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THE GENERAL ASSEMBLY OF PENNSYLVANIA

HOUSE BILL

No. 317 Session of 2013

INTRODUCED BY DiGIROLAMO, MICOZZIE, GINGRICH, KORTZ, FABRIZIO, BAKER, HAHN, DAVIS, DAVIDSON, WHITE, WATSON, KULA, GROVE, V. BROWN, HESS, R. BROWN, BROWNLEE, SANTARSIERO, CALTAGIRONE, PETRI, CLYMER, DeLUCA, GIBBONS, MILLER, MURT, KINSEY, FARRY, FREEMAN, NEUMAN AND HEFFLEY, JANUARY 24, 2013

AS REPORTED FROM COMMITTEE ON HUMAN SERVICES, HOUSE OF REPRESENTATIVES, AS AMENDED, FEBRUARY 12, 2013

AN ACT

Amending Title 44 (Law and Justice) of the Pennsylvania Consolidated Statutes, establishing the Pharmaceutical Accountability Monitoring System; and imposing penalties.

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

Section 1. Title 44 of the Pennsylvania Consolidated Statutes is amended by adding a chapter to read:

CHAPTER 27

PHARMACEUTICAL ACCOUNTABILITY MONITORING SYSTEM

Sec.

§ 2701. Short title of chapter.

This chapter shall be known and may be cited as the Pharmaceutical Accountability Monitoring System Act.

§ 2702. Purpose.

The purpose of this chapter is to reduce the abuse of controlled substances and fraud by providing a tool that will ensure that practitioners making prescribing decisions have complete and reliable information about what, if any, other prescription drugs have recently been prescribed to their patients. It is the purpose of this act to provide reporting mechanisms, with full confidentiality protections, in which dispensers report prescription information to a central repository, in order to identify ultimate user and practitioner behaviors that give rise to a reasonable suspicion that prescription drugs are being inappropriately obtained or prescribed, so that appropriate ameliorative and corrective action, including treatment for individuals suffering from drug and alcohol addiction, may be taken. This chapter is further

intended to help detect, refer to law enforcement and regulatory agencies and deter prescription drug fraud and diversion.

§ 2703. Scope of chapter.

This chapter is intended to improve the Commonwealth's ability to enable informed and responsible prescribing and dispensing of controlled substances and to reduce diversion and misuse of such drugs in an efficient and cost-effective manner that will not impede the appropriate medical utilization of licit controlled substances.

§ 2704. Definitions.

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

"Active investigation." An investigation that is being conducted with a reasonable good faith belief that it could lead to the filing of administrative, civil or criminal proceedings, or that is ongoing and continuing and for which there is a reasonable good faith anticipation of securing an arrest or prosecution in the foreseeable future.

"Alcohol and other drug addiction treatment program." Any facility or treatment program that is licensed by the Commonwealth to provide alcohol and other drug addiction treatment on a hospital, nonhospital residential or outpatient basis.

"ASAP." THE AMERICAN SOCIETY FOR AUTOMATION IN PHARMACY. <--

"Controlled substance." A drug, substance or immediate precursor included in Schedule II, III, IV or V of 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).

"Database." The Pharmaceutical Accountability Monitoring System established in section 2706 (relating to establishment of Pharmaceutical Accountability Monitoring System).

"Department." The Department of Drug and Alcohol Programs.

"Dispense." To deliver a controlled substance, other drug or device to an ultimate user by or pursuant to the lawful order of a practitioner.

"Dispenser." A practitioner who dispenses 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 or long-term care pharmacy that distributes such substances for the purpose of inpatient hospital, long-term care facility administration or licensed life provider.

(2) A practitioner or other authorized person who administers such a substance.

(3) A wholesale distributor of a controlled substance.

(4) A hospice care provider.

(5) A medical practitioner 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.

"Dispensing veterinarian." A veterinarian who dispenses in this Commonwealth.

"Internet pharmacy." A person, entity or Internet site, whether in the United States or abroad, that knowingly or intentionally delivers, distributes or dispenses, or offers or attempts to deliver, distribute or dispense, a controlled substance by means of the Internet, including a pharmacy.

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

"Mail-order pharmacy." A pharmacy that dispenses controlled substances using the United States Postal Service or any express delivery service.

"NDC." THE NATIONAL DRUG CODE. <--

"PAMS." The Pharmaceutical Accountability Monitoring System established in section 2706 (relating to establishment of Pharmaceutical Accountability Monitoring System).

