



# OHIO LEGISLATIVE SERVICE COMMISSION

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## Bill Analysis

Audra Tidball

### **Sub. H.B. 231**

132nd General Assembly  
(As Passed by the House)

**Reps.** Ginter and Sprague, Blessing, Green, Riedel, Seitz, Anielski, Antonio, Ashford, Craig, Greenspan, Hambley, Hill, Johnson, Landis, Lanese, Manning, Miller, Schaffer, Slaby, Stein, Young

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### **BILL SUMMARY**

- If an appropriation is made, requires the State Board of Pharmacy to operate a two-year pilot program to dispense schedule II controlled substances in lockable or tamper-evident containers.
  - Requires the Board to reimburse pharmacies for expenses incurred in participating in the pilot program.
  - As part of the pilot program, requires that patients be given a Board-developed educational statement with information on the potential for abuse and diversion of controlled substances.
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### **CONTENT AND OPERATION**

#### **Dispensing controlled substances in lockable or tamper evident containers**

The bill requires the State Board of Pharmacy to operate a two-year pilot program under which drugs containing a schedule II controlled substance are dispensed in lockable containers or tamper evident containers.<sup>1</sup> Operation of the program, however, is dependent on whether the General Assembly makes an appropriation for it. If the appropriation is made, the program must be developed and implemented within six months of the appropriation becoming available to the Board.<sup>2</sup>

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<sup>1</sup> Section 2.

<sup>2</sup> Section 3(A).

## Types of lockable and tamper-evident containers

The bill defines "lockable container" as a container that (1) has "special packaging," which is generally defined under federal law as packaging designed to be significantly difficult for children to open but not difficult for normal adults to use,<sup>3</sup> and (2) can be unlocked physically using a key, or physically or electronically using a code or password.<sup>4</sup> "Tamper-evident container" is defined by the bill as a container that has special packaging and displays a visual sign in the event of unauthorized entry or displays the time the container was last opened.<sup>5</sup>

## Requirements for pharmacies

The bill requires pharmacists at pharmacies participating in the pilot program (see "**Pharmacy participation**," below) to do both of the following:<sup>6</sup>

(1) Dispense a drug containing a schedule II controlled substance in a lockable or tamper-evident container, unless the patient or an individual acting on the patient's behalf requests that the drug not be dispensed in such a container;

(2) Before dispensing the drug, deliver an educational statement on abuse and diversion.

### Educational statement

The Board is required to develop the educational statement as part of the pilot program. The statement must inform patients about the serious potential for abuse and diversion of drugs containing controlled substances, including the possibility of pilfering by adolescents and unauthorized users. The statement must be brief, efficient, non-burdensome, and provide a plain and accurate warning of the risks of abuse, diversion, addiction, overdose, and death associated with controlled substances. The statement may be delivered in any manner the pharmacist chooses, including orally, electronically, or in writing. Also, the statement may be delivered by a delegate of the pharmacist.<sup>7</sup>

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<sup>3</sup> Section 1(C) (referencing the federal "Poison Prevention Packaging Act of 1970," 15 United States Code 1471).

<sup>4</sup> Section 1(B).

<sup>5</sup> Section 1(D).

<sup>6</sup> Section 2(C)(1) and (2).

<sup>7</sup> Section 2(D).



## **Reimbursement for costs**

The bill requires the Board to reimburse pharmacies for expenses incurred in participating in the pilot program, including administrative expenses and other expenses associated with stocking lockable or tamper-evident containers and dispensing schedule II controlled substances in those containers.<sup>8</sup> The bill also provides that expenses a pharmacy incurs for the containers cannot be charged to a patient, an individual acting on behalf of the patient, or a health insurer or other third-party payer.<sup>9</sup>

## **Pharmacy participation**

The Board is required to select pharmacies to be included in the pilot program from volunteers, and any pharmacy may volunteer to participate. In selecting the pharmacies, the Board must consider areas that have the highest levels of dispensing schedule II controlled substances. If some of those areas are not adequately represented by initial volunteers, the Board must make concerted efforts to recruit pharmacies from those areas. In addition, the Board must attempt to include pharmacies of varying types.<sup>10</sup>

The bill specifies that it does not preclude a nonparticipating pharmacy from stocking lockable or tamper-evident containers and offering to dispense schedule II controlled substances in those containers.<sup>11</sup>

## **Report**

The bill requires the Board to prepare a report regarding the pilot program's success. The report must be prepared not later than six months after the program ends and submitted to the General Assembly on completion.

In evaluating the pilot program's success, the Board must contract with a third-party research organization to assess whether a measured decrease in diversion of schedule II controlled substances occurred regarding drugs dispensed through the program as compared to those dispensed outside of the program.<sup>12</sup>

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<sup>8</sup> Section 2(A).

<sup>9</sup> Sections 1(E) and 2(C)(3).

<sup>10</sup> Section 2(B).

<sup>11</sup> Section 4.

<sup>12</sup> Section 2(F).



## Qualified immunity

The bill grants immunity from liability to pharmacists, pharmacist delegates, and pharmacies for actions taken in good faith in accordance with the bill. The bill's qualified immunity applies to damages in a civil action, criminal prosecution, and professional disciplinary action.<sup>13</sup>

## Rulemaking

If an appropriation is made for the pilot program, the bill requires the Board to adopt rules as necessary to administer the program. The rules must be adopted in accordance with the Administrative Procedure Act (R.C. Chapter 119).<sup>14</sup>

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## HISTORY

ACTION	DATE
Introduced	05-23-17
Reported, H. Health	05-29-18
Passed House (89-3)	06-20-18

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<sup>13</sup> Section 2(E).

<sup>14</sup> Section 3(B).

