AMENDMENTS TO HOUSE BILL NO. 1694

Sponsor: REPRESENTATIVE BAKER

Printer's No. 2353

Amend Bill, page 1, lines 9 through 18; pages 2 through 23, lines 1 through 30; page 24, lines 1 through 18, by striking out all of said lines on said pages and inserting

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 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 suspicion 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 suspicion of securing an arrest or prosecution in the foreseeable future.

"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).

"Continuing care provider." A facility licensed by the Department of Insurance under the act of June 18, 1984 (P.L.391, No.82), known as the Continuing-Care Provider Registration and Disclosure Act.

"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) The use of such substances on the order of a practitioner for the purpose of treating patients who are inpatient at a licensed hospital, a licensed ambulatory care facility, a continuing care provider or a licensed long-term care nursing facility.

(2) A licensed provider under the LIFE program.

(3) 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.

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

(5) A wholesale distributor of a controlled substance.

(6) A hospice care provider in the course of providing hospice care.

(7) 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 addiction treatment program." An alcohol and other drug addiction treatment program licensed by the department.

"Licensed health care facility." A health care facility that is licensed under the act of July 19, 1979 (P.L.130, No.48), known as the Health Care Facilities Act, or a personal care home or assisted living residence that is licensed under Article X of the act of June 13, 1967 (P.L.31, No.21), known as the Public Welfare Code.

"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.

"NPI." The National Provider Identifier.

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

"Practitioner." The term shall mean:

(1) a physician, dentist, pharmacist, podiatrist, physician assistant, certified registered nurse practitioner, optometrist, 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) The 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 persons authorized to access PAMS in accordance with section 2708 (relating to access to PAMS information).

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

(4) The development of criteria for referring prescription monitoring information to a professional licensing agency.

(5) The development of criteria for referring a practitioner 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) The development of technical standards for electronic reporting of prescription monitoring information.

(9) The maintenance of technological improvements to facilitate the interoperability of PAMS with other State prescription drug monitoring programs and electronic health information systems and to facilitate practitioners' access to and use of PAMS.

(10) The proper analysis and interpretation of prescription monitoring information.

(11) The 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 ultimate use or practitioner who is the subject of the information. Notwithstanding any other law to the contrary, any and all meetings of the PAMS advisory committee are to be

considered confidential and closed to the public. Members and staff shall maintain strict standards of confidentiality in the handling of all matters before the advisory committee. In addition, all relevant Federal and State laws regarding patient privacy and confidentiality will be adhered to. All material and information, regardless of form, medium or method of communication provided to or acquired by an advisory committee member or staff in the course of the advisory committee's work, shall be regarded as confidential information, shall not be disclosed and are not public records. In addition, all material and information, regardless of form, medium or method of communication, made or generated by a member of department staff in the course of the advisory committee's work, shall be regarded as confidential information and shall not be disclosed and are deemed not to be a public record. All necessary steps shall be taken by members and staff to safeguard the confidentiality of such material or information in conformance with Federal and State law.

(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 physician who is a member of the Pennsylvania Psychiatric Society specializing in addiction psychiatry.

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

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

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

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

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

(xi) A representative of pharmacies recommended by the Pennsylvania Association of Chain Drug Stores.

(xii) A representative of pharmacies recommended by

the Pennsylvania Pharmacists' Association.

(xiii) A representative recommended by the Pennsylvania State Nurses Association.

(2) The department may also seek input from 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.

(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.--With the input and advice of the advisory committee, the department shall establish and administer the Pharmaceutical Accountability Monitoring System (PAMS) for monitoring all controlled substances that are dispensed by dispensers or dispensing veterinarians within this Commonwealth, including, but not limited to, those dispensed to a person or shipped to an address within this Commonwealth. The system shall comply with the Health Insurance Portability and Accountability Act of 1996 (Public Law 104-191, 110 Stat. 1936) as it pertains to protected health information(PHI) and electronic protected health information (EPHI), as well as all other relevant Federal and State privacy and security laws and regulations.

(b) Disclosure.--Each practitioner shall disclose to all persons for whom a controlled substance is prescribed that the identifying prescription information will be entered into the PAMS when the controlled substance is dispensed and may be accessed only for limited purposes by specified individuals.

(c) 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.

(d) Registration.--Each dispenser, practitioner and person designated by each dispenser and practitioner in accordance with section 2707(d) (relating to requirements for Pharmaceutical Accountability Monitoring System) 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, using the most current version of the ASAP prescription monitoring program web service standard, 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 patient for whom the prescription was written and dispensed.