"Practitioner." The term shall mean:

(1) a physician, dentist, pharmacist, podiatrist, physician assistant, certified registered nurse practitioner, dispensing veterinarian or other person licensed, registered or otherwise permitted to distribute, dispense or to administer a controlled substance, other drug or device in the course of professional practice or research in this Commonwealth; or

(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 controlled substance, other drug or device in the course of professional practice or research in this Commonwealth.

"Ultimate user." A person who lawfully possesses a controlled substance, other drug, device or cosmetic for his own use or for the use of a member of his household or for

administering to an animal in his care.

§ 2705. Advisory committee.

(a) Establishment.--An advisory committee is established to provide input and advice to the department regarding the establishment and maintenance of PAMS, including, but not limited to:

(1) Use of PAMS to improve patient care, to identify and address addiction and to facilitate the goal of reducing misuse, abuse, overdose, addiction to and diversion of controlled substances and drugs of concern.

(2) Safeguards for the release of information to authorized users.

(3) The confidentiality of prescription monitoring information and the integrity of the patient's relationship with the patient's health care provider.

(4) Development of criteria for referring prescription monitoring information to a law enforcement or professional licensing agency.

(5) Development of criteria for referring a prescriber, dispensing veterinarian or dispenser to a professional licensing agency or impaired professionals association.

(6) The design and implementation of training, education or instruction.

(7) The provision of assessment and referral to alcohol and other drug addiction treatment as part of any other requirements of this chapter.

(8) Technical standards for electronic reporting of prescription monitoring information.

(9) Technological improvements to facilitate the interoperability of PAMS with other State prescription drug

monitoring programs and electronic health information systems and to facilitate prescribers' and dispensers' access to and use of PAMS.

(10) Proper analysis and interpretation of prescription monitoring information.

(11) Design and implementation of an evaluation component.

(12) Recommended appointments to the advisory committee.

(b) Confidentiality.--For the purpose of providing input and advice pursuant to subsection (a), no advisory committee member shall receive prescription monitoring information which identifies, or could reasonably be used to identify, the patient, prescriber, dispensing veterinarian, dispenser or other person who is the subject of the information.

(c) Membership.--

(1) The department shall establish an advisory committee comprised of the following:

(i) A representative recommended by the Department of State representing the State Board of Medicine, the State Board of Nursing and the State Board of Veterinary Medicine.

(ii) A representative recommended by the State Board of Pharmacy.

(iii) A representative recommended by the Attorney General.

(iv) Two physicians recommended by the Pennsylvania Medical Society, one of whom holds membership in the American Society of Addiction Medicine and the other who is a physician with expertise in chronic pain management and treatment.

(v) A representative recommended by the Pennsylvania District Attorneys Association.

(vi) A representative recommended by the Pennsylvania Coroners Association.

(vii) A representative recommended by the Drug and Alcohol Service Providers Organization of Pennsylvania.

(viii) A representative of chronic pain patients recommended by a physician with expertise in chronic pain management.

(ix) A representative of veterinary medicine with dispensing practice recommended by the Pennsylvania Veterinary Medical Association.

(2) The department may also appoint persons with recognized expertise, knowledge and experience in the establishment and maintenance of prescription monitoring programs, skills and expertise in alcohol and other drug addiction assessment and referral to addiction treatment or issues involving the misuse, abuse or diversion of, or the addiction to, controlled substances or drugs of concern.

(d) Quorum.--Nine members of the advisory committee shall constitute a quorum for the transaction of all business. The members shall elect a chairman and such other officers as deemed necessary whose duties shall be established by the advisory committee. The department shall convene the advisory committee at least quarterly using telecommunication whenever possible.

(e) Staff assistance.--The department shall provide the advisory committee with any staff services which may be necessary for the advisory committee to carry out its duties under this chapter.

§ 2706. Establishment of Pharmaceutical Accountability

Monitoring System.

(a) General rule.--The department shall establish and administer the Pharmaceutical Accountability Monitoring System (PAMS) for monitoring all controlled substances that are dispensed within this Commonwealth by all practitioners, dispensing veterinarians or dispensers, including, but not limited to, a practitioner, dispensing veterinarian or dispenser that dispenses to a person or ships to an address within this Commonwealth.

(b) Data compliance.--Data required by this section shall be submitted in compliance with this section to the department by the pharmacy or other dispensing entity.

(c) Registration.--Each dispenser and practitioner dispensing or prescribing controlled substances shall register with and establish a user name and personal identification number that permits access to the secure website housing PAMS established by this chapter.

