As Introduced

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H. B. No. 535

Representative Gavarone

Cosponsors: Representatives Young, Brown, Patton, Stein, Arndt, Hambley, Kick, Smith, R., Ryan, Sprague

A BILL

To amend sections 4729.01, 4729.44, 4729.75, 4729.79, and 4729.85 and to enact sections 3727.25 and 4765.45 of the Revised Code to require certain reports regarding overdoses and naloxone, to include naltrexone within the Ohio Automated Rx Reporting System, and to name this act the "Opioid Data and Communication Expansion Act."

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

Section 1. That sections 4729.01, 4729.44, 4729.75, 4729.79, and 4729.85 be amended and sections 3727.25 and 4765.45 of the Revised Code be enacted to read as follows:

Sec. 3727.25. (A) Each hospital shall report to the department of health on a monthly basis and in a manner prescribed by the department all of the following information for the previous month:

(1) The total number of drug overdose cases brought to the hospital for treatment;

(2) Of the number described in division (A)(1) of this section, the number that resulted in death and the number that did not result in death.

When submitting reports, the hospital shall not include any information that identifies or tends to identify specific patients.

(B) Each month, the department shall compile the information it receives under division (A) of this section and shall publish the information on its internet web site.

(C) The department may adopt rules as necessary to implement this section. The rules shall be adopted in accordance with Chapter 119. of the Revised Code.

Sec. 4729.01. As used in this chapter:

(A) "Pharmacy," except when used in a context that refers to the practice of pharmacy, means any area, room, rooms, place of business, department, or portion of any of the foregoing where the practice of pharmacy is conducted.

(B) "Practice of pharmacy" means providing pharmacist care requiring specialized knowledge, judgment, and skill derived from the principles of biological, chemical, behavioral, social, pharmaceutical, and clinical sciences. As used in this division, "pharmacist care" includes the following:

(1) Interpreting prescriptions;

(2) Dispensing drugs and drug therapy related devices;

(3) Compounding drugs;

(4) Counseling individuals with regard to their drug therapy, recommending drug therapy related devices, and

assisting in the selection of drugs and appliances for treatment of common diseases and injuries and providing instruction in the proper use of the drugs and appliances;

(5) Performing drug regimen reviews with individuals by discussing all of the drugs that the individual is taking and explaining the interactions of the drugs;

(6) Performing drug utilization reviews with licensed health professionals authorized to prescribe drugs when the pharmacist determines that an individual with a prescription has a drug regimen that warrants additional discussion with the prescriber;

(7) Advising an individual and the health care professionals treating an individual with regard to the individual's drug therapy;

(8) Acting pursuant to a consult agreement with one or more physicians authorized under Chapter 4731. of the Revised Code to practice medicine and surgery or osteopathic medicine and surgery, if an agreement has been established;

(9) Engaging in the administration of immunizations to the extent authorized by section 4729.41 of the Revised Code;

(10) Engaging in the administration of drugs to the extent authorized by section 4729.45 of the Revised Code.

(C) "Compounding" means the preparation, mixing, assembling, packaging, and labeling of one or more drugs in any of the following circumstances:

(1) Pursuant to a prescription issued by a licensed health professional authorized to prescribe drugs;

(2) Pursuant to the modification of a prescription made in

accordance with a consult agreement;

(3) As an incident to research, teaching activities, or chemical analysis;

(4) In anticipation of orders for drugs pursuant to prescriptions, based on routine, regularly observed dispensing patterns;

(5) Pursuant to a request made by a licensed health professional authorized to prescribe drugs for a drug that is to be used by the professional for the purpose of direct administration to patients in the course of the professional's practice, if all of the following apply:

(a) At the time the request is made, the drug is not commercially available regardless of the reason that the drug is not available, including the absence of a manufacturer for the drug or the lack of a readily available supply of the drug from a manufacturer.

(b) A limited quantity of the drug is compounded and provided to the professional.

