



# Ohio Legislative Service Commission

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## Fiscal Note & Local Impact Statement

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**Bill:** Sub. H.B. 93 of the 129th G.A. (with LSC amendments<sup>1</sup>)      **Date:** May 10, 2011

**Status:** In Senate Health, Human Services & Aging      **Sponsor:** Reps. Burke and Johnson

**Local Impact Statement Procedure Required:** No

**Contents:** Establishes and modifies the laws regarding the prevention of prescription drug abuse

### State Fiscal Highlights

- **Pain management clinics.** The State Board of Pharmacy will gain a minimal annual amount from the licensing of pain management clinics. The Board will also experience an ongoing increase in expenses related to licensing and overseeing additional terminal distributors of dangerous drugs, and enforcing new criminal prohibitions. Additional staff will likely be needed to perform these duties and responsibilities. The licensing revenues will be credited to, and the expenditures charged against, the Occupational Licensing and Regulatory Fund (Fund 4K90).
- **Enforcement of terminal distributors.** GRF-funded incarceration costs may increase, as additional felony offenders could be convicted and sentenced to prison. The state may gain a minimal amount of locally collected state court cost revenues that would be divided between the Indigent Defense Support Fund (Fund 5DY0) and the Victims of Crime/Reparations Fund (Fund 4020).
- **Criminal records checks.** The Attorney General's Bureau of Criminal Identification and Investigation will likely experience an increase in the number of requests for criminal background checks. Presumably, the revenues generated will offset any expenditure incurred. The revenues will be credited to, and the expenditures charged against, the General Reimbursement Fund (Fund 1060).
- **Standards for physicians regarding pain management.** The State Medical Board will experience a one-time increase in costs to adopt rules specified under the bill and ongoing costs to summarily suspend licenses in accordance with the bill. The Board may also experience a gain in fine revenue for violations of the rules of

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<sup>1</sup> On May 4, 2011, the Senate Health, Human Services and Aging Committee accepted the following LSC amendments: AM-0865, AM-1034-1, AM-1041, AM-1044-3, AM-1092, and AM-1106. Their fiscal effects, if any, have been incorporated into this version of the H.B. 93 Fiscal Note & Local Impact Statement.

operation or standards for pain management clinics. Operating expenditures of the Board are paid from, and fine revenue is deposited into, the State Medical Board Operating Fund (Fund 5C60). The bill also establishes the Education and Patient Safety Fund, which is to consist of grants solicited and accepted by the Board. Expenditures from the fund will be limited to the amount of grants deposited into the fund.

- **Drug Take-Back Program.** The Attorney General will likely experience an increase in expenditures to operate the Drug Take-Back Program. The participating agencies may obtain grants to fund the program, which will be deposited to the credit of the Drug Take-Back Program Fund created by the bill.
- **Ohio Automated Rx Reporting System (OARRS).** The State Board of Pharmacy will likely experience significant one-time costs of up to several hundreds of thousands of dollars in order to modify OARRS and to provide access to medical professionals with prescriptive authority. The bill also allows the Board to accept grants, gifts, or donations to operate the database, and establishes the Drug Database Fund for this purpose. The State Medical Board, the State Dental Board, the Board of Nursing, and the Board of Optometry will likely experience a minimal increase in expenditures to adopt rules to require physicians, physician assistants, dentists, nurses, and optometrists to check OARRS when issuing a prescription. With the exception of the State Medical Board, expenditures for the professional licensing boards mentioned above are charged against the Occupational Licensing and Regulatory Fund (Fund 4K90).
- **Law enforcement information.** The bill allows the State Medical Board and the State Nursing Board to access law enforcement information contained in the Ohio Law Enforcement Gateway (managed by the Office of the Attorney General) and the Law Enforcement Automated Data System (managed by the Department of Public Safety). These boards will have access to view, but not alter, information contained in these two databases. The two managing agencies, as well as the boards, may experience additional costs in drafting and implementing rules to address these changes, but these costs are likely to be negligible.

## **Local Fiscal Highlights**

- **Enforcement and criminal investigations of terminal distributors and misuse of OARRS.** As a result of violations of the bill's prohibited conduct, additional misdemeanor and felony criminal cases may be generated for county and municipal criminal justice systems to process, potentially increasing the costs to investigate, prosecute, adjudicate, and sanction violators. Courts would generally impose court costs and fines to be paid by violators.

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## Detailed Fiscal Analysis

### Pain management clinics

#### Licensure of pain management clinics

The bill requires the State Board of Pharmacy to license pain management clinics<sup>2</sup> as terminal distributors of dangerous drugs subject to the same requirements as other terminal distributors<sup>3</sup> of dangerous drugs and establishes a "pain management clinic" classification within that licensing category. The number of new licenses that will be issued annually will likely be minimal. The fee for a new license is \$150 per year. Some current holders of terminal distributor licenses will likely have their licenses converted to the new classification. There would be no charge for these reclassifications. Annual licensing fees will be deposited to the credit of the Occupational Licensing and Regulatory Fund (Fund 4K90). This provision of the bill will take effect 30 days after the bill's effective date.

