

**CHAPTER 107****(SB 14)**

AN ACT relating to drug control.

*Be it enacted by the General Assembly of the Commonwealth of Kentucky:*

Section 1. KRS 218A.202 is amended to read as follows:

- (1) The Cabinet for Health Services shall establish an electronic system for monitoring Schedules II, III, IV, and V controlled substances that are dispensed within the Commonwealth by a practitioner or pharmacist or dispensed to an address within the Commonwealth by a pharmacy ***that has obtained a license, permit, or other authorization to operate from***~~[licensed by]~~ the Kentucky Board of Pharmacy.
- (2) A practitioner or a pharmacist shall not have to pay a fee or tax specifically dedicated to the operation of the system.
- (3) Every dispenser within the Commonwealth or ***any other dispenser who has obtained a license, permit, or other authorization to operate from***~~[is licensed by]~~ the Kentucky Board of Pharmacy shall report to the Cabinet for Health Services the data required by this section in a timely manner as prescribed by the cabinet except that reporting shall not be required for:
  - (a) A drug administered directly to a patient; or
  - (b) A drug dispensed by a practitioner at a facility licensed by the cabinet provided that the quantity dispensed is limited to an amount adequate to treat the patient for a maximum of forty-eight (48) hours.
- (4) Data for each controlled substance that is dispensed shall include but not be limited to the following:
  - (a) Patient identifier;
  - (b) Drug dispensed;
  - (c) Date of dispensing;
  - (d) Quantity dispensed;
  - (e) Prescriber; and
  - (f) Dispenser.
- (5) The data shall be provided in the electronic format specified by the Cabinet for Health Services unless a waiver has been granted by the cabinet to an individual dispenser. ***The cabinet shall establish acceptable error tolerance rates for data. Dispensers shall ensure that reports fall within these tolerances. Incomplete or inaccurate data shall be corrected upon notification by the cabinet if the dispenser exceeds these error tolerance rates.***
- (6) The Cabinet for Health Services shall be authorized to provide data to:
  - (a) A designated representative of a board responsible for the licensure, regulation, or discipline of practitioners, pharmacists, or other person who is authorized to prescribe, administer, or dispense controlled substances and who is involved in a bona fide specific investigation involving a designated person;

- (b) *A Kentucky peace officer certified pursuant to KRS 15.380 to 15.404, a certified or full-time peace officer of another state, or a federal peace officer whose duty is to enforce the laws of this Commonwealth, of another state, or of the United States relating to drugs and who is engaged in a bona fide specific investigation involving a designated person;*
  - (c) A state-operated Medicaid program;
  - (d) A properly convened grand jury pursuant to a subpoena properly issued for the records;
  - (e) A practitioner or pharmacist who requests information and certifies that the requested information is for the purpose of providing medical or pharmaceutical treatment to a bona fide current patient;
  - (f) *In addition to the purposes authorized under paragraph (a) of this subsection, the Kentucky Board of Medical Licensure, for any physician who is:*
    - 1. *Associated in a partnership or other business entity with a physician who is already under investigation by the Board of Medical Licensure for improper prescribing practices;*
    - 2. *In a designated geographic area for which a trend report indicates a substantial likelihood that inappropriate prescribing may be occurring; or*
    - 3. *In a designated geographic area for which a report on another physician in that area indicates a substantial likelihood that inappropriate prescribing may be occurring in that area; or*
  - (g) *A judge or a probation or parole officer administering a diversion or probation program of a criminal defendant arising out of a violation of this chapter or of a criminal defendant who is documented by the court as a substance abuser who is eligible to participate in a court-ordered drug diversion or probation program.*
- (7) A person who receives data or any report of the system from the cabinet shall not provide it to any other person or entity except by order of a court of competent jurisdiction, *except that:*
- (a) *A peace officer specified in subsection (6)(b) of this section who is authorized to receive data or a report may share that information with other peace officers specified in subsection (6)(b) of this section authorized to receive data or a report, if the peace officers specified in subsection (6)(b) of this section are working on a bona fide specific investigation involving a designated person. Both the person providing and the person receiving the data or report under this paragraph shall document in writing each person to whom the data or report has been given or received and the day, month, and year that the data or report has been given or received. This document shall be maintained in a file by each law enforcement agency engaged in the investigation; and*
  - (b) *A representative of the Department for Medicaid Services may share data or reports regarding overutilization by Medicaid recipients with a board designated in paragraph (a) of subsection (6) of this section, or with a law enforcement officer designated in paragraph (b) of subsection (6) of this section.*

