As Introduced

132nd General Assembly
Regular Session **H. B. No. 167**
2017-2018

Representative Edwards
Cosponsor: Representative Householder

A BILL

To amend sections 4715.302, 4729.75, 4729.77, 4729.79, 4731.052, and 4731.055 and to enact sections 4715.303, 4731.058, 4731.059, and 5119.373 of the Revised Code regarding addiction treatment and opioid prescribing by physicians and dentists.

BE IT ENACTED BY THE GENERAL ASSEMBLY OF THE STATE OF OHIO:

Section 1. That sections 4715.302, 4729.75, 4729.77, 4729.79, 4731.052, and 4731.055 be amended and sections 4715.303, 4731.058, 4731.059, and 5119.373 of the Revised Code be enacted to read as follows:

Sec. 4715.302. (A) As used in this section:

(1) "Drug database" means the database established and maintained by the state board of pharmacy pursuant to section 4729.75 of the Revised Code.

(2) "Opioid analgesic" and "benzodiazepine" have the same meanings as in section 3719.01 of the Revised Code.

(B) Except as provided in divisions (C) and (E) of this

section, a dentist shall comply with all of the following as conditions of prescribing a drug that is either an opioid analgesic or a benzodiazepine, or personally furnishing a complete or partial supply of such a drug, as part of a patient's course of treatment for a particular condition:

(1) Before initially prescribing or furnishing the drug, the dentist or the dentist's delegate shall request from the drug database a report of information related to the patient that covers at least the twelve months immediately preceding the date of the request. If the dentist practices primarily in a county of this state that adjoins another state, the dentist or delegate also shall request a report of any information available in the drug database that pertains to prescriptions issued or drugs furnished to the patient in the state adjoining that county.

(2) If the patient's course of treatment for the condition continues for more than ninety days after the initial report is requested, the dentist or delegate shall make periodic requests for reports of information from the drug database until the course of treatment has ended. The requests shall be made at intervals not exceeding ninety days, determined according to the date the initial request was made. The request shall be made in the same manner provided in division (B)(1) of this section for requesting the initial report of information from the drug database.

(3) On receipt of a report under division (B)(1) or (2) of this section, the dentist shall assess the information in the report. The dentist shall document in the patient's record that the report was received and the information was assessed.

(C)~~(1)~~ Division (B) of this section does not apply if a

drug database report regarding the patient is not available. In this event, the dentist shall document in the patient's record the reason that the report is not available.

~~(2) Division (B) of this section does not apply if the drug is prescribed or personally furnished in an amount indicated for a period not to exceed seven days.~~

(D) The state dental board may adopt rules that establish standards and procedures to be followed by a dentist regarding the review of patient information available through the drug database under division (A)(5) of section 4729.80 of the Revised Code. The rules shall be adopted in accordance with Chapter 119. of the Revised Code.

(E) This section and any rules adopted under it do not apply if the state board of pharmacy no longer maintains the drug database.

Sec. 4715.303. (A) As used in this section, "opioid analgesic" has the same meaning as in section 3719.01 of the Revised Code.

(B) The state dental board shall determine, for the purposes of this section, what constitutes the practice of general dentistry.

(C) A dentist whose practice is primarily general dentistry shall not prescribe or personally furnish an opioid analgesic if either of the following is the case:

(1) The morphine equivalent daily dose for the drug exceeds fifty milligrams.

(2) Except as provided in division (D) of this section, the drug is prescribed or furnished in an amount indicated for a

period that exceeds three days.

(D) A dentist whose practice is primarily general dentistry may prescribe or personally furnish an opioid analgesic in an amount indicated for a period that exceeds three days but is not more than seven days if all of the following conditions are met:

(1) The dentist has completed at least eight hours of training approved by the state dental board relating to opioids and addiction.

(2) The dentist or dentist's employer or dental practice utilizes an electronic medical records system that provides direct access to reports of patient information from the drug database established and maintained by the state board of pharmacy pursuant to section 4729.75 of the Revised Code.

