Economic Impact Analysis
Virginia Department of Planning and Budget

18 VAC 110-50 – Regulations the Wholesale Distributors, Manufacturers and Warehousers
Department of Health Professions
January 4, 2007

Summary of the Proposed Regulation

Pursuant to Chapter 777 of the 2005 Acts of the Assembly and Chapter 632 of the 2006 Acts of the Assembly, the Board of Pharmacy proposes to establish a pedigree program for prescription drugs that will have the affect of requiring pedigrees for schedule II through IV drugs that are distributed through secondary wholesalers.

Result of Analysis

There is insufficient data to accurately compare the magnitude of the costs and benefits of the proposed regulatory change. Analysis of possible costs and benefits can be found below.

Estimated Economic Impact

Currently, Board of Pharmacy (board) regulations do not require that any class of drugs have a written, authenticated record of provenance. To address concerns that consumers are not being adequately protected from counterfeit drugs that might enter normal drug channels, the General Assembly passed legislation in 2005 that mandated that the board implement a pedigree requirement for "distribution of a controlled substance from sale by a pharmaceutical manufacturer through acquisition and sale by any wholesale distributor". An ad hoc committee formed by the board determined that drugs that are distributed through normal distribution channels are unlikely to be adulterated or counterfeit. The General Assembly passed subsequent legislation (in 2006) which limited the scope of any pedigree program to drugs which, at some point before their final use, leave the "normal distribution channel". Normal distribution channels, as defined in this legislation, encompass the "*chain of custody for a prescription drug from initial sale by a pharmaceutical manufacturer, through acquisition and sale by one wholesale distributor as defined in § 54.1-3401, that is not exempted pursuant to § 54.1-3401.1,*

until sale to a pharmacy or other person dispensing or administering the controlled substance; or a chain of custody for a prescription drug from initial sale by a pharmaceutical manufacturer, through acquisition and sale by one wholesale distributor as defined in § 54.1-3401, that is not exempted pursuant to § 54.1-3401.1, to a chain pharmacy warehouse to its intracompany pharmacies; or a chain of custody for a prescription drug from initial sale by a pharmaceutical manufacturer to a chain pharmacy warehouse to its intracompany pharmacies."

The proposed regulation incorporates this definition and additionally provides that drugs distributed on an emergency basis are exempt from pedigree requirements so long as the distributor of these drugs:

- Maintains documentation from the drug manufacturer attesting to a shortage
- Purchases the drug distributed only through an authorized distributor
- Maintains a list of all entities to whom these drugs are sold and
- Notifies the board of within 24 hours of any emergency distributions.

The proposed regulation requires that non-exempt entities buying and selling drugs in non-emergency situations generate a written pedigree that includes:

- The trade or generic name of the drug,
- The dosage form and strength of the drug,
- The container size for the drug as well as the number of containers and lot numbers of the purchase,
- The name of the manufacturer of the drug and
- Documentation for every transaction of the drug in question to include:
  - The business name and address of each entity involved in the chain of the drug's physical custody,
  - The telephone number and other contact information needed to authenticate the pedigree,
  - Sales invoice numbers or other unique shipping document numbers that identify each transaction and

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

Effectively, legislative mandate and this proposed regulation will require pedigrees only for drugs that are handled by secondary wholesalers on a non-emergency basis. Secondary wholesalers purchase overstocked drugs from primary wholesalers and unused drugs from pharmacies and tend to sell these drugs to other secondary wholesalers, pharmacies and government entities like prisons at lower cost than would normally be charged by a primary wholesaler. More specialized secondary wholesalers purchase drugs from primary wholesalers at their regular price and then sell those drugs to doctors' offices for a price that is greater than wholesale but less than retail; Secondary wholesalers can engage in this type of arbitrage because many primary wholesalers have traditionally refused to sell directly to doctors' offices. The provenance of drugs that are repeatedly sold and resold in this manner can become clouded and counterfeit drugs can more easily be introduced into a distribution stream that includes such sales and resales.

Counterfeit and adulterated drugs can be harmful, or even deadly, in several ways. Consumers are certainly harmed when they inadvertently take a counterfeit drug that will not have the beneficial effects anticipated when the drug was prescribed; these consumers may even die if the drug they are taking is meant to treat a condition (like diabetes) that can be fatal. Consumers can also be harmed, or even killed, by counterfeit drugs that are, on occasion, contaminated with bacteria or other harmful substances. This proposed regulation, and its originating legislation, will likely benefit the public by reducing the risk that counterfeit or adulterated drugs will be sold in the Commonwealth.

There will also be costs associated with the promulgation of this regulation. Secondary wholesalers will incur costs associated with gathering and maintaining the information required for pedigrees. The Department of Health Professions (DHP) reports that there is no information available that would indicate how much pedigrees will cost to maintain. Secondary distributors who do business in Virginia and Florida (where drug pedigrees are already required) will likely not see an appreciable increase in their costs because they will only be providing to the board pedigree information that they have already gathered and that they are already required to maintain. Secondary distributors that do not also do business in Florida will likely increase the

price they charge their customers to offset some or all of the costs associated with this pedigree program. DHP expects that some secondary distributors will choose to either seek primary distributor status (by buying directly from drug manufacturers) or will cease doing business in Virginia altogether. These factors, taken together, will likely mean that end purchasers of drugs will experience an increase in the price they, or their agents, pay for medication.

Businesses and Entities Affected

The proposed regulation will affect secondary wholesalers as well as their customers. The Board currently licenses 132 resident and 640 non-resident wholesale distributors. The vast majority of these are secondary distributors.

Localities Particularly Affected

The proposed regulation will affect all localities in the Commonwealth.

Projected Impact on Employment

The proposed regulation will likely have a negative impact on employment in the field of wholesale drug distribution.

Effects on the Use and Value of Private Property

Secondary wholesale drug distributors will incur greater costs on account of the proposed regulation. To the extent that they are unable to recover those costs by passing them on to their customers, secondary wholesale distributors are also likely to see lower profits.

Small Businesses: Costs and Other Effects

Secondary wholesale drug distributors will incur costs associated with gathering and maintaining the drug pedigree information required by the proposed regulation. Most of the wholesale drug distributors licensed by the board are secondary drug wholesale distributors that qualify as small businesses.

Small Businesses: Alternative Method that Minimizes Adverse Impact

There are likely no alternative methods that would both meet legislative requirements and further minimize adverse impacts.

Legal Mandate

The Department of Planning and Budget (DPB) has analyzed the economic impact of this proposed regulation in accordance with Section 2.2-4007.H of the Administrative Process Act and Executive Order Number 21 (02). Section 2.2-4007.H requires that such economic impact analyses include, but need not be limited to, the projected number of businesses or other entities to whom the regulation would apply, the identity of any localities and types of businesses or other entities particularly affected, the projected number of persons and employment positions to be affected, the projected costs to affected businesses or entities to implement or comply with the regulation, and the impact on the use and value of private property. Further, if the proposed regulation has adverse effect on small businesses, Section 2.2-4007.H requires that such economic impact analyses include (i) an identification and estimate of the number of small businesses subject to the regulation; (ii) the projected reporting, recordkeeping, and other administrative costs required for small businesses to comply with the regulation, including the type of professional skills necessary for preparing required reports and other documents; (iii) a statement of the probable effect of the regulation on affected small businesses; and (iv) a description of any less intrusive or less costly alternative methods of achieving the purpose of the regulation. The analysis presented above represents DPB's best estimate of these economic impacts.