THE GENERAL ASSEMBLY OF PENNSYLVANIA

SENATE BILL

No. 423

Session of 2013

INTRODUCED BY WARD, MENSCH, WAUGH, SOLOBAY, RAFFERTY, WOZNIAK AND BROWNE, MARCH 6, 2013

REFERRED TO PUBLIC HEALTH AND WELFARE, MARCH 6, 2013

AN ACT

Amending Title 44 (Law and Justice) of the Pennsylvania Consolidated Statutes, establishing the Prescription Drug 2 Monitoring Program; providing for powers and duties of the 3 Department of Drug and Alcohol Programs; and imposing 4 penalties. 5 6 The General Assembly of the Commonwealth of Pennsylvania 7 hereby enacts as follows: 8 Section 1. Title 44 of the Pennsylvania Consolidated Statutes is amended by adding a chapter to read: CHAPTER 27 10 11 PRESCRIPTION DRUG MONITORING PROGRAM 12 Sec. 13 2701. Scope of chapter. 14 2702. Definitions. 15 2703. Prescription Drug Monitoring Program. 16 2704. Requirements for monitoring system. 17 2705. Access to prescription information.

2706. Unlawful acts and penalties.

2707. Education and treatment.

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- 1 2708. Immunity.
- 2 2709. Additional provisions.
- 3 2710. Use of money collected.
- 4 <u>2711. Rules and regulations.</u>
- 5 <u>2712</u>. Evaluation, data analysis and reporting.
- 6 2713. Concurrent jurisdiction.
- 7 <u>§ 2701</u>. Scope of chapter.
- 8 This chapter relates to prescription drug monitoring.
- 9 § 2702. Definitions.
- The following words and phrases when used in this chapter
- 11 shall have the meanings given to them in this section unless the
- 12 context clearly indicates otherwise:
- 13 "Active investigation." An investigation that is being
- 14 conducted with a reasonable good faith belief that it could lead
- 15 to the filing of administrative, civil or criminal proceedings
- 16 or that is ongoing and continuing and for which there is a
- 17 reasonable good faith anticipation of securing an arrest or
- 18 prosecution in the forseeable future.
- 19 "Alcohol and other drug addiction treatment program." Any
- 20 facility or treatment program that is licensed by the
- 21 Commonwealth to provide alcohol and other drug addiction
- 22 treatment on a hospital, nonhospital residential or outpatient
- 23 basis.
- 24 "Controlled substance." A drug, substance or immediate
- 25 precursor included in Schedule II, III, IV or V of the act of
- 26 April 14, 1972 (P.L.233, No.64), known as The Controlled
- 27 <u>Substance, Drug, Device and Cosmetic Act, or the Controlled</u>
- 28 Substances Act (Public Law 91-513, 84 Stat. 1236).
- "Department." The Department of Drug and Alcohol Programs of
- 30 the Commonwealth.

- 1 "Dispense." To deliver a controlled substance, other drug or
- 2 device to an ultimate user by or pursuant to the lawful order of
- 3 <u>a practitioner.</u>
- 4 "Dispenser." A practitioner who dispenses in this
- 5 Commonwealth, including mail order and Internet sales of
- 6 pharmaceuticals. The term does not include any of the following:
- 7 (1) A licensed health care facility or long-term care
- 8 pharmacy that distributes the controlled substance, other
- 9 <u>drug or device for the purpose of inpatient hospital or long-</u>
- 10 term care facility administration.
- 11 (2) A practitioner or other authorized person who
- 12 <u>administers a controlled substance, other drug or device.</u>
- 13 (3) A wholesale distributor of a controlled substance.
- 14 (4) A hospice care provider.
- 15 (5) A medical practitioner at a health care facility
- licensed by this Commonwealth if the quantity of controlled
- 17 substances dispensed is limited to an amount adequate to
- 18 treat the patient for a maximum of 24 hours with not more
- 19 than two 24-hour cycles within any 15-day period.
- "Internet pharmacy." A person, entity or Internet website,
- 21 whether in the United States or abroad, that knowingly or
- 22 intentionally delivers, distributes or dispenses, or offers or
- 23 attempts to deliver, distribute or dispense, a controlled
- 24 substance by means of the Internet, including a pharmacy.
- 25 "Licensed health care facility." A health care facility that
- 26 is licensed under Article X of the act of June 13, 1967 (P.L.
- 27 31, No.21), known as the Public Welfare Code, or the act of July
- 28 19, 1979 (P.L.130, No.48), known as the Health Care Facilities
- 29 Act.
- 30 "Monitoring program." The Prescription Drug Monitoring