§ 2707. Requirements for Pharmaceutical Accountability Monitoring System.

(a) Submission.--The dispenser shall, regarding each controlled substance dispensed, submit by electronic means to the department the following information using methods of transmission protocols and in a format established by the department:

(1) Full name of the prescribing practitioner.

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

(3) Date the prescription was written.

(4) Date the prescription was dispensed.

(5) Full name, date of birth, gender and address of the

person for whom the prescription was written and dispensed.

~~(6) Name of the controlled substance.~~ <--

~~(7) Quantity of the controlled substance prescribed.~~

~~(8) Strength of the controlled substance.~~

~~(9) Quantity of the controlled substance dispensed.~~

(6) THE NDC. <--

~~(10)~~ (7) Dosage quantity and frequency prescribed. <--

~~(11)~~ (8) Name of the pharmacy or other entity dispensing the controlled substance. <--

~~(12)~~ (9) Dispensing entity's DEA registration number and NPI. <--

~~(13)~~ (10) Source of payment for the prescription. <--

~~(14)~~ (11) Other relevant information as established by department regulations. <--

(b) Veterinary dispensers.--The dispensing veterinarian shall, regarding each controlled substance dispensed, submit by electronic mail to the department the following information:

(1) Pet's name.

(2) Owner's name.

(3) Pet's or owner's address.

(4) Practice's name.

(5) Dispensing veterinarian's name.

(6) DEA license number.

(7) Date the prescription was written.

(8) Date the prescription was dispensed.

(9) Name of the controlled substance.

(10) Quantity and strength of the medication.

(11) Dosage and frequency of the medication.

(c) Frequency.--

(1) Each dispenser shall submit the information required

by this chapter not later than seven days after the dispensing of a controlled substance monitored by PAMS. The department shall implement a real-time reporting requirement as expeditiously as possible.

(2) Each dispensing veterinarian shall submit the information required by this chapter within six months of dispensing a controlled substance monitored by PAMS to the department.

(d) Maintenance.--The department shall maintain PAMS in an electronic file or by other means established by the department to facilitate use of the database.

(e) Recordkeeping.--The department shall maintain a record of PAMS queries for reference, including:

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

(2) The information provided to each person.

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

(f) Expungement.--The department shall remove from PAMS all identifying information more than six years old from the date of collection. Such information shall then 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. All requests shall comply with procedures adopted by the department.

§ 2708. Access to prescription information.

(a) General rule.--Except as set forth in subsection (c), prescription information submitted to the department 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) Privacy procedures.--The department shall maintain procedures to ensure that the privacy and confidentiality of patients and patient information collected, recorded, transmitted and maintained is not disclosed to persons except those enumerated in subsection (d).

(c) Queries.--

(1) THE MOST CURRENT VERSION OF THE ASAP PRESCRIPTION MONITORING PROGRAM WEB SERVICE STANDARD SHALL BE USED. <--

~~(1)~~ (2) A practitioner may query the data for an existing patient. <--

~~(2)~~ (3) A practitioner may query the data for prescriptions written using his or her own DEA number. <--

~~(3)~~ (4) A Federal or State law enforcement official whose duties include enforcing laws relating to controlled substances and prescription drugs shall be provided access to the information from PAMS relating to the person who is the subject of an active investigation of a drug abuse offense, including, but not limited to, violations of the act of April 14, 1972 (P.L.233, No.64), known as The Controlled Substance, Drug, Device and Cosmetic Act, insurance fraud, medicare fraud or medicaid fraud pursuant to an active investigation. <--

(d) Limited availability.--The department shall make information in PAMS available only to the following persons and in accordance with department regulations:

(1) Personnel of the department specifically assigned to conduct internal reviews related to controlled substances laws under the jurisdiction of the department.

(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) Qualified personnel for the purpose of bona fide research or education. Data elements that would reasonably identify a specific recipient, prescriber, dispensing veterinarian or dispenser shall be deleted or redacted from such information prior to disclosure. Release of the information shall only be made pursuant to a written agreement between such qualified personnel and the department in order to ensure compliance with this chapter.

(4) A practitioner, dispensing veterinarian 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 or dispensing veterinarian to whom the practitioner or dispensing veterinarian 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 out-of-State agency or board responsible for licensing or certifying prescribers, dispensing veterinarians or dispensers who is involved in a bona fide investigation of a

prescriber, dispensing veterinarian or dispenser whose professional practice was or is regulated by that agency or board.

