WEST VIRGINIA LEGISLATURE

2019 REGULAR SESSION

Introduced

House Bill 2896

FISCAL NOTE

BY DELEGATES MILEY, PYLES, FLUHARTY, ESTEP-BURTON, HORNBUCKLE, WILLIAMS, PUSHKIN, C. THOMPSON AND N. BROWN

[Introduced February 7, 2019; referred to the committee on Prevention and Treatment of Substance Abuse then the Judiciary.]

A BILL to amend the Code of West Virginia, 1931, as amended, by adding thereto a new section, designated as §30-5-35; and to amend said code by creating a new article, designated §46A-6K-1, §46A-6K-2, §46A-6K-3, §46A-6K-4,and §46A-6K-5, all relating to establishing a program to monitor and regulate dangerous pharmaceutical distribution practices; requiring the board of pharmacy to establish requirements for manufacturers and distributors of certain Schedule II drugs sold in the state; authorizing the Board of Pharmacy to promulgate legislative rules; providing legislative findings for the need for oversight and regulation of schedule II drugs; granting authority of the Attorney General to enforce unfair and deceptive practices relating to sales of Schedule II drugs; requiring Schedule II drug manufacturers and distributors to report sale figures to state pharmacies; providing for enforcement and remedies for violations; and requiring legislative authorization for Attorney General settlements with all Schedule II manufacturers and distributors.

Be it enacted by the Legislature of West Virginia:

CHAPTER 30. PROFESSIONS AND OCCUPATIONS.

ARTICLE 5. PHARMACISTS, PHARMACY TECHNICIANS, PHARMACY INTERNS AND PHARMACIES.

§30-5-35. Board to establish Schedule II drug sales monitoring program.

(a) The board shall administer a drug monitoring program to receive data on sales of drugs, listed in §60A-2-206 of this code, that are delivered to pharmacies in the state. Each pharmaceutical manufacturer or distributor selling those drugs in the state shall report monthly sales to the board. The purpose of the program is to monitor dispensing trends for health and law-enforcement purposes and proprietary sales data shall be kept confidential.

(b) The board shall monitor sales and identify sales patterns that may show that a drug, listed in §60A-2-206 of this code, is being sold in excessive amounts, used unlawfully, or if the

drug has a propensity for abuse or addiction, and the board has found that it has reason to believe the drug is being abused or misused by the public.

(c) All reported information is exempt from disclosure under the West Virginia Freedom of Information Act, §29B-1-1 *et seq*. of this code.

(d) The board may propose legislative rules, pursuant to §29A-3-1 *et seq*. of this code, establishing how pharmaceutical manufacturers and distributors who deliver Schedule II drugs in this state are to report sales to state licensed pharmacies, and procedures for reporting and certifying sales when the board has identified a drug, listed in §60A-2-206 of this code, as being sold in excessive amounts, used unlawfully, or has a propensity for abuse or addiction and the board has found that it has reason to believe are being abused or misused by the public. The board shall establish protocols for manufacturers and distributors to report sales of all drugs listed in §60A-2-206 of this code and suspicious excessive sales of those drugs, which the board finds may potentially be sold in excessive amounts, used unlawfully, or have a propensity for abuse or addiction. Upon a finding by the board that such drug is being abused or misused by the public and the harm caused by overprescribing of the drug is causing substantial harm to the health, safety, and welfare of the public, limitations or conditions may be placed by the board on further distribution of that drug. The board shall report to the Attorney General failure to comply with the provisions of this section, any rules promulgated pursuant thereto, or the provisions of §46A-6K-1 *et seq*. of this code.

CHAPTER 46A. WEST VIRGINIA CONSUMER CREDIT AND PROTECTION ACT.

ARTICLE 6K. PREVENTION OF DANGEROUS PHARMACEUTICAL DISTRIBUTION PRACTICES.

§46-6K-1. Legislative Findings.

