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SUMMARY

Addiction treatment

- Authorizes a pharmacist to administer by injection any long-acting or extended-release addiction treatment drug prescribed by a physician.
- Exempts from State Board of Pharmacy office-based opioid treatment licensure those facilities in which addiction treatment drugs are administered only on-site and directly by prescribers.
- Provides that a patient whose addiction treatment drugs are administered on-site directly by a prescriber is not to be counted when determining whether a facility offering office-based opioid treatment is required to be licensed by the Pharmacy Board.

OARRS

- Authorizes the Pharmacy Board to provide information from its Ohio Automated Rx Reporting System (OARRS) to a prescriber or pharmacist participating in a prescription monitoring program operated by a federal agency if certain conditions are met.

Open meetings exemption

- Expands and clarifies the Pharmacy Board's exemption from the open meetings requirement as related to certain actions the Board may take without a prior hearing.

Naloxone access

- Exempts from licensure as a terminal distributor of dangerous drugs a service entity that possess naloxone in order to permit an employee, volunteer, or contractor to personally furnish a supply of naloxone pursuant to a protocol established by a prescriber or board of health.

- Authorizes a terminal distributor to acquire a supply of naloxone, and to maintain the supply at an alternative location, to use in emergency situations and to distribute through an automated mechanism.
- Authorizes any person to access naloxone maintained by a terminal distributor and to administer it to an individual who appears to be experiencing an opioid-related overdose.
- Authorizes certain advanced practice registered nurses and physician assistants to develop protocols to permit individuals and employees of service entities to personally furnish or administer naloxone.
- Requires the Pharmacy Board to develop a program to educate certain license holders and others about the authority of pharmacists and pharmacy interns to dispense naloxone without a prescription.
- Specifies that a family member, friend, or other individual who assists an individual who is experiencing an opioid-related overdose is not liable for damages in a civil action related to providing that assistance.

Occasional sales at wholesale

- Extends to licensed terminal distributors of dangerous drugs that are not pharmacies the authority to sell occasionally at wholesale investigational drugs or products or certain prescription drugs, but only if authorized by rules adopted by the Pharmacy Board.

Hemp and hashish

- Alters the definition of "hashish" to clarify that it can be derived from not only marijuana, but also any part of a cannabis plant (which includes hemp), and that it must have a delta-9 tetrahydrocannabinol concentration of more than 0.3%.
- Specifies that "hashish" does not include a hemp byproduct that a licensed hemp processor produces, stores, or disposes of in accordance with the Hemp Law.

DETAILED ANALYSIS

Addiction treatment

Pharmacists administer addiction treatment drugs by injection

Law largely maintained by the act permits a pharmacist meeting specified conditions to administer by injection certain drugs. The act extends a pharmacist's administration authority

to include any injectable long-acting or extended-release addiction treatment drug, not just opioid antagonists as under prior law.[1]

Under law maintained by the act, a pharmacist may administer to an individual a drug by injection if it is prescribed by a physician and the physician has an ongoing physician-patient relationship with the individual. Other continuing requirements include that the pharmacist follow a protocol established by a physician, complete certain education in the administration of drugs, obtain the individual's permission before administering a drug, observe the individual for any adverse reactions, and notify the prescribing physician of the administration. With respect to an addiction treatment drug administered by injection, the pharmacist also may order blood or urine testing to determine whether it is appropriate to administer the drug.[2]

Office-based opioid treatment

"Office-based opioid treatment" is the treatment of opioid dependence or addiction using a controlled substance. Subject to several exemptions, a facility, clinic, or other location where a prescriber provides office-based opioid treatment to more than 30 patients must hold a category III terminal distributor of dangerous drugs license with an office-based opioid treatment classification.[3]

The act exempts from this licensure requirement a facility in which both:

1. Patients are treated on-site for opioid dependence or addiction exclusively through direct administration of addiction treatment drugs by physicians, physician assistants, or advanced practice registered nurses; and
2. Addiction treatment drugs are neither dispensed nor personally furnished to patients for self-administration off-site.[4]

The act also specifies that patients who receive treatment on-site for opioid dependence or addiction by this direct administration of drugs are not to be included when determining whether a prescriber is providing office-based opioid treatment to more than 30 patients at a particular location.[5]

Other locations exempt from office-based opioid treatment licensure under law continued by the act include (1) hospitals and hospital-operated facilities and practices, (2) clinical research facilities, (3) federally regulated opioid treatment programs, and

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[1] R.C. 4729.45(B)(1)(a). For information regarding types of addiction treatment medications, see National Institute on Drug Abuse, *Opioid Agonists and Partial Agonists (Maintenance Medications)*, https://www.drugabuse.gov/publications/research-reports/medications-to-treat-opioid-addiction/how-do-medications-to-treat-opioid-addiction-work.

[2] R.C. 4729.45(D) to (F).

[3] R.C. 4729.553(A)(4) and (B)(1).

[4] R.C. 4729.553(B)(2)(i).

