A B I L L

To amend sections 4723.52, 4729.45, 4729.553, 4730.56, and 4731.83 of the Revised Code regarding the administration of drugs for addiction treatment.

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

Section 1. That sections 4723.52, 4729.45, 4729.553, 4730.56, and 4731.83 of the Revised Code be amended to read as follows:

Sec. 4723.52. (A) As used in this section:

(1) "Community addiction services provider" has the same meaning as in section 5119.01 of the Revised Code.

(2) "Medication-assisted treatment" has the same meaning as in section 340.01 of the Revised Code.

(B) An advanced practice registered nurse shall comply with section 3719.064 of the Revised Code and rules adopted under section 4723.51 of the Revised Code when treating a patient for addiction with medication-assisted treatment or proposing to initiate such treatment.
(C) An advanced practice registered nurse who fails to comply with this section shall treat not more than thirty patients at any one time with medication-assisted treatment even if the facility or location at which the treatment is provided is either of the following:

(1) Exempted by divisions (B)(2)(a) to (d) or (i) of section 4729.553 of the Revised Code from being required to possess a category III terminal distributor of dangerous drugs license with an office-based opioid treatment classification;

(2) A community addiction services provider that provides alcohol and drug addiction services that are certified by the department of mental health and addiction services under section 5119.36 of the Revised Code.

Sec. 4729.45. (A) As used in this section, "physician" means an individual authorized under Chapter 4731. of the Revised Code to practice medicine and surgery or osteopathic medicine and surgery.

(B)(1) Subject to division (C) of this section, a pharmacist licensed under this chapter may administer by injection any of the following drugs as long as the drug that is to be administered has been prescribed by a physician and the individual to whom the drug was prescribed has an ongoing physician-patient relationship with the physician:

(a) An opioid antagonist—A drug used for treatment of drug addiction and administered in a long-acting or extended-release form;

(b) An antipsychotic drug administered in a long-acting or extended-release form;

(c) Hydroxyprogesterone caproate;
(d) Medroxyprogesterone acetate;

(e) Cobalamin.

(2) As part of engaging in the administration of drugs by injection pursuant to this section, a pharmacist may administer epinephrine or diphenhydramine, or both, to an individual in an emergency situation resulting from an adverse reaction to a drug administered by the pharmacist.

(C) To be authorized to administer drugs pursuant to this section, a pharmacist must do all of the following:

(1) Successfully complete a course in the administration of drugs that satisfies the requirements established by the state board of pharmacy in rules adopted under division (H)(1)(a) of this section;

(2) Receive and maintain certification to perform basic life-support procedures by successfully completing a basic life-support training course that is certified by the American red cross or American heart association or approved by the state board of pharmacy;

(3) Practice in accordance with a protocol that meets the requirements of division (F) of this section.

(D) Each time a pharmacist administers a drug pursuant to this section, the pharmacist shall do all of the following:

(1) Obtain permission in accordance with the procedures specified in rules adopted under division (H) of this section and comply with the following requirements:

(a) Except as provided in division (D)(1)(c) of this section, for each drug administered by a pharmacist to an individual who is eighteen years of age or older, the pharmacist...
shall obtain permission from the individual.

(b) For each drug administered by a pharmacist to an individual who is under eighteen years of age, the pharmacist shall obtain permission from the individual's parent or other person having care or charge of the individual.

(c) For each drug administered by a pharmacist to an individual who lacks the capacity to make informed health care decisions, the pharmacist shall obtain permission from the person authorized to make such decisions on the individual's behalf.

(2) In the case of an opioid antagonist a drug described in division (B)(1)(a) of this section, obtain in accordance with division (E) of this section test results indicating that it is appropriate to administer the drug to the individual if either of the following is to be administered:

(a) The initial dose of the drug;

(b) Any subsequent dose, if the administration occurs more than thirty days after the previous dose of the drug was administered.

(3) Observe the individual to whom the drug is administered to determine whether the individual has an adverse reaction to the drug;

(4) Notify the physician who prescribed the drug that the drug has been administered to the individual.

(E) A pharmacist may obtain the test results described in division (D)(2) of this section in either of the following ways:

(1) From the physician;
(2) By ordering blood and urine tests for the individual to whom the opioid antagonist drug is to be administered.

If a pharmacist orders blood and urine tests, the pharmacist shall evaluate the results of the tests to determine whether they indicate that it is appropriate to administer the opioid antagonist drug. A pharmacist's authority to evaluate test results under this division does not authorize the pharmacist to make a diagnosis.

(F) All of the following apply with respect to the protocol required by division (C)(3) of this section:

(1) The protocol must be established by a physician who has a scope of practice that includes treatment of the condition for which the individual has been prescribed the drug to be administered.

