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HOUSE BILL NO. 1961

Offered January 12, 2011
Prefiled January 11, 2011

A BILL to amend and reenact § 54.1-3307 of the Code of Virginia, relating to recusal of Board of Pharmacy members from certain proceedings.

Patron—Rust

Referred to Committee on Health, Welfare and Institutions

Be it enacted by the General Assembly of Virginia:

1. That § 54.1-3307 of the Code of Virginia is amended and reenacted as follows:

§ 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. *Recusal of individual Board members from participation in any disciplinary proceeding involving a pharmacy, pharmacist or pharmacy technician with whom the Board member works, or by whom the member is employed.*

10. 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. In order to maintain a current and appropriate list of drugs susceptible to counterfeiting, the Board may amend such list in its regulations. Such amendments to the list shall be exempt from the requirements of Article 2 (§ 2.2-4006 et seq.) of the Administrative Process Act. The Board shall establish in regulation a process for amending such list that provides notice and opportunity for public comment. The Board shall limit the implementation of a pedigree system to those drugs that have left the normal distribution channel as defined in subsection D. The pedigree shall also satisfy the requirements of 21 U.S.C. § 353(e), regarding requirements for wholesale distributors of drugs in interstate commerce. The Board may provide for exceptions to the pedigree requirements of this section for emergency medical reasons as defined in regulation.

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

D. For the purposes of this section:

"Normal distribution channel" means 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, 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.

"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 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.