

Date/Time Filed with Registrar of Regulations	VA.R. Document Number: R _____ - _____
	Date of Publication in Virginia Register:

Commonwealth of Virginia

RESPONSE TO PETITION FOR RULEMAKING

Check one: **Initial Agency Notice** **Agency Decision**

Regulatory Coordinator: Elaine J. Yeatts
Telephone: (804) 367-4688 **E-mail:** elaine.yeatts@dhp.virginia.gov

Agency Name: Board of Pharmacy, Department of Health Professions

Chapters affected:

VAC No. <i>(e.g., 4 VAC 20-490):</i>	Chapter Name <i>(e.g., Regulations Pertaining to Sharks):</i>
18 VAC 110-20	Regulations Governing the Practice of Pharmacy

Statutory Authority: 54.1-2400 and Chapters 33 and 34 of Title 54.1

Name of petitioner: Sherry Fortune on behalf of Partners Pharmacy of Virginia

Nature of petitioner's request: Amend regulations pertaining to access to drugs in emergency drug or stat boxes in long term care facilities to allow the use of a Pyxis stat-emergency unit and not require each facility to obtain a controlled substance registration.

INITIAL AGENCY NOTICE

Agency's plan for disposition of the request: The Board will received public comment on the petition for rule-making until 10/3/07 and will review the petition and any comment at its meeting on December 12, 2007 to make decision on whether to initiate rule-making.

Comments may be submitted until October 3, 2007

AGENCY DECISION

- Request Granted
- Request Denied

Statement of reasons for decision:

Agency Contact for Further Information:

Name: Elizabeth Scott Russell
Title: Executive Director, Board of Pharmacy
Address: 9960 Mayland Drive, Richmond, VA 2323e
Telephone: (804) 662-9911 **Fax:** (804) 662-9313 **Toll Free:** 1- -
E-mail: scotti.russell@dhp.virginia.gov

Date Submitted: 8/3/07

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AUG. 15. 2007 10:19AM

NO. 3277 P. 2

CDS-8/3/07

Partners
Partners
Partners



Commonwealth of Virginia
Department of Health Professions
Board of Pharmacy
6603 West Broad Street, 5th floor
Richmond, Virginia 23230-1712

August 15, 2007

To Whom It May Concern:

Partners Pharmacy of Virginia would like to remove the petition for rule making request submitted on July 3, 2007 which requests permission to replace the current stat/emergency/IV boxes with a PYXIS machine in nursing home facilities. We have decided to install the PYXIS as an automated dispensing device which will comply with 18VAC110-20-555. We thank you for your time and consideration in this matter.

Sincerely,

Sherry M. Fortune
Director, Partners Pharmacy of Virginia

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Commonwealth of Virginia

RESPONSE TO PETITION FOR RULEMAKING

Check one: **Initial Agency Notice** **Agency Decision**

Regulatory Coordinator: Elaine J. Yeatts
Telephone: (804) 367-4688 **E-mail:** elaine.yeatts@dhp.virginia.gov

Agency Name: Board of Pharmacy, Department of Health Professions

Chapters affected:

VAC No. <i>(e.g., 4 VAC 20-490):</i>	Chapter Name <i>(e.g., Regulations Pertaining to Sharks):</i>
18 VAC 110-20	Regulations Governing the Practice of Pharmacy

Statutory Authority: 54.1-2400 and Chapters 33 and 34 of Title 54.1

Name of petitioner: Ken Dandurand on behalf of MedNovations, Inc.

Nature of petitioner's request: Amend regulations to allow a non-resident pharmacy (licensed by Virginia) to remotely process a prescription for a Virginia patient in long-term care or a hospital by pharmacists not licensed in Virginia but licensed in the state where the non-resident pharmacy is located.

INITIAL AGENCY NOTICE

Agency's plan for disposition of the request: The Board will received public comment on the petition for rule-making until 10/31/07 and will review the petition and any comment at its meeting on December 12, 2007 to make decision on whether to initiate rule-making.

Comments may be submitted until October 31, 2007

AGENCY DECISION

Request Granted

Request Denied

Statement of reasons for decision:

Agency Contact for Further Information:

Name: Elizabeth Scott Russell
Title: Executive Director, Board of Pharmacy
Address: 9960 Mayland Drive, Richmond, VA 2323e
Telephone: (804) 367-4578 **Fax:** (804) 527-4472 **Toll Free:** 1- -
E-mail: scotti.russell@dhp.virginia.gov

Date Submitted: 8/30/07

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COMMONWEALTH OF VIRGINIA

Board of Pharmacy

6603 W. Broad Street, 6th Floor
 Richmond, Virginia 23230-1712

(804) 662-9911 (Tel)
 (804) 662-9943 (Fax)

Petition for Rule-making

The Code of Virginia (§ 2.2-4007) and the Public Participation Guidelines of this board require a person who wishes to petition the board to develop a new regulation or amend an existing regulation to provide certain information. Within 14 days of receiving a valid petition, the board will notify the petitioner and send a notice to the Register of Regulations identifying the petitioner, the nature of the request and the plan for responding to the petition. Following publication of the petition in the Register, a 21-day comment period will begin to allow written comment on the petition. Within 90 days after the comment period, the board will issue a written decision on the petition.

Please provide the information requested below. (Print or Type)		
Petitioner's full name (Last, First, Middle Initial, Suffix,)		
Dandurand, Kenneth		
Street Address	Area Code and Telephone Number	
316 Talbott Ave., Suite B	413-564-8100	
City	State	Zip Code
Laurel,	MD	20707
Email Address (optional)	Fax (optional)	
kdandur@clinpharm.com	413-564-8101	
Respond to the following questions:		
1. What regulation are you petitioning the board to amend? Please state the title of the regulation and the section/sections you want the board to consider amending.		
18 VAC 110-20-515. Remote prescription order processing for hospitals and long term care facilities. Section B 3		
2. Please summarize the substance of the change you are requesting and state the rationale or purpose for the new or amended rule.		
Please see attached		
3. State the legal authority of the board to take the action requested. In general, the legal authority for the adoption of regulations by the board is found in § 54.1-2400 of the Code of Virginia. If there is <u>other</u> legal authority for promulgation of a regulation, please provide that Code reference.		
54.1-3434-		
Signature:		Date: 8/17/07

