



OHIO LEGISLATIVE SERVICE COMMISSION

Bill Analysis

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Sub. S.B. 229

132nd General Assembly

(As Reported by S. Health, Human Services & Medicaid)

Sens. Eklund, Lehner, Beagle, Hackett

BILL SUMMARY

- Eliminates the statutory lists of drugs designated as schedule I, II, II, IV, and V controlled substances in Ohio and, in place of those lists, requires the State Board of Pharmacy to adopt and periodically update rules incorporating the five controlled substance schedules established under federal law.
- Requires the Pharmacy Board to add a previously unscheduled compound, mixture, preparation, or substance to schedule I if the Board determines that the item has no accepted medical use in treatment and poses an imminent hazard to public health, safety, or welfare.
- Requires certain records pertaining to controlled substances to be maintained for five years, instead of three years.
- Authorizes a schedule II controlled substance to be dispensed upon an electronic prescription.
- Modifies the general prohibition against dispensing or selling an opioid analgesic if the drug is to be used on an outpatient basis and more than 14 days have elapsed since the prescription was issued.
- Exempts the following from the Pharmacy Board's licensure of office-based opioid treatment (OBOT) facilities: federally qualified health centers, federally qualified health center look-alikes, state or local correctional facilities, and other facilities specified in rules adopted by the Board.
- Specifies that the exemption from OBOT licensure that exists for programs or facilities licensed or certified by the Ohio Department of Mental Health and

Addiction Services applies only if the licensure or certification is also approved by the Pharmacy Board.

- Requires each person seeking employment with a licensed OBOT to submit to a criminal records check.
- Narrows the disqualification from employment at a licensed OBOT by specifying that it applies to a person who was convicted of or pleaded guilty to a felony theft or drug offense within the ten years immediately preceding the date the person applied for employment (rather than at any time).
- Authorizes the Pharmacy Board to waive the disqualification from employment at a licensed OBOT even if the person was convicted or pleaded guilty within the ten-year period described above.
- Requires certain persons to submit to criminal background checks as a condition of licensure as a manufacturer, outsourcing facility, third-party logistics provider, repackager, or wholesale distributor of dangerous drugs.
- Excludes from the public records law various residential, familial, and other personal information about Pharmacy Board employees and medical directors or members of cooperating physician advisory boards of emergency medical service organizations.
- Specifies that the authority to possess a controlled substance through a prescription applies only if the prescription is for a legitimate medical purpose, is not altered or forged, and was not obtained through deception or theft.

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CONTENT AND OPERATION

Controlled substance schedules

Statutory schedules eliminated

The bill eliminates the lists of drugs that are designated in the Revised Code as controlled substances.¹ Under current law, these drugs are listed by name or chemical composition and separated into schedules I, II, III, IV, and V based on their potential for abuse or dependence. The schedules are numbered in descending order of severity, with schedule I consisting of drugs with no medicinal purpose and schedule V consisting of drugs with the lowest potential for abuse relative to the preceding schedules.

Ohio's controlled substance schedules are similar to the controlled substance schedules established under federal law (see "**Federal Controlled Substances Act**," below). The schedules under Ohio law are automatically updated when certain federal changes occur, subject to rule-making authority granted to the State Board of Pharmacy.²

Schedules established by rule

In place of Ohio's statutory controlled substance schedules, the bill requires the Pharmacy Board to adopt rules that establish schedules I, II, III, IV, and V.³ The rules are to incorporate the five schedules of controlled substances established under the federal

¹ R.C. 3719.41, repealed.

² R.C. 3719.43 and 3719.44.

³ R.C. 3719.41, new enactment.



drug abuse control laws.⁴ The bill specifies that the schedules are to be established for purposes of administration, enforcement, and regulation of the manufacture, distribution, dispensing, and possession of controlled substances.

