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THE GENERAL ASSEMBLY OF PENNSYLVANIA

HOUSE BILL

No. 1651 Session of 2011

INTRODUCED BY DiGIROLAMO, COHEN, BAKER, BISHOP, BOYD, BRENNAN, R. BROWN, CALTAGIRONE, CLYMER, DAVIS, J. EVANS, GEIST, GINGRICH, GROVE, HAHN, HARHAI, HARKINS, HEFFLEY, HELM, HENNESSEY, HESS, HORNAMAN, KILLION, KOTIK, KULA, MANN, MICOZZIE, MURPHY, MURT, MYERS, PYLE, QUINN, REICHLEY, SAYLOR, SCAVELLO, CULVER, K. SMITH, TAYLOR, THOMAS AND VULAKOVICH, JUNE 8, 2011

REFERRED TO COMMITTEE ON HUMAN SERVICES, JUNE 8, 2011

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.
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§ 2701. Short title of chapter.

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

§ 2702. 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.

§ 2703. 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:

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

"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 2704 (relating to establishment of Pharmaceutical Accountability Monitoring System).

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

"Dispenser." A provider who dispenses a scheduled drug to a patient in this Commonwealth but 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 or long-term care facility administration.

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

(3) A wholesale distributor of a scheduled drug.

(4) A hospice care provider.

"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.

"PAMS." The Pharmaceutical Accountability Monitoring System established in section 2704.

"Patient." The person who has lawfully obtained and who possesses any scheduled drug for the person's own use.

"Practitioner." The term shall mean:

(1) a physician, osteopath, dentist, veterinarian, pharmacist, podiatrist, nurse, scientific investigator or

other person 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; 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.

§ 2704. Establishment of Pharmaceutical Accountability Monitoring System.

(a) General rule.--The department shall establish and maintain an electronic system for monitoring all scheduled drugs that are dispensed within this Commonwealth by all professionals licensed to prescribe or dispense such substances in this Commonwealth, including, but not limited to, a practitioner or pharmacist or dispensed to an address within this Commonwealth by a pharmacy that has obtained a license, permit or other authorization to operate by the Pennsylvania Board of Pharmacy.

(b) Duties of department.--The department shall administer PAMS.

(c) Purpose.--The purpose of PAMS is to contain data as described in this section regarding every prescription for a controlled substance dispensed in this Commonwealth to any person other than an inpatient in a licensed health care facility or by a hospice care provider.

(d) 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.

(e) Data input.--A dispenser shall input data as required by the department.

(f) Queries.--A practitioner may query such data.

(g) Registration.--Each dispenser and practitioner licensed to practice in this Commonwealth shall register with and establish a user name and personal identification number that permits access to the secure website housing PAMS established by this act.

(h) Dispenser access.--Each dispenser required to report electronically pursuant to this act shall have online access to PAMS at all times when the dispenser provides pharmaceutical care to a patient potentially receiving a controlled substance.

§ 2705. 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 by transmission methods, 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) Patient information of the person for whom the prescription was written and dispensed, including full name, date of birth, gender and address.

(6) Positive identification of the person receiving the prescription, including the type of identification.

(7) Name of the controlled substance.

(8) Quantity of the controlled substance prescribed.

(9) Strength of the controlled substance.

(10) Quantity of the controlled substance dispensed.

(11) Dosage quantity and frequency prescribed.

(12) Name of the pharmacy or other entity dispensing the controlled substance.

(13) Name of the pharmacist dispensing the controlled substance.

(14) Dispensing entity's DEA registration number and NPI.

(15) Source of payment for the prescription.

(16) Other relevant information as established by department regulations.

(b) Frequency.--Each dispenser shall submit the information required by this act as frequently as specified by the department, but not later than two days after the dispensing of a controlled substance monitored by PAMS. The department shall implement a real-time reporting requirement as expeditiously as possible.

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

(1) Prescribing and dispensing practices and patterns for controlled substances.

(2) An individual patient's patterns of obtaining controlled substances from licensed practitioners and who subsequently obtain dispensed controlled substances from a drug outlet in quantities or with a frequency inconsistent with generally recognized standards of dosage for that controlled substance.

(3) Individuals presenting forged or otherwise false or altered prescriptions for controlled substances to a pharmacy.

(d) 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 or provided.

§ 2706. Access to prescription information.

(a) General rule.--Except as set forth in subsection (c), prescription information submitted to the department 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 (c).

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

(1) Personnel of the department specifically assigned to conduct investigations 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 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 licensed 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 of one of the following:

(i) The information relates to a current patient of the practitioner to whom the practitioner is prescribing or considering prescribing any controlled substance.

(ii) The information relates specifically to an individual who has access to the practitioner's DEA number, and the practitioner suspects that the individual may use the practitioner's DEA identification number to fraudulently acquire or prescribe controlled substances.

(iii) The information relates to the practitioner's own prescribing practices, except when specifically prohibited by department regulations.

(5) A licensed 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) Federal or State law enforcement authorities engaged in the administration, investigation or enforcement of the laws governing controlled substances and who are involved in one of the following:

(i) A bona fide specific drug-related investigation involving a designated person.

(ii) Investigating insurance fraud, Medicaid fraud or Medicare fraud.

(7) A designated representative from the Commonwealth or out-of-State agency or board responsible for licensing or certifying prescribers or dispensers who is involved in a bona fide investigation of a prescriber or dispenser whose professional practice was or is regulated by that agency or board.

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

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

(10) 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.

(11) A judicial authority under grand jury subpoena or court order or equivalent judicial process for investigation of a criminal violation of law governing controlled substances may access prescription monitoring information.

§ 2707. Unlawful acts and penalties.

(a) Knowing and intentional release.--Any person who knowingly and intentionally releases any information in PAMS in violation of the limitations under section 2706(c) (relating to access to prescription information) commits a felony of the third degree.

(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) Other person.--A person may not knowingly and intentionally use, release, publish or otherwise make available to any other person or entity any information obtained from PAMS for any purpose other than those specified in section 2706(c). Each separate violation of this subsection is a felony of the third degree and is subject to a civil penalty not to exceed $5,000.

(e) 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.

(f) Failure to submit.--The failure of a dispenser 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 pharmacy board to take the following action in accordance with the act of September 27, 1961 (P.L.1700, No.699), known as the Pharmacy Act.

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

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

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

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

(5) Issue a cease and desist order.

(6) Impose a civil penalty of not more than $1,000 for each dispensed prescription for which the required information was not submitted.

(g) A person authorized to have prescription monitoring information under this act who knowingly uses such information in violation of this act shall, upon conviction, be fined not less than $5,000, be sentenced to imprisonment of not more than 90 days, or both, for each offense.

§ 2708. Education and treatment.

(a) General rule.--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, or comparable association in this Commonwealth, and the medical society 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.

(b) Referral.--The department shall refer prescribers 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.--The department shall work with 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.

§ 2709. Immunity.

An individual who has submitted information to PAMS in accordance with this section may not be held civilly liable for having submitted the information.

§ 2710. 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 pharmacy.

(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.

§ 2711. 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 2707 (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 2707.

§ 2712. 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 2706 (relating to access to prescription information).

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

§ 2713. 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 patients identified through PAMS as potentially addicted to a controlled substance that were assessed for alcohol and other drug addictions;

(5) the number of patients in paragraph (4) that

received alcohol and other drug addiction treatment and the names of the licensed, certified or approved alcohol and other drug addiction treatment facilities in which the patients 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.

§ 2714. Severability.

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 2. This act shall take effect in 60 days.