Final/Approved – 10-31-05

VIRGINIA BOARD OF PHARMACY
MINUTES OF AD-HOC PEDIGREE COMMITTEE

September 19, 2005
Fifth Floor
Conference Room 1

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
Elaine J. Yeatts, Senior Regulatory Analyst
Howard M. Casway, Senior Assistant Attorney General

DISCUSSION: The committee discussed a draft that had been prepared by staff from the previous meeting (Attachment 1). The draft had been provided by email in advance to the committee members and persons who had requested to be notified of meetings of this committee. Cardinal Health had submitted suggested changes to this draft (Attachment 2). Both documents were discussed throughout the meeting.

In the previous meeting there had been discussion about exempting certain entities such as manufacturers, third party logistics providers, and authorized distributors of record (ADR); or exempting certain distribution channels, such as manufacturer to ADR to retail outlet from having to provide a pedigree. However, after reviewing the statute, staff did not consider the Board had the authority to provide such exemptions. Mr. Casway also advised the committee that the statute requires that the pedigree begin with the sale by the manufacturer through any acquisition and sale by any wholesale distributor until final sale to a pharmacy or other person dispensing or administering. He stated that this does not appear to allow for exemptions. The draft also included the elements of a pedigree as submitted by Cardinal Health in its original comments to the NOIRA. The draft included the list of susceptible products currently on NABP's susceptible product list with criteria for additions to and deletions from the list and a requirement for annual review for continued need to be on the list, including a provision for the use of emergency rulemaking to change the list.

The Board accepted public comment as part of the discussion throughout the meeting. Comments on and discussion of the draft primarily related to three areas:
1. Whether the Board could exempt certain entities or distribution scenarios;
2. Whether the NABP list should be included by reference or the drugs specifically listed; and
3. The elements for the pedigree, and trying to make these elements conform to a manufacturer's invoice in order that manufacturer's and ADR's would not need to do anything more than they are already doing.

Todd Kaufman, representing Genentech stated that he believes the statute does allow for exemptions of manufacturers and others and provided a suggested legal construction. Mr. Casway disagreed with him on this matter.

Robert Giacalone representing Cardinal Health suggested that if the manufacturers and ADRs could not be exempted from the pedigree requirement that they be allowed to forward a "pedigree statement" that would not be a true pedigree, but would be a statement that the drug was purchased directly from the manufacturer without all the elements of a pedigree included in the draft regulations. Mr. Casway stated that defining the elements of a pedigree was within the Board's authority, and that if such a pedigree statement included the elements of a pedigree as established by the Board in regulation, it should be acceptable.

There was a comment and subsequent discussion about adopting the NABP susceptible product list by reference and not the specific drugs so that the list would not become outdated. Ms. Yeatts explained that the Board has to specify the date of any document incorporated by reference and therefore it would still need to amend its rules to adopt a more recent version if NABP makes changes, and therefore adopting by reference did not provide any advantage. The wholesale distributors' representatives preferred the adoption of the standard list for ease of compliance rather than a listing of the drugs. Anne Leigh Kerr representing PhRMA indicated that she may seek legislation to allow the Board to amend the list without going through the rulemaking process. After discussion the committee decided to leave the names of the drugs in the working draft. The committee did remove the specific dollar value of a product from the criteria for adding a drug to the list, and just left the term "substantial wholesale cost" as one of the criteria. There were some other amendments made to the section to allow the Board to delete a drug as well as add a drug based on

the criteria.

There was lengthy discussion about minimal required information on a pedigree. A number of suggested amendments were made to the draft 18VAC110-50-190, Content of a pedigree. Most of the suggestions were made to try to conform the contents of a pedigree to information currently on a manufacturer's invoice.

The amended working draft which will be further discussed is Attachment 3 to these minutes.

NEXT MEETING DATE The next meeting was set for October 31, 2005 from 9AM until 11AM.

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

Elizabeth Scott Russell
Executive Director

John O. Beckner, Vice Chairman

Date

Part IV. Pedigree requirements

18VAC110-50-160. Susceptible products.