The bill permits the Pharmacy Board to include in the schedules any compound, mixture, preparation, or substance that was included in the schedules immediately before the effective date of the repeal of the statutory controlled substance schedules. However, this is to occur only if the inclusion does not have the effect of providing less stringent control of the compound, mixture, preparation, or substance than is provided under the federal drug abuse control laws or associated regulations.⁵

The rules must be adopted in accordance with the Administrative Procedure Act (R.C. Chapter 119).⁶ However, any rules that must be adopted pursuant to federal law, to become effective within 60 days of adoption, are exempt from existing requirements regarding the Joint Committee on Agency Rule Review, as long as the proposal contains a statement that it is being proposed to comply with federal law.⁷

Transition period for initial rule adoption

The bill's repeal of the statutory controlled substance schedules is delayed for one year.⁸ Prior to that repeal, the bill requires the Pharmacy Board to adopt rules establishing Ohio's controlled substance schedules as anticipated by that repeal. The rulemaking process must be completed so that the rules take effect when the repeal of the statutory schedules takes effect. The rules must be adopted in accordance with the Administrative Procedure Act. However, the Board is not subject to the business review requirements that otherwise would apply under existing law.⁹

Periodic updates and automatic changes

The bill requires the Pharmacy Board to periodically update Ohio's controlled substance schedules by rule to correspond to (1) any change in the federal drug abuse control laws or associated regulations, (2) any addition, transfer, or removal by

⁴ See R.C. 3719.01(I), not modified by the bill, and the federal "Comprehensive Drug Abuse Prevention and Control Act of 1970," 21 United States Code 801, as amended.

⁵ R.C. 3719.41(A).

⁶ R.C. 3719.41(A).

⁷ R.C. 119.03(C)(3).

⁸ Section 3.

⁹ Section 4.



Congress or the U.S. Attorney General, or (3) any addition, transfer, or removal by the Board through existing rulemaking authority.¹⁰ The only exception is when the Board is authorized to add a previously unscheduled compound, mixture, preparation, or substance to schedule I by emergency rule (see "**Emergency rules**," below).¹¹

As with Ohio's existing controlled substance schedules established in statute, the bill specifies that certain federal changes are to be automatically effected in the schedules established by Pharmacy Board rule. Under the bill, these automatic changes are to occur not only when the U.S. Attorney General adds, transfers, or removes a compound, mixture, preparation, or substance, but also when Congress does so. The bill also requires the Board to incorporate the addition, transfer, or removal into or from the schedules in its next update of the schedules.¹²

Emergency rules

The bill requires the Pharmacy Board, by emergency rule adopted in accordance with the Administrative Procedure Act,¹³ to add a previously unscheduled compound, mixture, preparation, or substance to schedule I if the Board determines that the compound, mixture, preparation, or substance has no accepted medical use in treatment in Ohio and poses an imminent hazard to the public health, safety, or welfare.¹⁴ The Board may make the determination by telephone conference call.¹⁵

In making the determination, the Pharmacy Board must consider all of the following with respect to the compound, mixture, preparation, or substance:¹⁶

- Its actual or relative potential for abuse;
- The scope, duration, and significance of that abuse;
- The risk it poses to the public health.

¹⁰ R.C. 3719.41(B) and 3719.44(L).

¹¹ R.C. 3719.43.

¹² R.C. 3719.43.

¹³ R.C. 119.03(G).

¹⁴ R.C. 3719.45(A)(1).

¹⁵ R.C. 3719.45(B)(2).

¹⁶ R.C. 3719.45(A)(2).

If the Pharmacy Board determines an imminent hazard is posed, the Board must issue a resolution requesting that the Governor issue an order authorizing the Board to adopt an emergency rule. The resolution must include the full text of the proposed emergency rule and the Board's reasons for its determination.¹⁷

An emergency rule adopted under the bill becomes invalid after its 180th day in effect if it is not adopted as a nonemergency rule during that time. Existing law provides that most other emergency rules become invalid after 120 days.¹⁸

The authority to adopt an emergency rule under the bill does not extend to distilled spirits, wine, or beer; dangerous drugs or prescription drugs approved by the U.S. Food and Drug Administration (FDA); or any FDA-approved drug to be sold over the counter.¹⁹ "Dangerous drug" is a statutory term that, in general, describes drugs that are available only by prescription.²⁰

Conforming changes

The bill makes conforming changes throughout the Revised Code to account for (1) the repeal of the statute listing the drugs included in Ohio's controlled substance schedules and (2) the additional rule-making authority granted to the Pharmacy Board for establishing the schedules by rule.²¹

Federal Controlled Substances Act – background

Title II of the "Comprehensive Drug Abuse Prevention and Control Act of 1970" is known as the "Controlled Substances Act" (CSA). The CSA placed all substances that were regulated in some manner under federal law at the time of its passage into one of five schedules based on the substance's medical use, potential for abuse, and safety or dependence liability. The CSA also provided a mechanism for a substance to be (1) controlled or added to a schedule, (2) decontrolled or removed from control, and (3) rescheduled or transferred from one schedule to another.²² The following describes

¹⁷ R.C. 3719.45(B)(1).

