



OHIO LEGISLATIVE SERVICE COMMISSION

Bill Analysis

Elizabeth Molnar

S.B. 154

132nd General Assembly
(As Introduced)

Sens. Schiavoni and Yuko, Brown, Sykes, Skindell, O'Brien, Tavares

BILL SUMMARY

- Requires certain health insurers and the Medicaid program to provide coverage for abuse-deterrent opioid analgesics and alcohol and drug abuse or addiction treatment and referral services, including medication-assisted treatment.
- Requires the Superintendent of Insurance to establish a reinsurance program to reimburse health insurers for costs incurred when providing coverage for alcohol and drug abuse or addiction treatment and referral services.
- Requires drug manufacturers to supply secure lock boxes or kiosks to retail pharmacies for the collection of drugs and makes other changes to the law governing the State Board of Pharmacy's drug take-back program.
- Requires local boards of health to establish awareness programs regarding safe drug disposal.
- Allows retail pharmacies and drug manufacturers or wholesalers to donate controlled substances to pharmacy schools.
- Requires the Ohio Department of Mental Health and Addiction Services to establish a web portal to monitor the availability of services from community addiction services providers.
- Requires the Ohio Department of Education to establish a grant program to fund school-based initiatives that seek to educate students about opioid dependence and addiction prevention.
- Transfers \$200 million from the Budget Stabilization Fund and makes appropriations.

- Declares an emergency.

TABLE OF CONTENTS

Health insurance and Medicaid coverage of abuse-deterrent opioids and treatment for substance abuse or addiction.....	2
Abuse-deterrent opioid analgesics	3
Reimbursement.....	3
Treatment with non-abuse deterrent opioids.....	4
Cost-sharing.....	4
Alcohol and drug abuse or addiction treatment and referral services.....	4
Prior authorization	4
Medication-assisted treatment drugs.....	4
Length of coverage.....	4
Copayments, coinsurance, and deductibles	4
Review of mandated benefits legislation	5
ERISA	5
Reinsurance program.....	5
Actuarial survey.....	6
Opioid Overdose and Treatment Reinsurance Fund.....	6
Drug take-back program	6
Background.....	6
Retail pharmacies	7
Secure lock boxes or kiosks	7
Drug manufacturers	7
Costs and fees	8
Removal, transport, or destruction of drugs.....	8
Current program.....	8
Compliance and penalties	8
Conforming changes	8
Safe drug disposal awareness	9
Controlled substance donations	9
Availability of addiction services	9
School-based education about opioid dependence and addiction	10
Transfer from the Budget Stabilization Fund and appropriations	10

CONTENT AND OPERATION

Health insurance and Medicaid coverage of abuse-deterrent opioids and treatment for substance abuse or addiction

The bill requires certain health insurers and the Medicaid program to provide coverage for each of the following:

- (1) Abuse-deterrent opioid analgesics;¹

¹ R.C. 1739.05, 1751.692, 3923.852, 5164.092, and 5167.12.



(2) Medical or psychological treatment and referral services for alcohol and drug abuse or addiction, including medication-assisted treatment.²

The health insurers subject to these requirements include all of the following, if they also provide coverage of prescription drugs, basic health services, basic hospital and surgical coverage, basic medical coverage, or major medical coverage, as applicable:

- Health insuring corporations;
- Sickness and accident insurers;
- Multiple employer welfare arrangements;
- Public employee benefit plans;
- The Medicaid program, including Medicaid managed care organizations.

In the case of health insurers, the coverage requirements apply to policies, contracts, agreements, or plans issued, delivered, renewed, established, or modified in Ohio on or after January 1, 2019. Similarly, the Medicaid program and Medicaid managed care organizations also must comply with the requirements on or after January 1, 2019.³

The bill's requirements do not apply to health insurance that is part of employee benefits offered by private employers that self-insure their benefit programs. These programs are generally precluded from state regulation by the federal Employee Retirement Income Security Act (ERISA) (see "**ERISA**," below).

Abuse-deterrent opioid analgesics

The bill defines "abuse-deterrent" as a labeling claim approved by the United States Food and Drug Administration indicating properties expected to deter or reduce drug abuse.

Reimbursement

The bill prohibits a health insurer and the Medicaid program from denying reimbursement for an abuse-deterrent opioid analgesic solely because a generically equivalent drug is available at a lower cost.

