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THE GENERAL ASSEMBLY OF PENNSYLVANIA

HOUSE BILL

No. 1005 Session of 2019

INTRODUCED BY COX, BERNSTINE, BROWN, IRVIN, KIRKLAND, MASSER, MILLARD, MURT, NEILSON, PICKETT, PYLE, READSHAW, SAYLOR, STRUZZI, ZIMMERMAN AND HEFFLEY, APRIL 9, 2019

AS AMENDED ON SECOND CONSIDERATION, HOUSE OF REPRESENTATIVES, JUNE 5, 2019

AN ACT

Amending the act of October 27, 2014 (P.L.2911, No.191), entitled "An act providing for prescription drug monitoring; creating the ABC-MAP Board; establishing the Achieving Better Care by Monitoring All Prescriptions Program; and providing for unlawful acts and penalties," further providing for purpose, for definitions, for powers and duties of board~~,~~ AND for establishment of program ~~and for requirements for dispensers and pharmacies~~; AND providing for requirements for first ~~responders; and further providing for access to prescription information.~~ RESPONDER AGENCIES AND HOSPITAL EMERGENCY DEPARTMENTS AND FOR REQUIREMENTS FOR CORONERS AND MEDICAL EXAMINERS. <--

The General Assembly of the Commonwealth of Pennsylvania hereby enacts as follows:

Section 1. Section 2 of the act of October 27, 2014 (P.L.2911, No.191), known as the Achieving Better Care by Monitoring All Prescriptions Program (ABC-MAP) Act, is amended to read:

Section 2. Purpose.

This act is intended to increase the quality of patient care by giving prescribers and dispensers access to a patient's prescription medication history, including, but not limited to,

any history of a ~~drug overdose~~ DRUG-RELATED OVERDOSE EVENT, <--
through an electronic system that will alert medical professionals to potential dangers for purposes of making treatment determinations. The act further intends that patients will have a thorough and easily obtainable record of their prescriptions for purposes of making educated and thoughtful health care decisions. Additionally, the act seeks to aid regulatory and law enforcement agencies in the detection and prevention of fraud, drug abuse and the criminal diversion of controlled substances.

Section 2. Section 3 of the act is amended by adding definitions to read:

Section 3. Definitions.

The following words and phrases when used in this act shall have the meanings given to them in this section unless the context clearly indicates otherwise:

* * *

"DRUG-RELATED OVERDOSE DEATH." AN INCIDENT WHERE AN OVER-THE-COUNTER DRUG, PRESCRIPTION OR CONTROLLED SUBSTANCE OR ILLEGAL SUBSTANCE IS THE PRIMARY OR SECONDARY CAUSE OF DEATH OF AN INDIVIDUAL OR MAY HAVE BEEN A CONTRIBUTING FACTOR TO THE DEATH OF AN INDIVIDUAL. <--

"DRUG-RELATED OVERDOSE EVENT." AS FOLLOWS:

(1) AN INCIDENCE OF A PHYSICAL STATE RESULTING FROM INTENTIONALLY OR UNINTENTIONALLY CONSUMING OR ADMINISTERING A TOXIC OR OTHERWISE HARMFUL LEVEL OF AN OVER-THE-COUNTER DRUG, PRESCRIPTION OR CONTROLLED SUBSTANCE OR ILLEGAL SUBSTANCE THAT MAY BE SUSPECTED BY ANY OF THE FOLLOWING:

(I) AN OBSERVATION OF SYMPTOMS REQUIRING MEDICAL RESPONSE.

(II) A CLINICAL SUSPICION OF A DRUG OVERDOSE.

(III) A POSITIVE URINE TOXICOLOGY SCREEN FOR A CONTROLLED SUBSTANCE OR A NEGATIVE URINE TOXICOLOGY SCREEN IF THERE ARE NO OTHER CONDITIONS TO EXPLAIN THE CLINICAL SYMPTOMS.

(2) THE TERM MAY INCLUDE, BUT IS NOT LIMITED TO, ANY OF THE FOLLOWING EVENTS THAT RESULTED FROM CONSUMING DRUGS:

(I) CENTRAL NERVOUS SYSTEM DEPRESSION RESULTING IN A DECREASED HEART RATE AND BREATHING, LOSS OF CONSCIOUSNESS OR DEATH.