¹⁸ R.C. 119.03(G).

¹⁹ R.C. 3719.45(D).

²⁰ R.C. 4729.01(F), not modified by the bill.

²¹ R.C. 2907.02(B), 2907.05(C)(1), 2925.03(J), 2925.11(H), 3313.752, 3345.41(A)(1), 3707.50(A)(1), 3719.01, 3719.40, 3719.44(A), 3796.01(B), 4729.01(W), 4729.46(A), 4729.52(A)(3), 4729.54(A)(5), and 4731.97(A)(1).

²² U.S. Drug Enforcement Administration, *Controlled Substances Act*, available at <http://bit.ly/2zM6Uj9>.



the standards that apply to each schedule and presents examples of the drugs they include:

Schedule I

- The drug or other substance has a high potential for abuse and no currently accepted medical use in treatment in the U.S.
- There is a lack of accepted safety for use of the drug or other substance under medical supervision.
- Examples: heroin, LSD, marijuana, and methaqualone.

Schedule II

- The drug or other substance has a high potential for abuse but has a currently accepted medical use in treatment in the U.S. or a currently accepted medical use with severe restrictions.
- Abuse of the drug or other substance may lead to severe psychological or physical dependence.
- Examples: morphine, PCP, cocaine, methadone, and methamphetamine.

Schedule III

- The drug or other substance has a potential for abuse less than the drugs or other substances in schedules I and II.
- The drug or other substance has a currently accepted medical use in treatment in the U.S.
- Abuse of the drug or other substance may lead to moderate or low physical dependence or high psychological dependence.
- Examples: anabolic steroids, codeine, hydrocodone with Tylenol[®], and some barbiturates.

Schedule IV

- The drug or other substance has a low potential for abuse relative to the drugs and substances in schedule III.
- The drug or other substance has a currently accepted medical use in treatment in the U.S.



- Abuse of the drugs or other substances may lead to limited physical dependence or psychological dependence relative to the drugs or other substances in schedule III.
- Examples: Darvon[®], Talwin[®], Equanil[®], Valium[®], and Xanax[®].

Schedule V

- The drug or other substance has a low potential for abuse relative to the drugs and other substances in schedule IV.
- The drug or other substance has a currently accepted medical use in treatment in the U.S.
- Abuse of the drug or other substance may lead to limited physical dependence or psychological dependence relative to the drugs and other substances in schedule IV.
- Example: Cough medicines with codeine that may be available without a prescription.

Requirements to maintain records pertaining to controlled substances

The bill requires certain records pertaining to controlled substances to be maintained for five years, instead of three years, unless otherwise specified in rules adopted by the Pharmacy Board.²³ The five year requirement applies to the following:

- Records relating to the sale of schedule II controlled substances;²⁴
- Records of controlled substances received, administered, dispensed, or used by licensed health professionals authorized to prescribe drugs;²⁵
- Records of controlled substances purchased;²⁶
- Records of controlled substances compounded, mixed, cultivated, grown, or produced by manufacturers, wholesalers, or other licensees, as well as controlled substances received and sold;²⁷

²³ R.C. 3719.04(B) and 3719.07(D).

²⁴ R.C. 3719.04(B).

²⁵ R.C. 3719.07(B)(1).

²⁶ R.C. 3719.07(B)(1).

- Records of controlled substances received and sold by category III terminal distributors of dangerous drugs;²⁸
- Records relating to the sale or purchase of certain schedule V controlled substances.²⁹

The bill also specifies that an official written order for a schedule II controlled substance must comply with all requirements of the federal drug abuse control laws and rules adopted by the Pharmacy Board. This replaces existing provisions that required such orders to be signed in triplicate and originals to be presented and maintained.³⁰

Electronic prescriptions for schedule II controlled substances

The bill specifies that a schedule II controlled substance may be dispensed upon an electronic prescription. Current law permits a schedule II controlled substance to be dispensed only upon a written prescription or, in certain emergency situations, through an oral prescription.³¹ Since 2010, U.S. Drug Enforcement Administration regulations have permitted controlled substance prescriptions to be electronic.³²

Limits on dispensing or selling opioid analgesics

14-day prescription deadline

The bill establishes additional exemptions to the existing law that generally prohibits an opioid analgesic from being dispensed or sold if the drug is to be used on an outpatient basis and more than 14 days have elapsed since the prescription was issued. The circumstances when an opioid analgesic can be dispensed or sold under these exemptions are described below.