For four years following this provision's effective date, the State Board of Pharmacy is required to prepare an annual report containing information related to its regulation of pain management clinics. The report is to be submitted to the Governor and the General Assembly. The cost to produce the report will likely be minimal.

#### Enforcement and criminal investigations

As a result of requiring pain management clinics to obtain a terminal distributor license, the State Board of Pharmacy will likely incur some additional expenses related to the consideration and issuance of such licenses, oversight of compliance with state law and administrative rules, and future criminal investigations if cases are brought to the Board's attention. According to Pharmacy Board staff, such investigations may be costly, with a recent case reaching \$400,000 to adjudicate.

Penalties for violating any of the provisions related to licensed terminal distributors as well as operating a pain management clinic without a license will range from a misdemeanor of the first degree (punishable by up to six months in jail and a maximum fine of \$1,000) to a felony of the third degree (punishable by 1, 2, 3, 4, or 5 years in prison and a maximum fine of \$10,000). In some of these cases, multiple

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<sup>2</sup> Pain management clinics are facilities in which the treatment of pain or chronic pain is the primary component of practice and the majority of patients are treated with controlled substances, tramadol, carisoprodol, or other drugs specified by the State Medical Board. This definition of pain management clinic does not include certain hospitals, certain schools, colleges or universities, licensed hospice programs, and ambulatory surgical facilities.

<sup>3</sup> "Terminal distributor of dangerous drugs" means a person who is engaged in the sale of dangerous drugs at retail, or any person, other than a wholesale distributor or a pharmacist, who has possession, custody, or control of dangerous drugs for any purpose other than for that person's own use and consumption.

charges could be stacked against an individual. There will likely be a number of successful prosecutions related to violations of the bill's prohibited conduct. As such, some individuals could be sentenced to a term of incarceration in a local jail or in state prison. Depending upon the number of successful prosecutions, the state could realize a gain in court cost revenues for the Indigent Defense Support Fund (Fund 5DY0) and the Victims of Crime/Reparations Fund (Fund 4020). In certain criminal investigations, the lead investigating law enforcement agency may retain a portion of the fine revenue.

The bill also authorizes the State Board of Pharmacy to impose administrative fines of no more than \$5,000 for two types of violations as follows:

- If a person is found to be operating a facility that is required to be licensed as a pain management clinic and has failed to do so, or if currently licensed, has failed to remain in compliance with that license, that individual could be subject to a fine of no more than \$5,000 per incident; and
- The Board may impose a no more than \$5,000 fine, per incident, on prescribers who do either of the following: (a) in any 30-day period, personally furnish an amount of all controlled substances combined that exceeds a total of 2,500 dosage units, or (b) in any 72-hour period, personally furnish to or for a patient an amount of a controlled substance that exceeds the amount necessary for the patient's use in that time period.

Any fine revenue will be deposited to the credit of the Occupational Licensing and Regulatory Fund (Fund 4K90).

The bill also permits the State Board of Pharmacy to suspend the license of a wholesaler of controlled substances without a hearing if the Board determines that there is clear and convincing evidence that the method used to distribute controlled substances presents a danger of immediate and serious harm to others.

### **Criminal records checks**

The bill requires that all employees of pain management clinics seeking licensure submit to a criminal records check. No employee may have been previously convicted of, or pleaded guilty to, any felony in this state or another state. The Attorney General's Bureau of Criminal Identification and Investigation charges \$22 to perform a state criminal records check and an additional \$24 to obtain information from the FBI to perform a federal criminal records check. Presumably, these charges will offset the cost of performing the background checks required by the bill. The revenue will be deposited to the credit of the General Reimbursement Fund (Fund 1060). Presumably, the revenues generated will offset any expenditure incurred.

### **Standards for physicians regarding pain management**

The bill requires the State Medical Board to adopt rules regarding both of the following:

- Standards for physician operation of pain management clinics and standards to be followed by physicians who provide care in such clinics; and

- Physician treatment and diagnosis of patients with "chronic pain" (currently "intractable pain" in Medical Board rules).

The rule-making process will increase expenditures for the Medical Board. The Board's staff would consult with and compensate physicians acting as clinical advisors in developing the rules. The Board will also have to pay a court reporter to document the public hearing prior to the rules being adopted.

### **Summary suspension of medical licenses**

The State Medical Board currently has summary suspension authority, and the bill extends this authority to physicians who hold a terminal distributor license with a pain management classification. The Board may incur additional costs due to the larger pool of licenses subject to suspension. The bill authorizes the Board to hold a telephone conference call with at least six members present to vote on the suspension of the medical license. Members would be compensated at the usual per diem rate of \$157.50 to \$204.96 for telephone conference calls.

### **Fines**

The State Medical Board is authorized to impose fines of up to \$20,000 on any physician who fails to comply with the rules of operation or standards for pain management clinics. Fine revenue is to be deposited into the State Medical Board Operating Fund (Fund 5C60).

