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HOUSE BILL NO. 2220

House Amendments in [] - January 27, 2011

A BILL to amend and reenact § 54.1-3434.1 of the Code of Virginia and to amend the Code of Virginia by adding in Article 2 of Chapter 34 of Title 54.1 a section numbered 54.1-3434.03, relating to continuous quality improvement of pharmacies.

Patron Prior to Engrossment—Delegate Rust

Referred to Committee on Health, Welfare and Institutions

Be it enacted by the General Assembly of Virginia:

1. That § 54.1-3434.1 of the Code of Virginia is amended and reenacted and that the Code of Virginia is amended by adding in Article 2 of Chapter 34 of Title 54.1 a section numbered 54.1-3434.03 as follows:

§ 54.1-3434.03. Continuous quality improvement program.

Each pharmacy shall implement a program for continuous quality improvement, according to regulations of the Board. Such program shall provide for a systematic, ongoing process of analysis of dispensing errors that uses findings to formulate an appropriate response and to develop or improve pharmacy systems and workflow processes designed to prevent or reduce future errors. The Board shall promulgate regulations to further define the required elements of such program.

Any pharmacy that actively reports to a patient safety organization that has as its primary mission continuous quality improvement under the Patient Safety and Quality Improvement Act of 2005 (P.L. 109-41), shall be deemed in compliance with this section.

§ 54.1-3434.1. Nonresident pharmacies to register with Board.

A. Any pharmacy located outside the Commonwealth that ships, mails, or delivers, in any manner, Schedule II through VI drugs or devices pursuant to a prescription into the Commonwealth shall be considered a nonresident pharmacy, shall be registered with the Board, shall designate a pharmacist in charge who is licensed as a pharmacist in Virginia and is responsible for the pharmacy's compliance with this chapter, and shall disclose to the Board all of the following:

1. The location, names, and titles of all principal corporate officers and the name and Virginia license number of the designated pharmacist in charge, if applicable. A report containing this information shall be made on an annual basis and within 30 days after any change of office, corporate officer, or pharmacist in charge.

2. That it maintains, at all times, a current unrestricted license, permit, certificate, or registration to conduct the pharmacy in compliance with the laws of the jurisdiction, within the United States or within another jurisdiction that may lawfully deliver prescription drugs directly or indirectly to consumers within the United States, in which it is a resident. The pharmacy shall also certify that it complies with all lawful directions and requests for information from the regulatory or licensing agency of the jurisdiction in which it is licensed as well as with all requests for information made by the Board pursuant to this section.

3. As a prerequisite to registering with the Board, the nonresident pharmacy shall submit a copy of the most recent inspection report resulting from an inspection conducted by the regulatory or licensing agency of the jurisdiction in which it is located. The inspection report shall be deemed current if the inspection was conducted within the past five years. However, if the nonresident pharmacy has not been inspected by the regulatory or licensing agency of the jurisdiction in which it is licensed within the past five years, the Board may accept an inspection report or other documentation from another entity that is satisfactory to the Board or the Board may cause an inspection to be conducted by its duly authorized agent and may charge an inspection fee in an amount sufficient to cover the costs of the inspection.

4. For a nonresident pharmacy that dispenses more than 50 percent of its total prescription volume pursuant to an original prescription order received as a result of solicitation on the Internet, including the solicitation by electronic mail, that it is credentialed and has been inspected and that it has received certification from the National Association of Boards of Pharmacy that it is a Verified Internet Pharmacy Practice Site, or has received certification from a substantially similar program approved by the Board. The Board may, in its discretion, waive the requirements of this subdivision for a nonresident pharmacy that only does business within the Commonwealth in limited transactions.

5. That it maintains its records of prescription drugs or dangerous drugs or devices dispensed to patients in the Commonwealth so that the records are readily retrievable from the records of other drugs dispensed and provides a copy or report of such dispensing records to the Board, its authorized agents, or any agent designated by the Superintendent of the Department of State Police upon request within

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59 seven days of receipt of a request.

60 6. That its pharmacists do not knowingly fill or dispense a prescription for a patient in Virginia in
61 violation of § 54.1-3303 and that it has informed its pharmacists that a pharmacist who dispenses a
62 prescription that he knows or should have known was not written pursuant to a bona fide
63 practitioner-patient relationship is guilty of unlawful distribution of a controlled substance in violation of
64 § 18.2-248.

65 7. *That it maintains a continuous quality improvement program as required of resident pharmacies,*
66 *pursuant to § 54.1-3434.03.*

67 The requirement that a nonresident pharmacy have a Virginia licensed pharmacist in charge shall not
68 apply to a registered nonresident pharmacy that provides services as a pharmacy benefits administrator.

69 B. Any pharmacy subject to this section shall, during its regular hours of operation, but not less than
70 six days per week, and for a minimum of 40 hours per week, provide a toll-free telephone service to
71 facilitate communication between patients in the Commonwealth and a pharmacist at the pharmacy who
72 has access to the patient's records. This toll-free number shall be disclosed on a label affixed to each
73 container of drugs dispensed to patients in the Commonwealth.

74 C. Pharmacies subject to this section shall comply with the reporting requirements of the Prescription
75 Monitoring Program as set forth in § 54.1-2521.

76 D. The registration fee shall be the fee specified for pharmacies within Virginia.

77 E. A nonresident pharmacy shall only deliver controlled substances that are dispensed pursuant to a
78 prescription, directly to the consumer or his designated agent, or directly to a pharmacy located in
79 Virginia pursuant to regulations of the Board.

80 **2. That the Board of Pharmacy shall promulgate regulations to implement the provisions of this**
81 **act to be effective within 280 days of its enactment.**

82 **[3. That the Board of Pharmacy shall work cooperatively with pharmacists representing all areas**
83 **of pharmacy practice in implementing the requirements of this act.]**