



# HOUSE COMMITTEE ON APPROPRIATIONS

## FISCAL NOTE

SENATE BILL NO. 1180

PRINTERS NO. 2370

PRIME SPONSOR: Vance

### COST / (SAVINGS)

FUND	FY 2014/15	FY 2015/16
General Fund	See Fiscal Impact	See Fiscal Impact

**SUMMARY:** Senate Bill 1180, Printer's Number 2370, the Achieving Better Care by Monitoring All Prescriptions Program (ABC-MAP) Act, creates the ABC-MAP in the Department of Health (DOH) for the purpose of improving patient care. The ABC-MAP will consist of an electronic data system that includes Schedule II through Schedule V controlled substances that are prescribed and dispensed in the Commonwealth.

**ANALYSIS:** This legislation creates the ABC-MAP Board for the purpose of establishing and overseeing the program and consisting of the following individuals or their designees:

- Secretary of Health
- Secretary of Human Services
- Secretary of Drug and Alcohol Programs
- Secretary of State
- Insurance Commissioner
- Secretary of Aging
- Commissioner of the State Police
- Attorney General
- Physician General, if the Secretary of Health is not a physician

Board members will serve for the duration of their elected or appointed position and will meet at least once a year for the purpose of assessing the costs and benefits of the program.

The board shall have the following responsibilities:

- Evaluate and secure a vendor of an electronic prescription monitoring system
- Appoint an advisory group not to exceed 12 members
- 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 ABC-MAP.
- Phase in an enforcement process so that prescribers and dispensers have adequate time to transition.
- Develop policies and procedures to accomplish the following:

- Require more frequent reporting should technology permit and there is little or no fiscal impact to the Commonwealth or those required to report
- Evaluate the information in the ABC-MAP system
- Allowed for authorized DOH personnel to conduct internal reviews, analyze and interpret data
- Safeguard the release of information to authorized users and DOH personnel and ensure the privacy and confidentiality of patients and patient information
- Aid prescribers in identifying at-risk individuals and referring them to drug addiction treatment professionals and programs
- Establish professionally developed criteria that generate referrals 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 for a dispenser or prescriber which appears to deviate from the clinical standard
- Provide training to prescribers and dispensers on the use of the system
- Assist professional organizations whose members prescribe, monitor or treat patients or dispense controlled substances to develop educational programs including identification of those at risk for controlled substance abuse and referral and treatment options for patients
- Permit individuals employed by prescribers, pharmacies and dispensers to query the system so long as each individual has a unique identifier when accessing the system
- Keep pace with technological advances
- Evaluate the costs and benefits of the program
- Convene an advisory group at least annually
- Direct DOH to operate and maintain the program on a daily basis
- Review the program for the purpose of compiling statistics, research, educational materials and outreach
- 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

The board shall establish and oversee and DOH shall administer the ABC-MAP program by performing budgetary, accounting, procurement and other support services as directed by the board. This program shall:

- Provide an electronic data system of controlled substances prescribed and dispensed in PA
- Be easily accessible by prescribers, dispensers and patients
- Provide an accessible website, where a patient may electronically request or download a form to request a copy of the patient's program record
- Provide training and support for those using the data system
- Contain processes for prescribers to refer patients to substance abuse treatment
- Maintain a record of database queries that contains:
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- The identity of each person who requests or receives information from the database
- The information provided to each person
- Date and time the information is requested and provided

The board shall remove all identifying information more than seven years old from the system unless retention is requested by a law enforcement agency or a professional licensing or certification agency or board for prescribers or dispensers has submitted a written request to DOH for retention of specific information for cause. DOH may not grant more than two one-year extensions unless required to do so by court order. The program shall also allow for dispensers and prescribers who are unable to submit data electronically to do so manually.

Current pharmacy reporting requirements to the Office of Attorney General (OAG) shall expire and shall no longer be enforceable upon the full implementation of the program. Any data that have been reported to the OAG that satisfies the retention requirements shall be transferred to the ABC-MAP.

**Dispenser and Pharmacy Requirements:**

According to the format determined by the board, a dispenser or pharmacy shall electronically submit information to the system regarding each controlled substance dispensed. All of the following shall be provided by a dispenser:

- Full name of the prescriber
- Prescriber's Drug Enforcement Agency (DEA) registration number
- Date prescription was written
- Date prescription was dispensed
- Full name, date of birth, gender and address of the person for whom the prescription was written and dispensed
- The National Drug Code
- Days' supply
- DEA registration number and National Provider Identifier of the dispenser or pharmacy
- Method of payment for the prescription

A dispenser or pharmacy shall submit all information to the program no later than 72 hours after dispensing a controlled substance. Dispensers may designate other pharmacy employees for the purpose of accessing the system to standards established by the board.