²⁷ R.C. 3719.07(B)(2).

²⁸ R.C. 3719.07(B)(3).

²⁹ R.C. 3719.07(B)(4).

³⁰ R.C. 3719.04(B).

³¹ R.C. 3719.05(A)(3).

³² 75 Federal Register 16236, March 31, 2010; see also U.S. Department of Justice, *Electronic Prescriptions for Controlled Substances*, available at: https://www.deadiversion.usdoj.gov/e_comm/e_rx/faq/faq.htm.



Filling prescriptions issued in advance

The bill permits a pharmacist or terminal distributor of dangerous drugs to dispense or sell the opioid analgesic after 14 days have elapsed since the prescription was issued if, on the date the prescription was issued, the prescriber issued only one prescription for the drug to the patient and both of the following apply:³³

--The prescriber provided written instructions on the prescription specifying the earliest date on which the prescription may be filled; and

--Not more than 14 days have elapsed since the earliest fill-date specified by the prescriber.

The bill permits the Pharmacy Board to adopt rules that further decrease the 14-day deadline relative to a single prescription. The same authority to decrease the deadline is extended to an existing provision under which the opioid analgesic may be dispensed or sold if a prescription is one of multiple prescriptions issued on the same day by a single prescriber with an earliest fill-date specified.³⁴

Refilling prescriptions for schedule III, IV, or V drugs

The bill permits a pharmacist or terminal distributor to dispense or sell the opioid analgesic by refilling the prescription after more than 14 days have elapsed since the prescription was issued if the opioid analgesic is included in schedule III, IV, or V.³⁵

Completing partially filled prescriptions

If the prescription for the opioid analgesic was partially filled within the applicable 14-day period, the bill permits a pharmacist or terminal distributor to dispense or sell the remaining amount of the opioid analgesic after more than 14 days have elapsed since the prescription was issued.³⁶

Drugs for treating opioid dependence or addiction

The bill also specifies that the 14-day prescription deadline, as well as an existing provision that prohibits the dispensing or selling of an opioid analgesic in an amount

³³ R.C. 4729.46(B)(3)(a).

³⁴ R.C. 4729.46(D).

³⁵ R.C. 4729.46(B)(3)(c).

³⁶ R.C. 4729.46(B)(3)(d).

that exceeds a 90-day supply, does not apply when the opioid analgesic is used as part of an individual's treatment for opioid dependence or addiction.³⁷

Office-based opioid treatment

Exceptions to licensure

With some exceptions, a facility where a physician or other prescriber provides office-based opioid treatment (OBOT) to more than 30 patients must hold a license issued by the Pharmacy Board. Specifically, it must hold a category III terminal distributor of dangerous drugs license with an office-based opioid treatment classification. "Office-based opioid treatment" is defined by current law as the treatment of opioid dependence or addiction using a controlled substance."³⁸

One of the current exceptions to the OBOT licensing requirement applies in the case of a program or facility that is licensed or certified by the Ohio Department of Mental Health and Addiction Services. Under the bill, a program or facility comes within this exception only if the license or certification issued by the Department is also approved by the Pharmacy Board.³⁹

The bill creates four new exceptions to the OBOT licensing requirement. The new exceptions apply to federally qualified health centers, federally qualified health center look-alikes, state or local correctional facilities, and any other facilities specified in rules adopted by the Pharmacy Board.⁴⁰

A federally qualified health center is a health center that receives a federal Public Health Service grant or another health center designated by the U.S. Health Resource and Services Administration as a federally qualified health center. A federally qualified health center look-alike is a public or nonprofit health center that meets federal grant requirements but does not receive grant funding.⁴¹

³⁷ R.C. 4729.46(C)(2).

³⁸ R.C. 4729.553(B)(2)(f).

³⁹ R.C. 4729.553(B)(2)(g), (h), and (i).

⁴⁰ R.C. 4729.553.

⁴¹ R.C. 3701.047, not in the bill.



