OHIO LEGISLATIVE SERVICE COMMISSION

Bill Analysis

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S.B. 119

132nd General Assembly
(As Introduced)

Sens. Hackett and Hottinger

BILL SUMMARY

Opioid analgesics

- Prohibits a primary care physician or general dentist from prescribing or furnishing an opioid analgesic in an amount indicated for a period greater than three days or with a morphine equivalent daily dose (MED) in excess of 50 milligrams.

- Permits a primary care physician or general dentist to exceed the three-day limit and prescribe or furnish an opioid analgesic for a period of not more than seven days if the physician or dentist satisfies specified conditions, including completing training in opioid addiction.

- Authorizes the State Medical and Dental Boards to establish limits on the amount or MED of an opioid analgesic that may be prescribed or furnished by a physician or dentist practicing in a specialty other than primary care or general dentistry.

Chronic pain

- Revises the law governing physician treatment of chronic pain with controlled substances, including requiring a physician to satisfy certain conditions, prohibiting treatment with a drug that exceeds 50 MED, and requiring review of federal guidelines when tapering a patient off a drug.

Medication-assisted treatment

- Requires a physician who provides medication-assisted treatment for addiction in accordance with federal law to offer each patient treatment with naltrexone.

- Requires the Department of Mental Health and Addiction Services to develop online courses that provide counseling and other services required by federal law for patients receiving office-based medication-assisted treatment.

OARRS

- Requires dispensing or furnishing naltrexone to be reported to the Ohio Automated Rx Reporting System (OARRS) and makes other changes to the law governing OARRS.

CONTENT AND OPERATION

Limits on prescribing or furnishing opioid analgesics

Physicians and dentists

The bill establishes limits on prescribing or furnishing opioid analgesics by physicians who practice primarily in primary care specialties and dentists who practice primarily general dentistry.[1] The State Medical and Dental Boards are required to determine for purposes of the bill what constitutes a primary care specialty or the practice of general dentistry.[2]

The bill defines "opioid analgesic" as a controlled substance that has analgesic pharmacologic activity at the opioid receptors of the central nervous system, including the following drugs and their varying salt forms or chemical congeners: buprenorphine, codeine (including acetaminophen and other combination products), fentanyl, hydrocodone (including acetaminophen combination products), hydromorphone, methadone, morphine sulfate, oxycodone (including acetaminophen, aspirin, and other combination products), and oxymorphone.[3]

Three-day and 50 MED limit

The bill prohibits a primary care physician or general dentist from prescribing or personally furnishing an opioid analgesic if either of the following is the case:

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[1] R.C. 4715.303 and 4731.059.

[2] R.C. 4715.303(B) and 4731.059(B).

[3] R.C. 3719.01, not in the bill, 4715.302, 4715.303, 4731.055, and 4731.059. Buprenorphine and methadone, which are included in the bill's definition of "opioid analgesic," are often used for long-term treatment of addiction. An amendment could be prepared to exempt from the bill's new provisions drugs, such as buprenorphine and methadone, prescribed or furnished to treat addiction.

(1) The drug is prescribed or furnished in an amount indicated for a period that exceeds three days;

(2) The morphine equivalent daily dose (MED) for the drug exceeds 50 milligrams.[4] (MED is a numerical standard against which the potency of most opioids can be compared.)[5]

Seven-day limit

A primary care physician or general dentist may exceed the three-day – but not the 50 MED limit – if the opioid analgesic is prescribed or furnished in an amount indicated for a period of not more than seven days and the following conditions are met:

(1) The physician or dentist completes at least eight hours of training approved by the State Medical Board or State Dental Board relating to opioids and addiction;

(2) The physician or dentist, physician's or dentist's employer, or medical or dental practice utilizes an electronic medical records system that provides direct access to reports of patient information from the Ohio Automated Rx Reporting System (OARRS);

(3) The physician or dentist completes on an annual basis at least two hours of continuing education approved by the Medical or Dental Board relating to opioid prescribing;

(4) In the case of a dentist, the dentist is able to refer patients to treatment for opioid dependence or addiction, which may include medication-assisted treatment and behavioral health services;

(5) In the case of a physician, the physician is able to provide treatment for opioid dependence or addiction, which may include medication-assisted treatment and behavioral health services. (The physician may refer a patient to another individual for behavioral health services.)[6]

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[4] R.C. 4715.303(C) and 4731.059(C).