² R.C. 1739.05, 1751.01, 1751.76, 3923.046, 5164.7512, and 5167.12.

³ Section 6.

Treatment with nonabuse deterrent opioids

The bill prohibits a health insurer and the Medicaid program from requiring treatment with an opioid analgesic that is not abuse-deterrent before providing coverage for an abuse-deterrent opioid analgesic.

Cost-sharing

The bill prohibits a health insurer and the Medicaid program from imposing cost-sharing requirements on an abuse-deterrent opioid analgesic that exceed the lowest cost-sharing requirements applied to opioid analgesic drugs without abuse-deterrent properties. An insurer and the Medicaid program cannot achieve compliance with this provision by increasing prescription cost-sharing requirements.

Alcohol and drug abuse or addiction treatment and referral services

Prior authorization

The bill prohibits a health insurer and the Medicaid program from imposing any prior authorization requirement on treatment and referral services for alcohol and drug abuse or addiction. It defines "prior authorization" as any practice in which the coverage of a health care service, device, or drug is dependent on a covered person or health care provider obtaining approval from the insurer prior to the service, device, or drug being performed, received, or prescribed.

Medication-assisted treatment drugs

The bill requires a health insurer and the Medicaid program to provide coverage for drugs prescribed for the treatment of alcohol and drug abuse or addiction, including buprenorphine and naltrexone.

Length of coverage

The bill requires a health insurer and the Medicaid program to provide coverage for treatment and referral services for alcohol and drug abuse or addiction for as long as they are needed.

Copayments, coinsurance, and deductibles

The bill specifies that a health insurer and the Medicaid program is not prohibited from imposing copayments, coinsurance, or deductibles for treatment and referral services.



Review of mandated benefits legislation

The bill exempts its requirements regarding health insurer coverage of (1) abuse-deterrent opioid analgesics and (2) treatment and referral services for alcohol and drug abuse or addiction from an existing law that could prevent these requirements from being applied until a review by the Superintendent of Insurance has been conducted with respect to mandated health benefits. Under current law, legislation mandating health benefits cannot be applied to any health benefits arrangement after the legislation is enacted unless the Superintendent holds a public hearing and determines that it can be applied fully and equally in all respects to (1) employee benefit plans that are subject to ERISA and (2) employee benefit plans established or modified by the state or its political subdivisions.⁴ Under the bill, the requirements for coverage of both abuse-deterrent opioid analgesics and treatment and referral services apply even if the bill's provisions are considered mandated benefits.

ERISA

ERISA is a comprehensive federal statute governing the administration of employee benefit plans. ERISA generally precludes state regulation of benefits offered by private employers that self-insure their benefit programs. Larger employers frequently choose to establish their own health insurance plans for their employees in lieu of purchasing coverage from a sickness and accident insurer or health insuring corporation.

Reinsurance program

The bill requires the Superintendent of Insurance – not later than January 1, 2019 – to establish and administer a program of reinsurance to reimburse health insurers for costs incurred in providing coverage of treatment and referral services for alcohol and drug abuse or addiction.⁵ It also requires each insurer subject to the treatment and referral services requirement to participate in the program.

As part of the program, the Superintendent must do all of the following:

- Establish standards and procedures for insurers to seek and obtain reimbursement;
- Employ staff to administer the program;
- Set levels of reinsurance adequate to ensure minimal losses for insurers;

⁴ R.C. 3901.71.

⁵ R.C. 3901.80.



- Adopt rules as necessary and in accordance with the Administrative Procedure Act.⁶

The Superintendent may fulfill these requirements by contracting with a reinsurer accredited by the Superintendent under existing law.⁷

Actuarial survey

Not later than July 1, 2018, the Superintendent of Insurance must conduct an actuarial survey to determine the estimated cost for the reinsurance program.⁸ But, the bill allows the Superintendent to contract with an actuary to conduct the required survey.

Opioid Overdose and Treatment Reinsurance Fund

In connection with the reinsurance program, the bill creates the Opioid Overdose and Treatment Reinsurance Fund in the state treasury.⁹ Any funds the Ohio Department of Insurance receives for the program must be deposited into this fund. Money in the fund must be used to reimburse insurers participating in the reinsurance program.