- 1 Program established in section 2703 (relating to Prescription
- 2 <u>Drug Monitoring Program</u>).
- 3 "Monitoring system." The monitoring program database
- 4 established and maintained under section 2704(c) (relating to
- 5 <u>requirements for monitoring system).</u>
- 6 "Practitioner." The term includes:
- 7 (1) A physician, dentist, veterinarian, pharmacist,
- 8 <u>podiatrist, physician assistant, certified registered nurse</u>
- 9 <u>practitioner or other person licensed, registered or</u>
- 10 <u>otherwise permitted to distribute, dispense or to administer</u>
- 11 <u>a controlled substance, other drug or device in the course of</u>
- 12 <u>professional practice or research in this Commonwealth.</u>
- 13 (2) A pharmacy, hospital, clinic or other institution
- licensed, registered or otherwise permitted to distribute,
- dispense, conduct research with respect to or to administer a
- 16 controlled substance, other drug or device in the course of
- 17 professional practice or research in this Commonwealth.
- 18 "Ultimate user." A person who lawfully possesses a
- 19 controlled substance, other drug, device or cosmetic for the
- 20 person's own use or for the use of a member of the person's
- 21 household or for administering to an animal in the person's
- 22 <u>care.</u>
- 23 § 2703. Prescription Drug Monitoring Program.
- 24 (a) General rule. -- The department shall establish and
- 25 <u>administer the Prescription Drug Monitoring Program for</u>
- 26 identifying controlled substances that are dispensed within this
- 27 Commonwealth by a practitioner or dispenser, including, but not
- 28 limited to, a practitioner or dispenser that dispenses to a
- 29 person or ships to an address within this Commonwealth.
- 30 (b) Data compliance. -- Data required by this section shall be

- 1 submitted in compliance with this section to the department by a
- 2 pharmacy or other dispensing entity.
- 3 (c) Registration. -- Each dispenser and practitioner
- 4 <u>dispensing or prescribing controlled substances shall register</u>
- 5 with and establish a user name and personal identification
- 6 number that permits access to the secure Internet website
- 7 housing the monitoring system.
- 8 (d) Practitioner queries. -- A practitioner may query data
- 9 through the department.
- 10 (e) Law enforcement queries. -- A Federal or State law
- 11 enforcement official whose duties include enforcing laws
- 12 relating to controlled substances and prescription drugs shall
- 13 be provided access to the information from the monitoring system
- 14 relating to the person who is the subject of an active
- 15 investigation of:
- 16 (1) A drug abuse offense, including, but not limited to,
- 17 violations of the act of April 14, 1972 (P.L.233, No.64),
- 18 known as The Controlled Substance, Drug, Device and Cosmetic
- 19 Act.
- 20 <u>(2) Insurance fraud.</u>
- 21 (3) Medicare fraud.
- 22 (4) Medicaid fraud.
- 23 § 2704. Requirements for monitoring system.
- 24 (a) Submission. -- The dispenser shall, regarding each
- 25 controlled substance dispensed, submit by electronic means to
- 26 the department the following information using methods of
- 27 <u>transmission protocols and in a format established by the</u>
- 28 department:
- 29 (1) Full name of the prescribing practitioner.
- 30 (2) Prescriber Drug Enforcement Agency (DEA)