A. A pedigree shall be required for all dosage forms, strengths and container sizes for the following list of drug products susceptible to adulteration, diversion or counterfeiting:

1. Combivir (lamivudine/zidovudine)
2. Crizivan (indinavir)
3. Diflucan (fluconazole)
4. Epivir (lamivudine)
5. Epogen (epoetin alfa)
6. Gamimune (globulin, immune)
7.Gammagard(globulin,immune)
8. Immune globulin
9. Lamisil (terbinafine)
10. Lipitor (atorvastatin)
11. Lupron (leuprolide)
12. Neupogen (filgrastim)
13. Nutropin AQ (somatropin, E-coli derived)
14. Panglobulin (globulin, immune)
15. Procrit (epoetin alfa)
16. Retrovir (zidovudine)
17. Risperdal (risperidone)
18. Rocephin (ceftriaxone)
19. Serostim (somatropin, mannalian derived)
20. Sustiva (efavirenz)
21.Trizivir(abacavir/lamivudine/zidovudine)
22. Venoglobulin (globulin, immune)
23. Viagra (sildenafil)
24. Videx (didanosine)
25. Viracept (nelfinavir)
26. Viramune (nevirapine)
27. Zerit (stavudine)
28. Ziagen (abacavir)
29. Zocor (simvastatin)
30. Zofran (ondansetron)
31. Zoladex (goserelin)
32. Zyprexa (olanzapine)

B. The board may place a drug on the list of susceptible products under its authority to adopt emergency regulations pursuant to § 2.2-4011 of the Administrative Process Act, if it has seized or issued a stop sale notice of a prescription drug or if it has received notice electronically or in writing from the FDA, a manufacturer, a wholesale distributor a state or federal law enforcement agency, or a government agency responsible for regulating the sale or distribution of prescription drugs that a drug has been adulterated, counterfeited or diverted from the legal channels of distribution; and the prescription drug satisfies one of the following criteria:

1. A shipment of a prescription drug has been reported to a law enforcement agency as having been stolen or missing;

2. The prescription drug is subject to a special, limited distribution process and is not generally sold to wholesale distributors by the manufacturer solely because of concerns about counterfeiting or diversion;

3. The board is aware of five or more instances in which pedigrees or similar documentation were not passed on other than because of unintentional oversight or have been passed on to or by a wholesale distributor and were fraudulent;

4. The prescription drug is used extensively for serious and/or life-threatening conditions, where drug nonresponsiveness would not be considered to be medically unusual;

5. The prescription drug is a single source injectable drug;

6. The prescription drug is commonly prescribed and available for normal use in dosages or strengths that have substantial wholesale cost (of $200 or more) or appears among the IMS top 50 single source revenue-generating prescription drugs; or

7. The prescription drug is in limited supply due to a national shortage that has a duration of not less than nine months.

C. The board may add a drug to the list of susceptible products pursuant to § 2.2-4012.1 of the Administrative Process Act, if any three of the above-listed seven criteria exist and the board determines that the drug is susceptible to adulteration, diversion from the legal channels of distribution, or counterfeiting.

D. Not less than annually, the board shall evaluate whether each prescription drug included on the list of susceptible drugs should remain on the list. In determining whether a prescription drug should remain on the list, the board shall consider the following:

1. The availability of generic forms of the drug;

2. Pricing of the drug that may impact diversion or counterfeiting potential since it was placed on the list; and

3. Whether the conditions contributing to the placement of the list continue to exist.

18VAC110-50-170. Requirement for a pedigree.

A. Pursuant to § 54.1-3307of the Code of Virginia, a pedigree shall be recorded for distribution of any drug listed in 18VAC110-50-160, starting with the sale by a manufacturer through acquisition and sale by any wholesale distributor, whether an authorized distributor of record or not, until final sale to a pharmacy or other authorized person administering or dispensing the susceptible drug.

B. The requirement for a pedigree shall be effective beginning (one year from the effective date of a final regulation).

C. All wholesale distributors shall provide a pedigree for those susceptible drug products sold or returned to another wholesale distributor before the transaction is made to such wholesale distributor.

D. The failure to obtain, authenticate or pass on a pedigree, when required by this chapter, may subject a licensee to disciplinary action by the board.

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

A. Wholesale distributors shall, at least quarterly, conduct authentications of pedigrees of at least 90% of sale units of distributions of drugs on the list of susceptible drug products that were purchased from another wholesale distributor.

B. Wholesale distributors that have engaged in the distribution of a drug, for which a purchasing wholesale distribution is conducting an authentication, shall provide requested information in a timely manner, to include the following:

1. Date of purchase;

2. Lot number or control number;

3. Sales invoice number; and

4. Contact information, including name, address, telephone number, and email address (if available) for the wholesale distributor that sold or purchased the drug, for which the distribution is being authenticated.

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.

