



OHIO LEGISLATIVE SERVICE COMMISSION

Bill Analysis

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Sens. Eklund, Lehner

BILL SUMMARY

- Eliminates the statutory lists of drugs that are 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 schedules of controlled substances 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.
- Modifies the general prohibition against dispensing or selling an opioid analgesic sold if the drug is to be used on an outpatient basis and more than 14 days have elapsed since the prescription was issued.
- Prohibits pharmacy interns from dispensing drugs subject to exceptions for naloxone and when the Governor declares an emergency.
- Exempts the following from the Pharmacy Board's licensure of office-based opioid treatment facilities: federally qualified health centers, state or local correctional facilities, other facilities specified in rules adopted by the Board.
- Specifies that the exemption from office-based opioid treatment 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 that each person seeking employment with a licensed office-based opioid treatment facility submit to a criminal records check.

- Narrows the disqualification from employment at a licensed office-based opioid treatment facility 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 with a licensed office-based opioid treatment facility even if the person was convicted or pleaded guilty within the ten-year period described above.
- Excludes from the Public Records Law various residential, familial, and other personal information about Pharmacy Board employees.
- 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 schedules of controlled substances, 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 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 day that is one year after the bill's effective date. But this is to occur only if the inclusion does not have the effect of providing less stringent control of the

¹ R.C. 3719.41, repealed.

² R.C. 3719.43 and 3719.44.

³ R.C. 3719.41, new enactment.

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.



compound, mixture, preparation, or substance than is provided under the federal drug abuse control laws or associated regulations.⁵

Transition period for initial rule adoption

The bill requires the Pharmacy Board to adopt the rules establishing Ohio's controlled substance schedules not later than one year after the bill's effective date. The rules must be adopted in accordance with the Administrative Procedure Act (R.C. Chapter 119.).⁶

Until the Pharmacy Board's rules take effect, the bill specifies that Ohio's statutory controlled substance schedules, as they existed immediately before the bill's effective date, continue to apply. Also, the conforming changes the bill makes in other statutes, as necessitated by the bill's transfer of the controlled substance schedules from statute to rule, do not apply until the rules take effect.⁷

Periodic updates and automatic changes

The bill requires the Pharmacy Board to periodically update Ohio's schedules by rule to correspond to any change in the federal drug abuse control laws or associated regulations, any addition, transfer, or removal by Congress or the U.S. Attorney General, or any addition, transfer, or removal by the Board through existing rule-making authority.⁸ The only exception to this requirement 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).⁹

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 required update of the schedules.¹⁰

⁵ R.C. 3719.41(A).

⁶ R.C. 3719.41(A).

⁷ R.C. 3719.41(C).

⁸ R.C. 3719.41(B) and 3719.44(L).

⁹ R.C. 3719.43.

¹⁰ R.C. 3719.43.

Emergency rules

The bill requires the Pharmacy Board, by emergency rule adopted in accordance with the Administrative Procedure Act,¹¹ 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.¹² The Board may make this determination by telephone conference call.¹³

In determining whether a previously unscheduled compound, mixture, preparation, or substance poses an imminent hazard to the public health, safety, or welfare, the Pharmacy Board must consider all of the following with respect to the compound, mixture, preparation, or substance:¹⁴

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

If the Pharmacy Board determines that a compound, mixture, preparation, or substance poses an imminent hazard to the public health, safety, or welfare, the Board must issue a resolution requesting that the Governor issue an order that authorizes 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 that the compound, mixture, preparation, or substance poses the imminent hazard.¹⁵

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.¹⁶ "Dangerous drugs" consist primarily of drugs available only by prescription.¹⁷

¹¹ R.C. 119.03(G).

¹² R.C. 3719.45(A)(1).

¹³ R.C. 3719.45(B)(2).

¹⁴ R.C. 3719.45(A)(2).

¹⁵ R.C. 3719.45(B)(1).

¹⁶ R.C. 3719.45(D).

¹⁷ R.C. 4729.01(F), not modified by the bill.



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.¹⁸

Federal Controlled Substances Act

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 the CSA's passage into one of five schedules based on the substance's medical use, potential for abuse, and safety or dependence liability (see below). The Act 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.¹⁹

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.