[5] *See* Brandeis University, Prescription Drug Monitoring Program Training and Technical Assistance Center, *Daily Morphine Milligrams Equivalent Calculator and Guide*, available at <http://www.pdmpassist.org/content/guidelines>.

[6] R.C. 4715.303(D) and 4731.059(D).

Exceptions to the limits – physicians only

The limits established by the bill do not apply when, as part of a physician's regular practice, the physician prescribes or furnishes opioid analgesics in any of the following circumstances:

(1) For the treatment of cancer or another condition associated with cancer;

(2) To a hospice patient in a hospice care program or to any other patient diagnosed as terminally ill;

(3) To an inpatient for administration in a hospital;

(4) To a nursing home or residential care facility resident for administration in the home or facility;

(5) To treat chronic pain in accordance with existing law.[7] (Existing law requires the State Medical Board to establish standards and procedures to be followed by physicians when treating chronic pain.)[8]

Specialists

The bill authorizes the Medical Board to establish limits on the amount or MED of an opioid analgesic that may be prescribed or furnished by a physician whose practice is primarily in a specialty other than primary care. Similarly, the bill permits the Dental Board to establish such limits for a dentist whose practice is primarily in a specialty other than general dentistry.[9]

Chronic pain

The bill adds new conditions that must be met by physicians treating chronic pain with controlled substances. Under existing law, after diagnosing a patient as having pain that has persisted for longer than three months after reasonable medical efforts to relieve it or cure its cause have failed, a physician may manage the pain with controlled substances and products containing tramadol.[10] The physician must (1) address with the patient the risks associated with protracted treatment with controlled substances, including informing the patient of the potential for dependence

[7] R.C. 4731.059(E).

[8] R.C. 4731.052.

[9] R.C. 4715.303(E) and 4731.059(F).

[10] R.C. 4731.052(A) and (C).

or addiction, (2) propose a written plan of treatment, (3) maintain records relating to the patient, and (4) periodically assess the patient's progress toward treatment objectives.[11]

The additional conditions for treating chronic pain established by the bill are as follows:

(1) The physician must complete at least eight hours of training approved by the Medical Board relating to addiction;

(2) The physician must utilize an electronic medical records system that provides direct access to reports of patient information from OARRS;

(3) The physician must annually complete at least two hours of continuing education approved by the Medical Board relating to prescribing controlled substances.[12]

MED limit

The bill prohibits a physician from prescribing, furnishing, or administering a controlled substance or product containing tramadol for treatment of chronic pain if the drug's MED exceeds 50 milligrams.[13]

Tapering treatment

For a patient diagnosed as having chronic pain who a physician determines will no longer benefit from treatment with a controlled substance or product containing tramadol, the bill requires the physician to do both of the following:

(1) Review the guidelines regarding opioid tapering or discontinuation established by the federal Centers for Disease Control and Prevention;[14]

(2) Modify the patient's plan of treatment to cause the patient's dosage to be tapered until the drug is no longer prescribed, furnished, or administered.[15]

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[11] R.C. 4731.052(D).

[12] R.C. 4731.052(D).

[13] R.C. 4731.052(D).

[14] *See* Centers for Disease Control and Prevention, *CDC Guideline for Prescribing Opioids for Chronic Pain*, available at <https://www.cdc.gov/drugoverdose/prescribing/guideline.html>.

[15] R.C. 4731.052(D).