Attachment

We are requesting that regulation 18VAC110-20-515 section B.3. be amended to allow a Virginia licensed non-resident pharmacy be allowed to remotely process a prescription by Pharmacists not licensed in Virginia but licensed in the State of Origin of the non resident licensed Pharmacy. This is consistent with what is currently allowed for mail order pharmacies outside the State of Virginia sending prescription medications to end users in Virginia as specified in 54.1-3434.1 Code of Virginia as well as regulation 18VAC110-20-276. Regulation 18VAC110-20-276 does not specify retail or hospital practice and allows for "...a check for accuracy on all processing done by the remote processor..." (section B.3), thus allowing processing by a non-resident pharmacy with pharmacists licensed in another State

By allowing this amendment the State of Virginia will not compromise patient safety and maintain accountability as the non-resident pharmacy must follow Virginia regulations and would be licensed in the State they process orders. Currently close to 70% of hospitals nationwide do not provide 24 hour pharmacist review of all medication orders. These situations allow nurses to review and administer medications without pharmacists review. After-hours remote pharmacy service will provide this needed review in a licensed and professional manner in real time. The current shortage of pharmacists will prevent all hospital pharmacies from reviewing all patient medication orders prior to administration unless alternative methods are available. The method we are requesting is consistent with Joint Commission Accreditation of Healthcare Organizations (JCAHO) standards of prospective pharmacist review of medication orders.

Virginia Administrative Code	18 VAC 110-50-10 et seq.
Regulation title	Regulations Governing the Wholesale Distributors, Manufacturers and Warehouse
Action title	Establishment of a pedigree system

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.

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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.

SUMMARY OF COMMENTS ON PROPOSED REGULATIONS

Virginia Board of Pharmacy

Regulations Governing Wholesale Distributors, Manufacturers and Warehousers 18 VAC 110-50-10 et seq.

Establishment of a Pedigree System

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.

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).*

- 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.

- 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.
- 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.
 - 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.
 - 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.

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.

The Administrative Process Act requires that a summary of comment be sent to all commenters at least five days prior to the adoption of a final regulation. The Board of Pharmacy will meet on September 12, 2007 to consider and respond to the comments and then to adopt a final regulation.



August 8, 2007

Elizabeth Scott Russell, RPh
Executive Director
Virginia Board of Pharmacy
Alcoa Bldg.
6603 W. Broad St., 5th Floor
Richmond, VA 23230-1712

Dear Ms. Russell:

On behalf of the Healthcare Distribution Management Association (HDMA) and our distributor members in Virginia, I submit the following comments regarding the Board of Pharmacy's Proposed Rules implementing amendments enacted in 2006 by the General Assembly under H 355 requiring the establishment and implementation of a pedigree system for drugs at risk for counterfeit activity.

HDMA commends you for your efforts in this area, as we continue to work in states across the country to identify and implement effective approaches to deter and prevent the introduction of counterfeit and adulterated prescription drug products in the nation's pharmaceutical supply chain.

As you know, HDMA and its members have actively participated in the legislative and regulatory process to ensure strict provisions to further enhance the safety of the prescription drug supply in Virginia and we appreciate this opportunity to provide comments. While HDMA and other industry stakeholders reached agreement on these proposed rules, much time has passed since their development and we urge you to consider an additional amendment to the proposed rules or future rules to implement the following recommendations to make the rules consistent with what is now commonly accepted by the industry.

Normal Distribution Channel

Since working with the Board and other industry stakeholders, several states have moved forward with alternative versions of pedigree legislation and the "normal distribution" concept. Included in many bills across the country this year was the addition of a 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. HDMA recommends the insertion of the following language in Section A of proposed rule 18 VAC 110-50-160:

6. 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.

Handwritten initials "KS" in black ink, located in the bottom right corner of the page.

HDMA Comments
August 10, 2007

HDMA believes that inclusion of this transaction path will both keep the normal supply channel limited enough to deter the entrance of counterfeits and ensure that small physician practices are able to continue to serve their patients appropriately.

Drop Shipment Definition

Additionally, we also urge the Board to consider the following alternative to the definition of "drop shipment" in proposed 18VAC 110-50-10:

"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).

HDMA believes that that the above definition more clearly reflects the practice of drop shipping prescription drugs and clarifies what transactions and entities are involved in the process.

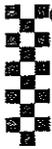
HDMA fully recognizes the necessity for strict measures to prevent the entry of counterfeits into the legitimate supply channel and we commend the Board for its efforts. If you have any questions or need further information, please contact me at 703-885-0234 or egallenagh@hdmanet.org.

HDMA supports the approach of requiring increased protections for those prescription drug products found to be susceptible to counterfeiting in order to ensure the safety of the drug supply.

Sincerely,



Elizabeth A. Gallenagh, Esq.
Senior Director, State Government Affairs



NATIONAL ASSOCIATION OF CHAIN DRUG STORES



August 7, 2007

Elizabeth Scott Russell
Executive Director
Virginia Board of Pharmacy
6603 West Broad Street
Richmond, VA 23230
Via facsimile: 804-662-9313

RE: 18 VAC 110-50 – Proposed Rules Establishing a Pedigree System for the Wholesale Distribution of Prescription Drugs

Dear Ms. Russell:

413 North Lee Street
P.O. Box 1417-D49
Alexandria, Virginia
22313-1480

On behalf of the approximately 1,022 chain pharmacies operating in Virginia, the National Association of Chain Drug Stores (NACDS) thanks you for the opportunity to submit comments on the Virginia Board of Pharmacy's ("Board") proposed rules concerning establishment of a pedigree system for the wholesale distribution of prescription drugs.

The chain pharmacy industry is committed to maintaining and enhancing the security and integrity of the prescription drug distribution chain from counterfeit prescription drugs. NACDS continues to work in the states to support legislation and regulations that strengthen the wholesale drug distribution process, and to support the recognition of the normal distribution channel as a safe and secure channel for distribution of prescription drugs. We were pleased to have participated on the Board's Ad Hoc Committee that worked to craft the proposed pedigree language.

NACDS believes that the language developed by the Board's Ad Hoc Committee will effectively secure the prescription drug distribution chain in Virginia. Requiring a pedigree for drugs susceptible to counterfeiting that leave the normal distribution channel will safeguard Virginia residents from the risk of receiving a counterfeit prescription drug. For this reason, we urge the Board to adopt the proposed rule without changes.

