A BILL

To amend sections 4723.52, 4729.45, 4729.553, 4729.80, 4730.56, and 4731.83 of the Revised Code regarding the administration of addiction treatment drugs and federal agency access to the Ohio Automated Rx Reporting System.

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

Section 1. That sections 4723.52, 4729.45, 4729.553, 4729.80, 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 used for treatment of drug
addiction and
An addiction treatment drug 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— an addiction treatment 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.

(3) "Hospital" means a hospital registered with the department of health under section 3701.07 of the Revised Code.

(4) "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 facility in which patients are treated on-site for opioid dependence or addiction exclusively 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 neither dispensed nor
personally furnished to patients for off-site self-
administration;

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

(3) A patient who receives treatment on-site 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. 4729.80. (A) If the state board of pharmacy establishes and maintains a drug database pursuant to section 4729.75 of the Revised Code, the board is authorized or required to provide information from the database only as follows:

(1) On receipt of a request from a designated representative of a government entity responsible for the licensure, regulation, or discipline of health care professionals with authority to prescribe, administer, or dispense drugs, the board may provide to the representative information from the database relating to the professional who is the subject of an active investigation being conducted by the government entity or relating to a professional who is acting as
an expert witness for the government entity in such an investigation.

(2) On receipt of a request from a federal officer, or a state or local officer of this or any other state, whose duties include enforcing laws relating to drugs, the board shall provide to the officer information from the database relating to the person who is the subject of an active investigation of a drug abuse offense, as defined in section 2925.01 of the Revised Code, being conducted by the officer's employing government entity.

(3) Pursuant to a subpoena issued by a grand jury, the board shall provide to the grand jury information from the database relating to the person who is the subject of an investigation being conducted by the grand jury.

(4) Pursuant to a subpoena, search warrant, or court order in connection with the investigation or prosecution of a possible or alleged criminal offense, the board shall provide information from the database as necessary to comply with the subpoena, search warrant, or court order.

(5) On receipt of a request from a prescriber or the prescriber's delegate approved by the board, the board shall provide to the prescriber a report of information from the database relating to a patient who is either a current patient of the prescriber or a potential patient of the prescriber based on a referral of the patient to the prescriber, if all of the following conditions are met:

(a) The prescriber certifies in a form specified by the board that it is for the purpose of providing medical treatment to the patient who is the subject of the request;
(b) The prescriber has not been denied access to the database by the board.

(6) On receipt of a request from a pharmacist or the pharmacist's delegate approved by the board, the board shall provide to the pharmacist information from the database relating to a current patient of the pharmacist, if the pharmacist certifies in a form specified by the board that it is for the purpose of the pharmacist's practice of pharmacy involving the patient who is the subject of the request and the pharmacist has not been denied access to the database by the board.

(7) On receipt of a request from an individual seeking the individual's own database information in accordance with the procedure established in rules adopted under section 4729.84 of the Revised Code, the board may provide to the individual the individual's own prescription history.

(8) On receipt of a request from a medical director or a pharmacy director of a managed care organization that has entered into a contract with the department of medicaid under section 5167.10 of the Revised Code and a data security agreement with the board required by section 5167.14 of the Revised Code, the board shall provide to the medical director or the pharmacy director information from the database relating to a medicaid recipient enrolled in the managed care organization, including information in the database related to prescriptions for the recipient that were not covered or reimbursed under a program administered by the department of medicaid.

(9) On receipt of a request from the medicaid director, the board shall provide to the director information from the database relating to a recipient of a program administered by the department of medicaid, including information in the
database related to prescriptions for the recipient that were not covered or paid by a program administered by the department.

(10) On receipt of a request from a medical director of a managed care organization that has entered into a contract with the administrator of workers' compensation under division (B)(4) of section 4121.44 of the Revised Code and a data security agreement with the board required by section 4121.447 of the Revised Code, the board shall provide to the medical director information from the database relating to a claimant under Chapter 4121., 4123., 4127., or 4131. of the Revised Code assigned to the managed care organization, including information in the database related to prescriptions for the claimant that were not covered or reimbursed under Chapter 4121., 4123., 4127., or 4131. of the Revised Code, if the administrator of workers' compensation confirms, upon request from the board, that the claimant is assigned to the managed care organization.

(11) On receipt of a request from the administrator of workers' compensation, the board shall provide to the administrator information from the database relating to a claimant under Chapter 4121., 4123., 4127., or 4131. of the Revised Code, including information in the database related to prescriptions for the claimant that were not covered or reimbursed under Chapter 4121., 4123., 4127., or 4131. of the Revised Code.

(12) On receipt of a request from a prescriber or the prescriber's delegate approved by the board, the board shall provide to the prescriber information from the database relating to a patient's mother, if the prescriber certifies in a form specified by the board that it is for the purpose of providing medical treatment to a newborn or infant patient diagnosed as
opioid dependent and the prescriber has not been denied access to the database by the board.