Criminal records checks

A facility that holds an OBOT license must require all employees of the facility to submit to criminal records checks. It must ensure that no person is employed who has been convicted of or pleaded guilty to a felony theft offense or felony drug offense.⁴²

Under the bill, a felony theft offense or felony drug offense disqualifies a person from employment by the facility only if the person was convicted of or pleaded guilty to the offense within the ten years immediately preceding the date the person applied for employment. Currently, the disqualification applies regardless of when the offense was committed. Even under the bill's ten-year look-back period, however, the bill grants the Board authority to waive an individual's disqualification from employment. This means that the Board could permit a facility to employ a person who was convicted of or pleaded guilty to a felony theft offense or felony drug offense within the ten-year period.⁴³

Licensure of manufacturers, wholesalers, and other distributors of dangerous drugs

Criminal records checks

As a condition of licensure as a manufacturer, outsourcing facility, third-party logistics provider, repackager, or wholesale distributor of dangerous drugs, the bill requires the following to submit to criminal records checks:

- (1) The applicant;
- (2) Any person seeking to serve as the responsible person on the license;
- (3) Any person who has an ownership interest;
- (4) Any person who is a corporate officer.⁴⁴

The bill requires the Pharmacy Board to adopt rules defining "responsible person" and specifying the persons with ownership interests and the corporate officers required to submit to the criminal records checks.⁴⁵

⁴² R.C. 4729.553(D).

⁴³ R.C. 4729.553(D)(5).

⁴⁴ R.C. 4729.53(A)(7).

⁴⁵ R.C. 4729.53(C).

Public records exclusion

The bill excludes from the public records law various types of information concerning both Pharmacy Board employees and medical directors or members of cooperating physician advisory boards of emergency medical service organizations. The excluded information includes the following:

- The address of the individual's personal residence;
- The individual's Social Security number, residential telephone number, emergency telephone number, bank account number, and debit card or credit card number;
- The individual's medical information;
- The name of any beneficiary of employment benefits provided to the individual;
- The identity and amount of any charitable or employment benefit deduction made by the individual;
- The following concerning the individual's spouse, former spouse, or child: name, residential address, employer name and address, Social Security number, residential telephone number, emergency telephone number, bank account number, and credit or debit card number.

The same type of information is currently excluded from the public records law for peace officers, parole officers, probation officers, bailiffs, prosecuting attorneys, assistant prosecuting attorneys, correctional employees, community-based correctional facility employees, youth services employees, firefighters, emergency medical technicians, Bureau of Criminal Identification and Investigation investigators, and federal law enforcement officers, as well as their spouses, former spouses, and children.⁴⁶

Lawful prescriptions

For purposes of the controlled substances law and other drug laws administered by the Pharmacy Board, the bill specifies that an individual's existing authority to

⁴⁶ R.C. 149.43(A)(1)(p) and (A)(7)(a), (c), (d), (e), and (f) and 149.45.



possess a controlled substance through a prescription applies only if the prescription meets the following conditions:⁴⁷

- (1) It is issued for a legitimate medical purpose;
- (2) It is not altered or forged;
- (3) It was not obtained through deception or commission of a theft offense.

Similar provisions specifying when a person is authorized to possess drugs through a prescription are included as part of the criminal drug laws. The bill modifies those laws by listing the conditions that a prescription must meet, as described above. In doing so, the bill eliminates the definition of "legitimate prescription" that contained the same criteria.⁴⁸

Statutory updates and other conforming changes

In addition to the changes described above, the bill makes a number of other changes in existing statutes related to drugs and the Pharmacy Board. These changes involve the removal of obsolete provisions, the coordination of various provisions, and the addition of other conforming or corrective provisions.⁴⁹

HISTORY

ACTION	DATE
Introduced	11-08-17
Reported, S. Health, Human Services & Medicaid	05-23-18

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⁴⁷ R.C. 3719.09; R.C. 4729.51(E)(2)(a)(ii), not in the bill.

⁴⁸ R.C. 2925.01 and 2925.11.

⁴⁹ See, for example, R.C. 1751.68, 2925.01(W), 2925.03(J), 2925.09(B), 2925.11(H), 2925.23(B), 2925.34, 3719.01, 3719.04(A)(1), 3719.061, 3719.07(B)(3), 3719.09(A), 3719.12, 3719.61, 3719.811, 3796.01, 3923.602, 4729.19, 4729.46 (relative to pharmacy interns dispensing drugs), 4729.55, and 5164.7511.