We thank the Board for considering our comments. Please do not hesitate to contact us if we can provide further assistance. I can be reached at 703-837-4200, or mcope@nacds.org.

Sincerely,

Michelle Cope
Manager, Legislative and Regulatory Affairs

(703) 549-3001

Fax (703) 836-4869

www.nacds.org

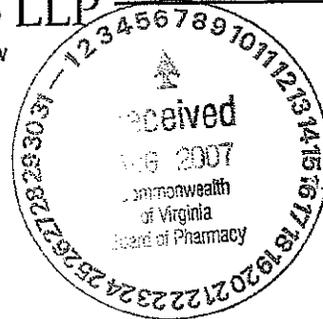
cc: Kevin N. Nicholson, R.Ph., J.D., Vice President, Pharmacy Regulatory Affairs, NACDS

TROUTMAN SANDERS LLP

ATTORNEYS AT LAW

TROUTMAN SANDERS BUILDING
1001 HAXALL POINT
RICHMOND, VIRGINIA 23219
www.troutmansanders.com
TELEPHONE: 804-697-1200
FACSIMILE: 804-697-1339

MAILING ADDRESS
P.O. BOX 1122
RICHMOND, VIRGINIA 23218-1122



Anne Leigh Kerr
anneleigh.kerr@troutmansanders.com

Direct Dial: 804-697-1465
Direct Fax: 804-698-6009

August 2, 2007

Ms. Elizabeth Scott Russell
Executive Director
Department of Health Professions
Board of Pharmacy
6603 West Broad Street, 5th Floor
Richmond, VA 23230-1712

Dear Scotti:

I appreciate the opportunity to speak to the Board of Pharmacy on Tuesday, June 12th at the Board's Public Hearing on behalf of my client, the Pharmaceutical Research and Manufacturers of America (PhRMA), about our authentication concerns raised in section 18 VAC 110-50-180. As I testified on Tuesday, a member company has brought to our attention the legal requirement to authenticate each and every pedigree for a drug which moves out of the normal distribution channel. PhRMA would like to ensure that buyers and sellers only have to undertake the time consuming process of authentication when they participate in transactions outside the normal chain of distribution. As such, we have fine-tuned our language and would suggest the following:

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

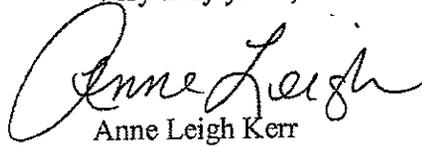
A. Upon request of a wholesale distributor who is attempting to authenticate a pedigree for a drug as specified in 18VAC110-50-160, any manufacturer or wholesale distributor listed on the pedigree shall provide requested information in a timely manner, *only for those applicable transactions outside the normal chain of distribution conducted by that manufacturer or wholesale distributor*, to include the following:

TROUTMAN SANDERS LLP
ATTORNEYS AT LAW
A LIMITED LIABILITY PARTNERSHIP

Ms. Elizabeth Scott Russell
August 2, 2007
Page 2

I appreciate the opportunity to work with you and the Board in this process. Please do not hesitate to contact me if you have any questions.

Very truly yours,



Anne Leigh Kerr

ALK/srl: #1635070

cc: Mr. Andrew Corsig

4A

Martha Russell
Regulatory Counsel
Director of Regulatory Affairs

Cardinal Health
1330 Enclave Parkway
Houston, Texas 77077
281.749.4810 tel
614.652.7337 fax
Martha.Russell@CardinalHealth.com

www.cardinal.com



VIA Email and Overnight United Parcel Service

August 9, 2007

Elizabeth Scott Russell, Executive Director
Virginia Board of Pharmacy
Alcoa Building
6603 West Broad Street, 5th Floor
Richmond, VA 23230-1712

Dear Ms. Russell:

On behalf of Cardinal Health, Inc., please accept these comments to your proposed regulations regarding the establishment of a pedigree system (18 VAC 110-50-10 et seq.). Cardinal Health appreciates your efforts in this area and your continued desire to work with industry members in drafting and implementing effective regulations to deter and prevent the introduction of counterfeit prescription drugs into our nation's pharmaceutical supply chain.

I. Definitions added to 18VAC110-50-10

We suggest adding two definitions: *authentication* and *co-licensed partner* to 18VAC110-50-10. *Authentication* is a term that is used in later in the proposed rules at 18VAC110-50-180 but is not defined. A definition of that term is therefore appropriate to add into section 18VAC110-50-10 Definitions.

We have also added the term *co-licensed partner* and included it within the definition of *drop shipment*. A *co-licensed partner* is an entity that has the right to engage in the manufacturing and/or marketing of a prescription drug along with another entity. An example of this arrangement is when a smaller manufacturer contracts with a larger manufacturer for marketing and distribution services of a

drug. With the adoption of the normal distribution channel across the states, this arrangement (manufacturer to co-licensed partner) has become a common “channel” in the *normal distribution channel* similar to the allowance for a drug to pass from a manufacturer to a *third-party logistics provider* or from a manufacturer to that *manufacturer’s exclusive distributor*. As it has become recognized as a legitimate arrangement among manufacturers, it should be included in Virginia’s channels within the definition of *drop shipment* and in the variations listed in the *normal distribution channel* at 18VAC110-50-160(A).

II. Returns

The statutory definition of *pedigree* concludes with a statement that “[r]eturns from a pharmacy to the originating wholesale distributor or pharmaceutical manufacturer shall not be subject to the pedigree requirements of this section.” See 54.1-3307(D). Your proposed regulations at 18 VAC 110-50-170(B) state:

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. (*emphasis added*).

The way this is currently written creates some confusion as to when a pedigree is/is not required. For instance, when drugs are returned by the pharmacy, the statute exempts them from pedigree; but if they are returned by one wholesaler to another wholesaler or back to the manufacturer does that require a pedigree? Further, if the return transaction between the pharmacy and the wholesaler doesn’t require a pedigree, should the redistribution of that returned drug by the wholesaler to another wholesaler or by the wholesaler to a pharmacy/dispenser include a pedigree that documents the drug’s history back to the manufacturer or just back to the pharmacy from whom the wholesaler received the return from?