- (8)~~(7)~~ The Cabinet for Health Services, all *peace officers specified in subsection (6)(b) of this section*~~law enforcement officers~~, all officers of the court, and all regulatory agencies and officers, in using the data for investigative or prosecution purposes, shall consider the nature of the prescriber's and dispenser's practice and the condition for which the patient is being treated.
- (9)~~(8)~~ The data and any report obtained therefrom shall not be a public record.
- (10)~~(9)~~ Knowing failure by a dispenser to transmit data to the cabinet as required by subsection (3), (4), or (5) of this section shall be a Class A misdemeanor.
- (11)~~(10)~~ Knowing disclosure of transmitted data to a person not authorized by subsection (6) *or* (7) of this section or authorized by KRS 315.121, or obtaining information under this section not relating to a bona fide specific investigation, shall be a Class D felony.
- (12)~~(11)~~ The Governor's Office for Technology, in consultation with the Cabinet for Health Services, shall submit an application to the United States Department of Justice for a drug diversion grant to fund a pilot project to study a real-time electronic monitoring system for Schedules II, III, IV, and V controlled substances. The pilot project shall:
- (a) Be conducted in two (2) rural counties that have an interactive real-time electronic information system in place for monitoring patient utilization of health and social services through a federally funded community access program; and
  - (b) Study the use of an interactive system that includes a relational data base with query capability.
- (13)~~(12)~~ Provisions in ~~subsections (1) to (10) of~~ this section that relate to data collection, disclosure, access, and penalties shall apply to the pilot project authorized under subsection (12)~~(11)~~ of this section.
- (14) *The Cabinet for Health Services may limit the length of time that data remain in the electronic system. Any data removed from the system shall be archived and subject to retrieval within a reasonable time after a request from a person authorized to review data under this section.*
- (15) (a) *The Cabinet for Health Services shall work with each board responsible for the licensure, regulation, or discipline of practitioners, pharmacists, or other persons who are authorized to prescribe, administer, or dispense controlled substances for the development of a continuing education program about the purposes and uses of the electronic system for monitoring established in this section.*
- (b) *The cabinet shall work with the Kentucky Bar Association for the development of a continuing education program for attorneys about the purposes and uses of the electronic system for monitoring established in this section.*
- (c) *The cabinet shall work with the Justice Cabinet for the development of a continuing education program for law enforcement officers about the purposes and users of the electronic system for monitoring established in this section.*

Section 2. KRS 218A.240 is amended to read as follows:

- (1) All police officers and deputy sheriffs directly employed full-time by state, county, city, or urban-county governments, the State Police, the Cabinet for Health Services, their officers and agents, and of all city, county, and Commonwealth's attorneys, and the Attorney General, within their respective jurisdictions, shall enforce all provisions of this chapter and

cooperate with all agencies charged with the enforcement of the laws of the United States, of this state, and of all other states relating to controlled substances.

