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THE GENERAL ASSEMBLY OF PENNSYLVANIA

SENATE BILL

No. 1180 Session of 2013

INTRODUCED BY VANCE, MENSCH, BAKER, WARD, STACK, GORDNER, VULAKOVICH, SOLOBAY, GREENLEAF, TOMLINSON, WAUGH, FERLO, BROWNE AND WILLIAMS, NOVEMBER 18, 2013

AS AMENDED ON THIRD CONSIDERATION, MAY 5, 2014

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.

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

Section 1. Short title.

This act shall be known and may be cited as the Achieving Better Care by Monitoring All Prescriptions Program (ABC-MAP) Act.

Section 2. Purpose.

This act is intended to increase the quality of patient care by giving prescribers and dispensers access to a patient's prescriptive history through an electronic data 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 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 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:

"Addiction specialist." A physician licensed by the State Board of Medicine and certified by the American Board of Addiction Medicine.

"Board." The ABC-MAP Board established in section 4.

"Controlled substance." A drug, substance or immediate

precursor included in the act of April 14, 1972 (P.L.233, No.64), known as The Controlled Substance, Drug, Device and Cosmetic Act, or the Controlled Substances Act (Public Law 91-513, 84 Stat. 1236).

"Department." The Department of Health of the Commonwealth.

"Dispense." To deliver a controlled substance, other drug or device to a patient by or pursuant to the lawful order of a prescriber.

"Dispenser." A person lawfully authorized to dispense in this Commonwealth, including mail order and Internet sales of pharmaceuticals. The term does not include any of the following:

(1) A licensed health care facility that distributes the controlled substance for the purpose of administration in the licensed health care facility.

(2) A correctional facility or its contractors if the confined person cannot lawfully visit a prescriber outside the correctional facility without being escorted by a corrections officer.

(3) An authorized person who administers a controlled substance, other drug or device.

(4) A wholesale distributor of a controlled substance.

(5) A licensed provider in the LIFE program.

(6) A provider of hospice as defined in the act of July 19, 1979 (P.L.130, No.48), known as the Health Care Facilities Act.

(7) A prescriber at a health care facility licensed by this Commonwealth if the quantity of controlled substances dispensed is limited to an amount adequate to treat the patient for a maximum of 24 hours with not more than two 24-hour cycles within any 15-day period.

(8) A veterinarian.

"Licensed health care facility." A health care facility that is licensed under Article X of the act of June 13, 1967 (P.L.31, No.21), known as the Public Welfare Code, or the act of July 19, 1979 (P.L.130, No.48), known as the Health Care Facilities Act.

"LIFE program." The program of medical and supportive services known as Living Independently For Elders.

"Prescriber." A person who is licensed, registered or otherwise lawfully authorized to distribute, dispense or to administer a controlled substance, other drug or device in the course of professional practice or research in this Commonwealth. The term does not include a veterinarian.

"Program." The Achieving Better Care by Monitoring All Prescriptions Program (ABC-MAP) created in section 6.

Section 4. ABC-MAP Board.

(a) Creation.--The ABC-MAP Board is created in the Department of Health. The board shall establish the program. The department shall operate the program by performing budgetary, accounting, procurement and other support services as directed by the board.

(b) Board composition.--The board shall consist of the following individuals or their designees:

(1) Secretary of Health, who shall serve as chairperson.

(2) Secretary of Public Welfare.

(3) Secretary of Drug and Alcohol Programs.

(4) Secretary of State.

(5) The Insurance Commissioner.

(6) Secretary of Aging.

(7) The Commissioner of Pennsylvania State Police.

(8) The Attorney General.

(9) The Physician General, if the Secretary of Health is not a physician.

(c) Term limits.--Each member of the board shall serve for the duration of their elected or appointed position.

(d) Meetings.--The board shall meet at least once a year for the purpose of assessing the costs and benefits of the program and effectuating any necessary changes. The board may meet more frequently at the discretion of the chairperson.

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, addiction specialists, patient and privacy advocates and individuals with expertise considered important to the operation of the program. All members shall have unique perspectives and will provide input and recommendations to the board regarding the establishment and maintenance of the program. The advisory group shall not exceed twelve members.

(3) Provide WRITTEN notice to patients that information regarding prescriptions for controlled substances is being collected by the ABC-MAP program and that the patient has a right to annually review and correct the information at no charge to the patient. The manner of notice may be determined by the board with the advice of the advisory group. THE NOTICE MUST INCLUDE ALL OF THE FOLLOWING: <-- <--

(I) THE MANNER IN WHICH THE PATIENT MAY ACCESS THE PATIENT'S PERSONAL INFORMATION USING A FORM OR ONLINE

ACCESS.

(II) AN EXPLANATION OF THE PROGRAM AND THE PROGRAM'S AUTHORIZED USERS.

(III) 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.