Because this process for returns can potentially become extremely confusing for both pharmacies and wholesalers, our suggestion is to delete returns from 18VAC110-50-170 and create a separate section for them altogether:

Returns from a pharmacy to the originating wholesaler or pharmaceutical manufacturer shall not be subject to the pedigree requirements of this section. A wholesale distributor shall receive prescription drug returns or exchanges from a pharmacy or other persons authorized to administer or dispense drugs pursuant to the terms and conditions of the agreement between the wholesale distributor and the pharmacy or chain pharmacy warehouse.

1. Returns of expired, damaged, recalled, or otherwise non-saleable pharmaceutical products shall be distributed by the receiving wholesale

distributor only to either the original manufacturer or a third party returns processor.

2. Returns or exchanges of prescription drugs (saleable or otherwise), including any redistribution by a receiving wholesaler, shall not be subject to the pedigree requirements of 18VAC110-50-170, so long as they are exempt from the pedigree requirement of the FDA's currently applicable Prescription Drug Marketing Act guidance.

Both licensees under this Act and pharmacies (or other persons authorized by law to administer or dispense drugs) shall be accountable for administering their returns process and ensuring that the aspects of this operation are secure and do not permit the entry of adulterated and counterfeit product.

This encompasses the returns language from the statute and creates clarity in when pedigrees are required. Further, this language has been adopted in several other states allowing for consistency in dealing with returns from state to state.

III. Authentication

Finally, Cardinal Health suggests adding one additional paragraph to your authentication section, 18VAC110-50-180. This addition would make 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 that drug.

Please see the attached redlined version of your rules for further changes. Thank you for the opportunity to submit comments. I have actively participated in the regulatory process in approximately 15 states and I look forward to working with the Virginia Board of Pharmacy. Should you have any questions, please call me at 281-749-4810 or email at Martha.Russell@cardinalhealth.com.

Sincerely,



Martha Russell
Director of Regulatory Affairs
Cardinal Health

Enclosure(s)

Virginia Administrative Code	18 VAC 110-50-10 et seq.
Regulation title	Regulations Governing the Wholesale Distributors, Manufacturers and Warehouse
Action title	Establishment of a pedigree system

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:

"Authentication" means to affirmatively verify before any wholesale distribution of a prescription drug occurs that each transaction listed on the pedigree has occurred.

Comment [MR1]: This term is used later in the proposed rules so a definition here would be appropriate.

"Authorized distributor of record" means a wholesale distributor with whom a manufacturer has entered into a written agreement under which such wholesale distributor, including any affiliated group of the 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. A manufacturer shall provide a current list of their authorized distributors of record; such list must be updated by the manufacturer on no less than a monthly basis.

"Co-licensed partner" means an instance where two or more parties have the right to engage in the manufacturing and/or marketing of a prescription drug, consistent with FDA's implementation of the Prescription Drug Marketing Act.

"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 to a wholesale distributor in which a manufacturer (or that manufacturer's third party logistics provider, co-licensed product partner or 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.

Comment [MR2]: See attached slide for graphic representation.

Deleted: ,

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"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.

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"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. Distributions by a co-licensed partner;

4. Drop shipments;

Deleted: 3

5. Distributions to a veterinarian for veterinary use; and

Deleted: 4

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:

Deleted: 5

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 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;

Comment [MR3]: Deleted "or returned" here because §54.1-3307(D) states in the definition of pedigree that "Returns from a pharmacy to the originating wholesale distributor or pharmaceutical manufacturer shall not be subject to pedigree requirements in this section." When a drug is returned by a pharmacy to a wholesaler it will not have a pedigree; therefore, it would be impossible for a secondary wholesaler to provide a complete "authenticated pedigree" to the original wholesaler. Returns are more appropriately addressed in a new section below.

Deleted: or returned

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 ownership of the drug;

Deleted: chain

Deleted: '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. Each person who is engaged in the wholesale distribution of a drug, who is provided a pedigree for a drug as specified in 18VAC110-50-160 and attempts to further distribute that prescription drug, shall affirmatively verify before any distribution of a prescription drug occurs 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, to include the following:

Deleted: A

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.

C. The wholesale distributor shall record the above information and maintain the information in accordance with 18VAC110-20-190.

Deleted: B

D. 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.

Deleted: C

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.

NEW SECTION: Returns

A. Returns from a pharmacy to the originating wholesaler or pharmaceutical manufacturer shall not be subject to the pedigree requirements of this section. A wholesale distributor shall receive prescription drug returns or exchanges from a pharmacy or other persons authorized to administer or dispense drugs pursuant to the terms and conditions of the agreement between the wholesale distributor and the pharmacy or chain pharmacy warehouse.

Comment [MR4]: Verbatim from statute (see definition of pedigree at §54.1-3307(D)).

Comment [MR5]: While returns from pharmacies do not require pedigrees pursuant to the statute, it is necessary that there be some sort of agreement between the wholesaler and the pharmacy evidencing both parties agreement to store and maintain those drugs properly.