(II) STIMULANT EFFECTS RESULTING IN AN INCREASED OR IRREGULAR HEART RATE, AGITATION OR HYPERTENSION.

(III) HALLUCINATIONS, SEIZURES OR UNRESPONSIVENESS.

"First responder." A firefighter, law enforcement officer or emergency medical services ~~personnel.~~ PROVIDER. <--

"FIRST RESPONDER AGENCY." A FEDERAL, STATE, LOCAL GOVERNMENTAL OR NONGOVERNMENTAL AGENCY THAT EMPLOYS FIRST RESPONDERS. THE TERM INCLUDES AN EMERGENCY MEDICAL SERVICES AGENCY AS DEFINED IN 35 PA.C.S. § 8103 (RELATING TO DEFINITIONS).

* * *

~~"Opioid overdose agent." A medication approved by the Food and Drug Administration to reverse the effects of an opioid drug.~~ <--

~~* * *~~

Section 3. Section 5 of the act is amended to read:

Section 5. Powers and duties of board.

The board shall have the following powers and duties:

(1) Evaluate and secure a vendor of an electronic prescription monitoring system for the purpose of carrying

out the provisions of this act.

(2) Appoint an advisory group comprised of dispensers, prescribers, law enforcement officials, addiction specialists, patient and privacy advocates and individuals with expertise considered important to the operation of the program. All members shall have varying perspectives and will provide input and recommendations to the board regarding the establishment and maintenance of the program. The advisory group shall not exceed 12 members.

(3) Create a written notice to be used by prescribers and used or displayed by dispensers to provide notice to patients that information regarding prescriptions for controlled substances and ~~opioid overdose agents~~ DRUG-RELATED OVERDOSE EVENTS <-- is being collected by the program and that the patient has a right to review and correct the information with the program. The notice must include all of the following:

(i) The manner in which the patient may access the patient's personal information. The notice shall state that one-time quarterly patient access shall be at no cost.

(ii) An explanation of the program and the program's authorized users.

(iii) The program's record retention policies.

(iv) An explanation that prescription information is confidential and is not subject to the act of February 14, 2008 (P.L.6, No.3), known as the Right-to-Know Law.

(v) Any cost associated with accessing the information more than once during each calendar quarter.

(4) Phase in an enforcement process so that dispensers

and prescribers may transition and have adequate time to make the necessary changes to their operating systems.

(5) Develop policies and procedures to:

(i) Require more frequent reporting of prescription medication information under section 7 should technology permit and so long as there is little or no fiscal impact to the Commonwealth or those required to report. Any change in the frequency of reporting shall be made in collaboration with the Board of Pharmacy and the Board of Pharmacy's members to ensure that a pharmacy is able to accommodate the change.

(ii) Evaluate the information in the system.

(iii) Allow for authorized department personnel to conduct internal reviews, analyses and interpret the data contained in the system.

(iv) Safeguard the release of information to authorized users and department personnel and ensure the privacy and confidentiality of patients and patient information.

(v) Aid prescribers in identifying at-risk individuals and referring them to drug addiction treatment professionals and programs.

(v.1) Aid prescribers in identifying individuals with a history of drug overdoses in order to provide alternative treatment options.

(vi) Establish professionally developed criteria, with the advice of the advisory group, that generates referrals of prescription monitoring information to the appropriate licensing board in the Department of State. A referral may only be generated when the system produces

an alert that there is a pattern of irregular data for a dispenser or prescriber which appears to deviate from the clinical standard.

(vii) Provide training to prescribers and dispensers on the use of the system.

(viii) Assist professional organizations whose members prescribe, monitor or treat patients or dispense controlled substances to patients to develop educational programs for those members relating to prescribing practices, pharmacology, controlled substance abuse~~, the use and availability of opioid overdose agents~~ and clinical standards, including: <--

(A) identification of those at risk for controlled substance abuse; and

(B) referral and treatment options for patients.