Drug take-back program

The bill makes several changes to the law governing the State Board of Pharmacy's drug take-back program.¹⁰ First, it limits the entities that may participate in the program to retail pharmacies only. Second, it requires drug manufacturers to supply retail pharmacies with secure lock boxes or kiosks so that individual consumers may dispose of drugs at the pharmacies. Third, it establishes penalties for knowingly failing to comply with the bill's requirements.

Background

As part of Am. Sub. H.B. 93, enacted by the 129th General Assembly, the State Board of Pharmacy, in collaboration with the Ohio Attorney General and Ohio Department of Mental Health and Addiction Services (ODMHAS), must administer a drug take-back program under which law enforcement agencies and authorized

⁶ See R.C. Chapter 119.

⁷ R.C. 3901.62, not in the bill.

⁸ Section 7.

⁹ R.C. 3901.801.

¹⁰ R.C. 4729.69.

collectors may accept prescription drugs, including controlled substances, and over-the-counter medications for destruction or disposal. Drugs may be collected by way of secured receptacles, mail-back programs, or local take-back events.¹¹ Authorized collectors include manufacturers, distributors, narcotic treatment programs, and hospitals or clinics with on-site pharmacies.¹² Participation in the program is voluntary and an entity is not subject to civil liability or professional discipline for declining to do so.

Retail pharmacies

The bill limits the entities that may participate in the program to retail pharmacies. It requires each retail pharmacy to have a secure and prominently displayed and labeled lock box or secure kiosk supplied by a drug manufacturer. The bill specifies that a retail pharmacy does not include an emergency medical service organization, mail-order pharmacy, pharmacy operated by a government entity, or pharmacy in which the majority of prescriptions filled are for patients of a drug treatment facility, hospital, intermediate care facility, nursing home, or other health care facility in which inpatient care is provided on a routine basis.¹³

Secure lock boxes or kiosks

The bill requires drug manufacturers to supply secure lock boxes or kiosks in which individual consumers may dispose of drugs at retail pharmacies. It also specifies that lock boxes or kiosks supplied under the bill are not to be used for the disposal of drugs by institutional consumers, including hospitals, ambulatory surgical facilities, veterinary clinics, nursing homes, correctional facilities, physician offices, pharmacies, or drug manufacturers.

Drug manufacturers

The Board, in consultation with the ODMHAS Director and Attorney General, must specify in rule a procedure for determining which prescription drug manufacturer is responsible for supplying a lock box or kiosk to each retail pharmacy. In doing so, the Board, ODMHAS Director, and Attorney General must consider the objectives of (1) achieving the efficient collection and destruction of unused drugs and (2) having manufacturers bear the costs on an equitable basis.

¹¹ R.C. 4729.69 and Ohio Administrative Code (O.A.C.) Chapter 4729-8.

¹² O.A.C. 4729-8-01.

¹³ R.C. 4729.51 and 4729.69(A) and (B).



Costs and fees

The bill requires drug manufacturers to pay all administrative and operational costs associated with the take-back program, including the cost of removing, transporting, and destroying drugs and associated packaging. It also requires the Board, in consultation with the ODMHAS Director and Attorney General, to specify in rule a schedule of fees to be charged to manufacturers to cover the Board's administrative costs for the program. With respect to consumers, they cannot be charged fees either at the time of drug sales or when depositing drugs into lock boxes or kiosks.

Removal, transport, or destruction of drugs

The Board, in consultation with the ODMHAS Director and Attorney General, must specify in rules standards for the proper removal, transport, or destruction of drugs deposited in each lock box or kiosk. The standards must comply with state and federal laws and with guidelines, if any, adopted by the U.S. Food and Drug Administration and Environmental Protection Agency.

Current program

The Board of Pharmacy may continue to administer the drug take-back program in place before the bill's effective date, but only to the extent that the program is not inconsistent with the bill's provisions.

Compliance and penalties

The bill prohibits the knowing failure to comply with its drug take-back program provisions and specifies that a violator is guilty of a misdemeanor.¹⁴ In addition to a criminal penalty, it authorizes the Board of Pharmacy, in an adjudication under the Administrative Procedure Act, to impose a fine of not more than \$1,000 per day for each violation.¹⁵ On the Board's request, the Attorney General must bring and prosecute to judgment a civil action to collect any fine imposed under the bill that remains unpaid.

Conforming changes

The bill includes conforming changes to other statutes addressing drug take-back programs.¹⁶

¹⁴ R.C. 4729.69(K) and 4729.99.