(c) The drug is compounded and provided to the professional as an occasional exception to the normal practice of dispensing drugs pursuant to patient-specific prescriptions.

(D) "Consult agreement" means an agreement that has been entered into under section 4729.39 of the Revised Code.

(E) "Drug" means:

(1) Any article recognized in the United States pharmacopoeia and national formulary, or any supplement to them, intended for use in the diagnosis, cure, mitigation, treatment, or prevention of disease in humans or animals;

(2) Any other article intended for use in the diagnosis, cure, mitigation, treatment, or prevention of disease in humans or animals;

(3) Any article, other than food, intended to affect the structure or any function of the body of humans or animals;

(4) Any article intended for use as a component of any article specified in division (E)(1), (2), or (3) of this section; but does not include devices or their components, parts, or accessories.

(F) "Dangerous drug" means any of the following:

(1) Any drug to which either of the following applies:

(a) Under the "Federal Food, Drug, and Cosmetic Act," 52 Stat. 1040 (1938), 21 U.S.C.A. 301, as amended, the drug is required to bear a label containing the legend "Caution: Federal law prohibits dispensing without prescription" or "Caution: Federal law restricts this drug to use by or on the order of a licensed veterinarian" or any similar restrictive statement, or the drug may be dispensed only upon a prescription;

(b) Under Chapter 3715. or 3719. of the Revised Code, the drug may be dispensed only upon a prescription.

(2) Any drug that contains a schedule V controlled substance and that is exempt from Chapter 3719. of the Revised Code or to which that chapter does not apply;

(3) Any drug intended for administration by injection into the human body other than through a natural orifice of the human body;

(4) Any drug that is a biological product, as defined in section 3715.01 of the Revised Code.

(G) "Federal drug abuse control laws" has the same meaning as in section 3719.01 of the Revised Code.

(H) "Prescription" means all of the following:

(1) A written, electronic, or oral order for drugs or combinations or mixtures of drugs to be used by a particular individual or for treating a particular animal, issued by a licensed health professional authorized to prescribe drugs;

(2) For purposes of sections 2925.61, 4723.488, ~~4729.44,~~ 4730.431, and 4731.94 of the Revised Code, a written, electronic, or oral order for naloxone issued to and in the name of a family member, friend, or other individual in a position to assist an individual who there is reason to believe is at risk of experiencing an opioid-related overdose.

(3) For purposes of section 4729.44 of the Revised Code, a written, electronic, or oral order for naloxone issued to and in the name of either of the following:

(a) An individual who there is reason to believe is at risk of experiencing an opioid-related overdose;

(b) A family member, friend, or other individual in a position to assist an individual who there is reason to believe is at risk of experiencing an opioid-related overdose.

(4) For purposes of sections 4723.4810, 4729.282, 4730.432, and 4731.93 of the Revised Code, a written, electronic, or oral order for a drug to treat chlamydia, gonorrhea, or trichomoniasis issued to and in the name of a patient who is not the intended user of the drug but is the sexual partner of the intended user;

~~(4)~~ (5) For purposes of sections 3313.7110, 3313.7111,

3314.143, 3326.28, 3328.29, 4723.483, 4729.88, 4730.433, 4731.96, and 5101.76 of the Revised Code, a written, electronic, or oral order for an epinephrine autoinjector issued to and in the name of a school, school district, or camp;

~~(5)~~ (6) For purposes of Chapter 3728. and sections 4723.483, 4729.88, 4730.433, and 4731.96 of the Revised Code, a written, electronic, or oral order for an epinephrine autoinjector issued to and in the name of a qualified entity, as defined in section 3728.01 of the Revised Code.