The Legislature finds that a drug epidemic of unsurpassed magnitude has descended upon this state the last decade that has destroyed the health and lives of countless persons and

their families. Further, the Legislature is morally bound to take action in response to this crisis, facilitated in our state by over 180 million hydrocodone and oxycodone pills being distributed in West Virginia over a 10-year period. These pills were sold without meaningful oversight or concern by pharmaceutical manufacturers and distributors regarding the medical necessity of the huge volume of sales to the small population of our state. As an example, over 20 million pills were sold over a 10-year period in one community in West Virginia with a population of less than 2,100 people. As a result of these sales, West Virginia has led the country in addiction, addiction-related deaths, and harm to our families and communities, straining local and state government resources, health care facilities, and social services. The pharmaceutical and health care industry's failure to self-regulate, all while simultaneously reaping huge profits selling highly addictive and dangerous drugs, combined with a failed state or federal regulatory oversight mechanism, facilitated this crisis. No human tragedy in modern times has grasped the citizenry of this state to this magnitude. Therefore, to address this ongoing epidemic, the Legislature is enacting this article to protect citizens health, safety and welfare, and that the intent of the Legislature is that this article be liberally construed so that its beneficial purposes may be served.

§46-6K-2. Definitions.

As used in this article, "unfair or deceptive practice" means:

(1) The sale by pharmaceutical manufacturers or distributers of drugs, listed in §60A-2-206 of this code, in volumes that are reasonably foreseeable to cause injury, by being in excess of the volume of drugs prescribed for lawful consumption, based on appropriate industry prescription practices and statistical evidence showing what reasonable demand based on state health demographics, population, age, and other factors that may reflect abuse of such drug;

(2) Any sales and distribution practices where it is reasonably expected that the distributor has knowledge that excessive volume of the drug has been occurring, and the

distributor has failed, in a timely fashion, to receive authorization for continued sales at an appropriated volume, as authorized by the West Virginia Board of Pharmacy; or

(3) Has failed to report to the Board of Pharmacy and to the Attorney General, sales of drugs listed in §60A-2-206 of this code or of suspected excessive sales of those drugs.

§46A-6K-3. Pharmaceutical manufacturers recordkeeping and reporting requirements.

Every pharmaceutical manufacturer or distributor distributing prescription drugs in this state shall submit once each month, a report of the total sales, by location, of all schedule II drugs distributed in the state to the state Attorney General.

§46A-6K-4. Attorney General enforcement; remedies.

(a) A violation of this article is an unfair or deceptive act or practice within the meaning of §46A-6-102 of this code and is subject to the enforcement provisions and remedies provided by this chapter.

(b) Any drug manufacturer or distributor violating the provisions of this article shall also be assessed civil penalty not excess of $5,000 per pill sold, using an unfair or deceptive practice.

(c) The remedies and penalties provided by this article are cumulative, and do not prohibit any other remedy or punishment available under the laws of this state.

(d) Any citizen may bring a civil action against the Attorney General for failure to enforce the provisions of this article.

§46A-6K-5. Legislative approval of settlements with drug manufacturers or distributors.

Prior to entering into any final settlement where a drug manufacturer or distributor has offered to settle a claim instigated by the Attorney General, in which the settlement may relieve the drug manufacturer or distributor of any liability, in whole or in part, for claims made by the state or its citizens; the Attorney General shall submit the proposed settlement to the Joint Committee on Government and Finance and may only enter into a final settlement agreement

upon passage of a concurrent resolution by both houses of the Legislature authorizing the proposed settlement.

NOTE: The purpose of this bill is to provide a mechanism to prevent the excessive distribution of dangerous prescription drugs in the state; providing for the state pharmacy board and the attorney general to monitor sales of these drugs and the board to restrict excessive sales, establishing reporting requirements for pharmaceutical distributors, granting authority under the consumer credit and protection act for the Attorney General to monitor and enforce distribution of dangerous drugs in the state; and requiring that the Attorney General to gain approval from the Legislature for any drug settlements.

Strike-throughs indicate language that would be stricken from a heading or the present law and underscoring indicates new language that would be added.