Virginia Regulatory Town Hall

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Notice of Intended Regulatory Action (NOIRA)
Agency Background Document

Agency name	Board of Pharmacy, Department of Health Professions
Virginia Administrative Code (VAC) citation	18VAC110-50-10 et seq.
Regulation title	Regulations Governing Wholesale Distributors, Warehousers and Manufacturers
Action title	Establishment of a Pedigree System
Document preparation date	6/7/05

This information is required for executive branch review and the Virginia Registrar of Regulations, pursuant to the Virginia Administrative Process Act (APA), Executive Orders 21 (2002) and 58 (1999), and the *Virginia Register Form, Style, and Procedure Manual.*

Purpose

Please describe the subject matter and intent of the planned regulatory action. Also include a brief explanation of the need for and the goals of the new or amended regulation.

The Board of Pharmacy intends to increase its oversight of the wholesale distribution market in order to prevent opportunities for counterfeiting of drugs and ensure the integrity, safety and efficacy of drugs or devices distributed in the Commonwealth by establishment of a pedigree system. "Pedigree" means a paper document or electronic file recording each distribution of a controlled substance from sale by a pharmaceutical manufacturer through acquisition and sale by any wholesale distributor, as defined in § 54.1-3401 and not exempted pursuant to § 54.1-3401.1, until final sale to a pharmacy or other person dispensing or administering the controlled substance.

Since the Board has already proposed the promulgation of Chapter 50, governing the practice of wholesale distributors, manufacturers, and warehousers, this action will add sections related to pedigree requirements to that chapter.

Legal basis

Please identify the state and/or federal legal authority to promulgate this proposed regulation, including (1) the most relevant law and/or regulation, including Code of Virginia citation and General Assembly chapter number(s), if applicable, and (2) promulgating entity, i.e., agency, board, or person. Describe the legal authority and the extent to which the authority is mandatory or discretionary.

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18 VAC 110-20-10 et seq. Regulations Governing the Practice of Pharmacy are promulgated under the general authority of Title 54.1, Chapter 24 of the Code of Virginia. Chapter 24 establishes the general powers and duties of health regulatory boards including the responsibility to promulgate regulations in accordance with the Administrative Process Act.

> ***§ 54.1-2400 -General powers and duties of health regulatory boards***
> *The general powers and duties of health regulatory boards shall be:*
> *…*
> *6. To promulgate regulations in accordance with the Administrative Process Act (§ 9-6.14:1 et seq.) which are reasonable and necessary to administer effectively the regulatory system. Such regulations shall not conflict with the purposes and intent of this chapter or of Chapter 1 (§ 54.1-100 et seq.) and Chapter 25 (§ 54.1-2500 et seq.) of this title. …*

The specific statutory authority for the Board to regulate the practice of pharmacy including the distribution of controlled substances is found in § 54.1-3307 of the Code of Virginia, which was amended by Chapter 777 of the 2005 Acts of the Assembly to require *establishment and implementation of a pedigree system.*

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

A. The Board shall regulate the practice of pharmacy and the manufacturing, dispensing, selling, distributing, processing, compounding, or disposal of drugs and devices. The Board shall also control the character and standard of all drugs, cosmetics and devices within the Commonwealth, investigate all complaints as to the quality and strength of all drugs, cosmetics, and devices and take such action as may be necessary to prevent the manufacturing, dispensing, selling, distributing, processing, compounding and disposal of such drugs, cosmetics and devices *that* do not conform to the requirements of law.

The Board's regulations shall include criteria for:

1. Maintenance of the quality, quantity, integrity, safety and efficacy of drugs or devices distributed, dispensed or administered.

2. Compliance with the prescriber's instructions regarding the drug, its quantity, quality and directions for use.

3. Controls and safeguards against diversion of drugs or devices.

4. Maintenance of the integrity of, and public confidence in, the profession and improving the delivery of quality pharmaceutical services to the citizens of Virginia.

5. Maintenance of complete records of the nature, quantity or quality of drugs or substances distributed or dispensed, and of all transactions involving controlled substances or drugs or devices so as to provide adequate information to the patient, the practitioner or the Board.

6. Control of factors contributing to abuse of legitimately obtained drugs, devices, or controlled substances.

7. Promotion of scientific or technical advances in the practice of pharmacy and the manufacture and distribution of controlled drugs, devices or substances.

8. Impact on costs to the public and within the health care industry through the modification of mandatory practices and procedures not essential to meeting the criteria set out in subdivisions 1 through 7 of this section.

9. Such other factors as may be relevant to, and consistent with, the public health and safety and the cost of rendering pharmacy services.

B. The Board's regulations to implement the criteria set forth in subsection A shall include, but shall not be limited to, the establishment and implementation of a pedigree system, as defined in subsection D. The Board shall structure the implementation of the pedigree with limited application to certain schedules or certain drugs, upon finding that such drugs are more subject to counterfeiting.