(2) The protocol must satisfy the requirements established in rules adopted under division (H)(1)(b) of this section.

(3) The protocol must do all of the following:

(a) Specify a definitive set of treatment guidelines;

(b) Specify the locations at which a pharmacist may engage in the administration of drugs pursuant to this section;

(c) Include provisions for implementing the requirements of division (D) of this section, including for purposes of division (D)(3) of this section provisions specifying the length of time and location at which a pharmacist must observe an individual who receives a drug to determine whether the individual has an adverse reaction to the drug;

(d) Specify procedures to be followed by a pharmacist when administering epinephrine, diphenhydramine, or both, to an
individual who has an adverse reaction to a drug administered by the pharmacist.

(G) A pharmacist shall not do either of the following:

(1) Engage in the administration of drugs pursuant to this section unless the requirements of division (C) of this section have been met;

(2) Delegate to any person the pharmacist's authority to engage in the administration of drugs pursuant to this section.

(H)(1) The state board of pharmacy shall adopt rules to implement this section. The rules shall be adopted in accordance with Chapter 119. of the Revised Code and include all of the following:

(a) Requirements for courses in administration of drugs;

(b) Requirements for protocols to be followed by pharmacists in administering drugs pursuant to this section;

(c) Procedures to be followed by a pharmacist in obtaining permission to administer a drug to an individual.

(2) The board shall consult with the state medical board before adopting rules regarding requirements for protocols under this section.

Sec. 4729.553. (A) As used in this section:

(1) "Advanced practice registered nurse" has the same meaning as in section 4723.01 of the Revised Code.

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

(2) "Hospital" means a hospital registered with the department of health under section 3701.07 of the Revised Code.
(3) "Office-based opioid treatment" means the treatment of opioid dependence or addiction using a controlled substance.

(5) "Physician" means an individual who is authorized under Chapter 4731. of the Revised Code to practice medicine and surgery or osteopathic medicine and surgery.

(6) "Physician assistant" means an individual who is licensed under Chapter 4730. of the Revised Code.

(B)(1) Except as provided in division divisions (B)(2) and (3) of this section, no person shall knowingly operate a facility, clinic, or other location where a prescriber provides office-based opioid treatment to more than thirty patients or that meets any other identifying criteria established in rules adopted under this section without holding a category III terminal distributor of dangerous drugs license with an office-based opioid treatment classification.

(2) Division (B)(1) of this section does not apply to any of the following:

(a) A hospital;

(b) A facility for the treatment of opioid dependence or addiction that is operated by a hospital;

(c) A physician practice owned or controlled, in whole or in part, by a hospital or by an entity that owns or controls, in whole or in part, one or more hospitals;

(d) A facility that conducts only clinical research and uses controlled substances in studies approved by a hospital-based institutional review board or an institutional review board that is accredited by the association for the
accreditation of human research protection programs, inc.;

(e) A facility that holds a category III terminal
distributor of dangerous drugs license in accordance with
section 4729.54 of the Revised Code for the purpose of treating
drug dependence or addiction as part of an opioid treatment
program and is the subject of a current, valid certification
from the substance abuse and mental health services
administration of the United States department of health and
human services pursuant to 42 C.F.R. 8.11;

(f) A program or facility that holds a license or
certification issued by the department of mental health and
addiction services under Chapter 5119. of the Revised Code if
the license or certification is approved by the state board of
pharmacy;

(g) A federally qualified health center or federally
qualified health center look-alike, as defined in section
3701.047 of the Revised Code;

(h) A state or local correctional facility, as defined in
section 5163.45 of the Revised Code;

(i) A place in which patients are treated for opioid
dependence or addiction through direct administration by a
physician, physician assistant, or advanced practice registered
nurse of drugs that are used for treatment of opioid dependence
or addiction and are not dispensed to patients for self-
administration;

(j) Any other facility specified in rules adopted under
this section.

(3) A patient who receives treatment for opioid dependence
or addiction through direct administration of a drug by a
physician, physician assistant, or advanced practice registered

nurse shall not be included in determining whether more than

thirty patients are being provided office-based opioid treatment

in a particular facility, clinic, or other location that is

subject to division (B)(1) of this section.

(C) To be eligible to receive a license as a category III

terminal distributor of dangerous drugs with an office-based

opioid treatment classification, an applicant shall submit

evidence satisfactory to the state board of pharmacy that the

applicant's office-based opioid treatment will be operated in

accordance with the requirements specified in division (D) of

this section and that the applicant meets any other applicable

requirements of this chapter.