- 1 registration number.
- 2 (3) Date the prescription was written.
- 3 <u>(4) Date the prescription was dispensed.</u>
- 4 (5) Full name, date of birth, gender and address of the
- 5 person for whom the prescription was written and dispensed.
- 6 (6) Name of the controlled substance.
- 7 (7) Quantity of the controlled substance prescribed.
- 8 (8) Strength of the controlled substance.
- 9 (9) Quantity of the controlled substance dispensed.
- 10 (10) Dosage quantity and frequency prescribed.
- 11 (11) Name of the pharmacy or other entity dispensing the
- 12 <u>controlled substance.</u>
- 13 (12) Dispensing entity's DEA registration number and
- National Provider Identifier (NPI).
- 15 (13) Source of payment for the prescription.
- 16 (14) Other relevant information as established by
- department regulations.
- (b) Frequency. -- Each dispenser shall submit the information
- 19 required by this chapter as frequently as specified by the
- 20 department, but not later than seven days after the dispensing
- 21 of a controlled substance identified by the monitoring program.
- 22 The department shall implement a real-time reporting requirement
- 23 as expeditiously as possible.
- 24 (c) Database. -- The department shall establish and maintain a
- 25 monitoring system in an electronic file or by other means
- 26 established by the department to facilitate use of the
- 27 <u>monitoring program database.</u>
- 28 (d) Recordkeeping. -- The department shall maintain a record
- 29 of the monitoring system queries for reference, including:
- 30 (1) Identification of each person who requests or

- 1 <u>receives information from the monitoring system.</u>
- 2 (2) The information provided to each person.
- 3 (3) The date and time the information is requested and
- 4 provided.
- 5 (e) Expungement. -- The department shall remove from the
- 6 monitoring system all identifying information more than six
- 7 years old from the date of collection. The information shall
- 8 then be destroyed unless a law enforcement agency or a
- 9 professional licensing or certification agency or board for
- 10 prescribers or dispensers has submitted a written request to the
- 11 <u>department for retention of specific information. All requests</u>
- 12 <u>shall comply with procedures adopted by the department.</u>
- 13 <u>§ 2705</u>. Access to prescription information.
- 14 (a) General rule. -- Except as set forth in subsection (c),
- 15 prescription information submitted to the department and records
- 16 of requests to query the data shall be confidential and not
- 17 subject to disclosure under the act of February 14, 2008 (P.L.6,
- 18 No.3), known as the Right-to-Know Law.
- 19 (b) Privacy procedures. -- The department shall maintain
- 20 procedures to ensure that the privacy and confidentiality of
- 21 patients and patient information collected, recorded,
- 22 <u>transmitted and maintained is not disclosed to persons except</u>
- 23 those enumerated in subsection (c).
- 24 (c) Limited availability. -- The department shall make
- 25 <u>information in the monitoring system available only to the</u>
- 26 following persons and in accordance with department regulations:
- 27 (1) Personnel of the department specifically assigned to
- 28 conduct internal reviews related to controlled substance laws
- 29 under the jurisdiction of the department.
- 30 (2) Authorized department personnel engaged in analysis

of controlled substance prescription information as a part of the assigned duties and responsibilities of their employment.

3 (3) Qualified personnel for the purpose of bona fide

research or education. Data elements that would reasonably identify a specific recipient, prescriber or dispenser shall

be deleted or redacted from the information prior to

disclosure. Release of the information shall only be made

pursuant to a written agreement between the qualified

personnel and the department in order to ensure compliance

with this chapter.