[5] R.C. 4729.553(B)(3).

(4) programs and facilities licensed or certified by the Department of Mental Health and Addiction Services.[6]

OARRS access and federal monitoring programs

Law unchanged by the act authorizes the Pharmacy Board to establish a drug database to monitor the misuse and diversion of medical marijuana, controlled substances, naltrexone, and other prescription drugs.[7] The database, known as OARRS, provides information about drug use to prescribers, pharmacists, and others.

In addition to the OARRS information the Pharmacy Board is authorized or required to provide, the act authorizes the Board to provide information requested by a prescriber or pharmacist from, or participating in, a prescription drug monitoring program operated by a federal agency. The Board may provide this information only if both:

- The Board has approved the federal agency's prescription drug monitoring program; and
- There is a written agreement between the Board and agency under which the information is to be used and disseminated according to Ohio law.[8]

Note that H.B. 166, the FY 2020-FY 2021 biennial budget act, included this authority, but the Governor vetoed it.

Open meetings exemption

The act expands the Pharmacy Board's exemption from open meetings requirements. Prior to the act, open meetings requirements did not apply to the Board when it used a telephone conference call to determine whether to suspend a license, certificate, or registration without a prior hearing because a person's professional practice or use of controlled substances or other dangerous drugs presents a danger of immediate and serious harm to others.[9] The act makes two changes. First, it specifies that the exemption applies when the Board is determining whether to suspend a license, certification, or registration without a prior hearing, regardless of whether the determination is through a telephone conference or another method, under any of the laws governing controlled substances, the practice of pharmacy, medical marijuana, or home medical services. Second, it applies the exemption when the Board exercises its authority to determine without a prior hearing whether to restrict a person from obtaining further information from OARRS.

[6] R.C. 4729.553(B)(2).

[7] R.C. 4729.75.

[8] R.C. 4729.80.

[9] R.C. 121.22(D)(8); see also R.C. 4729.16 and 3719.121, not in the act.

Naloxone access

Service entities

The act modifies Ohio law related to a service entity's procurement of naloxone. A "service entity" is a public or private entity that may provide services to individuals at risk of experiencing an opioid-related overdose, including churches, schools, prisons, homeless shelters, and similar entities. The act specifies that a service entity also may "interact with" individuals at risk of overdosing (it does not have to "provide services" as stated under prior law). It further specifies that libraries are service entities.

Under continuing law, service entities are exempt from licensure as a terminal distributor of dangerous drugs when naloxone is possessed for use in an emergency. The act adds that a service entity may maintain a supply of naloxone and permit its employees, volunteers, and contractors to personally furnish a supply of naloxone pursuant to a protocol (see "**APRN and PA naloxone protocol**" below). It also exempts service entities from licensure as a terminal distributor when personally furnishing supplies of naloxone.

The act extends preexisting qualified immunities for service entities to personally furnishing naloxone.[10]

Terminal distributor maintenance of supply

The act authorizes a terminal distributor to acquire and maintain, including at a location other than the location licensed as a terminal distributor, a supply of naloxone for use in emergency situations and for distribution through an automated mechanism. Individuals may access emergency naloxone supplies, or receive naloxone through an automated system, and administer it to an individual at risk of experiencing an opioid-related overdose. An individual who does so must make a good faith effort to activate emergency medical services as soon as possible unless the individual who administers the naloxone is part of an emergency medical services system or is at a hospital.[11]

Naloxone for use in emergency situations

A terminal distributor that maintains naloxone for use in emergency situations is required by the act to do the following:[12]

1. Provide instructions regarding emergency administration to any individual who accesses the naloxone, including an instruction to summon emergency services;
2. Specify a process to be used to notify the terminal distributor that the naloxone has been accessed within a reasonable time of it being accessed; and

[10] R.C. 4729.514.

[11] R.C. 4729.515(A) and (D).

[12] R.C. 4729.515(B).

3. Maintain the naloxone in accordance with manufacturer or distributor instructions.

Naloxone for distribution through automated mechanism

The act requires that in the case of naloxone for distribution through an automated mechanism, a terminal distributor must comply with standards and procedures specified in rules that the act requires the Pharmacy Board to adopt. The rules must be adopted in accordance with the Administrative Procedure Act.[13]

Qualified immunity

The act specifies that an individual is not liable for or subject to damages in a civil action, criminal prosecution, or professional disciplinary action related to injury, death, or loss to person or property allegedly arising from any action associated with accessing emergency naloxone supplies, receiving naloxone through an automated system, or administering it to an individual at risk of experiencing an opioid-related overdose.[14]

APRN and PA naloxone protocol

The act permits clinical nurse specialists, certified nurse-midwives, certified nurse practitioners (collectively "APRNs") and physician assistants to develop protocols to permit individuals and employees, volunteers, and contractors of service entities to personally furnish or administer naloxone to individuals at risk of experiencing opioid-related overdoses, and to family and friends of such individuals. It imposes on this authority the same conditions as continuing law imposes on physicians: the protocol must be in writing and include various provisions such as the naloxone dosage and training requirements.