¹⁸ R.C. 2907.02(B), 2907.05(C)(1), 3313.752, 3345.41(A)(1), 3707.50(A)(1), 3719.01(R) and (BB), 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).

¹⁹ U.S. Drug Enforcement Administration, *Controlled Substances Act*, available at <http://bit.ly/2zM6Uj9>.



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.
- Over-the-counter cough medicines with codeine are classified in schedule V.

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. These circumstances when the opioid analgesic can be dispensed or sold under these exemptions are described below.

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:²⁰

--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 aforementioned date.

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.²¹

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.²²

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

²⁰ R.C. 4729.46(B)(3)(a).

²¹ R.C. 4729.46(D).

²² R.C. 4729.46(B)(3)(c).



dispense or sell the remaining amount of the opioid analgesic after more than 14 days have elapsed since the prescription was issued.²³

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 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.²⁴

Pharmacy interns

The bill generally prohibits pharmacy interns from dispensing dangerous drugs.²⁵ However, it maintains current authority for pharmacy interns to dispense naloxone pursuant to a protocol or to dispense dangerous drugs when the Governor declares an emergency.²⁶

The bill defines "dispense" by reference to rules adopted by the Pharmacy Board. A current rule of the Board defines "dispense" as the "final association of a drug with a particular patient pursuant to the prescription, drug order, or other lawful order of a prescriber and the professional judgment of and the responsibility for interpreting, preparing, compounding, labeling, and packaging a specific drug."²⁷

Office-based opioid treatment

Exceptions to licensure

With some exceptions, a facility where a physician or other prescriber provides office-based opioid treatment to more than 30 patients must hold a license issued by the Pharmacy Board. The license is a category III terminal distributor of dangerous drugs license with an office-based opioid treatment classification. "Office-based opioid treatment" is defined in current law as the treatment of opioid dependence or addiction using a controlled substance."²⁸

²³ R.C. 4729.46(B)(3)(d).

²⁴ R.C. 4729.46(C)(2).

²⁵ R.C. 4729.01(F), 4729.28, 4729.43, and 4729.46.

²⁶ R.C. 3701.048 and 4729.44, not in the bill.

²⁷ Ohio Administrative Code 4729-5-01.

²⁸ R.C. 4729.553(B)(2)(f).



One of the current exceptions to the requirement that a facility hold the license applies if the program or facility 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.²⁹

The bill creates three new exceptions to the license requirement. The new exceptions apply to federally qualified health centers, state or local correctional facilities, and any other facilities specified in rules adopted by the Pharmacy Board.³⁰ 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.³¹

Criminal records checks

A facility that holds a license for office-based opioid treatment 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. The bill requires, instead, that each person employed by or seeking employment with the facility submit to the criminal records check.³²

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 with respect to 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.³³

Public records exclusion

The bill excludes from the public records law various types of information concerning a Pharmacy Board employee, including the following:

²⁹ R.C. 4729.553(B)(2)(g), (h), and (i).

³⁰ R.C. 4729.553.

³¹ R.C. 3701.047, not in the bill.

³² R.C. 4729.553(D)(4).

³³ R.C. 4729.553(D)(5).



--The address of the employee's personal residence;

--The employee's Social Security number, residential telephone number, emergency telephone number, bank account number, and debit card or credit card number;

--The employee's medical information;

--The name of any beneficiary of employment benefits provided to the employee;

--The identity and amount of any charitable or employment benefit deduction made by the employee;

--The following concerning the employee's spouse, former spouse, or child: that individual's 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 concerning 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, is currently excluded from the public records law.³⁴

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 possess a controlled substance through a prescription applies only if the prescription meets the following conditions:³⁵

- (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.

³⁴ R.C. 149.43(A)(1)(p) and (A)(7)(a), (c), (d), (e), and (f) and 149.45.

³⁵ R.C. 3719.09; R.C. 4729.51(E)(2)(a)(ii), not in the bill.



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.³⁶

HISTORY

ACTION	DATE
Introduced	11-08-17

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³⁶ R.C. 2925.01 and 2925.11.