- (4) A practitioner or a representative employed by the practitioner, designated by the practitioner pursuant to criteria established by the department, having authority to prescribe controlled substances to the extent that the information relates to a current patient of the practitioner to whom the practitioner is prescribing or considering prescribing any controlled substance.
- (5) A pharmacist or a designee employed by the pharmacist, designated by the pharmacist pursuant to criteria established by the department, having authority to dispense controlled substances to the extent the information relates specifically to a current patient to whom that pharmacist is dispensing or considering dispensing any controlled substance.
 - (6) A designated representative from the Commonwealth or an out-of-State agency or board responsible for licensing or certifying prescribers or dispensers who is involved in an active investigation of a prescriber or dispenser whose professional practice was or is regulated by that agency or board.

- 1 (7) A medical examiner or county coroner for the purpose
- of investigating the death of an individual.
- 3 (8) A designated prescription monitoring official of a
- 4 <u>state with which this Commonwealth has an interoperability</u>
- 5 <u>agreement who may access prescription drug monitoring</u>
- 6 information in accordance with the provisions of this chapter
- and procedures adopted by the department.
- 8 (9) An individual who is the recipient of a controlled
- 9 <u>substance prescription entered into the monitoring system</u>
- 10 upon providing evidence satisfactory to the monitoring system
- 11 manager that the individual requesting the information is in
- fact the person about whom the data entry was made.
- 13 (10) The Office of Attorney General or the equivalent
- law enforcement officer of another state to the extent
- 15 necessary for an active investigation of a criminal violation
- of law governing controlled substances.
- 17 (d) Dispenser access. -- No person may knowingly hinder a
- 18 practitioner who dispenses who is eligible to receive
- 19 information from the monitoring system from requesting and
- 20 receiving the information in a timely fashion.
- 21 § 2706. Unlawful acts and penalties.
- 22 (a) Prohibition. -- A person may not knowingly and
- 23 intentionally use, release, publish or otherwise make available
- 24 any information obtained from the monitoring system for any
- 25 purpose other than those specified in section 2705(c) (relating
- 26 to access to prescription information).
- 27 (b) Penalty. -- A person who violates subsection (a):
- 28 (1) Is subject to a civil penalty of not less than
- \$5,000 for each violation.
- 30 (2) Commits a felony of the third degree.

- 1 (c) Misrepresentation or fraud. -- Any person who obtains or
- 2 attempts to obtain information from the monitoring system by
- 3 misrepresentation or fraud commits a felony of the third degree.
- 4 (d) Unauthorized purpose. -- Any person who obtains or
- 5 <u>attempts to obtain information from the monitoring system for a</u>
- 6 purpose other than a purpose authorized by this chapter or by
- 7 <u>department regulations commits a felony of the third degree.</u>
- 8 (e) Civil violation. -- The procedure for determining a civil
- 9 <u>violation of this section shall be in accordance with department</u>
- 10 regulations. Civil penalties assessed under this section shall
- 11 be:
- 12 (1) Deposited in the General Fund.
- 13 (2) Appropriated to the department.
- 14 (3) Dedicated to the monitoring program.
- 15 (f) Failure to submit. -- The failure of a dispenser to submit
- 16 information to the monitoring system as required under this
- 17 chapter, after the department has submitted a specific written
- 18 request for the information or when the department determines
- 19 the dispenser has a demonstrable pattern of failure to submit
- 20 the information as required, is grounds for the appropriate
- 21 licensing board to take the following action in accordance with
- 22 the appropriate licensing act:
- 23 (1) Prohibit an Internet pharmacy from conducting
- business in this Commonwealth.
- 25 (2) Refuse to issue a license to the individual.
- 26 (3) Refuse to renew the individual's license.
- 27 (4) Revoke, suspend, restrict or place on probation the
- license.
- 29 (5) Issue a public or private reprimand to the
- 30 individual.

