

No. 2014-191

AN ACT

SB 1180

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.

TABLE OF CONTENTS

- Section 1. Short title.
- Section 2. Purpose.
- Section 3. Definitions.
- Section 4. ABC-MAP Board.
- Section 5. Powers and duties of board.
- Section 6. Establishment of program.
- Section 7. Requirements for dispensers and pharmacies.
- Section 8. Requirements for prescribers.
- Section 9. Access to prescription information.
- Section 10. Unlawful acts and penalties.
- Section 11. Program funding.
- Section 12. Annual reports.
- Section 13. Regulations.
- Section 14. Concurrent jurisdiction.
- Section 39. Expiration.
- Section 40. Effective date.

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 prescription medication history 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 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 licensed health care facility if the quantity of controlled substances dispensed is limited to an amount adequate to treat the patient for a maximum of five days and does not allow for a refill.

(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.

"Pharmacy." As defined in the act of September 27, 1961 (P.L.1700, No.699), known as the Pharmacy Act.

"Prescriber." A person who is licensed, registered or otherwise lawfully authorized to distribute, dispense or 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) established in section 6.

"System." The program's electronic prescription monitoring system with a database component.

Section 4. ABC-MAP Board.

(a) Creation.—The ABC-MAP Board is created in the Department of Health.

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

- (1) The Secretary of Health, who shall serve as chairperson.
- (2) The Secretary of Human Services.
- (3) The Secretary of Drug and Alcohol Programs.
- (4) The Secretary of State.
- (5) The Insurance Commissioner.
- (6) The Secretary of Aging.
- (7) The Commissioner of the 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 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 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.

(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 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.

Section 6. Establishment of program.

(a) General rule.—The board shall establish and oversee the program. The department shall administer the program by performing budgetary, accounting, procurement and other support services as directed by the board.

(b) Program components.—The program shall:

(1) Provide an electronic system of controlled substances prescribed and dispensed in this Commonwealth.

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

(3) Provide an accessible Internet website¹ where a patient may electronically request or download a form to request a copy of the patient's program record.

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

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

(c) System queries.—The program shall maintain a record of system queries that contains all of the following:

(1) The identity of each person who requests or receives information from the system.

(2) The information provided to each person who requests or receives information from the system.

(3) The date and time the information is requested and provided.

(d) Record retention.—The board shall remove from the system all identifying information more than seven 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 unless required to do so by court order.

(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. Any data that has been reported to the Office of Attorney General pursuant to 28 Pa. Code § 25.131 (relating to

¹"an accessible website" in enrolled bill.

every dispensing practitioner) that satisfies the retention requirements of subsection (d) shall be transferred to the program.

Section 7. Requirements for dispensers and pharmacies.

(a) **Submission.**—A dispenser or pharmacy shall, according to the format determined by the board, electronically submit information to the system regarding each controlled substance dispensed.

(b) **Data elements.**—All of the following information shall be provided by a dispenser or pharmacy:

- (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.

(c) **Frequency.**—A dispenser or pharmacy shall submit all information required under subsection (b) to the system no later than 72 hours after dispensing a controlled substance.

(d) **Dispenser designee.**—Dispensers may designate other pharmacy employees for purposes of accessing the system according to standards established by the board.

Section 8. Requirements for prescribers.

(a) **System query.**—A prescriber shall query the system:

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

(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 system 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 system.

(c) **Prescriber designee.**—Prescribers may designate employees for purposes of accessing the system 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, in the exercise of sound 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 system prior to prescribing or dispensing so long as the prescriber or dispenser is otherwise in compliance.

(e) **Immunity.**—A prescriber or dispenser who has submitted or received information from the system in accordance with this section and section 7,

and has held the information in confidence as required by section 9, shall not be held civilly liable or disciplined in a licensing board action for submitting the information or not seeking or obtaining information from the system prior to prescribing or dispensing a controlled substance.

Section 9. Access to prescription information.

(a) Confidentiality.—Except as set forth in subsection (b), prescription information submitted to the system and records of requests to query the system 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 system according to procedures determined by the board and with the following limitations:

- (1) Prescribers may query the system for:
 - (i) an existing patient; and
 - (ii) prescriptions written using the prescriber's own Drug Enforcement Agency number.
- (2) Dispensers may query the system for a current patient to whom the dispenser is dispensing or considering dispensing any controlled substance.
- (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.
- (ii) Data obtained by a law enforcement agency under this paragraph shall only be used to establish probable cause to obtain a search warrant or arrest warrant.
- (iii) Requests made to the Office of Attorney General to query the system under this paragraph shall be made in a form or manner prescribed by the Office of Attorney General and shall include the court order, when applicable. Each individual designee of the Office of Attorney General shall have a unique identifier when accessing the system.

(4) The Office of Attorney General shall query the system on behalf of a grand jury investigating a criminal violation of a law governing controlled substances.

(5) Approved department personnel may query the system 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) Designated Commonwealth personnel who are responsible for the development and evaluation of quality improvement strategies, program integrity initiatives or conducting internal compliance reviews and data reporting for the medical assistance program, Children's Health Insurance Program (CHIP), Pharmaceutical Assistance Contract for the Elderly (PACE) or Pharmaceutical Assistance Contract for the Elderly Needs Enhancement Tier (PACENET).

(8) Personnel from the Department of Drug and Alcohol Programs engaged in the administration of the Methadone Death and Incident Review Team.

(9) A medical examiner or county coroner for the purpose of investigating the death of the individual whose record is being queried.

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

(11) Upon providing evidence of identity and within 30 days from the date of the request, an individual who is the recipient of a controlled substance prescription entered into the system, the individual's parent or guardian if the individual is under 18 years of age or the individual's health care power of attorney.

(c) Access for active investigation.—In the case where a law enforcement agency has accessed the system for an active investigation, the information about that query shall be withheld from the individual subject to the query for a period of six months after the conclusion of the investigation.

Section 10. Unlawful acts and penalties.

(a) Unlawful acts.—

(1) A person commits a misdemeanor of the first degree if the person knowingly or intentionally obtains or attempts to obtain information from the system for purposes other than those specified in section 8 or 9 or by misrepresentation or fraud.

(2) A person commits a felony of the third degree if the person knowingly or intentionally releases, publishes, sells, transfers or otherwise makes available or attempts to release, publish, sell, transfer or

otherwise make available the information from the system for purposes other than those specified in sections 8 and 9.

(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 system 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 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. No fee shall be assessed to the patient by the dispenser or prescriber due to the need to submit information to the system.

(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. Annual reports.

(a) Board 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 system has been legally and illegally accessed.

(2) The rate at which prescribers are utilizing the system.

(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) The number of law enforcement accesses via section 9(b)(3) and the number of search warrants issued as a result.

(7) Other information as determined by the board.

(b) Other report.—Within two years of the effective date of this act and annually thereafter, the Office of Attorney General, in conjunction with law enforcement, shall submit an annual report to the General Assembly.

Section 13. Regulations.

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

Section 14. Concurrent jurisdiction.

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

Section 39. Expiration.

This act shall expire June 30, 2022.

Section 40. Effective date.

This act shall take effect as follows:

(1) Section 4 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.

APPROVED—The 27th day of October, A.D. 2014

TOM CORBETT