(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 protocols and policies to:

(i) Require more frequent reporting of data should technology permit and so long as there is little or no fiscal impact to the Commonwealth or those reporting. 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 program.

(iii) Allow for authorized department personnel to conduct internal reviews, analyses and interpret program data.

(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.

(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 only when the system produces an alert that there is a pattern of irregular data deviating from the clinical standard.

(vii) Train, educate and instruct prescribers and dispensers on the use of the system.

(viii) Permit individuals employed by prescribers and dispensers to query the program as designees and set explicit standards to QUALIFY INDIVIDUALS AUTHORIZED TO QUERY THE PROGRAM AND TO ensure the security of the system when ~~a designee is indicated~~ USED BY A DESIGNEE. <--

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

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

(xi) Convene the advisory group at least annually.

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

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

Section 6. Establishment of program.

(a) General rule.--The board shall establish and oversee and the department shall administer the Achieving Better Care by Monitoring All Prescriptions Program.

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

(1) Provide an electronic data system of controlled

substances prescribed and dispensed in this Commonwealth.

(2) Be easily accessible by prescribers, dispensers and patients.

(3) Provide training and support for those using the data system.

(4) Contain processes for prescribers to refer patients to substance abuse treatment.

(c) Program queries.--The program shall maintain a record of database queries that contains all of the following:

(1) Identification of each person who requests or receives information from the database.

(2) Information provided to each person.

(3) Date and time the information is requested and provided.

(d) Record retention.--The board shall remove from the program all identifying information more than three years old from the date of collection. The information shall be destroyed unless a law enforcement agency or a professional licensing or certification agency or board for prescribers or dispensers has submitted a written request to the department for retention of specific information for cause. The information may be kept for an additional period of one year and all requests shall comply with procedures adopted by the board. The department may not grant more than two extensions regarding the retention of the same identified specific information.

(e) Good cause exception.--The program shall contain a good cause exception for dispensers and prescribers who are unable to submit the required data electronically and shall allow for the manual submission of data if the dispenser or prescriber does not have Internet access.

(f) Expiration.--Current pharmacy reporting requirements to the Attorney General shall expire and shall no longer be enforceable upon the full implementation of the program.

Section 7. Requirements for dispensers.

(a) Submission.--A dispenser shall, according to the format determined by the board, electronically submit information to the program regarding each controlled substance dispensed.

(b) Data elements.--All of the following information shall be provided by a dispenser:

(1) Full name of the prescriber.

(2) Prescriber Drug Enforcement Agency (DEA) registration number.

(3) Date prescription was written.

(4) Date prescription was dispensed.

(5) 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) Dosage quantity and days' supply.

(8) DEA registration number and National Provider Identifier.

(9) Method of payment for the prescription.

(c) Frequency.--A dispenser shall submit all information required under subsection (b) to the program no later than 72 hours after dispensing a controlled substance.

Section 8. Requirements for prescribers.

(a) Program query.--A prescriber shall query the program:

(1) for each patient the first time the patient is prescribed a controlled substance by the prescriber for purposes of establishing a base line and a thorough medical record; and

(2) if a prescriber believes or has reason to believe, using sound clinical judgment, that a patient may be abusing or diverting drugs.

(b) Medical record entries.--A prescriber shall indicate the information obtained from the program in the patient's medical record if:

(1) the individual is a new patient; or

(2) the prescriber determines a drug should not be prescribed or furnished to a patient based upon the information from the program.

(c) Prescriber designee.--Prescribers may designate employees for purposes of accessing the program according to standards established by the board. In assigning a designee, a prescriber shall give preference to a professional nurse licensed by the State Board of Nursing.

(d) Nonviolation.--A prescriber or dispenser who, using a sound standard of care in the exercise of clinical judgment, does not believe that a patient is abusing or diverting controlled substances shall not be in violation of this act for not seeking or obtaining information from the program prior to prescribing or dispensing so long as the prescriber or dispenser is otherwise in compliance.

Section 9. Access to prescription information.

(a) Confidentiality.--Except as set forth in subsection (b), prescription information submitted to the program and records of requests to query the data shall be confidential and not subject to disclosure under the act of February 14, 2008 (P.L.6, No.3), known as the Right-to-Know Law.

(b) Authorized users.--The following individuals may query the program according to procedures determined by the board and

with the following limitations:

(1) Prescribers may query the program for:

(i) an existing patient; and

(ii) prescriptions written using the prescriber's own Drug Enforcement Agency number.

(2) Dispensers may query the program for a current patient to whom the dispenser is dispensing or considering dispensing any controlled substance.

(3) (i) Federal and State law enforcement officials may query the program 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. 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.

(ii) Data obtained under this paragraph may only be

used by a law enforcement official to establish probable cause to obtain a search warrant or arrest warrant.

(4) A grand jury may query the program if investigating a criminal violation of a law governing controlled substances.