¹⁵ R.C. 4729.69(J).

¹⁶ R.C. 109.90 and 5119.49.



Safe drug disposal awareness

The bill requires each local board of health to establish an awareness program regarding safe drug disposal, including promoting awareness of collection locations, state and national drug take-back days, and drug repository programs.¹⁷ Each awareness program must do at least the following:

- Provide information to pharmacies, prescription drug manufacturers, health care facilities, and government entities regarding the State Board of Pharmacy's drug repository program for the collection of unused drugs that are in sealed, tamper-evident packaging;¹⁸
- Encourage law enforcement agencies to participate in drug take-back days.

Controlled substance donations

Existing Ohio law permits retail pharmacies and drug manufacturers or wholesalers to donate prescription drugs to pharmacy schools for instructional purposes if certain conditions are met.¹⁹ At present, a pharmacy, manufacturer, or wholesaler is prohibited from donating a controlled substance.²⁰ The bill allows for a controlled substance to be donated if the donor and recipient each comply with all state and federal laws governing the donation, possession, or use of such a drug.

Availability of addiction services

The bill requires ODMHAS to establish and maintain a web portal to monitor the availability of services and supports from community addiction services providers.²¹ ODMHAS may contract with a separate entity to establish and maintain all or any part of the web portal on its behalf.

Under the bill, the web portal must allow information to be updated instantaneously and to be presented by county. The bill also requires each community addiction services provider to submit to ODMHAS any information ODMHAS determines is necessary for maintaining the portal.

¹⁷ R.C. 3707.60.

¹⁸ See R.C. 3715.87 to 3715.873, not in the bill.

¹⁹ R.C. 3715.90, not in the bill.

²⁰ R.C. 3715.89.

²¹ R.C. 5119.368.



School-based education about opioid dependence and addiction

The bill requires the Ohio Department of Education (ODE) to establish a grant program to fund school-based initiatives that seek to educate students about opioid dependence and addiction.²² It also appropriates for the grant program \$2 million in fiscal year 2018 and \$2 million in fiscal year 2019.²³

ODE may adopt rules as necessary to implement the bill's provisions. In adopting rules, ODE must comply with the Administrative Procedure Act.²⁴

In awarding grants, ODE must give priority to initiatives that do both of the following:

- Collaborate with individuals, organizations, or entities engaged in activities at the local level to prevent or treat opioid dependence and addiction, including health care professionals, treatment providers, and law enforcement officials;
- Concentrate efforts on students enrolled in grades kindergarten through eight.

Transfer from the Budget Stabilization Fund and appropriations

The bill requires the Director of the Office of Budget and Management (OBM) to transfer \$200 million from the Budget Stabilization Fund, commonly known as the Rainy Day Fund. The OBM Director must make the transfer on the bill's effective date or as soon as possible thereafter.²⁵

From this \$200 million, the bill appropriates \$100 million to counties for the following purposes: boards of alcohol, drug addiction and mental health services (ADAMHS boards), law enforcement, child protective services, kinship care, first responders, or establishing or expanding drug courts.²⁶ Within six months of the bill's effective date, each county must prepare a written report to ODMHAS regarding its expenditures.

²² R.C. 3301.97.

²³ Section 3.

²⁴ R.C. Chapter 119., not in the bill.

²⁵ Section 5.

²⁶ Sections 3 and 4.



Of the remaining \$100 million, \$10 million is appropriated to ODMHAS for allocation to ADAMHS boards.²⁷ Each board must use the funds to provide ODMHAS with the following information: the programs and services available within its jurisdiction to address opioid addiction; the number of individuals each board is serving by program or service; the number of individuals each board is capable of serving by program or service; and an estimate of the number of individuals addicted to opioids within its jurisdiction.

With respect to the remaining \$90 million, ODMHAS must distribute it to programs providing treatment for addiction.²⁸ In distributing funds, ODMHAS must give priority to programs that are currently in operation and scalable statewide and that provide transportation to individuals receiving services. Any program receiving these funds must use them to increase the number of facilities providing services or the number of beds available within a facility. The bill also specifies that services must be provided regardless of an individual's county of residence.

HISTORY

ACTION	DATE
Introduced	05-17-17

S0154-I-132.docx/ec

²⁷ Sections 3 and 4.

²⁸ Sections 3 and 4.