- (2) For the purpose of enforcing the provisions of this chapter, the designated agents of the Cabinet for Health Services shall have the full power and authority of peace officers in this state, including the power of arrest and the authority to bear arms, and shall have the power and authority to administer oaths, to enter upon premises at all times for the purpose of making inspections, to seize evidence, to interrogate all persons, to require the production of prescriptions, of books, papers, documents or other evidence, to employ special investigators, and to expend funds for the purpose of obtaining evidence.
- (3) The Kentucky Board of Pharmacy, its agents and inspectors, shall have the same powers of inspection and enforcement as the Cabinet for Health Services.
- (4) Designated agents of the Cabinet for Health Services and the Kentucky Board of Pharmacy are empowered to remove from the files of a pharmacy or the custodian of records for that pharmacy any controlled substance prescription or other controlled substance record upon tendering a receipt. The receipt shall be sufficiently detailed to accurately identify the record. A receipt for the record shall be a defense to a charge of failure to maintain the record.
- (5) Notwithstanding the existence or pursuit of any other remedy, civil or criminal, any law enforcement authority may maintain, in its own name, an action to restrain or enjoin any violation of this chapter, or to forfeit any property subject to forfeiture under KRS 218A.410, irrespective of whether the owner of the property has been charged with or convicted of any offense under this chapter.
  - (a) Any civil action against any person brought pursuant to this section may be instituted in the Circuit Court in any county in which the person resides, in which any property owned by the person and subject to forfeiture is found, or in which the person has violated any provision of this chapter.
  - (b) A final judgment rendered in favor of the Commonwealth in any criminal proceeding brought under this chapter shall estop the defendant from denying the essential allegations of the criminal offense in any subsequent civil proceeding brought pursuant to this section.
  - (c) The prevailing party in any civil proceeding brought pursuant to this section shall recover his costs, including a reasonable attorney's fee.
  - (d) Distribution of funds under this section shall be made in the same manner as in KRS 218A.435, except that if the Commonwealth's attorney has not initiated the forfeiture action under this section, his percentage of the funds shall go to the agency initiating the forfeiture action.
- (6) The Cabinet for Health Services shall make or cause to be made examinations of samples secured under the provisions of this chapter to determine whether any provision has been violated.
- (7) (a) ***The Cabinet for Health Services shall use the data compiled in the electronic system created in Section 1 of this Act for investigations, research, statistical analysis, and educational purposes, and shall proactively identify trends in controlled substance usage and other potential problem areas. Only cabinet personnel who have undergone training for the electronic system and who have been approved to use the***

*system shall be authorized access to the data and reports under this subsection. The cabinet shall notify a board responsible for the licensure, regulation, or discipline of each practitioner, pharmacist, or other person who is authorized to prescribe, administer, or dispense controlled substances, if a report or analysis conducted under this subsection indicates that further investigation about inappropriate or unlawful prescribing or dispensing may be necessary by the board.*

- (b) The cabinet shall develop criteria, in collaboration with the Board of Medical Licensure and the Board of Pharmacy, to be used to generate trend reports from the data obtained by the system. Meetings at which the criteria are developed shall be meetings, as defined in KRS 61.805, that comply with the open meetings laws, KRS 61.805 to 61.850.*
- (c) The cabinet shall, on a quarterly basis, publish trend reports from the data obtained by the system.*
- (d) Peace officers authorized to receive data under Section 1 of this Act may request trend reports not specifically published pursuant to paragraph (c) of this subsection. A report under this paragraph may be based upon the criteria developed under paragraph (b) of this subsection or upon any of the data collected pursuant to subsection (4) of Section 1 of this Act, except that the report shall not identify an individual prescriber, dispenser, or patient.*
- (e) No trend report generated under this subsection shall identify an individual prescriber, dispenser, or patient.*

SECTION 3. A NEW SECTION OF KRS CHAPTER 218A IS CREATED TO READ AS FOLLOWS:

- (1) The secretary of the Cabinet for Health Services may enter into reciprocal agreements with any other state or states of the United States to share prescription drug monitoring information if the other state's prescription drug monitoring program is compatible with the program in Kentucky. If the secretary elects to evaluate the prescription drug monitoring program of another state as authorized by this section, priority shall be given to a state that is contiguous with the borders of the Commonwealth.*
- (2) In determining compatibility, the secretary shall consider:*
  - (a) The essential purposes of the program and the success of the program in fulfilling those purposes;*
  - (b) The safeguards for privacy of patient records and its success in protecting patient privacy;*
  - (c) The persons authorized to view the data collected by the program;*
  - (d) The schedules of controlled substances monitored;*
  - (e) The data required to be submitted on each prescription;*
  - (f) Any implementation criteria deemed essential for a thorough comparison; and*
  - (g) The costs and benefits to the Commonwealth in mutually sharing particular information available in the Commonwealth's database with the program under consideration.*

