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Bill Analysis

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Audra Tidball, Attorney

SUMMARY

Naltrexone access and administration

- Authorizes various licensed health care professionals and police officers to administer by injection, in accordance with a physician-established protocol, long-acting or extended-release forms of naltrexone, which is an opioid antagonist used to treat substance use disorders.
- As part of that authorization, modifies a pharmacist's existing authority to administer by injection opioid antagonists for drug treatment.
- Requires prescribers who prescribe opioid analgesics to offer administration of injectable long-acting or extended-release forms of naltrexone and permits delegation of the administration in accordance with existing law.

Methadone and buprenorphine

- Requires prescribers who prescribe methadone and noninjectable forms of buprenorphine to taper the patient off the drug within 60 days if possible; if not possible, limits the provision of those drugs to daily oral doses thereafter.
- Requires prescribers who have obtained a federal waiver to treat opioid addiction to have completed training regarding injectable long-acting or extended-release forms of naltrexone and buprenorphine.

Procuring naltrexone and buprenorphine

- Requires the Department of Mental Health and Addiction Services to procure long-acting or extended-release forms of naltrexone and buprenorphine directly from drug manufacturers and coordinate with state and local agencies to distribute those drugs to drug-addicted individuals.

- Requires the Department to contract with a licensed terminal distributor of dangerous drugs to serve as a central pharmacy for obtaining statewide contract pricing and from which political subdivisions can directly purchase long-acting or extended-release forms of naltrexone and buprenorphine.

Loss of tax-exempt status for hospitals

- Provides that if a hospital fails to treat drug addiction with at least eight inpatient beds and an outpatient program, various exemptions and exclusions from taxation that otherwise apply to hospitals under existing law cease to apply.

DETAILED ANALYSIS

Naltrexone access and administration

Naltrexone is a drug approved by the U.S. Food and Drug Administration to treat opioid use disorders. It does so by blocking opioid receptors. Unlike methadone and buprenorphine, which are discussed below, naltrexone is considered to lack abuse and diversion potential.¹

Naltrexone administration in accordance with a protocol

The bill authorizes certain individuals to administer by injection long-acting or extended-release naltrexone to treat drug addiction. The administration must be in accordance with a protocol that (1) is established by a physician whose regular practice includes drug addiction treatment and (2) satisfies requirements established by the State Medical Board in rules.²

Authorized individuals

The following individuals are authorized, but not required,³ by the bill to administer naltrexone in accordance with a protocol:

1. Licensed pharmacists;
2. Licensed psychologists;
3. Individuals licensed by the Chemical Dependency Professionals Board;
4. Individuals licensed by the Counselor, Social Worker, and Marriage and Family Therapist Board;
5. Individuals licensed by the State Board of Emergency Medical, Fire, and Transportation Services;
6. Police officers;

¹ Substance Abuse and Mental Health Services Administration, *Naltrexone*, <https://www.samhsa.gov/medication-assisted-treatment/treatment/naltrexone>.

² R.C. 4731.92(B), (F), and (I).

³ R.C. 4731.92(H).

7. Other licensed health care professionals identified in the protocol.⁴

In order for an authorized individual to administer the naltrexone in accordance with a protocol, the individual must successfully complete an online course in the administration of drugs that satisfies requirements established by the Medical Board in rules. The individual must also receive and maintain certification to perform basic life-support procedures.⁵

Duties related to administration

Obtaining test results

The bill generally requires an authorized individual administering naltrexone in accordance with a protocol to obtain test results indicating that it is appropriate to administer the drug.⁶ The test results may be obtained from a physician, the drug database (see below), a hospital (see below), or the person on whom the test was performed.⁷

If the authorized individual is unable to obtain the test results and the recipient of the naltrexone declares that the recipient cannot get the test, the authorized individual may administer the drug to the recipient for not more than 60 days.⁸

Regarding obtaining test results from a hospital, the bill requires each hospital to perform, on demand and regardless of ability to pay or health insurance coverage, a laboratory test of liver function, the results of which may be used by an authorized individual.⁹

Drug database reporting

The bill requires the authorized individuals identified above,¹⁰ as well as any prescriber who administers injectable long-acting or extended-release forms of naltrexone,¹¹ to submit the following information to the Pharmacy Board's drug database, the Ohio Automated Rx Reporting System (OARRS):¹²

1. The name of the individual submitting the information and that individual's licensing board;
2. The name of the individual receiving the drug by injection;
3. The date the drug was administered;

⁴ R.C. 4731.92(B).