(3) The dentist annually completes at least two hours of continuing education approved by the state dental board relating to prescribing opioids.

(4) The dentist is able to refer patients to treatment for opioid dependence or addiction, which may include medication-assisted treatment and behavioral health services.

(E) The state dental board may establish limits on the amount or morphine equivalent daily dose of an opioid analgesic that may be prescribed or personally furnished by a dentist whose practice is primarily in a specialty other than general dentistry.

Sec. 4729.75. The state board of pharmacy may establish and maintain a drug database. The board shall use the drug database to monitor the misuse and diversion of the following: controlled substances, as defined in section 3719.01 of the

Revised Code; medical marijuana, as authorized under Chapter 3796. of the Revised Code; naltrexone; and other dangerous drugs the board includes in the database pursuant to rules adopted under section 4729.84 of the Revised Code. In establishing and maintaining the database, the board shall electronically collect information pursuant to sections 4729.77, 4729.771, and 4729.79 of the Revised Code and shall disseminate information as authorized or required by sections 4729.80 and 4729.81 of the Revised Code. The board's collection and dissemination of information shall be conducted in accordance with rules adopted under section 4729.84 of the Revised Code.

Sec. 4729.77. (A) If the state board of pharmacy establishes and maintains a drug database pursuant to section 4729.75 of the Revised Code, each pharmacy licensed as a terminal distributor of dangerous drugs that dispenses drugs to patients in this state and is included in the types of pharmacies specified in rules adopted under section 4729.84 of the Revised Code shall submit to the board the following prescription information:

(1) Terminal distributor identification;

(2) Patient identification;

(3) Prescriber identification;

(4) Date prescription was issued by prescriber;

(5) Date drug was dispensed;

(6) Indication of whether the drug dispensed is new or a refill;

(7) Name, strength, and national drug code of the drug dispensed;

(8) Quantity of drug dispensed;

(9) Number of days' supply of drug dispensed;

(10) Serial or prescription number assigned by the terminal distributor;

(11) Source of payment for the drug dispensed;

(12) If applicable, the morphine equivalent daily dose of the drug dispensed.

(B)(1) The information shall be transmitted as specified by the board in rules adopted under section 4729.84 of the Revised Code.

(2) The information shall be submitted electronically in the format specified by the board, except that the board may grant a waiver allowing the distributor to submit the information in another format.

(3) The information shall be submitted in accordance with any time limits specified by the board, except that the board may grant an extension if either of the following occurs:

(a) The distributor suffers a mechanical or electronic failure, or cannot meet the deadline for other reasons beyond the distributor's control.

(b) The board is unable to receive electronic submissions.

(C) This section does not apply to a prescriber personally furnishing or administering dangerous drugs to the prescriber's patient.

Sec. 4729.79. (A) If the state board of pharmacy establishes and maintains a drug database pursuant to section 4729.75 of the Revised Code, each licensed health professional

authorized to prescribe drugs, except as provided in division (C) of this section, who personally furnishes to a patient a controlled substance, naltrexone, or other dangerous drug the board includes in the database pursuant to rules adopted under section 4729.84 of the Revised Code shall submit to the board the following information:

(1) Prescriber identification;

(2) Patient identification;

(3) Date drug was furnished by the prescriber;

(4) Indication of whether the drug furnished is new or a refill;

(5) Name, strength, and national drug code of drug furnished;

(6) Quantity of drug furnished;

(7) Number of days' supply of drug furnished;

(8) Source of payment for the drug furnished;

(9) Identification of the owner of the drug furnished;

(10) If applicable, the morphine equivalent daily dose of the drug furnished.

(B)(1) The information shall be transmitted as specified by the board in rules adopted under section 4729.84 of the Revised Code.

(2) The information shall be submitted electronically in the format specified by the board, except that the board may grant a waiver allowing the prescriber to submit the information in another format.

(3) The information shall be submitted in accordance with any time limits specified by the board, except that the board may grant an extension if either of the following occurs:

(a) The prescriber's transmission system suffers a mechanical or electronic failure, or the prescriber cannot meet the deadline for other reasons beyond the prescriber's control.