D. If the authentication is satisfactorily completed, the wholesale distributor shall maintain records of the authentication for three years and shall produce them to the board upon request.

18VAC110-50-190. Content of a pedigree.

The pedigree shall minimally include the following information on a prescription drug on the susceptible list:

1. The proprietary and established name of the drug;

2. The amount of the drug, its dosage form and strength, the container size, number of containers;

3. The date of the purchase, the sales invoice number, and lot number(s) or control number(s) with expiration dates;

4. The name of the manufacturer and repackager, if applicable, of the finished drug product;

5. The business name, address, telephone number and email address, if available, of each entity involved in the chain of the drug's custody.

6. The license number issued by the Virginia Board of Pharmacy of each entity involved in the chain of the drug's custody;

7. The sales invoice number or other unique shipping document number that identifies the transaction;

8. The dates of the transactions to include the shipping date when the seller ships the product and the receiving date when the purchaser receives the product.

9. The name and address of each person certifying delivery or receipt of the drug;

10. A certification that each recipient has authenticated the pedigree; and

11. A certification from the licensed entity that the information contained therein is true and accurate.

18VAC110-50-200. Recordkeeping.

Wholesale distributors shall establish and maintain inventories and records of all transactions relating to the receipt and distribution or other disposition of drugs included on the list of susceptible drugs for a period of not less than three years.

Part IV. Pedigree requirements

18VAC110-50-160. Susceptible products.

A. A pedigree or pedigree statement shall be required for all dosage forms, strengths and container sizes for the following list of drug products susceptible to adulteration, diversion or counterfeiting:

1. Combivir (lamivudine/zidovudine)
2. Crizivan (indinavir)
3. Diflucan (fluconazole)
4. Epivir (lamivudine)
5. Epogen (epoetin alfa)
6. Gamimune (globulin, immune)
7.Gammagard(globulin,immune)
8. Immune globulin
9. Lamisil (terbinafine)
10. Lipitor (atorvastatin)
11. Lupron (leuprolide)
12. Neupogen (filgrastim)
13. Nutropin AQ (somatropin, E-coli derived)
14. Panglobulin (globulin, immune)
15. Procrit (epoetin alfa)
16. Retrovir (zidovudine)
17. Risperdal (risperidone)
18. Rocephin (ceftriaxone)
19. Serostim (somatropin, mannalian derived)
20. Sustiva (efavirenz)
21.Trizivir(abacavir/lamivudine/zidovudine)
22. Venoglobulin (globulin, immune)
23. Viagra (sildenafil)
24. Videx (didanosine)
25. Viracept (nelfinavir)
26. Viramune (nevirapine)
27. Zerit (stavudine)
28. Ziagen (abacavir)
29. Zocor (simvastatin)
30. Zofran (ondansetron)
31. Zoladex (goserelin)
32. Zyprexa (olanzapine)

B. The board shall adopt the National Specified List of Susceptible Products issued by the National Association of Boards of Pharmacy (NABP) for purposes of establishing a list of susceptible products. However, the Board may place a drug on the list of susceptible products under its authority to adopt emergency regulations pursuant to § 2.2-4011 of the Administrative Process Act, if it has seized or issued a stop sale notice of a prescription drug or if it has received notice electronically or in writing from the FDA, a manufacturer, a wholesale distributor a state or federal law enforcement agency, or a government agency responsible for regulating the sale or distribution of prescription drugs that a drug

has been adulterated, counterfeited or diverted from the legal channels of distribution; and the prescription drug satisfies one of the following criteria:

1. A shipment of a prescription drug has been reported to a law enforcement agency as having been stolen or missing;

2. The prescription drug is subject to a special, limited distribution process and is not generally sold to wholesale distributors by the manufacturer solely because of concerns about counterfeiting or diversion;

3. The board is aware of five or more instances in which pedigrees or similar documentation were not passed on other than because of unintentional oversight or have been passed on to or by a wholesale distributor and were fraudulent;

4. The prescription drug is used extensively for serious and/or life-threatening conditions, where drug nonresponsiveness would not be considered to be medically unusual;

5. The prescription drug is a single source injectable drug;

6. The prescription drug is commonly prescribed and available for normal use in dosages or strengths that have substantial wholesale cost (of $200 or more) or appears among the IMS top 50 single source revenue-generating prescription drugs; or

7. The prescription drug is in limited supply due to a national shortage that has a duration of not less than nine months.