**Prescriber Requirements:**

A prescriber shall query the system:

- For each patient the first time the patient is prescribed a controlled substance by the prescriber; or
- If a prescriber believes or has reason to believe, using sound clinical judgment, that a patient may be abusing or diverting drugs

- A prescriber shall indicate the information obtained from the system in the patient's medical record if:
  - The individual is a new patient; or
  - The prescriber determines a drug should not be prescribed or furnished to a patient based upon the information from the system

**Prescriber/Dispenser Immunity:**

A prescriber or dispenser who has submitted or received information from the program in accordance with program requirements and has held the information in confidence 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.

**Access to Data:**

Information in the ABC-MAP system is not subject to the Right to Know Law (Act 3 of 2004).

The following individuals may access the ABC-MAP system under the following circumstance:

- Prescribers may query the system for the following:
  - An existing patient
  - Prescriptions written using the prescriber's DEA number
- Dispensers may query the system for a current patient to whom the dispenser is dispensing or considering dispensing any controlled substance
- The OAG shall query the system on behalf of all law enforcement agencies, including the OAG and Federal, State, and local law enforcement agencies for:
  - Schedule II controlled substances
  - All other schedules upon receipt of a court order obtained by the requesting law enforcement agency. Data obtained by a law enforcement agency shall only be used to establish probable cause to obtain a search or arrest warrant
  - On behalf of the grand jury investigating a criminal violation of a law governing controlled substances

Each OAG designee must have a unique identifier when accessing the system
- Medical Examiners or Coroners for the purpose of investigating the death of an individual whose record is being queried
- Upon providing evidence of identity and within 30 days from receipt, an individual who is the recipient of a prescription for a controlled substance entered into the system or the parent or guardian if the individual is under 18 or the individual's power-of-attorney
- DOH personnel in the following instances:
  - Conducting internal reviews related to controlled substance laws; or
  - Engaging in the analysis of controlled substance prescription information as part of the assigned duties and responsibilities of employment.
- Licensing boards and agencies

- Representatives from PA or out-of-State agencies or boards 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
- Designated Commonwealth personnel who are responsible for the development and evaluation of quality improvement strategies, program integrity initiatives, or conducting internal compliant reviews and data reporting for CHIP, PACE or PACENET
- Personnel from the Department of Drug and Alcohol Programs engaged in the administration of the Methadone Death and Incident Review Team
- A prescription drug monitoring official, dispenser or prescriber of a state with which PA has an interoperability agreement.

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

**Unlawful Acts and Penalties:**

- Unlawful Acts
  - Misdemeanor of the 1st degree if an individual knowingly or intentionally obtains or attempts to obtain information from the system for purposes other than those specified
  - Felony of the 3rd degree if an individual knowingly or intentionally releases, publishes, sells, transfers or otherwise makes available the information from the system for purposes other than those specified, or attempts to do so
- Civil violations
  - Knowing, intentional and negligent release or use of information from the program is subject to a civil penalty of not less than \$2,500 per offense
- Other civil penalties shall be assessed in accordance with DOH regulations
- Sanctions by the licensing board of the prescriber/dispenser

**Funding:**

To carry out the requirements of this act, DOH may use money from the General Fund appropriated to them. Additionally, all civil penalties assessed under this act shall be deposited in the General Fund and appropriated to DOH.

All costs associated with recording and submitting data shall be assumed by the submitting dispenser. Dispensers and prescribers shall not be required to pay a fee or tax specifically dedicated to the establishment, operation or maintenance of the program; and no fees shall be assessed to patients by dispensers/prescribers due to the need to submit information to the program.

**Annual Reports:**

The initial report is due within two years of the effective date of this act; reports are due annually thereafter. The ABC-MAP Board shall submit the annual report to the General Assembly and make the report available on DOH's publicly accessible website. Information required in the report is:

- Number of times the system has been accessed legally and illegally.
- The rate at which prescribers are utilizing the system.
- Any impact on prescribing controlled substances.
- The cost effectiveness of the frequency of data submission.
- The effectiveness of the interoperability with other states and electronic medical records.
- The number of law enforcement accesses and the number of search warrants as a result
- Other information as determined by the ABC-MAP Board.

Within two years of the effective date of this act and annually thereafter, the OAG in conjunction with law enforcement shall submit an annual report to the General Assembly.

Effective date: The section regarding organization and meetings of the board will take effect in 90 days; the remainder of the act will take effect June 30, 2015. This act expires June 30, 2022.

**FISCAL IMPACT:** This legislation prohibits a fee or tax dedicated to establishing, operating or maintaining the ABC-MAP system, therefore all costs will be paid by the General Fund. There is also the potential to utilize federal Justice Assistance Grants funding to offset General Fund costs.

Based on information from the Department of Health and reviewing cost information from other states, the estimated first-year cost to the department could range from \$1,100,000 to \$2,100,000 depending on the amount of customization required for the implementation of the database system. Ongoing annual costs for staffing, system operation, maintenance and training are estimated to range from \$600,000 to \$1,000,000. These costs will be offset by a reduction in the OAG's budget of approximately \$120,000 per year when ABC-MAP is operational and the OAG's existing database is discontinued.

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**DATE:** October 8, 2014

*Estimates are calculated using the best information available. Actual costs and revenue impact incurred may vary from estimates.*