

## CHAPTER 138

## ( HB 314 )

AN ACT relating to monitoring and evaluation programs in the Cabinet for Health and Family Services.

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 and Family Services shall establish *and maintain* 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 the Kentucky Board of Pharmacy~~. The cabinet may contract for the design, upgrade, or operation of this system if the contract preserves all of the rights, privileges, and protections guaranteed to Kentucky citizens under this chapter and the contract requires that all other aspects of the system be operated in conformity with the requirements of this or any other applicable state or federal law.
- (2) A practitioner or a pharmacist authorized to prescribe or dispense controlled substances to humans shall register with the cabinet to use the system provided for in this section and shall maintain such registration continuously during the practitioner's or pharmacist's term of licensure and shall not have to pay a fee or tax specifically dedicated to the operation of the system.
- (3) Every *practitioner or pharmacy which dispenses*~~dispenser within the Commonwealth who is licensed, permitted, or otherwise authorized to prescribe or dispense~~ a controlled substance to a person *in Kentucky, or to a person at an address* in Kentucky, shall report to the Cabinet for Health and Family Services the data required by this section, *which includes the reporting of any Schedule II controlled substance dispensed at a facility licensed by the cabinet and a Schedule II through Schedule V controlled substance regardless of dosage when dispensed by the emergency department of a hospital to an emergency department patient.* ~~except that reporting~~*Reporting* shall not be required for:
  - (a) A drug administered directly to a patient in a hospital, a resident of a health care facility licensed under KRS Chapter 216B, a resident of a child-caring facility as defined by KRS 199.011, or an individual in a jail, correctional facility, or juvenile detention facility;
  - (b) *A Schedule III through Schedule V controlled substance dispensed by 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 and is not dispensed by the emergency department of a hospital;* ~~or~~

~~A drug, other than any Schedule II controlled substance or a Schedule III controlled substance containing hydrocodone, 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; or~~
  - (c) A drug administered or dispensed to a research subject enrolled in a research protocol approved by an institutional review board that has an active federalwide assurance number from the United States Department of Health and Human Services, Office for Human Research Protections, where the research involves single, double, or triple blind drug administration or is additionally covered by a certificate of confidentiality from the National Institutes of Health.
- (4) *In addition to the data required by subsection (5) of this section, a Kentucky-licensed acute care hospital or critical access hospital shall report to the cabinet all positive toxicology screens that were performed by the hospital's emergency department to evaluate the patient's suspected drug overdose.*
- (5) Data for each controlled substance that is *reported*~~dispensed~~ shall include but not be limited to the following:
  - (a) Patient identifier;
  - (b) National drug code of the drug dispensed;
  - (c) Date of dispensing;
  - (d) Quantity dispensed;

- (e) Prescriber; and
- (f) Dispenser.

~~(6)(5)~~ The data shall be provided in the electronic format specified by the Cabinet for Health and Family 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.

~~(7)(6)~~ The Cabinet for Health and Family Services shall only disclose data to persons and entities authorized to receive that data under this section. Disclosure to any other person or entity, including disclosure in the context of a civil action where the disclosure is sought either for the purpose of discovery or for evidence, is prohibited unless specifically authorized by this section. The Cabinet for Health and Family 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) Employees of the Office of the Inspector General of the Cabinet for Health and Family Services who have successfully completed training for the electronic system and who have been approved to use the system, *federal prosecutors*, Kentucky Commonwealth's attorneys and assistant Commonwealth's attorneys, county attorneys and assistant county attorneys, a peace officer certified pursuant to KRS 15.380 to 15.404, a certified or full-time peace officer of another state, or a federal ~~agent~~~~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 in conformity with subsection ~~(8)~~~~(7)~~ of this section;
- (d) A properly convened grand jury pursuant to a subpoena properly issued for the records;
- (e) A practitioner or pharmacist, or employee of the practitioner's or pharmacist's practice acting under the specific direction of the practitioner or pharmacist, who ~~requests information and~~ certifies that the requested information is for the purpose of:
  1. Providing medical or pharmaceutical treatment to a bona fide current or prospective patient;~~or~~
  2. *Reviewing data on controlled substances that have been reported for the birth mother of an infant who is currently being treated by the practitioner for neonatal abstinence syndrome, or has symptoms that suggest prenatal drug exposure; or*
  3. Reviewing and assessing the individual prescribing or dispensing patterns of the practitioner or pharmacist or to determine the accuracy and completeness of information contained in the monitoring system;
- (f) The chief medical officer of a hospital or long-term-care facility, an employee of the hospital or long-term-care facility as designated by the chief medical officer and who is working under his or her specific direction, or a physician designee if the hospital or facility has no chief medical officer, if the officer, employee, or designee certifies that the requested information is for the purpose of providing medical or pharmaceutical treatment to a bona fide current or prospective patient or resident in the hospital or facility;
- (g) 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 or dispensing practices;
  2. In a designated geographic area for which a trend report indicates a substantial likelihood that inappropriate prescribing or dispensing 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 or dispensing may be occurring in that area;