- (3) *The secretary shall review any agreement on an annual basis to determine its continued compatibility with the Kentucky prescription drug monitoring program.*
- (4) *The secretary shall prepare an annual report to the Governor and the Legislative Research Commission that summarizes any agreement under this section and that analyzes the effectiveness of that agreement in monitoring the dispensing of controlled substances in the Commonwealth.*
- (5) *Any agreement between the cabinet and another state shall prohibit the sharing of information about a Kentucky resident, practitioner, pharmacist, or other prescriber for any purpose not otherwise authorized by this section or Section 1 of this Act.*

Section 4. KRS 315.0351 is amended to read as follows:

- (1) Every pharmacy located outside this Commonwealth which, other than on an incidental basis, does business within this Commonwealth within the meaning of KRS Chapter 315, shall hold a current pharmacy permit as provided in KRS 315.035(1) and (4) issued by the Kentucky Board of Pharmacy. The pharmacy shall be designated an "out-of-state pharmacy" and the permit shall be designated an "out-of-state pharmacy permit." The fee for the permit shall not exceed the current in-state pharmacy permit fee as provided under KRS 315.035.
- (2) Every out-of-state pharmacy granted an out-of-state pharmacy permit by the board shall disclose to the board the location, names, and titles of all principal corporate officers and all pharmacists who are dispensing prescription drugs to residents of the Commonwealth. A report containing this information shall be made to the board on an annual basis and within thirty (30) days after any change of office, corporate officer, or pharmacist.
- (3) Every out-of-state pharmacy granted an out-of-state pharmacy permit shall comply with all statutorily-authorized directions and requests for information from any regulatory agency of the Commonwealth and from the board in accordance with the provisions of this section. The out-of-state pharmacy shall maintain at all times a valid unexpired permit, license, or registration to conduct the pharmacy in compliance with the laws of the *jurisdiction*~~{state}~~ in which it is a resident. As a prerequisite to seeking a permit from the Kentucky Board of Pharmacy, the out-of-state pharmacy shall submit a copy of the most recent inspection report resulting from an inspection conducted by the regulatory or licensing agency of the *jurisdiction*~~{state}~~ in which it is located. Thereafter, the out-of-state pharmacy granted a permit shall submit to the Kentucky Board of Pharmacy a copy of any subsequent inspection report on the pharmacy conducted by the regulatory or licensing body of the *jurisdiction*~~{state}~~ in which it is located.
- (4) Every out-of-state pharmacy granted an out-of-state pharmacy permit by the board shall maintain records of any controlled substances or dangerous drugs or devices dispensed to patients in the Commonwealth so that the records are readily retrievable from the records of other drugs dispensed.
- (5) Records for all prescriptions delivered into Kentucky shall be readily retrievable from the other prescription records of the out-of-state pharmacy.
- (6) Each out-of-state pharmacy shall, during its regular hours of operation, but not less than six (6) days per week and for a minimum of forty (40) hours per week, provide a toll-free telephone service directly to the pharmacist in charge of the out-of-state pharmacy and available to both the patient and each licensed and practicing in-state pharmacist for the purpose of facilitating communication between the patient and the Kentucky pharmacist

with access to the patient's prescription records. A toll-free number shall be placed on a label affixed to each container of drugs dispensed to patients within the Commonwealth.

- (7) Each out-of-state pharmacy shall have a pharmacist in charge who shall be responsible for compliance by the pharmacy with the provisions of this section.

**Approved April 9, 2004**