⁵ R.C. 4731.92(C).

⁶ R.C. 4731.92(D)(1).

⁷ R.C. 4731.92(E)(1).

⁸ R.C. 4731.92(E)(2).

⁹ R.C. 3727.61.

¹⁰ R.C. 4729.791(A)(1)(b).

¹¹ R.C. 4729.791(A)(1)(a).

¹² R.C. 4731.92(D)(2); *see also* R.C. 4729.75.

4. The name, strength, and national drug code;
5. Other information specified by the Pharmacy Board in rules.¹³

Additionally regarding OARRS, the bill requires (1) the Pharmacy Board to provide authorized individuals with OARRS information pertaining to a patient's treatment for drug addiction¹⁴ and (2) licensed health professionals who receive test results indicating whether or not it is appropriate to administer injectable long-acting or extended-release naltrexone to report those results to the Pharmacy Board for inclusion in OARRS.¹⁵

Qualified immunity

The bill provides authorized individuals immunity from damages in a civil action, prosecution in a criminal proceeding, and professional disciplinary action for administering naltrexone in accordance with a protocol. The immunity applies unless the authorized individual's act or omission constitutes willful or wanton misconduct.¹⁶

Related changes to current law

Pharmacist administration of opioid antagonists by injection

The bill removes the authorization in current law for pharmacists to administer opioid antagonists, which include naltrexone. Under current law, a pharmacist may administer an opioid antagonist for drug addiction treatment in a long-acting or extended-release form as long as it has been prescribed by a physician who has an ongoing physician-patient relationship with the individual to whom the drug is administered.¹⁷ Instead, the bill includes pharmacists as individuals authorized to administer naltrexone under its protocol provisions.¹⁸

Nonroutine naltrexone administration

Current law provides qualified immunity for the administration of naltrexone when an individual is unable to have the drug administered by a person who, and at a facility where, the drug is routinely administered. Specifically, absent gross negligence or intentional misconduct, a person administering naltrexone by injection, the person's employer, and a facility where naltrexone is administered are not liable in a civil action or subject to criminal prosecution or professional disciplinary action related to injury or damage caused by a naltrexone injection if certain conditions are met, including that the person administering it is legally authorized to administer it even though not the prescriber or routine administrator of the drug.¹⁹ The

¹³ R.C. 4729.791(A).

¹⁴ R.C. 4729.80(A)(23).

¹⁵ R.C. 4729.791(B).

¹⁶ R.C. 4731.92(G).

¹⁷ R.C. 4729.45(B)(1)(a).

¹⁸ R.C. 4731.92, conforming changes in R.C. 1751.91, 3923.89, 4729.283, and 5164.14.

¹⁹ R.C. 3719.063.

requirements for administering naltrexone in those specific circumstances do not apply to individuals who administer naltrexone in accordance with the bill's protocol provisions.²⁰

Providing naltrexone access where opioid analgesics are prescribed

The bill requires that prescribers who prescribe opioid analgesics must offer administration of long-acting or extended release forms of naltrexone during business hours at the location where the prescriber practices. The administration of naltrexone may be delegated in accordance with existing rules governing delegation by health care professionals. The bill provides immunity from damages in a civil action related to delegation that is in accordance with existing laws and rules.²¹

Current law requires prescribers to provide patients beginning medication-assisted treatment with information about all drugs approved for use in medication-assisted treatment.²²

Methadone and buprenorphine

Methadone and buprenorphine are drugs that are often used to treat opioid use disorders.²³ The bill requires a prescriber who prescribes methadone or noninjectable forms of buprenorphine to taper the patient off the drug within 60 days. If such tapering is not possible, only daily doses of those drugs may be personally furnished by the prescriber thereafter.²⁴

The bill also requires that any prescriber who has obtained a waiver to treat opioid addiction under federal law²⁵ must have completed training regarding injectable long-acting or extended-release forms of naltrexone and buprenorphine. The Pharmacy Board is required to review training programs and approve those that it determines meet the training requirement.²⁶

²⁰ R.C. 3719.063(E).