### **Medical Board Education and Patient Safety Fund**

The bill creates the Medical Board Education and Patient Safety Fund, which is to be used to develop and maintain programs that address patient safety and education, supply and demand of healthcare professionals, and information sharing with the public and individuals regulated by the Board. Fund revenue will consist of grants solicited and accepted by the Board from public and private sources. Expenditures will be limited to amounts deposited into the fund.

### **Drug Take-Back Program**

The bill requires the State Board of Pharmacy, in conjunction with the Attorney General and the Department of Alcohol and Drug Addiction Services, to develop a program under which drugs are collected from the community for destruction or disposal. The bill specifies that the Attorney General is responsible for the costs of the program and authorizes the participating agencies to obtain grants to fund the program. Any grants received will be credited to the Drug Take-Back Program Fund, which is created by the bill. Costs to operate the program would likely include personnel, advertising, and disposal.

## **Ohio Automated Rx Reporting System (OARRS)**

### **System modifications**

The bill modifies the operation of OARRS<sup>4</sup> and establishes criminal penalties for failing to comply with certain requirements of the system. In addition to these changes, the bill allows the State Board of Pharmacy to accept grants, gifts, or donations to operate the database, and establishes the Drug Database Fund for this purpose. The bill requires the Board to consider improvements to Ohio's method of monitoring the misuse and diversion of controlled substances through OARRS. The Board is to submit a report not later than six months after the bill's effective date.

These modifications and expansions will require the Board to make hardware and software updates to the existing database. These one-time costs, as well as those associated with new programming, could be several hundreds of thousands of dollars. The Board also anticipates that additional staff will be required to help assist in the increased workload.

The bill will permit the State Board of Pharmacy to enter into contracts with private entities in order to support its activities, and requires any money received by the Board from the contracts be deposited into the Occupational Licensing and Regulatory Fund (Fund 4K90). The amount of revenue that could be generated annually from such contracts is uncertain.

### **Criminal prohibitions**

The bill establishes several criminal prohibitions and penalties for the misuse of the information contained within OARRS. The number of possible criminal cases that could be generated annually would likely be small. Therefore, any related fiscal effect on local criminal justice systems would be minimal at most. Depending upon the number of successful prosecutions, the state could realize a gain in court cost revenues generated annually to the credit of the Indigent Defense Support Fund (Fund 5DY0) and the Victims of Crime/Reparations Fund (Fund 4020).

### **Medical professionals required to check OARRS**

The bill requires the State Medical Board, the State Dental Board, the Board of Nursing, and the Board of Optometry to adopt rules to require physicians, physician assistants, dentists, nurses, and optometrists to check OARRS when issuing a prescription. Each board will likely experience a minimal increase in expenditures to adopt these rules. Additionally, the State Board of Pharmacy may experience an increase in costs to provide access to OARRS to those medical professionals.

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<sup>4</sup> OARRS was first authorized by Sub. H.B. 377 of the 125th General Assembly. The Act, which became effective May 2005, permitted the Board to establish and maintain an electronic database to monitor the misuse and diversion of controlled substances and certain dangerous drugs. The program began full operation in October 2006.

## **Coordinated services program**

Currently, the Ohio Department of Job and Family Services (ODJFS) has a program that identifies individuals who overuse Medicaid pharmacy benefits. The bill requires ODJFS to establish a coordinated services program (also referred to as Lock-in) under which a Medicaid recipient who overuses the prescription drug benefit is required to use a single pharmacy. If the program established under the bill results in an increase in the number of individuals identified as overusing pharmacy benefits, additional program savings could be achieved. If the program created by the bill essentially codifies existing practice, there would be no fiscal impact. Furthermore, the bill would require managed care organizations (MCOs) to operate a Lock-in program if Medicaid prescription drug coverage is provided by MCOs in the future.

The bill also requires the Bureau of Workers' Compensation (BWC) to establish and operate a coordinated services program for individuals who have obtained prescription drugs at a frequency or in an amount that is not medically necessary. The bill specifies this program is to be similar to the Medicaid coordinated services program. Currently, BWC has a process by which medical claims are evaluated to ensure claimants are receiving appropriate services. BWC would likely experience an increase in costs to develop and operate the program specified under the bill. If the program required under the bill results in an increase in the number of individuals identified as overusing pharmacy benefits, additional program savings may be achieved.

## **Other miscellaneous provisions**

The bill allows the State Medical Board and the State Nursing Board to access law enforcement information contained in the Ohio Law Enforcement Gateway<sup>5</sup> (managed by the Office of the Attorney General) and the Law Enforcement Automated Data System<sup>6</sup> (managed by the Department of Public Safety). These boards will have access to view, but not alter, information contained in these two databases. The two managing agencies, as well as the boards, may experience additional costs in drafting and implementing rules to address these changes, but these costs are likely to be negligible.

## **Emergency clause**

The bill contains an emergency clause which generally makes the bill go into immediate effect, as opposed to the normal effective date of 91 days after it is filed with the Secretary of State for final enrollment. This provision may accelerate the incurrence of costs, receipt of revenues, and realization of costs savings that result from the bill.

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<sup>5</sup> Also known as OHLEG.

<sup>6</sup> Also known as LEADS.