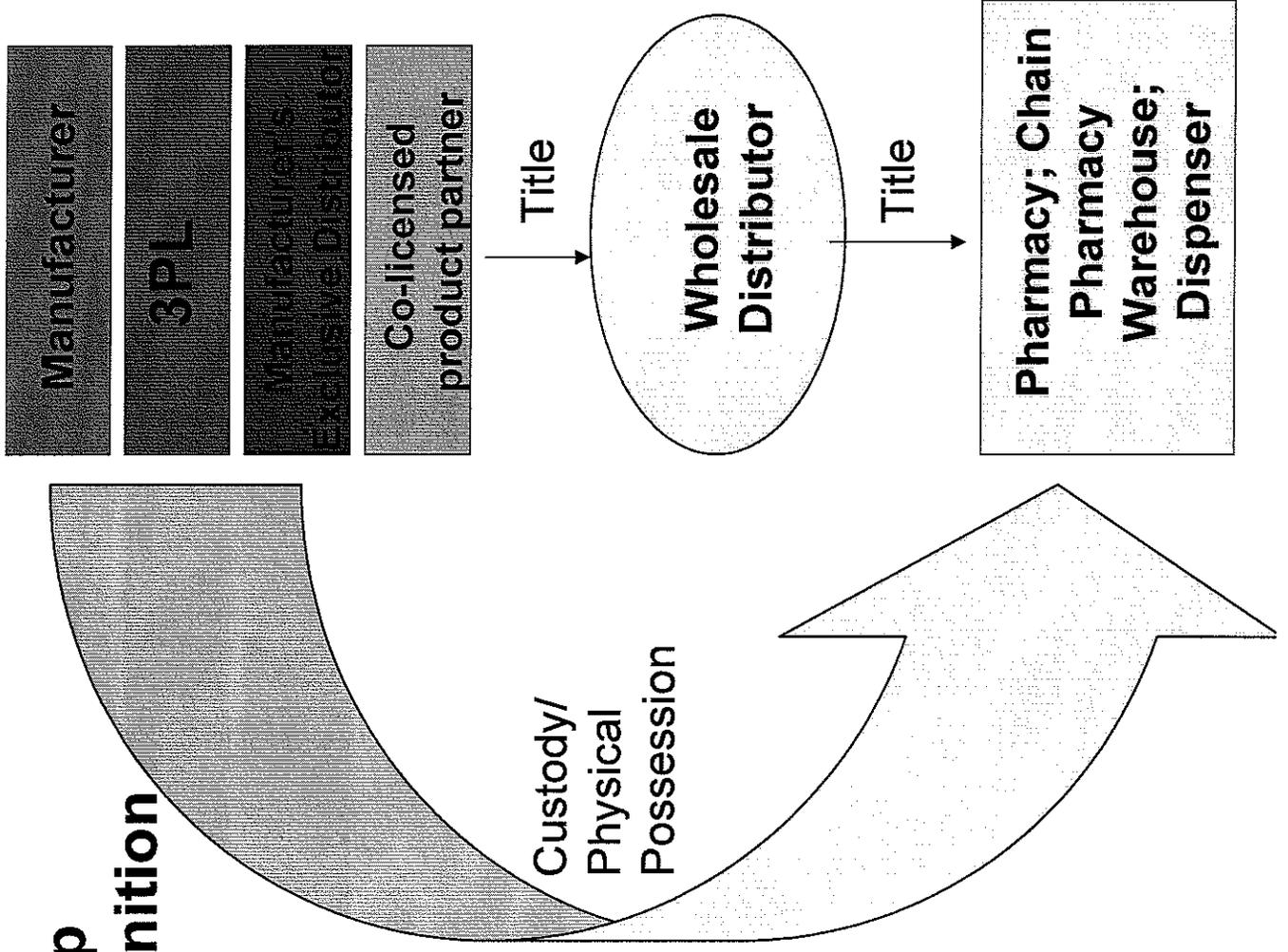
1. Returns of expired, damaged, recalled, or otherwise non-saleable pharmaceutical products shall be distributed by the receiving wholesale distributor only to either the original manufacturer or a third party returns processor.

2. Returns or exchanges of prescription drugs (saleable or otherwise), including any redistribution by a receiving wholesaler, shall not be subject to the pedigree requirements of 18VAC110-50-170, so long as they are exempt from the pedigree requirement of the FDA's currently applicable Prescription Drug Marketing Act guidance.

Both licensees under this Act and pharmacies (or other persons authorized by law to administer or dispense drugs) shall be accountable for administering their returns process and ensuring that the aspects of this operation are secure and do not permit the entry of adulterated and counterfeit product.

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Proposed Drop Shipment Definition



SANCTIONING REFERENCE POINTS

INSTRUCTION MANUAL

Board of Pharmacy
September 2007

Virginia Department of Health Professions
Board of Health Professions

SANCTIONING REFERENCE POINTS

INSTRUCTION MANUAL

Board of Pharmacy
September 2007

Prepared for
Virginia Department of Health Professions
Perimeter Center
9960 Mayland Drive, Suite 300
Richmond, Virginia 23233
804-367-4400 tel

Prepared by
VisualResearch, Inc.
Post Office Box 1025
Midlothian, Virginia 23113
804-794-3144 tel

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Overview

The Virginia Board of Health Professions has spent the last 4 years studying sanctioning in disciplinary cases. The study is examining all 13 health regulatory boards, with the greatest focus most recently on the Board of Pharmacy. The Board of Pharmacy is now in a position to implement the results of the research by using a set of voluntary *Sanctioning Reference Points*. This manual contains some background on the project, the goals and purposes of the system, and the offense-based sanction worksheet that will be used to help Board members determine how a similarly situated respondent has been treated in the past. This sanctioning system is based on a specific sample of cases, and thus only applies to those persons sanctioned by the Virginia Board of Pharmacy. Moreover, the worksheet has not been tested or validated on any other groups of persons. Therefore, they should not be used at this point to sanction respondents coming before other health regulatory boards, other states, or other disciplinary bodies.

The Sanctioning Reference system is comprised of a single worksheet which scores case type, prior history and offense factors identified using statistical analysis. These factors have been isolated and tested in order to determine their influence on sanctioning outcomes. Sanctioning thresholds found on the offense worksheet recommend a range of sanctions from which the Board may select in a particular case.

In addition to this instruction booklet, separate coversheets and worksheets are available to record the respondent's score, recommended sanction, actual sanction and any reasons for departure (if applicable). The completed coversheets and worksheets will be evaluated as part of an on-going effort to monitor and refine the Sanctioning Reference Points. These instructions and the use of the Sanctioning Reference Points system fall within current Department of Health Professions and Board of Pharmacy policies and procedures. Furthermore, all sanctioning recommendations are those currently available to and used by the Board and are specified within existing Virginia statutes.

Background

In April of 2001, the Virginia Board of Health Professions (BHP) approved a work plan to conduct an analysis of health regulatory board sanctioning and to consider the appropriateness of developing historically-based sanctioning reference points for health regulatory boards, including the Board of Pharmacy (BOP). The Board of Health Professions and project staff recognize the complexity and difficulty in sanction decision-making and have indicated that for any sanction reference system to be successful, it must be "*developed with complete Board oversight, be value-neutral, be grounded in sound data analysis, and be totally voluntary*"—that is, the system is viewed strictly as a Board decision tool.