(7) A medical examiner or county coroner for the purpose of investigating the death of an individual.

(8) A designated prescription monitoring official of a state with which this Commonwealth has an interoperability agreement may access prescription monitoring information in accordance with the provisions of this chapter and procedures adopted by the department.

(9) An individual who is the recipient of a controlled substance prescription entered into PAMS upon providing evidence satisfactory to the PAMS manager that the individual requesting the information is in fact the person about whom the data entry was made.

(10) The Office of Attorney General of Pennsylvania or the equivalent law enforcement officer of another state may access information from the PAMS for an active investigation of a criminal violation of law governing controlled substances.

(11) Authorized personnel of the Department of Public Welfare engaged in the administration of the medical assistance program.

(e) Dispenser access.--No person shall knowingly hinder a pharmacist, dispensing veterinarian or practitioner who dispenses who is eligible to receive information from PAMS from requesting and receiving such information in a timely fashion.

§ 2709. Unlawful acts and penalties.

(a) Knowing and intentional release or use.--A person may not knowingly and intentionally use, release, publish or

otherwise make available any information obtained from PAMS for any purpose other than those specified in section 2708(c) (relating to access to prescription information). A person who does knowingly and intentionally release or use information from PAMS that is not authorized in section 2708(c) commits a felony of the third degree and is subject to a civil penalty of not less than $5,000, or shall be sentenced to imprisonment of not more than 90 days, or both, for each offense.

(b) Misrepresentation or fraud.--Any person who obtains or attempts to obtain information from PAMS by misrepresentation or fraud commits a felony of the third degree.

(c) Unauthorized purpose.--Any person who obtains or attempts to obtain information from PAMS for a purpose other than a purpose authorized by this section or by department regulations commits a felony of the third degree.

(d) Civil violation.--The procedure for determining a civil violation of this subsection shall be in accordance with department regulations. Civil penalties assessed under this subsection shall be deposited in the General Fund, appropriated to the department and dedicated to the controlled substance PAMS operations.

(e) Failure to submit.--The failure of a dispenser or dispensing veterinarian to submit information to PAMS as required under this section, after the department has submitted a specific written request for the information or when the department determines the individual has a demonstrable pattern of knowing that failure to submit the information as required, is grounds for the appropriate licensing board to take the following action in accordance with the appropriate licensing act.

(1) Prohibit an Internet pharmacy from conducting business in this Commonwealth.

(2) Refuse to issue a license to the individual.

(3) Refuse to renew the individual's license.

(4) Revoke, suspend, restrict or place on probation the license.

(5) Issue a public or private reprimand to the individual.

(6) Issue a cease and desist order.

(7) Impose a civil penalty of not more than $1,000 for each failure to submit information required by this act.

§ 2710. Education and treatment.

(a) General rule.--With the input and advice of the advisory committee, the department shall:

(1) assist the appropriate agency, board or association for each category of authorized user in this act to incorporate the appropriate information regarding PAMS into the training, education or instruction provided to each category of authorized user;

(2) assist the State or regional chapter of the American Society of Addiction Medicine, the Pennsylvania Medical Society, the Pennsylvania Veterinary Medical Association, the Pennsylvania Academy of Family Physicians and the Pennsylvania Coalition of Nurse Practitioners to develop a continuing education course for health care professionals on prescribing practices, pharmacology and identification, referral and treatment of patients addicted to or abusing controlled substances monitored by PAMS; and

(3) implement, or assist other appropriate agencies to implement, an educational program to inform the public about

the use, diversion and abuse of, addiction to and treatment for the addiction to the controlled substances monitored by PAMS, including the nature and scope of PAMS.

(b) Referral.--With the input and advice of the advisory committee, the department shall refer prescribers, dispensing veterinarians and dispensers it has reason to believe may be impaired to the appropriate professional licensing or certification agency, and to the appropriate impaired professionals associations, to provide intervention, assessment and referral to alcohol and other drug addiction treatment programs, and ongoing monitoring and follow-up.

(c) Identification.--With the input and advice of the advisory committee, the department shall work with the patient's individual practitioner and the appropriate alcohol and other drug addiction treatment professionals to provide that patients identified through PAMS as potentially addicted to a controlled substance are assessed and referred to alcohol and other drug addiction treatment programs.

§ 2711. Immunity.

An individual who has submitted to or received information from PAMS in accordance with section 2706 (relating to establishment of Pharmaceutical Accountability Monitoring System) may not be held civilly liable or disciplined in a licensing board action for having submitted the information or for not seeking or obtaining information from the prescription monitoring program prior to prescribing or dispensing a controlled substance to an ultimate user.