(6) The NDC.

(7) Quantity and days' supply.

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

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

(10) Source of payment for the prescription.

At the start up of the program, the most current version of the ASAP prescription monitoring program standard shall be used and updates are only required when substantive changes are made to the standard.

(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 seventy-two hours 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.

(4) In the event that a request was made by the Office of Attorney General on behalf of Federal or State law enforcement officials, the name shall be listed as "OAG" so the names of law enforcement officials remain confidential.

(f) Expungement.--The department shall remove from PAMS all information identifying the ultimate user or practitioner 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 PAMS information.

(a) General rule.--All information entered into the database or otherwise 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.--

(1) The department shall maintain procedures to ensure that the privacy and confidentiality of patients and patient information collected, recorded, entered, transmitted and maintained is not disclosed to persons except those enumerated in subsections (e) and (f).

(2) All transmissions of data under this section shall comply with relevant Federal and State privacy and security laws and regulations.

(c) Investigations.--The department shall not disclose the existence of an active investigation.

(d) Database queries.--In addition to the department:

(1) A practitioner may query the database for the following information about an existing patient:

(i) A practitioner or one person employed, designated and supervised by a practitioner pursuant to criteria established by the department 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.

(ii) A pharmacist or designated pharmacy associate under the supervision of 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.

(2) A practitioner may query the database for prescriptions written using his or her own Drug Enforcement Agency number.

(e) Information.--Upon written request, in the manner and form required by the department, information contained in PAMS shall be made available by the department only to the following persons and in accordance with department regulations:

(1) Authorized personnel of the department who are specifically assigned to conduct internal reviews related to controlled substances laws under the jurisdiction of the department.

(2) Authorized personnel of the department who are engaged in analysis of controlled substance prescription information as a part of the assigned duties and responsibilities of their employment.

(3) Researchers for the purpose of bona fide research or education. All information that would identify the ultimate user or practitioner 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 researcher and the department in order to ensure compliance with this chapter.

(4) A designated representative from the Commonwealth or out-of-State agency or board responsible for licensing or certifying practitioners 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.

(5) A coroner for the purpose of investigating the death of an individual.

(6) 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.

(7) An individual about whom information has been entered into PAMS upon providing evidence satisfactory to the department that the individual requesting the information is in fact the person about whom the data entry was made.

(8) Authorized personnel of the Department of Public Welfare engaged in the administration of the medical assistance program, authorized personnel of the Insurance Department engaged in the administration of the Children's Health Insurance Program (CHIP) and authorized personnel of the Department of Aging engaged in the administration of the Pharmaceutical Assistance Contract for the Elderly program.

(f) Dispenser access.--No person shall knowingly hinder a practitioner who is eligible to receive information from PAMS from requesting and receiving such information in a timely

fashion.

(g) Law enforcement access.--

(1) The Office of Attorney General shall submit requests for information from PAMS to the department on behalf of all law enforcement agencies, including, but not limited to, the Office of Attorney General and Federal, State and local law enforcement agencies, as well as an Attorney General or similar official from another state. The department shall provide the Office of Attorney General access to information as follows:

(i) Upon request of the Office of Attorney General, the department shall provide information from PAMS in relation to a controlled substance on Schedule II of the act of April 14, 1972 (P.L.233, No.64), known as The Controlled Substance, Drug, Device and Cosmetic Act.

(ii) If the Attorney General determines that information in PAMS is relevant to an active investigation, upon request of the Office of Attorney General, the department shall provide the office access to information from PAMS in relation to a controlled substance on Schedules III, IV and V of The Controlled Substance, Drug, Device and Cosmetic Act only as it relates to persons who are the subject of the active investigation.

(2) The department may provide access to information from PAMS to a grand jury empaneled to investigate a criminal violation of a law governing controlled substances, including, but not limited to, violations of The Controlled Substance, Drug, Device and Cosmetic Act, and to investigate insurance, Medicare or Medicaid fraud.

(3) Law enforcement officials may only use PAMS data to aid in establishing probable cause in order to obtain a search or arrest warrant.

§ 2709. Unlawful acts and penalties.

(a) Unlawful acts.--A person commits an offense when the person:

(1) Knowingly, intentionally or negligently uses, releases, publishes or otherwise makes available any information obtained from PAMS for any purpose other than those specified in section 2708 (relating to access to PAMS information).

(2) Obtains or attempts to obtain information from PAMS by misrepresentation or fraud.