(b) The board is unable to receive electronic submissions.

(C)(1) The information required to be submitted under division (A) of this section may be submitted on behalf of the prescriber by the owner of the drug being personally furnished or by a delegate approved by that owner.

(2) The requirements of this section to submit information to the board do not apply to a prescriber who is a veterinarian.

(D) If the board becomes aware of a prescriber's failure to comply with this section, the board shall notify the government entity responsible for licensing the prescriber.

Sec. 4731.052. (A) As used in this section:

(1) "Chronic pain" means pain that has persisted after reasonable medical efforts have been made to relieve the pain or cure its cause and that has continued, either continuously or episodically, for longer than three continuous months. "Chronic pain" does not include pain associated with a terminal condition or with a progressive disease that, in the normal course of progression, may reasonably be expected to result in a terminal condition.

(2) "Controlled substance" has the same meaning as in section 3719.01 of the Revised Code.

(3) "Physician" means an individual authorized under this

chapter to practice medicine and surgery or osteopathic medicine and surgery.

(B) The state medical board shall adopt rules in accordance with Chapter 119. of the Revised Code that establish standards and procedures to be followed by physicians in the diagnosis and treatment of chronic pain, including standards for a physician's consultation with one or more other physicians who specialize in the treatment of the area, system, or organ of the body perceived as the source of pain and managing chronic pain by prescribing, personally furnishing, or administering controlled substances or products containing tramadol.

(C) When a physician diagnoses a patient as having chronic pain, the physician may, subject to division (D) of this section, treat the pain by managing it with controlled substances and products containing tramadol. The physician's diagnosis and treatment decisions shall be made according to accepted and prevailing standards for medical care. For the purpose of assisting with the diagnosis of chronic pain, the physician shall obtain and review all available medical records or detailed written summaries of the patient's treatment for chronic pain or the condition causing the chronic pain. It is recommended that the physician also consider having the patient evaluated by one or more other physicians who specialize in the treatment of the area, system, or organ of the body perceived as the source of the pain.

(D)(1) To be authorized to treat chronic pain with a controlled substance or product containing tramadol, a physician must do all of the following:

(a) Complete at least eight hours of training approved by the state medical board relating to addiction;

(b) Utilize an electronic medical records system that provides direct access to reports of patient information from the drug database established and maintained by the state board of pharmacy pursuant to section 4729.75 of the Revised Code;

(c) Annually complete at least two hours of continuing education approved by the state medical board relating to prescribing controlled substances.

(2) A physician shall not prescribe, furnish, or administer a controlled substance or product containing tramadol for treatment of chronic pain if its morphine equivalent daily dose exceeds fifty milligrams.

(3) For each patient a physician diagnoses as having chronic pain, the physician shall maintain a written record of all of the following:

~~(1)~~ (a) Medical history and physical examination of the patient;

~~(2)~~ (b) The diagnosis of chronic pain, including signs, symptoms, and causes;

~~(3)~~ (c) The plan of treatment proposed, the patient's response to treatment, and any modification to the plan of treatment, including all of the following:

~~(a)~~ (i) Documentation that other medically reasonable treatments for relief of the patient's chronic pain have been offered or attempted without adequate or reasonable success;

~~(b)~~ (ii) Periodic assessment and documentation of the patient's functional status, including the ability to engage in work or other purposeful activities, the pain intensity and its interference with activities of daily living, quality of family

life and social activities, and physical activity of the patient;

~~(c)~~ (iii) Periodic assessment and documentation of the patient's progress toward treatment objectives, including the intended role of controlled substances or products containing tramadol within the overall plan of treatment;

~~(d)~~ (iv) Periodic assessment and documentation for indicators of possible addiction, drug abuse, or drug diversion;

~~(e)~~ (v) Notation of any adverse drug effects.