(I) "Licensed health professional authorized to prescribe drugs" or "prescriber" means an individual who is authorized by law to prescribe drugs or dangerous drugs or drug therapy related devices in the course of the individual's professional practice, including only the following:

(1) A dentist licensed under Chapter 4715. of the Revised Code;

(2) A clinical nurse specialist, certified nurse-midwife, or certified nurse practitioner who holds a current, valid license to practice nursing as an advanced practice registered nurse issued under Chapter 4723. of the Revised Code;

(3) An optometrist licensed under Chapter 4725. of the Revised Code to practice optometry under a therapeutic pharmaceutical agents certificate;

(4) A physician authorized under Chapter 4731. of the Revised Code to practice medicine and surgery, osteopathic medicine and surgery, or podiatric medicine and surgery;

(5) A physician assistant who holds a license to practice as a physician assistant issued under Chapter 4730. of the Revised Code, holds a valid prescriber number issued by the

state medical board, and has been granted physician-delegated prescriptive authority;

(6) A veterinarian licensed under Chapter 4741. of the Revised Code.

(J) "Sale" or "sell" includes any transaction made by any person, whether as principal proprietor, agent, or employee, to do or offer to do any of the following: deliver, distribute, broker, exchange, gift or otherwise give away, or transfer, whether the transfer is by passage of title, physical movement, or both.

(K) "Wholesale sale" and "sale at wholesale" mean any sale in which the purpose of the purchaser is to resell the article purchased or received by the purchaser.

(L) "Retail sale" and "sale at retail" mean any sale other than a wholesale sale or sale at wholesale.

(M) "Retail seller" means any person that sells any dangerous drug to consumers without assuming control over and responsibility for its administration. Mere advice or instructions regarding administration do not constitute control or establish responsibility.

(N) "Price information" means the price charged for a prescription for a particular drug product and, in an easily understandable manner, all of the following:

(1) The proprietary name of the drug product;

(2) The established (generic) name of the drug product;

(3) The strength of the drug product if the product contains a single active ingredient or if the drug product contains more than one active ingredient and a relevant strength

can be associated with the product without indicating each active ingredient. The established name and quantity of each active ingredient are required if such a relevant strength cannot be so associated with a drug product containing more than one ingredient.

(4) The dosage form;

(5) The price charged for a specific quantity of the drug product. The stated price shall include all charges to the consumer, including, but not limited to, the cost of the drug product, professional fees, handling fees, if any, and a statement identifying professional services routinely furnished by the pharmacy. Any mailing fees and delivery fees may be stated separately without repetition. The information shall not be false or misleading.

(O) "Wholesale distributor of dangerous drugs" or "wholesale distributor" means a person engaged in the sale of dangerous drugs at wholesale and includes any agent or employee of such a person authorized by the person to engage in the sale of dangerous drugs at wholesale.

(P) "Manufacturer of dangerous drugs" or "manufacturer" means a person, other than a pharmacist or prescriber, who manufactures dangerous drugs and who is engaged in the sale of those dangerous drugs.

(Q) "Terminal distributor of dangerous drugs" or "terminal distributor" means a person who is engaged in the sale of dangerous drugs at retail, or any person, other than a manufacturer, repackager, outsourcing facility, third-party logistics provider, wholesale distributor, or pharmacist, who has possession, custody, or control of dangerous drugs for any

purpose other than for that person's own use and consumption. "Terminal distributor" includes pharmacies, hospitals, nursing homes, and laboratories and all other persons who procure dangerous drugs for sale or other distribution by or under the supervision of a pharmacist or licensed health professional authorized to prescribe drugs.

(R) "Promote to the public" means disseminating a representation to the public in any manner or by any means, other than by labeling, for the purpose of inducing, or that is likely to induce, directly or indirectly, the purchase of a dangerous drug at retail.

(S) "Person" includes any individual, partnership, association, limited liability company, or corporation, the state, any political subdivision of the state, and any district, department, or agency of the state or its political subdivisions.

(T) "Animal shelter" means a facility operated by a humane society or any society organized under Chapter 1717. of the Revised Code or a dog pound operated pursuant to Chapter 955. of the Revised Code.

(U) "Food" has the same meaning as in section 3715.01 of the Revised Code.