²¹ R.C. 3719.064.

²² R.C. 3719.067, renumbered in the bill from R.C. 3719.064; conforming changes in R.C. 4723.52, 4730.56, 4731.83, and 5119.363.

²³ Substance Abuse and Mental Health Services Administration, *Medication and Counseling Treatment*, <https://www.samhsa.gov/medication-assisted-treatment/treatment#medications-used-in-mat>.

²⁴ R.C. 3719.065(A).

²⁵ Under the Drug Addiction Treatment Act of 2000 (DATA 2000), physicians are required to complete an eight-hour training to qualify for a waiver to prescribe and dispense buprenorphine. Substance Abuse and Mental Health Services Administration, *Buprenorphine Training for Physicians*, <https://www.samhsa.gov/medication-assisted-treatment/training-materials-resources/buprenorphine-physician-training>.

²⁶ R.C. 3719.065(B).

Procuring naltrexone and buprenorphine

The bill requires the Department of Mental Health and Addiction Services to procure injectable long-acting or extended-release forms of naltrexone and buprenorphine directly from drug manufacturers. The Department also must coordinate with state, county, and municipal agencies to distribute those drugs as needed to treat drug-addicted individuals in Ohio, including distributing to individuals authorized to administer naltrexone under the bill's protocol provisions, as discussed above. The Department must require monitoring and monthly administration of the drugs by boards of health, boards of alcohol, drug addiction, and mental health services, courts, and parole and probation officers.²⁷

The bill also requires the Department to contract with a licensed pharmacy to serve as a central pharmacy (1) that would be responsible for obtaining statewide contract pricing and (2) from which political subdivisions could make direct purchases of injectable long-acting or extended-release naltrexone and buprenorphine.²⁸

The bill authorizes the Department to use rebates to further discount the price of drugs procured as required by the bill.²⁹

Loss of tax-exempt status for hospitals

The bill specifies that if a hospital fails to treat drug addiction with at least eight inpatient beds and an outpatient program, certain exemptions and exclusions from taxation that otherwise apply to the hospital under continuing law will cease,³⁰ including those related to:

1. Public hospitals and their income;³¹
2. Government and public property;³²
3. Property used for public or charitable purposes;³³
4. Excise taxes on retail sales;³⁴ and
5. Nonprofit organizations and state agencies, instrumentalities, and political subdivisions.³⁵

²⁷ R.C. 5119.441(A).

²⁸ R.C. 5119.441(B).

²⁹ R.C. 5119.441(C).

³⁰ R.C. 3727.27.

³¹ R.C. 140.08, not in the bill.

³² R.C. 5709.08, not in the bill.

³³ R.C. 5709.12 and 5709.121, not in the bill.

³⁴ R.C. 5739.02(B)(1) and (12), not in the bill.

³⁵ R.C. 5751.01(E)(8), not in the bill.

Instead, the hospital's real property will be subject to property taxation, purchases of tangible personal property or services by the hospital will be subject to sales and use taxes, and the hospital will become a taxpayer for purposes of existing law governing the commercial activity tax.

The bill does not affect existing exemptions from taxation for the following obligations to pay costs of hospital facilities, or exemptions related to refunding or transferring those obligations, interest and other income from them, or profit made from their sale:

1. County revenue securities;³⁶
2. Revenue obligations issued by a public hospital agency;³⁷
3. Revenue obligations issued by a hospital commission of any county or a board of county hospital trustees;³⁸
4. Obligations authorized by the Municipal Home Rule Amendment to the Ohio Constitution.³⁹

The Director of Health is required to determine if a hospital meets the bill's drug treatment requirements, and the Director may adopt rules as the Director considers necessary.⁴⁰

HISTORY

Action	Date
Introduced	06-10-20

H0700-I-133/ar

³⁶ R.C. 133.08, not in the bill.

³⁷ R.C. 140.06, not in the bill.

³⁸ R.C. 339.15, not in the bill.

³⁹ Ohio Constitution, Article XVIII, Section 3.

⁴⁰ R.C. 3727.27.