(ix) Permit individuals employed by prescribers, pharmacies and dispensers to query the system as designees so long as each individual designee has a unique identifier when accessing the system and set explicit standards to qualify individuals authorized to query the system and to ensure the security of the system when used by a designee.

(x) Keep pace with technological advances that facilitate the interoperability of the system with other states' prescription drug monitoring systems and electronic health information systems.

(xi) Evaluate the costs and benefits of the program.

(xii) Convene the advisory group at least annually.

(xiii) Direct the department to operate and maintain the program on a daily basis.

(xiv) Review the program for the purpose of compiling statistics, research and educational materials and outreach.

(xv) Identify any controlled substance that has been shown to have limited or no potential for abuse and therefore should not be reported to the program.

(xvi) Require and ensure registration of all prescribers and dispensers with the program.

(xvii) Identify additional medications that could assist prescribers in making treatment options for patients who are at risk for a substance use disorder.

~~Section 4. Section 6(b) of the act is amended by adding a paragraph to read:~~ <--

SECTION 4. SECTION 6(B)(1) OF THE ACT IS AMENDED AND THE SECTION IS AMENDED BY ADDING PARAGRAPHS TO READ: <--

Section 6. Establishment of program.

* * *

(b) Program components.--The program shall:

(1) PROVIDE AN ELECTRONIC SYSTEM OF CONTROLLED SUBSTANCES PRESCRIBED AND DISPENSED IN THIS COMMONWEALTH AND OF DRUG-RELATED OVERDOSE EVENTS THAT OCCURRED IN THIS COMMONWEALTH. <--

* * *

(6) Establish a protocol for ~~health care professionals~~ HOSPITAL EMERGENCY DEPARTMENTS and first ~~responders~~ RESPONDER AGENCIES to ensure data submitted to the system with respect to ~~an opioid overdose~~ DRUG-RELATED OVERDOSE EVENTS is not duplicative. <--

(7) PROVIDE DRUG-RELATED OVERDOSE DEATH EVENT INFORMATION, INCLUDING ANY DRUGS THAT CONTRIBUTED TO THE <--

OVERDOSE, ON THE PATIENT'S PROGRAM RECORD.

* * *

~~Section 5. Section 7(b) and (c) of the act are amended and the section is amended by adding a subsection to read:~~ <--

~~Section 7. Requirements for dispensers and pharmacies.~~

~~* * *~~

~~(b) Data elements.--All of the following information shall be provided by a dispenser or pharmacy~~, ~~except as provided in subsection (b.1)~~:

~~(1) The full name of the prescriber.~~

~~(2) The prescriber's Drug Enforcement Agency (DEA) registration number.~~

~~(3) The date the prescription was written.~~

~~(4) The date the prescription was dispensed.~~

~~(5) The full name, date of birth, gender and address of the person for whom the prescription was written and dispensed.~~

~~(6) The National Drug Code.~~

~~(7) The quantity and days' supply.~~

~~(8) The DEA registration number and National Provider Identifier of the dispenser or pharmacy.~~

~~(9) The method of payment for the prescription.~~

~~(b.1) Opioid overdose agent information.--With respect to an opioid overdose agent, the following information shall be provided by the treating health care practitioner after administration of the opioid overdose agent in accordance with section 13.7 of the act of April 14, 1972 (P.L.233, No.64), known as The Controlled Substance, Drug, Device and Cosmetic Act:~~

~~(1) The full name, date of birth, gender and address of~~

~~the person to whom the opioid overdose agent was administered.~~

~~(2) The date the opioid overdose agent was administered.~~

~~(3) The brand name, if any, of the opioid overdose agent.~~

~~(4) The National Drug Code.~~

~~(5) The DEA registration number and National Provider Identifier of the dispenser or pharmacy.~~

~~(6) The method of administration of the opioid overdose agent.~~

~~(7) The amount of the opioid overdose agent necessary to treat the person.~~

~~(c) Frequency.--~~

~~(1) A dispenser or pharmacy shall submit all information required under subsection (b) to the system no later than the close of the subsequent business day after dispensing a controlled substance.~~