Goals

The Board of Health Professions and the Board of Pharmacy cite the following purposes and goals for establishing Sanctioning Reference Points:

- Making sanctioning decisions more predictable
- Providing an education tool for new Board members
- Adding an empirical element to a system that is inherently subjective
- Providing a resource for BOP and those involved in proceedings.
- "Neutralizing" sanctioning inconsistencies
- Validating Board member or staff recall of past cases
- Constraining the influence of undesirable factors—e.g., Board member ID, overall Board makeup, race or ethnic origin, etc.
- Helping predict future caseloads and need for probation services and terms

Methodology

The fundamental question when developing a sanctioning reference system is deciding whether the supporting analysis should be grounded in historical data (*a descriptive approach*) or whether it should be developed normatively (*a prescriptive approach*). A normative approach reflects what policymakers feel sanction recommendations *should be*, as opposed to what they *have been*. Sanctioning reference points

can also be developed using historical data analysis with normative adjustments to follow. This approach combines information from past practice with policy adjustments, in order to achieve some desired outcome. The Board of Pharmacy chose a descriptive approach with a limited number of normative adjustments.

Qualitative Analysis

Researchers conducted in-depth personal interviews of some past and all current BOP members, Board staff, and representatives from the Attorney General's office. The interview results were used to build consensus regarding the purpose and utility of sanctioning reference points and to further frame the analysis. Additionally, interviews helped ensure the factors that Board members consider when sanctioning were included during the quantitative phase of the study. A literature review of sanctioning practice across the United States was also conducted.

Quantitative Analysis

Researchers analyzed detailed information on BOP disciplinary cases ending in a violation between 1997 and 2002; approximately 361 sanctioning "events" covering close to 450 cases. Over 100 different factors were collected on each case in order to describe the case attributes Board members identified as potentially impacting sanction decisions. Researchers used data available through the DHP case management system combined with primary data collected from hard copy files. The hard copy files contained investigative reports, Board notices, Board orders, and all other documentation that is made available to Board members when deciding a case sanction.

A comprehensive database was created to analyze the offense and respondent factors which were identified as potentially influencing sanctioning decisions. Using statistical analysis to construct a "historical portrait" of past sanctioning decisions, the significant factors along with their relative weights were derived. These factors and weights were formulated into a sanctioning worksheet with three thresholds, which are the basis of the Sanctioning Reference Points.

Offense factors such as patient injury, financial gain and case severity (priority level) were analyzed as

well as prior history factors such as substance abuse, and previous Board orders. Some factors were deemed inappropriate for use in a structured sanctioning reference system. For example, respondent gender and presence of an attorney are considered "extra-legal" factors, and were explicitly excluded from the sanction reference points. Although many factors, both "legal" and "extra-legal" can help explain sanction variation, only those "legal" factors the Board felt should consistently play a role in a sanction decision were included in the final product. By using this method, the hope is to achieve more neutrality in sanctioning, by making sure the Board considers the same set of "legal" factors in every case.

Wide Sanctioning Ranges

The Sanctioning Reference Points consider and weigh the circumstances of an offense and the relevant characteristics of the respondent, providing the Board with a sanction range that encompasses roughly 79% of historical practice. This means that 21% of past cases had received sanctions either higher or lower than what the reference points indicate, acknowledging that aggravating and mitigating factors play a role in sanctioning. The wide sanctioning ranges recognize that the Board will sometimes reasonably disagree on a particular sanction outcome, but that a broad selection of sanctions fall within the recommended range.

Any sanction recommendation the Board derives from the Sanctioning Reference Points worksheets must fall within Virginia law and regulations. If a Sanctioning Reference Point worksheet recommendation is more or less severe than a Virginia statute or DHP regulation, the existing laws or policies supercede any worksheet recommendation.

Three Sanctioning Thresholds

The Board indicated early in the study that sanctioning is influenced by variety of circumstances beyond the instant offense. The empirical analysis supported the notion that not only case type but offense factors and prior history impacted sanction outcomes. To this end, the Sanction Reference Points system, as designed for the Board of Pharmacy, makes use of three factors that combine for a sanctioning outcome that lies within one of three thresholds. The first dimension assesses factors

related to case type, the second assesses factors related to the offense, and the third dimension relates to prior history.

So a respondent before the Board for an unlicensed activity case may also receive points for having had substance abuse problems, or for having a history of disciplinary violations for other types of cases. In the first dimension points are assigned for type of case the Board is currently considering. The second dimension assigns points for factors related to the offense. For example, the respondent may receive points if they were impaired at the time of the offense. The last dimension assigns points for prior history. In this category, a respondent's prior Board orders and/or any past substance abuse are considered.

Voluntary Nature

The Sanctioning Reference Points system is a tool to be utilized by the Board of Pharmacy. Compliance with the Sanctioning Reference Points is voluntary. The Board will use the system as a reference tool and may choose to sanction outside the recommendation. The Board maintains complete discretion in determining the sanction handed down. However, a structured sanctioning system is of little value if the Board is not provided with the appropriate coversheet and worksheet in every case eligible for scoring. A coversheet and worksheet should be completed in cases resolved by Informal Conferences and Consent Orders that come before Informal Conference committees. The coversheet and worksheets will be referenced by Board members during Closed Session.

Worksheets Not Used in Certain Cases

The Sanctioning Reference Points will not be applied in any of the following circumstances:

- Formal Hearings — Sanction Reference Points will not be used in cases that reach a Formal Hearing level.
- Mandatory suspensions – Virginia law requires that under certain circumstances (conviction of a felony, declaration of legal incompetence or incapacitation, license revocation in another jurisdiction) the license of a physician must be suspended. The sanction is defined by law and is therefore excluded from the Sanctioning Reference Point system.
- Compliance/reinstatements – The Sanctioning Reference Points should be applied to new cases only.
- Action by another Board – When a case which has already been adjudicated by a Board from another state appears before the Virginia Board of Pharmacy, the Board often attempts to mirror the sanction handed down by the other Board. The Virginia Board of Pharmacy usually requires that all conditions set by the other Board are completed or complied with in Virginia. The Sanctioning Reference Points do not apply as the case has already been heard and adjudicated by another Board.
- Confidential Consent Agreements (CCA) - Sanction Reference Points will not be used in cases settled by CCA.