- (h) In addition to the purposes authorized under paragraph (a) of this subsection, the Kentucky Board of Nursing, for any advanced practice registered nurse who is:
1. Associated in a partnership or other business entity with a physician who is already under investigation by the Kentucky Board of Medical Licensure for improper prescribing or dispensing practices;
  2. Associated in a partnership or other business entity with an advanced practice registered nurse who is already under investigation by the Board of Nursing for improper prescribing practices;
  3. In a designated geographic area for which a trend report indicates a substantial likelihood that inappropriate prescribing or dispensing may be occurring; or
  4. In a designated geographic area for which a report on a physician or another advanced practice registered nurse in that area indicates a substantial likelihood that inappropriate prescribing or dispensing may be occurring in that area;
- (i) 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; or
- (j) A medical examiner engaged in a death investigation pursuant to KRS 72.026.
- ~~(8)(7)~~ The Department for Medicaid Services shall use any data or reports from the system for the purpose of identifying Medicaid providers or recipients whose prescribing, dispensing, or usage of controlled substances may be:
- (a) Appropriately managed by a single outpatient pharmacy or primary care physician; or
  - (b) Indicative of improper, inappropriate, or illegal prescribing or dispensing practices by a practitioner or drug seeking by a Medicaid recipient.
- ~~(9)(8)~~ 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 as provided in this section, in another statute, or by order of a court of competent jurisdiction and only to a person or entity authorized to receive the data or the report under this section, except that:
- (a) A person specified in subsection ~~(7)(6)~~(b) of this section who is authorized to receive data or a report may share that information with any other persons specified in subsection ~~(7)(6)~~(b) of this section authorized to receive data or a report if the persons specified in subsection ~~(7)(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 agency engaged in the investigation;
  - (b) A representative of the Department for Medicaid Services may share data or reports regarding overutilization by Medicaid recipients with a board designated in subsection ~~(7)(6)~~(a) of this section, or with a law enforcement officer designated in subsection ~~(7)(6)~~(b) of this section;
  - (c) The Department for Medicaid Services may submit the data as evidence in an administrative hearing held in accordance with KRS Chapter 13B;
  - (d) If a state licensing board as defined in KRS 218A.205 initiates formal disciplinary proceedings against a licensee, and data obtained by the board is relevant to the charges, the board may provide the data to the licensee and his or her counsel, as part of the notice process required by KRS 13B.050, and admit the data as evidence in an administrative hearing conducted pursuant to KRS Chapter 13B, with the board and licensee taking all necessary steps to prevent further disclosure of the data; and
  - (e) A practitioner, pharmacist, or employee who obtains data under subsection ~~(7)(6)~~(e) of this section may share the report with the patient or person authorized to act on the patient's behalf. **Any practitioner, pharmacist, or employee who obtains data under subsection (7)(e) of this section may** ~~and~~ place the report in the patient's medical record, **in which case the** ~~with that~~ individual report **shall**