If the board determines that an applicant meets all of the

requirements, the board shall issue to the applicant a license

as a category III terminal distributor of dangerous drugs with

an office-based opioid treatment classification.

(D) The holder of a category III terminal distributor

license with an office-based opioid treatment classification

shall do all of the following:

(1) Be in control of a facility that is owned and operated

solely by one or more physicians authorized under Chapter 4731.

of the Revised Code to practice medicine and surgery or

osteopathic medicine and surgery, unless the state board of

pharmacy waives this requirement for the holder;

(2) Comply with the requirements for conducting office-

based opioid treatment, as established by the state medical

board in rules adopted under section 4731.056 of the Revised

Code;
(3) Require any person with ownership of the facility to submit to a criminal records check in accordance with section 4776.02 of the Revised Code and send the results of the criminal records check directly to the state board of pharmacy for review and decision under section 4729.071 of the Revised Code;

(4) Require each person employed by or seeking employment with the facility to submit to a criminal records check in accordance with section 4776.02 of the Revised Code;

(5) Ensure that a person is not employed by the facility if the person, within the ten years immediately preceding the date the person applied for employment, was convicted of or pleaded guilty to either of the following, unless the state board of pharmacy permits the person to be employed by waiving this requirement for the facility:
   (a) A theft offense, described in division (K)(3) of section 2913.01 of the Revised Code, that would constitute a felony under the laws of this state, any other state, or the United States;
   (b) A felony drug offense, as defined in section 2925.01 of the Revised Code.

(6) Maintain a list of each person with ownership of the facility and notify the state board of pharmacy of any change to that list.

(E) No person subject to licensure as a category III terminal distributor of dangerous drugs with an office-based opioid treatment classification shall knowingly fail to remain in compliance with the requirements of division (D) of this section and any other applicable requirements of this chapter.

(F) The state board of pharmacy may impose a fine of not
more than five thousand dollars on a person who violates division (B) or (E) of this section. A separate fine may be imposed for each day the violation continues. In imposing the fine, the board's actions shall be taken in accordance with Chapter 119. of the Revised Code.

(G) The state board of pharmacy shall adopt rules as it considers necessary to implement and administer this section. The rules shall be adopted in accordance with Chapter 119. of the Revised Code.

Sec. 4730.56. (A) As used in this section:

(1) "Community addiction services provider" has the same meaning as in section 5119.01 of the Revised Code.

(2) "Medication-assisted treatment" has the same meaning as in section 340.01 of the Revised Code.

(B) A physician assistant shall comply with section 3719.064 of the Revised Code and rules adopted under section 4730.55 of the Revised Code when treating a patient with medication-assisted treatment or proposing to initiate such treatment.

(C) A physician assistant who fails to comply with this section shall treat not more than thirty patients at any one time with medication-assisted treatment even if the facility or location at which the treatment is provided is either of the following:

(1) Exempted by divisions (B)(2)(a) to (d) or (i) of section 4729.553 of the Revised Code from being required to possess a category III terminal distributor of dangerous drugs license with an office-based opioid treatment classification;
(2) A community addiction services provider that provides alcohol and drug addiction services that are certified by the department of mental health and addiction services under section 5119.36 of the Revised Code.

Sec. 4731.83. (A) As used in this section:

(1) "Medication-assisted treatment" has the same meaning as in section 340.01 of the Revised Code.

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

(B) A physician shall comply with section 3719.064 of the Revised Code and rules adopted under section 4731.056 of the Revised Code when treating a patient with medication-assisted treatment or proposing to initiate such treatment.

(C) A physician who fails to comply with this section shall treat not more than thirty patients at any one time with medication-assisted treatment even if the facility or location at which the treatment is provided is either of the following:

(1) Exempted by divisions (B)(2)(a) to (d) or (i) of section 4729.553 of the Revised Code from being required to possess a category III terminal distributor of dangerous drugs license with an office-based opioid treatment classification;

(2) A community addiction services provider that provides alcohol and drug addiction services that are certified by the department of mental health and addiction services under section 5119.36 of the Revised Code.

Section 2. That existing sections 4723.52, 4729.45, 4729.553, 4730.56, and 4731.83 of the Revised Code are hereby
repealed.

Section 3. Section 4729.553 of the Revised Code is presented in this act as a composite of the section as amended by both Sub. H.B. 101 and Sub. S.B. 229 of the 132nd General Assembly. The General Assembly, applying the principle stated in division (B) of section 1.52 of the Revised Code that amendments are to be harmonized if reasonably capable of simultaneous operation, finds that the composite is the resulting version of the section in effect prior to the effective date of the section as presented in this act.