~~(4)~~ (d) The dates on which controlled substances or products containing tramadol were prescribed, furnished, or administered, the name and address of the patient to or for whom the controlled substances or products containing tramadol were prescribed, furnished, or administered, and the amounts~~ and~~, dosage forms, and if applicable, morphine equivalent daily dose for the controlled substances or products containing tramadol prescribed, furnished, or administered;

~~(5)~~ (e) A copy of any record or report made by another physician that was used or consulted for the purpose of diagnosing the patient's chronic pain or treating the patient for chronic pain.

(4) For each 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 physician shall do both of the following:

(a) Review the guidelines regarding opioid tapering or discontinuation established by the federal centers for disease control and prevention and presented in the document "CDC Guideline for Prescribing Opioids for Chronic Pain - United

States, 2016" or a successor document, unless the guidelines are no longer in effect at the time of the physician's determination;

(b) Modify the plan of treatment to cause the patient's dosage to be tapered until the controlled substance or product is no longer prescribed, furnished, or administered.

(E) A physician shall not prescribe, personally furnish, or administer to a patient a controlled substance or product containing tramadol without taking into account the potential for abuse of the controlled substance or product, the possibility the controlled substance or product may lead to dependence, the possibility the patient will obtain the controlled substance or product for a nontherapeutic use or distribute it to other persons, and the potential existence of an illicit market for the controlled substance or product. In addition, the physician shall address with the patient the risks associated with protracted treatment with controlled substances or products containing tramadol, including informing the patient of the potential for dependence, tolerance, and addiction and the clinical or monitoring tools the physician may use if signs of addiction, drug abuse, or drug diversion are present.

(F) A physician who treats chronic pain by managing it with controlled substances or products containing tramadol is not subject to disciplinary action by the board under section 4731.22 of the Revised Code solely because the physician treated the chronic pain with controlled substances or products containing tramadol.

Sec. 4731.055. (A) As used in this section:

(1) "Drug database" means the database established and

maintained by the state board of pharmacy pursuant to section 4729.75 of the Revised Code.

(2) "Physician" means an individual authorized under this chapter to practice medicine and surgery, osteopathic medicine and surgery, or podiatric medicine and surgery.

(3) "Opioid analgesic" and "benzodiazepine" have the same meanings as in section 3719.01 of the Revised Code.

(B) Except as provided in divisions (C) and (E) of this section, a physician shall comply with all of the following as conditions of prescribing a drug that is either an opioid analgesic or a benzodiazepine, or personally furnishing a complete or partial supply of such a drug, as part of a patient's course of treatment for a particular condition:

(1) Before initially prescribing or furnishing the drug, the physician or the physician's delegate shall request from the drug database a report of information related to the patient that covers at least the twelve months immediately preceding the date of the request. If the physician practices primarily in a county of this state that adjoins another state, the physician or delegate also shall request a report of any information available in the drug database that pertains to prescriptions issued or drugs furnished to the patient in the state adjoining that county.

(2) If the patient's course of treatment for the condition continues for more than ninety days after the initial report is requested, the physician or delegate shall make periodic requests for reports of information from the drug database until the course of treatment has ended. The requests shall be made at intervals not exceeding ninety days, determined according to the

date the initial request was made. The request shall be made in the same manner provided in division (B)(1) of this section for requesting the initial report of information from the drug database.

(3) On receipt of a report under division (B)(1) or (2) of this section, the physician shall assess the information in the report. The physician shall document in the patient's record that the report was received and the information was assessed.

(C) Division (B) of this section does not apply in any of the following circumstances:

(1) A drug database report regarding the patient is not available, in which case the physician shall document in the patient's record the reason that the report is not available.

(2) ~~The drug is prescribed or personally furnished in an amount indicated for a period not to exceed seven days.~~

~~(3)~~ The drug is prescribed or personally furnished for the treatment of cancer or another condition associated with cancer.

~~(4)~~ (3) The drug is prescribed or personally furnished to a hospice patient in a hospice care program, as those terms are defined in section 3712.01 of the Revised Code, or any other patient diagnosed as terminally ill.

~~(5)~~ (4) The drug is prescribed or personally furnished for administration in a hospital, nursing home, or residential care facility.