§ 2712. Additional provisions.

(a) Funding.--A practitioner or a pharmacist shall not be required to pay a fee or tax specifically dedicated to

establishment, operation or maintenance of the system.

(b) Costs.--All costs associated with recording and submitting data as required in this section shall be assumed by the submitting dispenser.

(c) Use of data.--Except as provided in subsection (d), data provided to, maintained in or accessed from PAMS that may be identified to, or with, a particular person 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.

(d) Exceptions.--The restrictions in subsection (c) do not apply to:

(1) A criminal proceeding.

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

§ 2713. Use of money collected.

(a) General rule.--The department may use the moneys deposited in the General Fund and appropriated to the department for the following purposes:

(1) Maintenance and replacement of PAMS equipment, including hardware and software.

(2) Training of staff.

(3) Pursuit of grants and matching funds.

(b) Collections.--The department may collect any penalty imposed under section 2709 (relating to unlawful acts and penalties) 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.

(c) Legal assistance.--The department may seek legal assistance from the Attorney General or the county or district attorney of the county in which the action is brought to collect the fine.

(d) Attorney fees and costs.--The court shall award reasonable attorney fees and costs to the department for successful collection actions under section 2709.

§ 2714. Rules and regulations.

The department shall promulgate rules and regulations setting forth the procedures and methods for implementing this chapter. At a minimum, the rules and regulations shall include the following:

(1) Effectively enforce the limitations on access to PAMS prescribed in section 2708 (relating to access to prescription information).

(2) Establish standards and procedures to ensure accurate identification of individuals requesting information or receiving information from PAMS.

(3) Allow adequate time following implementation of this chapter for dispensers, dispensing veterinarians and practitioners to make the changes to their operational systems necessary to comply with this chapter.

(4) Allow for dispensers and dispensing veterinarians to have ease of transition to comply with the requirements of the Pharmaceutical Accountability Monitoring System.

(5) Not place an undue burden on law enforcement seeking information related to an investigation.

(6) Dispensers, dispensing veterinarians and practitioners licensed to practice in this Commonwealth shall not be held liable for failure to comply with PAMS

requirements until all changes are fully operational and dispensers, dispensing veterinarians and practitioners have had adequate time to make necessary adjustments to operating systems and to receive training to fully accommodate such changes upon promulgation of the regulations, but not later than one year after the effective date of this chapter.

(7) Dispensers and dispensing veterinarians who can show good cause for not submitting data electronically may be authorized to submit data manually if they lack Internet access.

§ 2715. Evaluation, data analysis and reporting.

(a) General rule.--The department shall design and implement an evaluation component to identify:

(1) cost benefits of PAMS;

(2) the impact on efforts to reduce misuse, abuse, overdose and diversion of, or addiction to, controlled substances;

(3) the impact on prescribing practices for controlled substances;

(4) the number of ultimate users identified through PAMS as potentially addicted to a controlled substance that were assessed for alcohol and other drug addictions;

(5) the number of ultimate users in paragraph (4) that received alcohol and other drug addiction treatment and the names of the licensed alcohol and other drug addiction treatment facilities in which the ultimate users were treated;

(6) the progress made in implementing real-time reporting; and

(7) other information relevant to policy, research and

education involving controlled substances and drugs of concern monitored by PAMS.

(b) Annual report.--The department shall annually report the information specified in subsection (a) to the Public Health and Welfare Committee of the Senate, the Human Services Committee of the House of Representatives, the United States Department of Justice, the Substance Abuse and Mental Health Services Administration of the Office of National Drug Control Policy and members of Pennsylvania's United States Congressional delegation. Additionally, the department shall make the annual report available to the public on its publicly accessible Internet website.

§ 2716. Concurrent jurisdiction.

The Attorney General shall have concurrent prosecutorial jurisdiction with the county district attorney for violations of this chapter. No person charged with a violation of this chapter by the Attorney General shall have standing to challenge the authority of the Attorney General to prosecute the case and, if any such challenge is made, the challenge shall be dismissed and no relief shall be available in the courts of this Commonwealth to the person making the challenge.

Section 2. The provisions of this act are severable. If any provision of this act or its application to any person or circumstance is held invalid, the invalidity shall not affect other provisions or applications of this act which can be given effect without the invalid provision or application.

Section 3. This act shall take effect in 60 days.