(V) "Pain management clinic" has the same meaning as in section 4731.054 of the Revised Code.

(W) "Investigational drug or product" means a drug or product that has successfully completed phase one of the United States food and drug administration clinical trials and remains under clinical trial, but has not been approved for general use by the United States food and drug administration.

"Investigational drug or product" does not include controlled substances in schedule I, as established pursuant to section 3719.41 of the Revised Code, and as amended.

(X) "Product," when used in reference to an investigational drug or product, means a biological product, other than a drug, that is made from a natural human, animal, or microorganism source and is intended to treat a disease or medical condition.

(Y) "Third-party logistics provider" means a person that provides or coordinates warehousing or other logistics services pertaining to dangerous drugs including distribution, on behalf of a manufacturer, wholesale distributor, or terminal distributor of dangerous drugs, but does not take ownership of the drugs or have responsibility to direct the sale or disposition of the drugs.

(Z) "Repackager of dangerous drugs" or "repackager" means a person that repacks and relabels dangerous drugs for sale or distribution.

(AA) "Outsourcing facility" means a facility that is engaged in the compounding and sale of sterile drugs and is registered as an outsourcing facility with the United States food and drug administration.

Sec. 4729.44. (A) As used in this section:

(1) "Board of health" means a board of health of a city or general health district or an authority having the duties of a board of health under section 3709.05 of the Revised Code.

(2) "Physician" means an individual authorized under Chapter 4731. of the Revised Code to practice medicine and surgery, osteopathic medicine and surgery, or podiatric medicine

and surgery.

(B) If use of the protocol developed pursuant to rules adopted under division (G) of this section has been authorized under section 3707.56 or 4731.942 of the Revised Code, a pharmacist or pharmacy intern may dispense naloxone without a prescription to either of the following in accordance with that protocol:

(1) An individual who there is reason to believe is experiencing or at risk of experiencing an opioid-related overdose;

(2) A family member, friend, or other ~~person~~ individual in a position to assist an individual who there is reason to believe is at risk of experiencing an opioid-related overdose.

(C) A pharmacist or pharmacy intern who dispenses naloxone under this section shall instruct the individual to whom naloxone is dispensed to summon emergency services as soon as practicable either before or after administering naloxone.

(D) A pharmacist may document on a prescription form the dispensing of naloxone by the pharmacist or a pharmacy intern supervised by the pharmacist ~~on a prescription form~~. The form may be assigned a number for record-keeping purposes.

(E) This section does not affect the authority of a pharmacist or pharmacy intern to fill or refill a prescription for naloxone.

(F) A board of health that in good faith authorizes a pharmacist or pharmacy intern to dispense naloxone without a prescription in accordance with a protocol developed pursuant to rules adopted under division (G) of this section is not liable for or subject to any of the following for any action or

omission of the individual to whom the naloxone is dispensed: damages in any civil action, prosecution in any criminal proceeding, or professional disciplinary action.

A physician who in good faith authorizes a pharmacist or pharmacy intern to dispense naloxone without a prescription in accordance with a protocol developed pursuant to rules adopted under division (G) of this section is not liable for or subject to any of the following for any action or omission of the individual to whom the naloxone is dispensed: damages in any civil action, prosecution in any criminal proceeding, or professional disciplinary action.

A pharmacist or pharmacy intern authorized under this section to dispense naloxone without a prescription who does so in good faith is not liable for or subject to any of the following for any action or omission of the individual to whom the naloxone is dispensed: damages in any civil action, prosecution in any criminal proceeding, or professional disciplinary action.

(G) The state board of pharmacy shall, after consulting with the department of health and state medical board, adopt rules to implement this section. The rules shall specify a protocol under which pharmacists or pharmacy interns may dispense naloxone without a prescription.

All rules adopted under this section shall be adopted in accordance with Chapter 119. of the Revised Code.

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; and other dangerous drugs the board includes in the database pursuant to rules adopted under section 4729.84 of the Revised Code. ~~In~~

The board also shall use the drug database to monitor naltrexone.