(5) Approved department personnel may query the program for the purpose of:

(i) conducting internal reviews related to controlled substance laws; or

(ii) engaging in the analysis of controlled substance prescription information as part of the assigned duties and responsibilities of employment.

(6) Designated representatives from the Commonwealth or out-of-State agency or board responsible for licensing or certifying prescribers or dispensers whose professional practice was or is regulated by that agency or board for the purpose of conducting administrative investigations or proceedings.

(7) Personnel from the Department of Public Welfare engaged in the administration of the medical assistance program.

(8) Personnel from the Insurance Department engaged in the administration of the Children's Health Insurance Program (CHIP).

(9) Personnel from the Department of Aging engaged in the administration of the Pharmaceutical Assistance Contract for the Elderly (PACE) and the Pharmaceutical Assistance Contract for the Elderly Needs Enhancement Tier (PACENET) programs.

(10) A medical examiner or county coroner for the

purpose of investigating the death of the individual being queried.

(11) A prescription drug monitoring official, dispenser or prescriber of a state with which this Commonwealth has an interoperability agreement.

(12) Upon providing evidence of identity and within ~~six months~~ 30 DAYS from the date of the request, an individual who is the recipient of a controlled substance prescription entered into the program, the individual's parent or guardian if the individual is under 18 years of age or the individual's health care power of attorney. <--

Section 10. Unlawful acts and penalties.

(a) Unlawful acts.--A person commits a misdemeanor of the second degree if the person:

(1) Knowingly or intentionally releases, publishes or otherwise makes available the information from the program for purposes other than those specified in ~~section 8~~ SECTIONS 8 AND 9. <--

(2) Obtains or attempts to obtain information from the program for purposes other than those specified in ~~section 8~~ SECTIONS 8 AND 9 or by misrepresentation or fraud. <--

(b) Criminal violations.--Each violation under subsection (a) shall constitute a separate offense.

(c) Civil violations.--

(1) Knowing, intentional and negligent release or use of information from the program shall be subject to a civil penalty of not less than $2,500 for each offense.

(2) Other civil penalties shall be assessed in accordance with department regulations.

(d) Collection of penalties.--The department shall be

entitled to reasonable attorney fees and costs for successful collection actions and may:

(1) Collect any penalty imposed under this section and which is not paid by bringing an action in the court of common pleas of the county in which the person owing the debt resides or in the county where the department is located.

(2) Seek legal assistance from the Attorney General, the county or the district attorney of the county in which the action is brought to collect the penalty.

(e) Additional sanctions.--A prescriber or dispenser violating provisions of this act shall also be subject to sanctions under the prescriber's or dispenser's professional practice acts and by the appropriate licensing boards.

Section 11. Program funding.

(a) General rule.--The department may use the money deposited in the General Fund and appropriated to the department to carry out the requirements of this act.

(b) Civil penalties.--All civil penalties assessed under this act shall be deposited in the General Fund and appropriated to the department to implement the program.

(c) Data fees.--All costs associated with recording and submitting data shall be assumed by the submitting dispenser.

(d) Other funding opportunities.--The board may direct the department to pursue Federal funding and grants, both public and private.

(e) Fees prohibited.--A dispenser or prescriber shall not be required to pay a fee or tax specifically dedicated to the establishment, operation or maintenance of the program.

(f) Transfer of funds.--Any funds currently appropriated shall be redirected and used for the operation of the program.

Additional agencies utilizing the system, including licensing boards, may also transfer funds to the department for operation of the program.

Section 12. Admissibility.

(a) Use of data.--Except as provided in subsection (b), data provided to, maintained in or accessed from the program that may be identified to, or with a particular individual is not subject to discovery, subpoena or similar compulsory process in any civil, judicial, administrative or legislative proceeding, nor shall any individual or organization with lawful access to the data be compelled to testify with regard to the data.

(b) Exceptions.--The restrictions in subsection (a) do not apply to:

(1) a criminal proceeding; or

(2) a civil, judicial or administrative action brought to enforce the provisions of this act.

Section 13. Annual report.

Within two years of the effective date of this act and annually thereafter, the board shall submit a report to the General Assembly. The report shall also be made available on the department's publicly accessible Internet website and shall include all of the following:

(1) The number of times the program has been legally and illegally accessed.

(2) The rate by which prescribers are utilizing the program.

(3) Any impact on prescribing practices for controlled substances.

(4) The cost effectiveness of the frequency of data submission.

(5) The effectiveness of the interoperability with other states and electronic medical records.

(6) Other information as determined by the board.

Section 14. Regulations.

The department shall promulgate regulations to implement the provisions of this act.

Section 15. Concurrent jurisdiction.

The Attorney General shall have concurrent prosecutorial jurisdiction with the county district attorney for violations of this act.

Section 16. Effective date.

This act shall take effect as follows:

(1) Section 4 of the act shall take effect in 90 days.

(2) This section shall take effect immediately.

(3) The remainder of this act shall take effect June 30, 2015.