Case Selection When Multiple Cases Exist

When multiple cases have been combined into one “event” (one order) for disposition by the Board, only one coversheet and worksheet should be completed and it should encompass the entire event. If a case (or set of cases) has more than one offense type, one case type is selected for scoring according to the offense group which appears highest on the following table and receives the highest point value. For example, a pharmacist found in violation of both a direction error and personal drug use would have receive fifty points, since Inability to Safely Practice is above Error on the list and receives most points. If an offense type is not listed, find the most analogous offense type and use the appropriate score. The case type that has been selected from the list below is the only case type that receives points on the sanctioning worksheet.

Sanctioning Reference Points Case Type Table

Case Type	Included Categories	Point Assignment
Inability to Safely Practice	Incapacitation – mental/physical Impairment – drugs/alcohol Inability to Safely Practice - other Drug Related - Excessive Dispensing Drug Related – Security Drug Related - Obtaining Drugs by Fraud Drug Related – Personal Use Drug Related – Other	50
Professional Practice Issues	Criminal Activity Business Practice Issues Fraud Unlicensed Activity Records/Inspections/Audits Unprofessional Conduct	35
Prescription Error	Strength/Quantity Error Directions/Expired Medications Error Wrong Drug Error Wrong Patient/Physician Name Error Generic/Brand Error	10

Completing the Coversheet & Worksheet

Ultimately, it is the responsibility of the BOP to complete the Sanction Reference Point coversheet and worksheet in all applicable cases.

The information relied upon to complete a coversheet and worksheet is derived from the case packet provided to the Board and respondent. It is also possible that information discovered at the time of the informal conference may impact worksheet scoring. The Sanction Reference Point coversheet and worksheet, once completed, are confidential under the Code of Virginia. However, complete copies of the Sanction Reference Point Manual, including blank coversheets and worksheets, can be found on the Department of Health Professions web site: www.dhp.state.va.us (paper copy also available on request).

Sanctioning Worksheet

Instructions for case scoring are contained adjacent to each worksheet in subsequent sections of this manual. Instructions are provided for each line item of each worksheet and should be referenced to ensure accurate scoring for a specific factor. When scoring a worksheet, the scoring weights assigned to a factor on the worksheet *cannot be adjusted*. The scoring weights can only be applied as ‘yes or no’ with all or none of the points applied. In instances where a scoring factor is difficult to interpret, the Board has final say in how a case is scored.

Coversheet

The coversheet is completed to ensure a uniform record of each case and to facilitate recordation of other pertinent information critical for system monitoring and evaluation.

If the Board feels the sanctioning threshold does not recommend an appropriate sanction, the Board is encouraged to depart either high or low when

handing down a sanction. If the Board disagrees with the sanction recommendation and imposes a sanction greater or less than the recommended sanction, a short explanation can be recorded on the coversheet. The explanation could identify the factors and the reasons for departure. This process will ensure worksheets are revised appropriately to reflect current Board practice. If a particular reason is continually cited, the Board can examine the issue more closely to determine if the worksheets should be modified to better reflect Board practice.

Aggravating and mitigating circumstances that may influence Board decisions can include, but should not be limited to, such things as:

- Prior record
- Dishonesty/Obstruction
- Motivation
- Remorse
- Victim vulnerability
- Restitution/Self-corrective action
- Multiple offenses/Isolated incident

A space is provided on the coversheet to record the reason(s) for departure. Due to the uniqueness of each case, the reason(s) for departure may be wide-ranging. Sample scenarios are provided below:

Departure Example #1

Sanction Grid Result: Remove from practice.

Imposed Sanction: Probation with terms – practice restriction.

Reason(s) for Departure: Respondent was particularly remorseful and had already begun corrective action.

Departure Example #2

Sanction Grid Result: Reprimand.

Imposed Sanction: Continue on terms – practice monitoring.

Reason(s) for Departure: Respondent may be trending towards future violations, implement oversight now to avoid future problems.

Determining a Specific Sanction

The Sanction thresholds have three separate sanctioning outcomes: Monitoring/Treatment/Refer to Formal, Reprimand/Monetary Penalty, and Knowledge Based. The table below lists the most frequently cited sanctions under the three sanctioning outcomes that are part of the sanction threshold. After considering the sanction recommendation, the Board should fashion a more detailed sanction(s) based on the individual case circumstances.

Sanctioning Reference Point Threshold Table

Worksheet Threshold	Available Sanctions
Monitoring/Treatment/Refer to Formal	Recommend Formal (revocation or suspension may result) Suspension Stayed Suspension Probation Terms Quarterly performance evaluations from employer Written notification to pharmacist in charge Quarterly self reports/DEA forms Inform board of any changes in employment Random drug screenings Begin/continue AA/NA, caduceus, etc. Inform board upon resuming practice Continue in therapy and therapist provides quarterly reports Aftercare/peer assistance group contract – continue Chemical dependency/psych/mental/phys/ evaluation Quarterly reports from probation/parole officer Provide board with court order
Reprimand/Monetary Penalty	Monetary Penalty Reprimand Terms Shall not be Pharmacist in Charge Abstain from alcohol and controlled substances
Knowledge Based	No Sanction Terms Continuing Education – general Drug Diversion Awareness Program



Sanctioning Reference Points COVERSHEET for Board of Pharmacy

- Complete *Case Type Score* section on the Sanctioning Reference Point Worksheet.
- Complete the *Offense Factor* section on the Sanctioning Reference Point Worksheet.
- Complete the *Prior History* section on the Sanctioning Reference Point Worksheet.
- Determine the *Recommended Sanction* using the scoring results and the *Sanction Thresholds*.
- Complete this Coversheet.