- 1 (6) Issue a cease and desist order.
- 2 (7) Impose a civil penalty of not more than \$1,000 for
- 3 <u>each failure to submit information required by this chapter.</u>
- 4 § 2707. Education and treatment.
- 5 <u>(a) General rule. -- The department shall:</u>
- 6 (1) Assist the appropriate agency, board or association
- 7 <u>for each category of authorized user in this chapter to</u>
- 8 <u>incorporate the appropriate information regarding the</u>
- 9 <u>monitoring program into the training, education or</u>
- instruction provided to each category of authorized user.
- 11 (2) Assist the State or regional chapter of the American
- 12 <u>Society of Addiction Medicine, the Pennsylvania Medical</u>
- Society, the Pennsylvania Academy of Family Physicians and
- 14 <u>the Pennsylvania Coalition of Nurse Practitioners to develop</u>
- a continuing education course for health care professionals
- on prescribing practices, pharmacology and identification,
- 17 referral and treatment of patients addicted to or abusing
- 18 controlled substances identified by the monitoring program.
- 19 (3) Implement or assist other appropriate agencies to
- implement an educational program to inform the public about
- 21 the use, diversion and abuse of, addiction to and treatment
- for the addiction to the controlled substances identified by
- 23 the monitoring program, including the nature and scope of the
- 24 program.
- 25 (b) Referral.--The department shall refer prescribers and
- 26 dispensers it has reason to believe may be impaired to the
- 27 appropriate professional licensing or certification agency and
- 28 to the appropriate impaired professionals associations to
- 29 provide intervention, assessment and referral to alcohol and
- 30 other drug addiction treatment programs and ongoing monitoring

- 1 and follow-up.
- 2 (c) Identification. -- The department shall work with the
- 3 patient's individual practitioner and the appropriate alcohol
- 4 and other drug addiction treatment professionals to provide that
- 5 patients identified through the monitoring system as potentially
- 6 addicted to a controlled substance are assessed and referred to
- 7 <u>alcohol and other drug addiction treatment programs.</u>
- 8 <u>§ 2708. Immunity.</u>
- 9 <u>An individual who has submitted to or received information</u>
- 10 from the monitoring system in accordance with this chapter may
- 11 not be held civilly liable or disciplined in a licensing board
- 12 <u>action for having submitted the information or for not seeking</u>
- 13 or obtaining information from the monitoring program prior to
- 14 prescribing or dispensing a controlled substance to a patient.
- 15 § 2709. Additional provisions.
- 16 (a) Funding. -- A practitioner shall not be required to pay a
- 17 fee or tax specifically dedicated to establishment, operation or
- 18 maintenance of the monitoring program.
- 19 (b) Costs.--All costs associated with recording and
- 20 submitting data as required in this chapter shall be assumed by
- 21 the submitting dispenser.
- 22 (c) Use of data. -- Except as provided in subsection (d), data
- 23 provided to, maintained in or accessed from the monitoring
- 24 system that may be identified to or with a particular person is
- 25 not subject to discovery, subpoena or similar compulsory process
- 26 in any civil, judicial, administrative or legislative
- 27 proceeding, nor shall any individual or organization with lawful
- 28 access to the data be compelled to testify with regard to the
- 29 <u>data.</u>
- 30 (d) Exceptions. -- The restrictions in subsection (c) do not

- 1 apply to:
- 2 (1) A criminal proceeding.
- 3 (2) A civil, judicial or administrative action brought
- 4 <u>to enforce this chapter.</u>
- 5 § 2710. Use of money collected.
- 6 (a) General rule. -- The department may use the moneys
- 7 <u>deposited in the General Fund and appropriated to the department</u>
- 8 for the following purposes:
- 9 <u>(1) Maintenance and replacement of monitoring system</u>
- 10 equipment, including hardware and software.
- 11 <u>(2) Training of staff.</u>
- 12 (3) Pursuit of grants and matching funds.
- 13 (b) Collections. -- The department may collect any penalty
- 14 <u>imposed under section 2706</u> (relating to unlawful acts and
- 15 penalties) and which is not paid by bringing an action in the
- 16 court of common pleas of the county in which the person owing
- 17 the debt resides or in the county where the department is
- 18 located.
- 19 (c) Legal assistance. -- The department may seek legal
- 20 assistance from the Attorney General or the county or district
- 21 attorney of the county in which the action is brought to collect
- 22 the fine.
- 23 (d) Attorney fees and costs.--The court shall award
- 24 reasonable attorney fees and costs to the department for
- 25 successful collection actions under section 2706.
- 26 § 2711. Rules and regulations.
- 27 The department shall promulgate rules and regulations setting
- 28 forth the procedures and methods for implementing this chapter.
- 29 At a minimum, the rules and regulations shall include the
- 30 following:

- 1 (1) Effectively enforce the limitations on access to the
- 2 <u>monitoring system prescribed in section 2705 (relating to</u>
- 3 <u>access to prescription information).</u>
- 4 (2) Establish standards and procedures to ensure
- 5 <u>accurate identification of individuals requesting information</u>
- 6 <u>or receiving information from the monitoring system.</u>
- 7 (3) Allow adequate time following implementation of this
- 8 <u>chapter for dispensers and practitioners to make the changes</u>
- 9 <u>to their operational systems necessary to comply with this</u>
- 10 chapter.
- 11 (4) Allow for dispensers to have ease of transition to
- 12 <u>comply with the requirements of the monitoring system.</u>
- 13 (5) Not place an undue burden on law enforcement seeking
- information related to an investigation.
- 15 (6) Provide that dispensers and practitioners licensed
- to practice in this Commonwealth shall not be held liable for
- failure to comply with monitoring system requirements until
- 18 all changes are fully operational and dispensers and
- 19 <u>practitioners have had adequate time to make necessary</u>
- 20 adjustments to operating systems and to receive training to
- 21 fully accommodate the changes upon promulgation of the
- 22 regulations, but not later than one year after the effective
- 23 date of this chapter.
- 24 (7) Provide that dispensers who can show good cause for
- 25 <u>not submitting data electronically may be authorized to</u>
- 26 submit data manually if they lack Internet access.
- 27 § 2712. Evaluation, data analysis and reporting.
- 28 (a) General rule. -- The department shall design and implement
- 29 an evaluation component to identify:
- 30 (1) Cost benefits of the monitoring program.

1	(2) The impact on efforts to reduce misuse, abuse,
2	overdose and diversion of or addiction to controlled
3	substances.
4	(3) The impact on prescribing practices for controlled
5	substances.
6	(4) The number of patients identified through the
7	monitoring system as potentially addicted to a controlled
8	substance that were assessed for alcohol and other drug
9	addictions.
10	(5) The number of patients in paragraph (4) that
11	received alcohol and other drug addiction treatment and the
12	names of the licensed alcohol and other drug addiction
13	treatment facilities in which the patients were treated.
14	(6) The progress made in implementing real-time
15	reporting.
16	(7) Other information relevant to policy, research and
17	education involving controlled substances and drugs of
18	concern identified by the monitoring program.
19	(b) Annual report The department shall annually report the
20	information specified in subsection (a) to the Public Health and
21	Welfare Committee of the Senate and the Human Services Committee
22	of the House of Representatives. Additionally, the department
23	shall make the annual report available to the public on its
24	publicly accessible Internet website.
25	§ 2713. Concurrent jurisdiction.
26	The Attorney General shall have concurrent prosecutorial
27	jurisdiction with the county district attorney for violations of
28	this chapter. No person charged with a violation of this chapter

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authority of the Attorney General to prosecute the case and, if

by the Attorney General shall have standing to challenge the

- 1 <u>a challenge is made, the challenge shall be dismissed, and no</u>
- 2 relief shall be available in the courts of this Commonwealth to
- 3 the person making the challenge.
- 4 Section 2. The provisions of this act are severable. If any
- 5 provision of this act or its application to any person or
- 6 circumstance is held invalid, the invalidity shall not affect
- 7 other provisions or applications of this act which can be given
- 8 effect without the invalid provision or application.
- 9 Section 3. This act shall take effect in 60 days.