In establishing and maintaining the database, the board shall electronically collect information pursuant to sections 4729.77, 4729.771, 4729.772, 4729.78, 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. 4729.79. (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.

(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. 4729.85. If the state board of pharmacy establishes and maintains a drug database pursuant to section 4729.75 of the Revised Code, the board shall prepare reports regarding the database and present or submit them in accordance with both of the following:

(A) The board shall present a biennial report to the standing committees of the house of representatives and the senate that are primarily responsible for considering health and human services issues. Each report shall include all of the following:

(1) The cost to the state of establishing and maintaining the database;

(2) Information from the board, terminal distributors of dangerous drugs, prescribers, and retail dispensaries licensed under Chapter 3796. of the Revised Code regarding the board's effectiveness in providing information from the database;

(3) The board's timeliness in transmitting information from the database.

(B) The board shall submit a semiannual report to the governor, the president of the senate, the speaker of the house of representatives, the attorney general, the chairpersons of the standing committees of the house of representatives and the senate that are primarily responsible for considering health and human services issues, the department of public safety, the state dental board, the board of nursing, the state vision professionals board, the state medical board, and the state veterinary medical licensing board. The state board of pharmacy

shall make the report available to the public on its internet web site. Each report submitted shall include all of the following for the period covered by the report:

(1) An aggregate of the information submitted to the board under section 4729.77 of the Revised Code regarding prescriptions for controlled substances containing opioids, including all of the following:

(a) The number of prescribers who issued the prescriptions;

(b) The number of patients to whom the controlled substances were dispensed;

(c) The average quantity of the controlled substances dispensed per prescription;

(d) The average daily morphine equivalent dose of the controlled substances dispensed per prescription.

(2) An aggregate of the information submitted to the board under section 4729.79 of the Revised Code regarding controlled substances containing opioids that have been personally furnished to a patient by a prescriber, other than a prescriber who is a veterinarian, including all of the following:

(a) The number of prescribers who personally furnished the controlled substances;

(b) The number of patients to whom the controlled substances were personally furnished;

(c) The average quantity of the controlled substances that were furnished at one time;

(d) The average daily morphine equivalent dose of the

controlled substances that were furnished at one time.

(3) An aggregate of the information submitted to the board under section 4729.771 of the Revised Code regarding medical marijuana;

(4) An aggregate of the information submitted to the board under sections 4729.77 and 4729.79 of the Revised Code regarding naltrexone, including all of the following:

(a) The number of prescribers who issued the prescriptions for or personally furnished the drug;

(b) The number of patients to whom the drug was dispensed or personally furnished;

(c) The average quantity of the drug dispensed per prescription or furnished at one time.

Sec. 4765.45. (A) If the department of public safety collects any of the following information regarding the administration of naloxone by emergency medical service personnel or any firefighter or volunteer firefighter, the department of public safety shall report the information to the department of health on a monthly basis and in a manner prescribed by the department of health:

(1) The five-digit postal zip code plus four-digit add-on where the naloxone was administered;

(2) The date on which the naloxone was administered;

(3) The number of doses administered;

(4) The name of the emergency medical service organization or fire department that administered the naloxone;

(5) Whether or not an overdose was reversed;

(6) Whether the individual was taken to a hospital.

When reporting to the department of health, the department of public safety shall not include any information that identifies or tends to identify specific individuals to whom naloxone was administered.

(B) Each month, the department of health shall compile the information received under division (A) of this section, organize it by county, and forward it to each board of alcohol, drug addiction, and mental health services in this state.

(C) The department of health may adopt rules as necessary to implement this section. The rules shall be adopted in accordance with Chapter 119. of the Revised Code.

Section 2. That existing sections 4729.01, 4729.44, 4729.75, 4729.79, and 4729.85 of the Revised Code are hereby repealed.

Section 3. This act shall be known as the "Opioid Data and Communication Expansion Act."