~~(6)~~ (5) The drug is prescribed or personally furnished to treat acute pain resulting from a surgical or other invasive procedure or a delivery.

(D) The state medical board may adopt rules that establish

standards and procedures to be followed by a physician regarding the review of patient information available through the drug database under division (A)(5) of section 4729.80 of the Revised Code. The rules shall be adopted in accordance with Chapter 119. of the Revised Code.

(E) This section and any rules adopted under it do not apply if the state board of pharmacy no longer maintains the drug database.

Sec. 4731.058. (A) As used in this section:

(1) "Opioid agonist treatment medication" and "opioid treatment program" have the same meanings as in 42 C.F.R. 8.2.

(2) "Physician" means an individual authorized under this chapter to practice medicine and surgery or osteopathic medicine and surgery.

(B) To the extent permitted by federal law, a patient accepted for treatment of opioid dependence or addiction by either of the following shall be offered treatment with naltrexone:

(1) An opioid treatment program that is the subject of a valid certification pursuant to 42 C.F.R. 8.11;

(2) A physician who practices in a location other than an opioid treatment program, but holds a waiver pursuant to 21 U.S.C. 823(g)(2) and is authorized to issue prescriptions for buprenorphine from the practice location.

(C) When offering treatment with naltrexone, a physician described in division (B)(2) of this section or practicing in an opioid treatment program shall 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 an opioid agonist treatment medication such as buprenorphine;

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

(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.

Sec. 4731.059. (A) As used in this section:

(1) "Opioid analgesic" has the same meaning as in section 3719.01 of the Revised Code.

(2) "Physician" means an individual authorized under this chapter to practice medicine and surgery or osteopathic medicine and surgery.

(B) The state medical board shall determine, for the purposes of this section, what constitutes a primary care specialty.

(C) Except as provided in division (E) of this section, a physician whose practice is primarily in a primary care specialty shall not prescribe or personally furnish an opioid analgesic if either of the following is the case:

(1) The morphine equivalent daily dose for the drug exceeds fifty milligrams.

(2) Except as provided in division (D) of this section, the drug is prescribed or furnished in an amount indicated for a period that exceeds three days.

(D) A physician whose practice is primarily in a primary care specialty may prescribe or personally furnish an opioid analgesic in an amount indicated for a period that exceeds three days but is not more than seven days if all of the following conditions are met:

(1) The physician has completed at least eight hours of training approved by the state medical board relating to opioids and addiction.

(2) The physician or physician's employer or medical practice utilizes an electronic medical records system that provides direct access to reports of patient information from the drug database established and maintained by the state board of pharmacy pursuant to section 4729.75 of the Revised Code.

(3) The physician completes on an annual basis at least two hours of continuing education approved by the state medical board relating to prescribing opioids.

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

(E) This section does not apply when, as part of the physician's regular practice, a physician prescribes or personally 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, as those terms are defined in section 3712.01 of the Revised Code,

or to any other patient diagnosed as terminally ill;

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

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

(5) To treat chronic pain in accordance with section 4731.052 of the Revised Code.

(F) The state medical board may establish limits on the amount or morphine equivalent daily dose of an opioid analgesic that may be prescribed or personally furnished by a physician whose practice is primarily in a specialty other than primary care.

Sec. 5119.373. (A) The department of mental health and addiction services shall develop and make available one or more online courses that provide the counseling and other ancillary services required by 21 C.F.R. 1301.28(b)(1)(ii) to the patients of a physician who meets all of the following criteria:

(1) Is authorized under Chapter 4731. of the Revised Code to practice medicine and surgery or osteopathic medicine and surgery;

(2) Holds a waiver issued pursuant to 21 U.S.C. 823(g)(2);

(3) Practices in a location other than an opioid treatment program and is authorized to issue prescriptions for buprenorphine from the practice location.

(B) In developing the online courses required by this section, 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.

Section 2. That existing sections 4715.302, 4729.75, 4729.77, 4729.79, 4731.052, and 4731.055 of the Revised Code are hereby repealed.

Section 3. This act shall be known as Daniel's Law.