(3) Obtains or attempts to obtain information from PAMS for a purpose other than a purpose authorized by this chapter or by department regulations.

(b) Grading.--A person who violates subsection (a)(1), (2) or (3) commits a felony of the third degree and shall, upon conviction, be sentenced to pay a fine of not less than $5,000 or to imprisonment for not more than 90 days, or both.

(c) 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 PAMS operations.

(d) 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 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 or suspend the license.

(5) Restrict or place on probation the licensee.

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

(7) Issue a cease and desist order.

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

(9) Authorize any other action under the appropriate licensing act.

(e) Medical record.--Nothing in this section shall prohibit a practitioner from maintaining a PAMS patient report as part of the patient's medical record.

§ 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 person authorized to contribute or access information from PAMS 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 Psychiatric 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 and notification.--In accordance with criteria established by the advisory committee in section 2705(a) (relating to advisory committee), the department shall:

(1) Refer a practitioner it has reasonable suspicion to believe may be impaired to the appropriate impaired professionals associations to provide intervention, assessment and referral to alcohol and other drug addiction treatment programs, including ongoing monitoring and follow-up.

(2) Notify the appropriate licensing agency or board.

(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 a licensed addiction treatment program.

§ 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 except as otherwise determined by a licensing agency or board or as set forth in this chapter.

§ 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 internal 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, criminal, 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 a civil, judicial or administrative action brought to enforce the provisions of this chapter.

§ 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.

(4) Implementing and complying with the provisions of this chapter.

(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 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, the Attorney General or the district attorney of the county in which the action is brought to collect the fine for successful collection actions under section 2709 (relating to unlawful acts and penalties).

§ 2714. Rules and regulations.

With input and advice from the advisory committee, 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) Practitioners shall not be held liable for failure to comply with PAMS requirements until all changes are fully operational 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.--With input and advice from the advisory committee, 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, and addiction to, controlled substances;

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

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

(5) the number of individuals in paragraph (4) that were referred for alcohol and other drug addiction treatment and the names of the licensed addiction treatment programs in which the individuals 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.

(c) Evaluation.--Within six years of the effective date of this act, the department shall submit to the chairman and minority chairman of the Public Health and Welfare Committee of the Senate and the chairman and minority chairman of the Human Services Committee of the House of Representatives, a written report containing information regarding the collection of data within PAMS. The report must include, but need not be limited to, the following information pertaining to the data collected within PAMS since its inception:

(1) The number of times information from PAMS has been illegally accessed.

(2) The number of times a patient's privacy or confidentiality was compromised through use of the system.

(3) The number of times the security of the PAMS database has been breached by hackers operating under malicious purposes.

(4) A comparison of the rate of death by accidental overdose before the implementation of PAMS and the rate of death by accidental overdose after the implementation of PAMS.

(5) The rate by which practitioners are utilizing PAMS to query patients identified as being potentially addicted to a controlled substance through PAMS for referral to alcohol and other drug addiction treatment programs.

(6) The cost effectiveness of the frequency of data submission.

(7) Any impact on efforts to reduce misuse, abuse, overdose and diversion of, or addiction to, controlled substances.

(8) Any impact on prescribing practices for controlled substances.

(9) The number of patients that were referred for alcohol and other drug addiction treatment.

(10) The effectiveness of the interoperability with other states.

(11) Recommendations for updates and improvements to this chapter or other law.

§ 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.

§ 2717. Nonapplicability.

The requirements of this chapter shall not apply to:

(1) the direct administration of a controlled substance to the body of an ultimate user; or

(2) the administration or dispensing of a controlled substance that is otherwise exempted as determined by the United States Secretary of Health and Human Services under the National All Schedules Prescription Electronic Reporting Act of 2005 (Public Law 109-60, 119 Stat. 1979).

§ 2718. Expiration of chapter and expungement.

This chapter shall expire seven years after the date of the enactment of this chapter. All information in PAMS shall be expunged upon the expiration of this chapter.

Section 2. The regulation of the Department of Health in 28 Pa. Code § 25.131 (relating to every dispensing practitioner) is abrogated.

Section 3. Upon the full operation of PAMS, the Department of Drug and Alcohol Programs shall transmit notice to the Legislative Reference Bureau for publication in the Pennsylvania Bulletin.

Section 4. 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 5. This act shall take effect as follows:

(1) Section 2 shall take effect 90 days after publication of the notice under section 3 of this act.

(2) This section shall take effect immediately.

(3) The remainder of this act shall take effect in 60 days.