Medication-assisted treatment

Medication-assisted treatment is the use of medication, often in combination with counseling and behavioral therapies, to treat substance use disorders and prevent overdose. It is used primarily to treat addiction to opioids such as heroin or prescription pain relievers. According to the Substance Abuse and Mental Health Services Administration (SAMHSA) of the U.S. Department of Health and Human Services, the medication prescribed as part of this treatment operates to normalize brain chemistry, block the euphoric effects of opioids, relieve physiological cravings, and regulate bodily functions without the negative effects of the abused drug.[16]

Methadone, buprenorphine, and naltrexone are drugs approved by the federal Food and Drug Administration (FDA) to treat opioid dependence and addiction. In general, methadone is dispensed from SAMHSA-certified opioid treatment programs, while buprenorphine is prescribed or furnished by a physician practicing in such a program or holding a SAMHSA-issued waiver authorizing office-based treatment. Naltrexone may be prescribed outside of an opioid treatment program and without the prescriber obtaining a SAMHSA waiver.

Treatment with naltrexone

The bill provides that, to the extent permitted by federal law, each patient accepted for treatment by an opioid treatment program or a physician holding a SAMHSA-issued waiver must be offered treatment with naltrexone. Naltrexone, also known as Vivitrol, is reported to reduce opioid cravings and may prevent the feeling of getting high if a person relapses and uses the problem drug.[17]

Under the bill, when offering treatment with naltrexone, a physician must do all of the following:

(1) Discuss with the patient the benefits and risks of treatment with naltrexone as opposed to the benefits and risks of treatment with a medication such as buprenorphine;

(2) Obtain a consent form signed by the patient indicating the type of treatment to be provided;

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[16] Substance Abuse and Mental Health Services Administration, *Medication-Assisted Treatment*, *Medication and Counseling Treatment*, available at <https://www.samhsa.gov/medication-assisted-treatment/treatment>.

[17] *See* Substance Abuse and Mental Health Services Administration, *Medication-Assisted Treatment, Medication and Counseling Treatment, Naltrexone*, available at <https://www.samhsa.gov/medication-assisted-treatment/treatment/naltrexone>.

(3) Sign the consent form after it is signed by the patient;

(4) Place in the patient's medical record a copy of the consent form signed by the patient and physician.[18]

Counseling and other ancillary services

Federal law requires a physician seeking to prescribe or dispense buprenorphine as part of office-based treatment to certify to SAMHSA that the physician has the capacity to refer medication-assisted treatment patients for appropriate counseling and other ancillary services.[19] The bill requires the Ohio Department of Mental Health and Addiction Services to develop and make available one or more online courses to provide such services. In developing the online courses, the Department may consult with one or more individuals or entities specializing in providing services, including counseling, educational, or vocational services, to persons treated for opioid dependence or addiction.[20]

OARRS

The bill makes three changes to the law governing OARRS, the State Board of Pharmacy's database for monitoring the misuse and diversion of controlled substances,[21] including adding naltrexone to the drugs monitored by the Board.

Naltrexone

The bill requires a pharmacist or prescriber after dispensing or personally furnishing naltrexone to report this information to OARRS.[22]

Morphine equivalent daily dose (MED)

Existing law requires certain information concerning a drug to be provided to OARRS after the drug is dispensed or furnished, including its name, strength, and quantity. The bill requires the report to also include, if applicable, the drug's MED.[23]

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[18] R.C. 4731.058.

[19] 21 Code of Federal Regulations (C.F.R.) 1301.28(b)(1)(ii).

[20] R.C. 5119.373.

[21] R.C. 4729.75.

[22] R.C. 4729.77 and 4729.79.

[23] R.C. 4729.77 and 4729.79.

Review of patient information – seven-day exception

Before initially prescribing or personally furnishing an opioid analgesic, current law requires that a physician or dentist to review patient information from OARRS that covers at least the previous 12 months.[24] An exception from the required review applies if the drug is prescribed or furnished in an amount indicated for a period not exceeding seven days. The bill eliminates this exception.[25]

HISTORY

ACTION	DATE
Introduced	03-28-17

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[24] R.C. 4715.302 and 4731.055.

[25] R.C. 4715.302(C) and 4731.055(C).