~~(2) Paragraph (1) shall not apply to the dispensing of an opioid overdose agent either through prescription or as a result of a standing order.~~

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Section ~~6~~ 5. The act is amended by adding ~~a section~~ SECTIONS <-- to read:

~~Section 7.1. Requirements for first responders.~~ <--

~~(a) Submission.--A first responder shall, according to the format determined by the board, electronically submit information to the system regarding each opioid overdose agent administered in the course of the first responder's professional duties for any individual not transported to a hospital for additional health care services.~~

~~(b) Data elements.--All of the following information shall be provided by the first responder:~~

~~(1) The full name, date of birth, gender and address of the person to whom the opioid overdose agent was administered.~~

~~(2) The date the opioid overdose agent was administered.~~

~~(3) The brand name, if any, of the opioid overdose agent.~~

~~(4) The National Drug Code.~~

~~(5) The DEA registration number and National Provider Identifier of the dispenser or pharmacy.~~

~~(6) The method of administration of the opioid overdose agent.~~

~~(7) The amount of the opioid overdose agent necessary to treat the person.~~

~~(c) Frequency.--A first responder shall submit all information required under subsection (b) to the system not later than 72 hours after administration of the opioid overdose agent.~~

~~(d) First responder's designee.--A first responder may designate an employee or agent of the first responder's organization to submit the information required under subsection (b) to the system according to standards established by the board.~~

~~Section 7. Section 9(b)(3)(i) of the act is amended to read:~~

~~Section 9. Access to prescription information.~~

~~* * *~~

~~(b) Authorized users.--The following individuals may query the system according to procedures determined by the board and with the following limitations:~~

~~* * *~~

~~(3) (i) The Office of Attorney General shall query the system on behalf of all law enforcement agencies, including, but not limited to, the Office of the Attorney General and Federal, State and local law enforcement agencies for:~~

~~(A) Schedule II controlled substances as indicated in the act of April 14, 1972 (P.L.233, No.64), known as The Controlled Substance, Drug, Device and Cosmetic Act, and in the manner determined by the Pennsylvania Attorney General pursuant to 28 Pa. Code § 25.131 (relating to every dispensing practitioner); [and]~~

~~(B) all other schedules upon receipt of a court order obtained by the requesting law enforcement agency. Upon receipt of a motion under this clause, the court may enter an ex parte order granting the motion if the law enforcement agency has demonstrated by a preponderance of the evidence that:~~

~~(I) the motion pertains to a person who is the subject of an active criminal investigation with a reasonable likelihood of securing an arrest or prosecution in the foreseeable future; and~~

~~(II) there is reasonable suspicion that a criminal act has occurred[.]~~; and

~~(C) information with respect to the administration of an opioid overdose agent shall not be subject to a query by the Office of Attorney General.~~

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SECTION 7.1. REQUIREMENTS FOR FIRST RESPONDER AGENCIES AND HOSPITAL EMERGENCY DEPARTMENTS. <--

(A) SUBMISSION.--A FIRST RESPONDER AGENCY OR HOSPITAL EMERGENCY DEPARTMENT SHALL, IN THE FORMAT DETERMINED BY THE DEPARTMENT, ELECTRONICALLY SUBMIT DRUG-RELATED OVERDOSE EVENT INFORMATION TO THE DEPARTMENT.

(B) DATA ELEMENTS.--ALL OF THE FOLLOWING INFORMATION SHALL BE PROVIDED BY A FIRST RESPONDER AGENCY OR HOSPITAL EMERGENCY DEPARTMENT:

(1) THE FULL NAME, DATE OF BIRTH, GENDER AND ADDRESS OF AN INDIVIDUAL WHO EXPERIENCED A DRUG-RELATED OVERDOSE EVENT.

(2) THE DATE AND TIME OF THE DRUG-RELATED OVERDOSE EVENT.

(3) THE ADDRESS WHERE THE INDIVIDUAL WAS PICKED UP OR WHERE THE DRUG-RELATED OVERDOSE EVENT TOOK PLACE.

(4) WHETHER AN EMERGENCY OPIOID ANTAGONIST WAS ADMINISTERED TO THE INDIVIDUAL.