APRNs, physician assistants, and individuals authorized to personally furnish naloxone pursuant to a protocol have qualified immunity from civil liability, criminal prosecution, and professional disciplinary action related to the provisions described above.[15]

Civil liability protection for layperson naloxone administration

The act specifies that a family member, friend, or other individual who, as authorized by law unchanged by the act, assists an individual who is experiencing an opioid-related overdose is not liable for damages in a civil action related to providing that assistance. Prior to the act, Ohio law specified that such individuals are not subject to criminal prosecution, but immunity from civil liability was not expressly provided. As conditions to immunity, both for the continuing criminal prosecution immunity and the act's civil liability immunity, the individual must act in good faith and obtain the naloxone through a channel authorized by Ohio law,

[13] R.C. 4729.515(C) and (F).

[14] R.C. 4729.515(E).

[15] R.C. 4723.485, 4723.486, 4730.435, and 4730.436; technical renumbering of other sections and related conforming changes.

administer it to an individual who is apparently experiencing an opioid-related overdose, and attempt to summon emergency services as soon as practicable.[16]

Naloxone education program

Law unchanged by the act allows a physician or local board of health to authorize one or more pharmacists and pharmacy interns to dispense naloxone without a prescription in accordance with a protocol established by the Pharmacy Board.[17] The act requires the Pharmacy Board to develop a program to educate the following individuals who engage in the sale or dispensing of naloxone without a prescription about the authority of pharmacists and pharmacy interns to dispense naloxone without a prescription:

- Holders of licenses issued by the Board, including pharmacies, pharmacists, and pharmacy interns;
- Registered pharmacy technicians, certified pharmacy technicians, and pharmacy technician trainees registered by the Board; and
- Other individuals who are employed by license holders.[18]

As part of the program, the Pharmacy Board also must educate these license holders, pharmacy technicians, and employees about (1) maintaining an adequate supply of naloxone and (2) methods for determining a pharmacy's naloxone stock. The act authorizes the Board to use its website to share information under the program.

Occasional sales at wholesale

Generally, a licensed terminal distributor of dangerous drugs **that is not a pharmacy** may make occasional sales at wholesale, but only for certain drugs. These include naloxone and prescription drugs that are in shortage. The act extends to these licensed terminal distributors the authority to sell occasionally at wholesale investigational drugs or products or prescription drugs other than naloxone or drugs in shortage – but only if authorized by rules adopted by the Pharmacy Board.[19]

Hemp and hashish

The act re-classifies all resins that have a delta-9 tetrahydrocannabinol (THC) concentration above 0.3% and are derived from the plant cannabis – which includes marijuana and hemp – as hashish. As a result, the possession or trafficking in hashish derived from hemp, not merely from marijuana, can be prosecuted. This change addresses an effect of the 2019 legislation that legalized hemp (see "**Background**," below).

[16] R.C. 2925.61(B).

[17] R.C. 3707.56, not in the act, 4729.44(B), and 4731.942, not in the act.

[18] R.C. 4729.44(H).

[19] R.C. 4729.51(A)(3).

Specifically, the act alters the definition of "hashish" in the criminal law. Instead of being defined as a resin or a preparation of resin that is derived from **marijuana**, it defines "hashish" as a resin or a preparation of resin that (1) is derived from **any part of a cannabis plant** and (2) has a THC concentration exceeding 0.3%.

It also specifies that "hashish" does not include a hemp byproduct that is:

1. In the possession of a licensed hemp processor (under R.C. Chapter 928); and
2. Being produced, stored, and disposed of in accordance with rules adopted under the Hemp Law.[20]

Under continuing law, a hemp byproduct may exceed 0.3% THC only if (1) and (2) are satisfied.[21]

Background

Prior to the 2019 enactment of the Hemp Law in S.B. 57 of the 133rd General Assembly, there was no legal distinction between "hemp" and marijuana. Thus, the possession of or trafficking in hashish derived from either marijuana or what is currently defined as "hemp" could be prosecuted.

S.B. 57 excluded "hemp" or a "hemp product" from the definition of "marijuana" and allowed its cultivation and processing. (Hemp and hemp products contain 0.3% THC or less.)[22] However, S.B. 57 did not alter the definition of hashish, which was generally defined as the resin derived from marijuana. As such, after S.B. 57 was enacted, even though it was possible for a resin to be derived from hemp that had a THC greater than 0.3%, it was not legally considered "hashish" because it was derived from hemp (not marijuana).

HISTORY

Action	Date
Introduced	09-23-19
Reported, H. Health	01-15-20
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Reported, S. Health, Human Services & Medicaid	06-09-20
Passed Senate (31-0)	06-24-20
House concurred in Senate amendments (92-2)	09-01-20

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[20] R.C. 2925.01(Z).

[21] R.C. 928.03(R), not in the act.

[22] R.C. 3719.01(M), not in the act.