Case Number(s)	<table border="1" style="display: inline-table; border-collapse: collapse;"> <tr><td style="width: 20px; height: 20px;"></td><td style="width: 20px; height: 20px;"></td></tr> </table> <table border="1" style="display: inline-table; border-collapse: collapse; margin-left: 20px;"> <tr><td style="width: 20px; height: 20px;"></td><td style="width: 20px; height: 20px;"></td></tr> </table>												
Respondent Name	<table style="width: 100%; border-collapse: collapse;"> <tr> <td style="width: 33%; border-bottom: 1px solid black; text-align: center;">Last</td> <td style="width: 33%; border-bottom: 1px solid black; text-align: center;">First</td> <td style="width: 33%; border-bottom: 1px solid black; text-align: center;">Title</td> </tr> </table>	Last	First	Title									
Last	First	Title											
License Number													
Case type	<input type="checkbox"/> Inability to Safely Practice <input type="checkbox"/> Professional Practice Issues <input type="checkbox"/> Prescription Error												
Sanction Threshold Result	<input type="checkbox"/> Knowledge Based <input type="checkbox"/> Reprimand/Monetary <input type="checkbox"/> Monitoring/Treatment/Refer to Formal												
Imposed Sanction	<input type="checkbox"/> Revocation <input type="checkbox"/> Suspension <input type="checkbox"/> Stayed Revocation - Immediate <input type="checkbox"/> Stayed Suspension - Immediate <input type="checkbox"/> Probation - duration in months _____ <input type="checkbox"/> Monetary Penalty - enter amount \$ _____ <input type="checkbox"/> Reprimand <input type="checkbox"/> No Sanction <input type="checkbox"/> Terms: _____ _____ _____												
Reasons for Departure from Sanction Threshold Result	_____ _____ _____ _____ _____												
Worksheet Prepared by:													
Date completed:													

Confidential pursuant to §14.1-3400.2 of the Code of Virginia.

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BOARD OF PHARMACY ■ SANCTION REFERENCE POINT WORKSHEET INSTRUCTIONS

Case Type

(score only one, see list page 5)

- A. Enter "50" if case involves an Inability to Safely Practice. These cases include:
- Incapacitation— mental/physical
 - Impairment— drugs/alcohol
 - Inability to Safely Practice— other
 - Drug Related— excessive dispensing
 - Drug Related— security
 - Drug Related— obtaining drugs by fraud
 - Drug Related— personal use
 - Drug Related— other
- B. Enter "35" if the case involves Professional Practice Issues. These cases include:
- Criminal Activity
 - Business Practice Issues
 - Fraud
 - Unlicensed Activity
 - Records/Inspections/Audits
 - Unprofessional Conduct
- C. Enter "10" if the case involves a Prescription Error. These cases include:
- Strength/Quantity
 - Directions/Expired Medications
 - Wrong Drug
 - Wrong Patient/Physician Name
 - Generic/Brand

Offense Factor Scoring

(score all that apply)

- A. Enter "70" in cases where an individual may have committed an act or is highly likely to commit an act that constitutes significant and substantial danger to the health and safety of any person (Priority A) or in cases where an individual may have committed a harmful act to another person but does not pose an imminent threat to public safety (Priority B).

- B. Enter "50" if there was financial or other material gain from the offense.
- C. Enter "50" if there was an act of commission. An act of "commission" is interpreted as purposeful, intentional, or clearly not accidental.
- D. Enter "50" if the respondent was impaired at the time of the incident. Impairment can include drugs, alcohol, mental and/or physical.
- E. Enter "10" if the patient was injured. Patient injury includes any injury reported by the consumer regardless of follow up treatment.

Prior History Scoring

(score all that apply)

- A. Enter "30" if the respondent has had any past difficulties or treatment in any of the following areas: drugs, alcohol, mental health and/or physical health. Difficulties in these areas must be relevant to the current case and treatment must have been provided by a bono fide health care practitioner.
- B. Enter "10" if the respondent has had one or more prior Board violation.
- C. Enter "10" if the respondent has had a prior violation similar to the current case. Cases are considered similar when they fall within the same category.

Inability to Safely Practice

- Incapacitation— mental/physical
- Impairment— drugs/alcohol
- Inability to Safely Practice— other
- Drug Related— excessive dispensing
- Drug Related— security

- Drug Related— obtaining drugs by fraud
- Drug Related— personal use
- Drug Related— other

Professional Practice Issues

- Criminal Activity
- Business Practice Issues
- Fraud
- Unlicensed Activity
- Records/Inspections/Audits
- Unprofessional Conduct

Prescription Error

- Strength/Quantity
- Directions/Expired Medications
- Wrong Drug
- Wrong Patient/Physician Name
- Generic/Brand

Total Score

Sum all points on the worksheet and locate the sanction recommendation on the threshold table provided.

Scoring Outcome

The use of the Sanction Reference Points is voluntary. In addition, the worksheet sanction result may be combined with sanctions from lower sanction thresholds. For example, should a respondent fall within the "Reprimand/Monetary" area with a score of 40, the Board may choose a sanction package that includes a "Monetary Penalty" and a "Knowledge Based" sanction.

BOARD OF PHARMACY • SANCTION REFERENCE POINT WORKSHEET

Case Type (score one)	Points	Score
Inability to Safely Practice	50	_____
Professional Practice Issues	35	_____
Prescription Error	10	_____

Offense Factors (score all that apply)	Points	Score
Priority A or B	70	_____
Financial/Material gain	50	_____
Act of commission	50	_____
Respondent impaired during incident	50	_____
Patient injured	10	_____

Prior History (score all that apply)	Points	Score
Any past substance abuse or treatment	30	_____
One or more prior Board violations	10	_____
Any prior similar Board violations	10	_____

Total Respondent Score

THRESHOLDS	
Knowledge Based	0-30
Reprimand/Monetary	31-120
Monitoring/Treatment/Refer to Formal	121 or more

Respondent: _____ License Number: _____

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From: Abernathy, Gill B.
Sent: Wednesday, March 21, 2007 4:56 PM
To: Russell, Scotti
Subject: Do we need to discontinue use of initial stampers?

Scotti,

Question relating to our Board inspection here last week. 3 years ago we started use of initial stampers as part of a crackdown to assure every dose dispensed got 2 sets of initials on it. We found that with over 130 staff and monthly new hires, departures and name changes, it was easier to read and distinguish initials when we used stampers with 3 initials. Following up on errors was sometimes hard with manual 2 letter initials since we have many B__ or M__ or __K people and when initialing something dozen's (sometimes 100's) of times per day asking someone to write legibly each time isn't realistic.

We got a recommendation to go back to manual initials instead of stampers. I realize that the CII-V dispensing records say a signature is needed. Other reg verbage though says "the initials of". Is it acceptable to continue use of stampers when "initials of" is stated if we find that works better for us?

We're not wedded to it, just think it is genuinely a better system for our place,
Thanks, Gill

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