(5) THE LOCATION WHERE THE EMERGENCY OPIOID ANTAGONIST WAS ADMINISTERED, IF AVAILABLE.

(6) THE AMOUNT OF EMERGENCY OPIOID ANTAGONIST ADMINISTERED, IF AVAILABLE.

(7) WHETHER THE DRUG-RELATED OVERDOSE EVENT RESULTED IN DEATH.

(8) THE SUSPECTED OR CONFIRMED DRUG INVOLVED IN THE DRUG-RELATED OVERDOSE EVENT.

(C) FREQUENCY.--A FIRST RESPONDER AGENCY OR HOSPITAL EMERGENCY DEPARTMENT SHALL SUBMIT ALL INFORMATION REQUIRED UNDER SUBSECTION (B) TO THE PROGRAM NO LATER THAN 72 HOURS AFTER A DRUG-RELATED OVERDOSE EVENT WAS REPORTED.

(D) DEFINITION.--AS USED IN THIS SECTION, THE TERM "EMERGENCY OPIOID ANTAGONIST" MEANS A MEDICATION APPROVED BY THE UNITED STATES FOOD AND DRUG ADMINISTRATION TO REVERSE THE EFFECTS OF AN OPIOID DRUG.

SECTION 7.2. REQUIREMENTS FOR CORONERS AND MEDICAL EXAMINERS.

(A) SUBMISSION.--A COUNTY CORONER OR MEDICAL EXAMINER IN THIS COMMONWEALTH SHALL ELECTRONICALLY SUBMIT DATA, IN THE FORMAT PUBLISHED UNDER SUBSECTION (C), ON A DRUG-RELATED OVERDOSE DEATH TO THE DEPARTMENT WITHIN FIVE BUSINESS DAYS OF FINALIZING THE CAUSE AND MANNER OF THE DRUG-RELATED OVERDOSE DEATH.

(B) CONTENTS OF DATA.--IN COMPLYING WITH SUBSECTION (A), A COUNTY CORONER OR MEDICAL EXAMINER SHALL PROVIDE ALL OF THE FOLLOWING INFORMATION TO THE DEPARTMENT:

(1) DEMOGRAPHIC INFORMATION OF THE DECEDENT, INCLUDING BUT NOT LIMITED TO, THE FULL NAME, ADDRESS AND DATE OF BIRTH OF THE DECEDENT.

(2) THE TOXICOLOGY REPORT.

(3) THE AUTOPSY REPORT.

(4) THE CIRCUMSTANCES OF THE DRUG-RELATED OVERDOSE DEATH.

(C) PUBLICATION.--THE DEPARTMENT SHALL TRANSMIT A NOTICE OF THE FORMAT FOR DATA SUBMISSION UNDER SUBSECTION (A) TO THE LEGISLATIVE REFERENCE BUREAU FOR PUBLICATION IN THE PENNSYLVANIA BULLETIN WITHIN 30 DAYS OF THE EFFECTIVE DATE OF THIS SUBSECTION.

(D) PUBLIC REPORTS.--THE DEPARTMENT SHALL USE THE DATA SUBMITTED UNDER SUBSECTION (A) TO COMPILE PUBLICLY AVAILABLE REPORTS CONTAINING STATISTICS AND PATTERNS RELATING TO DRUG-RELATED OVERDOSE DEATHS ON A QUARTERLY BASIS TO HELP IDENTIFY

THREATS TO PUBLIC HEALTH AND SAFETY.

(E) LIABILITY.--ANY INDIVIDUAL WHO, IN GOOD FAITH, PROVIDES DATA TO THE DEPARTMENT UNDER THIS SECTION SHALL NOT BE SUBJECT TO ANY CIVIL OR CRIMINAL LIABILITY AS A RESULT OF PROVIDING THE DATA.

SECTION 6. SECTION 9 HEADING OF THE ACT IS AMENDED TO READ:

SECTION 9. ACCESS TO PRESCRIPTION INFORMATION AND DRUG-RELATED OVERDOSE EVENT INFORMATION.

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Section ~~8~~ 7. This act shall take effect in ~~60~~ 180 days. **<--**