts certain distribution processes from pedigree requirements due to the fact that those processes make products less susceptible to counterfeiting. The committee also added some definitions related primarily to the pedigree exceptions.

The committee will send the draft to interested parties for comment and will present it to the Board at the September 27 Board meeting for adoption as proposed regulations. (Attachment A).

NEXT MEETING DATE The committee will not meet again unless deemed necessary by the Chair based on comments received on the draft.

ADJOURN: With all business concluded, the meeting adjourned at noon

Elizabeth Scott Russell
Executive Director

John O. Beckner, Vice Chairman

Date

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 authorized to distribute that manufacturer's prescription drug products, either all 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 by a manufacturer, third party logistics provider, or the manufacturer's exclusive distributor directly to a pharmacy, chain drug warehouse, or other person authorized to dispense or administer the prescription drug, in which a wholesale distributor takes title to the prescription drug and invoices the pharmacy, chain pharmacy warehouse or other authorized person, but does not take physical possession.

"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 drug list.

A. A pedigree shall be required for the distribution of all prescription drugs in Schedules II through VI, except that a pedigree is not required for those prescription drugs that are generally not considered susceptible to counterfeiting, defined as those 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;

3. Distribution by a third party logistics provider;

4. Drop shipments;

5. Distributions to a veterinarian for veterinary use; and

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, 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 listed 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 the list in subsection A. 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 listing in subsection A shall become effective upon filing with the Registrar of Regulations.

18VAC110-50-170. Requirements of a pedigree.

A. For distributions of prescription drugs deemed susceptible to counterfeiting that require a pedigree in accordance with § 54.1.3307 of the Code of Virginia and section 18VAC110-50-160 of these regulations, 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. A wholesale distributor shall provide an authenticated pedigree for susceptible prescription 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 on the susceptible list:

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.

7. 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 for susceptible prescription drugs 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 listed 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 included 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.