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

D. For the purposes of this section:

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

Substance

Please detail any changes that will be proposed. For new regulations, include a summary of the proposed regulatory action. Where provisions of an existing regulation are being amended, explain how the existing regulation will be changed. Include the specific reasons why the agency has determined that the proposed regulatory action is essential to protect the health, safety, or welfare of citizens. Delineate any potential issues that may need to be addressed as the regulation is developed.

The proposed action may follow the outline of the Model Rules of the National Association of Boards of Pharmacy and may include definitions for terms not currently defined in the Drug Control Act, specific criteria for a pedigree, provisions for inspections and requirements for personnel, security, anti-counterfeiting measures, recordkeeping, and quality control.

In an increasingly complex environment for the marketing and distribution of prescription drugs and devices, the Board of Pharmacy has an obligation to be proactive in ensuring the safety, integrity and quality of controlled substances that are distributed in the Commonwealth. In instances where due diligence has not been observed in other states, drugs that were adulterated or counterfeited have entered the consumer market and resulted in harm to the public. Harm may come from an adulterated or counterfeited drug or device to which a patient has an adverse reaction or which does not have the strength or quality to achieve the intended result from pharmacotherapy.

It is the Board's responsibility to set out rules that will ensure that the drug supply is safe and efficacious, that records are being adequately maintained, and that there is sufficient oversight through a pedigree system to deter adulteration or counterfeiting. With the adoption of regulations for a pedigree on many prescription drugs and devices, the Board intends to add rules that offer clear standards of practice that provide for both deterrence and enforcement.

Alternatives

Please describe all viable alternatives to the proposed regulatory action that have been or will be considered to meet the essential purpose of the action.

There are no alternatives to the promulgation of regulations as action is mandated by SB1326 (Chapter 777) of the 2005 General Assembly, which states that: *The Board's regulations to implement the criteria set forth in subsection A shall include, but shall not be limited to, the establishment and implementation of a pedigree system, as defined in subsection D.*

In recognition of the need to address actual and potential problems with distribution of drugs that meet standards for purity, quality and safety, the National Association of Boards of Pharmacy has issued Model Rules for the Licensure of Wholesale Distributors. Effective February 20, 2004, the Model Rules include security and anti-counterfeiting measures for the authentication of drug and devices through the system from manufacturing to distribution to the retail market. Model Rules also require the development of policies and procedures and sets out prohibited acts that are unlawful for a person to perform or to aid in the performance of such acts.

During the consideration of regulations for wholesale distributors, the ad hoc committee of the Board received suggested regulations from Pfizer that included the elements of pedigree papers for drugs and devices and requirements for authentication of a pedigree before distribution. The Board will also use the Pfizer draft as a resource document, along with regulations and experiences of other states that have implemented regulations for a pedigree system.

In accordance with § 54.1-3307, the Board will limit the applicability of the pedigree requirements. The law requires the Board to: "*structure the implementation of the pedigree with limited application to certain schedules or certain drugs, upon finding that such drugs are more subject to counterfeiting*." In addition, the statute provides that certain types of transactions are not subject to pedigree requirements: "*Returns from a pharmacy to the originating wholesale distributor or pharmaceutical manufacturer shall not be subject to the pedigree requirements of*

this section." And finally, as defined in § 54.1-3401, the following Practices are not considered wholesale distribution and therefore, would not be subject to regulations on pedigrees:

1. Intracompany sales, including any transaction or transfer between any division, subsidiary, parent, and/or affiliated or related company under the common ownership and control of a corporate entity;

2. The purchase or other acquisition by a hospital or other health care entity that is a member of a group purchasing organization of a drug for its own use from the group purchasing organization or from other hospitals or health care entities that are members of such organization;

3. The sale, purchase, or trade of a drug or an offer to sell, purchase, or trade a drug by a charitable organization, described in § 501 (c) (3) of the Internal Revenue Code of 1986 (26 U.S.C. § 501 (c) (3)), to a nonprofit affiliate of such organization to the extent otherwise permitted by law;

4. The sale, purchase, or trade of a drug or an offer to sell, purchase, or trade a drug among hospitals or other health care entities that are under common control;

5. The sale, purchase, or trade of a drug or an offer to sell, purchase, or trade a drug for emergency medical reasons;

6. The sale, purchase, or trade of a drug or an offer to sell, purchase, or trade a drug, or the dispensing of a drug pursuant to a prescription;

7. The distribution of drug samples by manufacturers' representatives or distributors' representatives; or

8. The sale, purchase, or trade of or the offer to sell, purchase, or trade blood and blood components intended for transfusion.

It is the Board's intent to use the Model Rules as a guideline rather than to adopt them by reference or incorporate wholly into its regulation. In addition, the Board will look at regulations in other states for pedigrees and will involve advisors who have familiarity with the business in the development of rules that will achieve the goal of protecting the integrity and safety of prescription drugs and devices but avoid requirements that may be onerous and without justification.

Family impact

Assess the potential impact of the proposed regulatory action on the institution of the family and family stability.

There is no potential impact on the family and family stability.