~~C. The board may add a drug to the list of susceptible products pursuant to § 2.2-4012.1 of the Administrative Process Act, if any three of the above-listed seven criteria exist and the board determines that the drug is susceptible to adulteration, diversion from the legal channels of distribution, or counterfeiting.~~

~~D. Not less than annually, the board shall evaluate whether each prescription drug included on the list of susceptible drugs should remain on the list. In determining whether a prescription drug should remain on the list, the board shall consider the following:~~

~~1. The availability of generic forms of the drug;~~

~~2. Pricing of the drug that may impact diversion or counterfeiting potential since it was placed on the list; and~~

~~3. Whether the conditions contributing to the placement of the list continue to exist.~~

18VAC110-50-170. Requirements for a pedigree system.

A. Pursuant to § 54.1-3307 of the Code of Virginia, a pedigree shall be recorded for distribution of any drug listed in 18VAC110-50-160, starting with the sale by a manufacturer through acquisition and sale by any wholesale distributor that is~~, whether~~ not an authorized distributor of record ~~or not~~, until final sale to a pharmacy or other authorized person administering or dispensing the susceptible drug.

B. Notwithstanding paragraph (A), each wholesale distributor who is an authorized distributor of record and intends to distribute a susceptible drug to another wholesaler, shall provide a written pedigree statement for the wholesale distribution of that susceptible drug that states one of the following:

1. If the establishment is not a member of an affiliated group: "This establishment purchased the specific unit of the specified drug directly from the manufacturer"; or

2. If the establishment is a member of an affiliated group: "This establishment or a member of my affiliated group purchased the specific unit of the specified drug directly from the manufacturer"; or

3. If the establishment is a member of an affiliated group: "This establishment or a member of my affiliated group purchased the specific unit of the specified drug directly from the manufacturer or another authorized distributor of record that purchased the specific unit of the specified drug directly from the manufacturer".

CB. The requirement for a pedigree or pedigree statement shall be effective beginning (one year from the effective date of a final regulation).

DC. All wholesale distributors shall provide a pedigree or pedigree statement for those susceptible drug products sold or returned to another wholesale distributor before the transaction is made to such wholesale distributor. However, a third party logistics provider is deemed an agent of the manufacturer and therefore is not required to provide a pedigree paper provided the manufacturer retains title to the prescription drug and the third party logistics provider meets the requirements to be permitted as a wholesale distributor in accordance with § 54.1-3435.

ED. The failure to obtain, authenticate or pass on a pedigree or to provide a pedigree statement, when required by this chapter, may subject a licensee to disciplinary action by the board.

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

A. Wholesale distributors shall, at least quarterly, conduct authentications of pedigrees of at least 90% of sale units of distributions of drugs on the list of susceptible drug products that were purchased from another wholesale distributor.

B. Wholesale distributors that have engaged in the distribution of a drug, for which a purchasing wholesale distribution is conducting an authentication, shall provide requested information in a timely manner, to include the following:

1. Date of purchase;

2. Lot number or control number;

3. Sales invoice number or other unique shipping document number that identifies the transaction; and

4. Contact information, including name, address, telephone number, and email address (if available) for the wholesale distributor that sold or purchased the drug, for which the distribution is being authenticated.

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.

D. If the authentication is satisfactorily completed, the wholesale distributor shall maintain records of the authentication for three years and shall produce them to the board upon request.

18VAC110-50-190. Content of a pedigree.

The pedigree shall minimally include the following information on a prescription drug on the susceptible list:

1. The proprietary and established name of the drug;

2. The amount of the drug, its dosage form and strength, the container size, number of containers;

3. The date of the purchase, the sales invoice number or other unique shipping document number that identifies the transaction, and lot number(s) or control number(s) with expiration dates;

4. The name of the manufacturer and repackager, if applicable, of the finished drug product;

5. The business name, address, telephone number and email address, if available, of each entity involved in the chain of the drug's custody.

6. The license number issued by the Virginia Board of Pharmacy of each entity involved in the chain of the drug's custody;

7. The sales invoice number or other unique shipping document number that identifies the transaction;

8. The dates of the transactions to include the shipping date when the seller ships the product and the receiving date when the purchaser receives the product.

9. The name and address of each person certifying delivery or receipt of the drug;

10. A certification that each recipient has authenticated the pedigree; and

11. A certification from the licensed entity that the information contained therein is true and accurate.

18VAC110-50-200. Recordkeeping.

