OHIO LEGISLATIVE SERVICE COMMISSION

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H.B. 341
133rd General Assembly

Bill Analysis

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Version: As Passed by the House

Primary Sponsor: Rep. Ginter

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SUMMARY

- Authorizes a pharmacist to administer by injection any long-acting or extended-release addiction treatment drug prescribed by a physician, instead of limiting the pharmacist's authority to the administration of opioid antagonists as under current law.
- Exempts from State Board of Pharmacy office-based opioid treatment licensure requirements those facilities in which addiction treatment drugs are administered only on-site and directly by prescribers, rather than off-site by patients.
- 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 Board.
- Authorizes the 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.

DETAILED ANALYSIS

Pharmacist authority to administer addiction treatment drugs by injection

Current law permits a pharmacist meeting specified conditions to administer by injection certain drugs, including long-acting or extended-release opioid antagonists used to treat drug addiction. The bill extends to the pharmacist authority to administer any injectable long-acting or extended-release addiction treatment drug, not just opioid antagonists as under existing law.[1]

[1] R.C. 4729.45(B)(1)(a).

Types of drugs prescribed to treat opioid addiction

According to the National Institute on Drug Abuse, there are effective medications to treat opioid use disorders.[2] These include opioid antagonists and agonists. An opioid antagonist is a drug, like naltrexone, that blocks the activation of opioid receptors in the brain. It treats opioid use disorder by preventing any opioid drug from producing rewarding effects such as euphoria.

Opioid agonists occupy and activate the brain's opioid receptors, eliminating withdrawal symptoms and relieving drug cravings. There are two types of agonists – full and partial. Methadone is an example of a full agonist, a slow-acting opioid that binds fully to the opioid receptor, while buprenorphine is a partial agonist, meaning it binds to the same receptors but activates them less strongly than full agonists do.[3]

At present, the only addiction treatment drugs available for administration by injection are Vivitrol, a long-acting form of naltrexone (an opioid antagonist)[4] and Sublocade, an injectable form of buprenorphine (a partial agonist) which was approved by the United States Food and Drug Administration in 2017.[5]

Conditions on pharmacist administration by injection generally

Under existing law maintained by the bill, 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.

The bill retains other current law requirements governing injections by a pharmacist, including 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.[6] 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.[7]

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[2] *See* https://www.drugabuse.gov/publications/research-reports/medications-to-treat-opioid-addiction/overview.

[3] *See* https://www.drugabuse.gov/publications/research-reports/medications-to-treat-opioid-addiction/how-do-medications-to-treat-opioid-addiction-work.

[4] *See* https://www.vivitrol.com/opioid-dependence/what-is-vivitrol.

[5] *FDA approves first once-monthly buprenorphine injection, a medication-assisted treatment option for opioid use disorder*, United States Food and Drug Administration, November 30, 2017, available at https://www.fda.gov/NewsEvents/Newsroom/PressAnnouncements/ucm587312.htm.

[6] R.C. 4729.45(C), (D), and (F).

[7] R.C. 4729.45(D) and (E).

Office-based opioid treatment

Current law defines "office-based opioid treatment" as the treatment of opioid dependence or addiction using a controlled substance.[8] 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 issued by the State Board of Pharmacy.[9]

The bill exempts from this licensure requirement a facility in which both of the following apply:

1. Patients are treated on-site for opioid dependence or addiction exclusively through direct administration of addiction treatment drugs by the following prescribers – 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.[10]

The bill 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.[11]

Locations currently exempt from office-based opioid treatment licensure include (1) hospitals and hospital-operated facilities and practices, (2) clinical research facilities, (3) federally regulated opioid treatment programs, and (4) programs and facilities licensed or certified by the Department of Mental Health and Addiction Services.[12] The bill maintains these exemptions.

OARRS access and federal monitoring programs

Existing law authorizes the Board of Pharmacy to establish a drug database to monitor the misuse and diversion of medical marijuana, controlled substances, naltrexone, and other prescription drugs.[13] The Board's database, known as OARRS, provides information about drug use to prescribers, pharmacists, and others.

In addition to the OARRS information the Board is authorized or required under current law to provide, the bill authorizes the Board to provide information requested by a prescriber

[8] R.C. 4729.553(A)(4).

[9] R.C. 4729.553(B)(1).

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

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

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

[13] R.C. 4729.75.

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 of the following apply:

- The Board has approved the federal agency's prescription drug monitoring program;
- There is a written agreement between the Board and agency under which the information is to be used and disseminated according to Ohio law.[14]

Note that H.B. 166, the biennial budget bill enacted by the 133rd General Assembly, included this authority, but the Governor vetoed those provisions.[15]

HISTORY

Action	Date
Introduced	09-23-19
Reported, H. Health	01-15-20
Passed House (96-0)	02-12-20

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[14] R.C. 4729.80.

[15] *See* https://www.legislature.ohio.gov/download?key=12387&format=pdf.