(13) On receipt of a request from the director of health, the board shall provide to the director information from the database relating to the duties of the director or the department of health in implementing the Ohio violent death reporting system established under section 3701.93 of the Revised Code.

(14) On receipt of a request from a requestor described in division (A)(1), (2), (5), or (6) of this section who is from or participating with another state's prescription monitoring program, the board may provide to the requestor information from the database, but only if there is a written agreement under which the information is to be used and disseminated according to the laws of this state.

(15) On receipt of a request from a delegate of a retail dispensary licensed under Chapter 3796. of the Revised Code who is approved by the board to serve as the dispensary's delegate, the board shall provide to the delegate a report of information from the database pertaining only to a patient's use of medical marijuana, if both of the following conditions are met:

(a) The delegate certifies in a form specified by the board that it is for the purpose of dispensing medical marijuana for use in accordance with Chapter 3796. of the Revised Code.

(b) The retail dispensary or delegate has not been denied access to the database by the board.

(16) On receipt of a request from a judge of a program certified by the Ohio supreme court as a specialized docket program for drugs, the board shall provide to the judge, or an
employee of the program who is designated by the judge to
receive the information, information from the database that
relates specifically to a current or prospective program
participant.

(17) On receipt of a request from a coroner, deputy
coronor, or coroner's delegate approved by the board, the board
shall provide to the requestor information from the database
relating to a deceased person about whom the coroner is
carrying or has conducted an autopsy or investigation.

(18) On receipt of a request from a prescriber, the board
may provide to the prescriber a summary of the prescriber's
prescribing record if such a record is created by the board.
Information in the summary is subject to the confidentiality
requirements of this chapter.

(19)(a) On receipt of a request from a pharmacy's
responsible person, the board may provide to the responsible
person a summary of the pharmacy's dispensing record if such a
record is created by the board. Information in the summary is
subject to the confidentiality requirements of this chapter.

(b) As used in division (A)(19)(a) of this section,
"responsible person" has the same meaning as in rules adopted by
the board under section 4729.26 of the Revised Code.

(20) The board may provide information from the database
without request to a prescriber or pharmacist who is authorized
to use the database pursuant to this chapter.

(21)(a) On receipt of a request from a prescriber or
pharmacist, or the prescriber's or pharmacist's delegate, who is
a designated representative of a peer review committee, the
board shall provide to the committee information from the
database relating to a prescriber who is subject to the committee's evaluation, supervision, or discipline if the information is to be used for one of those purposes. The board shall provide only information that it determines, in accordance with rules adopted under section 4729.84 of the Revised Code, is appropriate to be provided to the committee.

(b) As used in division (A)(21)(a) of this section, "peer review committee" has the same meaning as in section 2305.25 of the Revised Code, except that it includes only a peer review committee of a hospital or a peer review committee of a nonprofit health care corporation that is a member of the hospital or of which the hospital is a member.

(22) On receipt of a request from a requestor described in division (A)(5) or (6) of this section who is from or participating with a prescription monitoring program that is operated by a federal agency and approved by the board, the board may provide to the requestor information from the database, but only if there is a written agreement under which the information is to be used and disseminated according to the laws of this state.

(23) Any personal health information submitted to the board pursuant to section 4729.772 of the Revised Code may be provided by the board only as authorized by the submitter of the information and in accordance with rules adopted under section 4729.84 of the Revised Code.

(B) The state board of pharmacy shall maintain a record of each individual or entity that requests information from the database pursuant to this section. In accordance with rules adopted under section 4729.84 of the Revised Code, the board may use the records to document and report statistics and law
enforcement outcomes.

The board may provide records of an individual's requests for database information only to the following:

(1) A designated representative of a government entity that is responsible for the licensure, regulation, or discipline of health care professionals with authority to prescribe, administer, or dispense drugs who is involved in an active criminal or disciplinary investigation being conducted by the government entity of the individual who submitted the requests for database information;

(2) A federal officer, or a state or local officer of this or any other state, whose duties include enforcing laws relating to drugs and who is involved in an active investigation being conducted by the officer's employing government entity of the individual who submitted the requests for database information;

(3) A designated representative of the department of medicaid regarding a prescriber who is treating or has treated a recipient of a program administered by the department and who submitted the requests for database information.

(C) Information contained in the database and any information obtained from it is confidential and is not a public record. Information contained in the records of requests for information from the database is confidential and is not a public record. Information contained in the database that does not identify a person, including any licensee or registrant of the board or other entity, may be released in summary, statistical, or aggregate form.

(D) A pharmacist or prescriber shall not be held liable in damages to any person in any civil action for injury, death, or
loss to person or property on the basis that the pharmacist or
prescriber did or did not seek or obtain information from the
database.

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, 4729.80, 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.