Wholesale distributors shall establish and maintain inventories and records of all transactions relating to the receipt and distribution or other disposition of drugs included on the list of susceptible drugs for a period of not less than three years.

Proposed New Addtion:

18VAC110-20-400. Returning of drugs and devices.

A. Drugs may be accepted for return or exchange by any pharmacist or pharmacy for resale in accordance with the provisions of §54.1-3411.1 of the Code of Virginia. Devices may be accepted for return or exchange provided the device is in the manufacturer's original sealed packaging.

B. Any pharmacy accepting drugs returned from nursing homes for the purpose of redispensing to the indigent free of charge shall maintain a copy of a written agreement with the nursing home in accordance with §54.1-3411.1 B of the Code of Virginia and a current policy and procedure manual describing the following:

1. Method of delivery from the nursing home to the pharmacy and of tracking of all prescription medications;

2. Procedure for determining the suitability and integrity of drugs for redispensing to include assurance that the drugs have been stored according to official compendial standards; and

3. Procedure for assigning a beyond-use date on redispensed drugs.

C. Returns of prescription drugs to wholesale distributors

1. The returns or exchanges of saleable prescription drugs, received by the wholesale distributor as provided by this subsection and in accordance with §54.1-3307(B) of the Code of Virginia are permissible provided that: (a) the returned product does not appear on the list of susceptible products as defined under **18VAC110-50-160**; and, (b) the returning entity or authorized healthcare practitioner provides the wholesale distributor with a written statement accompanying the returned product that states that the returned product was originally purchased from that wholesale distributor and has been stored, handled, and shipped by that entity or authorized healthcare practitioner in accordance with all applicable Federal, state and local laws and such product has not been adulterated or misbranded within the meaning of the Federal Food, Drug and Cosmetic Act.

2. Any drug that appears on the on the list of susceptible products as defined under **18VAC110-50-160** shall be returned directly to the product's manufacturer unless that drug: (a) was ordered or delivered in error from the Wholesale Distributor; (b) was identified as such within three (3) business days of delivery; (c) that drug was then subsequently physically returned within three (3) business days of notifying the Wholesale Distributor of that error and, (d) the returning entity or authorized practitioner provides the wholesale distributor with a written statement accompanying the returned product that states that the returned product was originally purchased from that wholesale distributor and has been stored, handled, and shipped by that entity or authorized practitioner in accordance with all applicable Federal, state and local laws and such product has not been adulterated or misbranded within the meaning of the Federal Food, Drug and Cosmetic Act.

3. Wholesale distributors are responsible for establishing systems, including policies and procedures, that help to assure that the returns process is designed to prevent the entry of an adulterated or counterfeit product into distribution.

Part IV. Pedigree requirements

18VAC110-50-160. Susceptible products.

A. A pedigree shall be required for all dosage forms, strengths and container sizes for the following list of drug products susceptible to adulteration, diversion or counterfeiting:

1. Combivir (lamivudine/zidovudine)
2. Crixivan (indinavir)
3. Diflucan (fluconazole)
4. Epivir (lamivudine)
5. Epogen (epoetin alfa)
6. Gamimune (globulin, immune)
7.Gammagard(globulin,immune)
8. Immune globulin
9. Lamisil (terbinafine)
10. Lipitor (atorvastatin)
11. Lupron (leuprolide)
12. Neupogen (filgrastim)
13. Nutropin AQ (somatropin, E-coli derived)
14. Panglobulin (globulin, immune)
15. Procrit (epoetin alfa)
16. Retrovir (zidovudine)
17. Risperdal (risperidone)
18. Rocephin (ceftriaxone)
19. Serostim (somatropin, mannalian derived)
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21.Trizivir(abacavir/lamivudine/zidovudine)
22. Venoglobulin (globulin, immune)
23. Viagra (sildenafil)
24. Videx (didanosine)
25. Viracept (nelfinavir)
26. Viramune (nevirapine)
27. Zerit (stavudine)
28. Ziagen (abacavir)
29. Zocor (simvastatin)
30. Zofran (ondansetron)
31. Zoladex (goserelin)
32. Zyprexa (olanzapine)

B. The board may place a drug on the list of susceptible products under its authority to adopt emergency regulations pursuant to § 2.2-4011 of the Administrative Process Act, if it has seized or issued a stop sale notice of a prescription drug or if it has received notice electronically or in writing from the FDA, a manufacturer, a wholesale distributor a state or federal law enforcement agency, or a government agency responsible for regulating the sale or distribution of prescription drugs that a drug has been adulterated, counterfeited or diverted from the legal channels of distribution; and the prescription drug satisfies one of the following criteria:

1. A shipment of a prescription drug has been reported to a law enforcement agency as having been stolen or missing;

2. The prescription drug is subject to a special, limited distribution process and is not generally sold to wholesale distributors by the manufacturer solely because of concerns about counterfeiting or diversion;

3. The board is aware of five or more instances in which pedigrees or similar documentation were not passed on other than because of unintentional oversight or have been passed on to or by a wholesale distributor and were fraudulent;

4. The prescription drug is used extensively for serious and/or life-threatening conditions, where drug nonresponsiveness would not be considered to be medically unusual;

5. The prescription drug is a single source injectable drug;

6. The prescription drug is commonly prescribed and available for normal use in dosages or strengths that have substantial wholesale cost or appears among the IMS top 50 single source revenue-generating prescription drugs; or

7. The prescription drug is in limited supply due to a national shortage that has a duration of not less than nine months.

C. The board may add a drug to the list of susceptible products pursuant to § 2.2-4012.1 of the Administrative Process Act, if the drug is added to the National Association of Boards of Pharmacy Susceptible Product List, or if any three of the above-listed seven criteria exist and the board determines that the drug is susceptible to adulteration, diversion from the legal channels of distribution, or counterfeiting.

D. The board may delete a drug from the list of susceptible products pursuant to § 2.2-4012.1 of the Administrative Process Act, if the drug is deleted from the National Association of Boards of Pharmacy Susceptible Product List, or if the board otherwise determines that a drug should be deleted from the list as specified in paragraph E of this section.

E. Not less than annually, the board shall evaluate whether each prescription drug included on the list of susceptible drugs should remain on the list. In determining whether a prescription drug should remain on the list, the board shall consider the following:

1. The availability of generic forms of the drug;

2. Pricing of the drug that may impact diversion or counterfeiting potential since it was placed on the list; and

3. Whether the conditions contributing to the placement of the list continue to exist.

18VAC110-50-170. Requirement for a pedigree.

A. Pursuant to § 54.1-3307of the Code of Virginia, a pedigree shall be recorded for distribution of any drug listed in 18VAC110-50-160, starting with the sale by a manufacturer through acquisition and sale

by any wholesale distributor, whether an authorized distributor of record or not, until final sale to a pharmacy or other authorized person administering or dispensing the susceptible drug.

B. The requirement for a pedigree shall be effective beginning (one year from the effective date of a final regulation).

C. All wholesale distributors shall provide a pedigree for those susceptible drug products sold or returned to another wholesale distributor before the transaction is made to such wholesale distributor.

D. The failure to obtain, authenticate or pass on a pedigree, when required by this chapter, may subject a licensee to disciplinary action by the board.

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

A. Wholesale distributors shall, at least quarterly, conduct authentications of pedigrees of at least 90% of sale units of distributions of drugs on the list of susceptible drug products that were purchased from another wholesale distributor.

B. Wholesale distributors that have engaged in the distribution of a drug, for which a purchasing wholesale distribution is conducting an authentication, shall provide requested information in a timely manner, to include the following:

1. Date of purchase;

2. Lot number or control number;

3. Sales invoice number; and

4. Contact information, including name, address, telephone number, and email address (if available) for the wholesale distributor that sold or purchased the drug, for which the distribution is being authenticated.

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.

D. If the authentication is satisfactorily completed, the wholesale distributor shall maintain records of the authentication for three years and shall produce them to the board upon request.

18VAC110-50-190. Content of a pedigree.

The pedigree shall minimally include the following information on a prescription drug on the susceptible list:

1. The trade and 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. The business name, address, telephone number and email address, if available, of each entity involved in the chain of the drug's custody.

5. The sales invoice number or other unique shipping document number that identifies the transaction;

6. The dates of the transactions to include the shipping date when the seller ships the product and the receiving date when the purchaser receives the product.

7. The name and address of each person certifying delivery or receipt of the drug;

*8. A certification that each recipient has authenticated the pedigree; and

*9. A certification from the licensed entity that the information contained therein is true and accurate.

18VAC110-50-200. Recordkeeping.

Wholesale distributors shall establish and maintain inventories and records of all transactions relating to the receipt and distribution or other disposition of drugs included on the list of susceptible drugs for a period of not less than three years.

* did not complete work on this section, and may need further revision.