- then ~~be being~~ deemed a medical record subject to disclosure on the same terms and conditions as an ordinary medical record in lieu of the disclosure restrictions otherwise imposed by this section.
- (10)(9) The Cabinet for Health and Family Services, all peace officers specified in subsection (7)(6)(b) of this section, 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.
- (11)(10) The data and any report obtained therefrom shall not be a public record, except that the Department for Medicaid Services may submit the data as evidence in an administrative hearing held in accordance with KRS Chapter 13B.
- (12)(11) Intentional failure *to comply with the reporting requirements of this section* ~~by a dispenser to transmit data to the cabinet as required by subsection (3), (4), or (5) of this section~~ shall be a Class B misdemeanor for the first offense and a Class A misdemeanor for each subsequent offense.
- (13)(12) Intentional disclosure of transmitted data to a person not authorized by *subsections* ~~subsection~~ (7)(6) to ~~subsection~~ (9)(8) of this section or authorized by KRS 315.121, or obtaining information under this section not relating to a bona fide *current or prospective patient or a bona fide* specific investigation, shall be a Class B misdemeanor for the first offense and a Class A misdemeanor for each subsequent offense.
- (14)(13) ~~(a) The Commonwealth Office of Technology, in consultation with the Cabinet for Health and Family Services, may submit an application to the United States Department of Justice for a drug diversion grant to fund a pilot or continuing project to study, create, or maintain a real time electronic monitoring system for Schedules II, III, IV, and V controlled substances.~~
- ~~(b) The pilot project shall:~~
- ~~1. 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~~
  - ~~2. Study the use of an interactive system that includes a relational data base with query capability.~~
- ~~(c) Funding to create or maintain a real time electronic monitoring system for Schedules II, III, IV, and V controlled substances may be sought for a statewide system or for a system covering any geographic portion or portions of the state.~~
- ~~(14) Provisions in this section that relate to data collection, disclosure, access, and penalties shall apply to the pilot project authorized under subsection (13) of this section.~~
- (15) The Cabinet for Health and Family Services may, by promulgating an administrative regulation, 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)(16) (a) The Cabinet for Health and Family 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 and Public Safety Cabinet for the development of a continuing education program for law enforcement officers about the purposes and uses of the electronic system for monitoring established in this section.
- (16)(17) If the cabinet becomes aware of a prescriber's or dispenser's failure to comply with this section, the cabinet shall notify the licensing board or agency responsible for licensing the prescriber or dispenser. The licensing board shall treat the notification as a complaint against the licensee.
- (17)(18) The cabinet shall promulgate administrative regulations to implement the provisions of this section. Included in these administrative regulations shall be:

- (a) An error resolution process allowing a patient to whom a report had been disclosed under subsection (9)~~(8)~~ of this section to request the correction of inaccurate information contained in the system relating to that patient; and
- (b) ~~Beginning July 1, 2013,~~ A requirement that data be reported to the system under subsection (3) of this section within one (1) day of dispensing.

➔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, urban-county, or consolidated local governments, the Department of Kentucky State Police, the Cabinet for Health and Family 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 and Family 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 and to use data obtained under KRS 218A.202~~(7)~~ in any administrative proceeding before the cabinet.
- (3) The Kentucky Board of Pharmacy, its agents and inspectors, shall have the same powers of inspection and enforcement as the Cabinet for Health and Family Services.
- (4) Designated agents of the Cabinet for Health and Family 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 or her 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.420, except that if the Commonwealth's attorney has not initiated the forfeiture action under this section, his or her percentage of the funds shall go to the agency initiating the forfeiture action.
- (6) The Cabinet for Health and Family 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 and Family Services shall proactively use the data compiled in the electronic system created in KRS 218A.202 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 state licensing board listed in KRS 218A.205 if a report or analysis conducted under this subsection indicates that further investigation about improper, inappropriate or illegal prescribing or dispensing may be necessary by the board. The board shall consider each report and may,

after giving due consideration to areas of practice, specialties, board certifications, and appropriate standards of care, request and receive a follow-up report or analysis containing relevant information as to the prescriber or dispenser and his or her patients.

- (b) The cabinet shall develop criteria, in collaboration with the Board of Medical Licensure, the Board of Nursing, the Office of Drug Control Policy, and the Board of Pharmacy, to be used to generate public 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. The cabinet shall, on a quarterly basis, publish trend reports from the data obtained by the system. Except as provided in subsection (8) of this section, these trend reports shall not identify an individual prescriber, dispenser, or patient. Peace officers authorized to receive data under KRS 218A.202 may request trend reports not specifically published pursuant to this paragraph except that the report shall not identify an individual prescriber, dispenser, or patient.
- (8) If the cabinet deems it to be necessary and appropriate, upon the request of a state licensing board listed in KRS 218A.205, the cabinet shall provide the requesting board with the identity of prescribers, dispensers, and patients used to compile a specific trend report.
- (9) Any hospital or other health care facility may petition the cabinet to review data from the electronic system specified in KRS 218A.202 as it relates to employees of that facility to determine if inappropriate prescribing or dispensing practices are occurring. The cabinet may initiate any investigation in such cases as he or she determines is appropriate, and may request the assistance from the hospitals or health care facilities in the investigation.

➔SECTION 3. A NEW SECTION OF KRS 205.520 TO 205.630 IS CREATED TO READ AS FOLLOWS:

*If the Department for Medicaid Services considers the fair market value of an applicant's property for purposes of determining eligibility, "fair market value" means:*

- (1) *An estimate of the value of an asset if sold at the prevailing price at the time it was actually transferred, based on:*
  - (a) *The most recent certified assessed value of the property as listed by the local property valuation administrator; or*
  - (b) *The professional opinion of an independent, licensed appraiser; or*
- (2) *The price brought on the property at a public auction conducted by a licensed auctioneer.*

**Signed by Governor March 27, 2017.**