

1 AN ACT relating to controlled substance monitoring.

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

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

- 4 (1) The Cabinet for Health and Family Services shall establish ***and maintain*** an
5 electronic system for monitoring Schedules II, III, IV, and V controlled substances~~]~~
6 ~~that are dispensed within the Commonwealth by a practitioner or pharmacist or~~
7 ~~dispensed to an address within the Commonwealth by a pharmacy that has obtained~~
8 ~~a license, permit, or other authorization to operate from the Kentucky Board of~~
9 ~~Pharmacy]~~. The cabinet may contract for the design, upgrade, or operation of this
10 system if the contract preserves all of the rights, privileges, and protections
11 guaranteed to Kentucky citizens under this chapter and the contract requires that all
12 other aspects of the system be operated in conformity with the requirements of this
13 or any other applicable state or federal law.
- 14 (2) A practitioner or a pharmacist authorized to prescribe or dispense controlled
15 substances to humans shall register with the cabinet to use the system provided for
16 in this section and shall maintain such registration continuously during the
17 practitioner's or pharmacist's term of licensure and shall not have to pay a fee or tax
18 specifically dedicated to the operation of the system.
- 19 (3) Every ***practitioner or pharmacist***~~[dispenser within the Commonwealth]~~ who is
20 licensed, permitted, or otherwise authorized to prescribe or dispense a controlled
21 substance to a person ***in Kentucky, or for delivery to a person at an address*** in
22 Kentucky, shall report to the Cabinet for Health and Family Services the data
23 required by this section, ***which includes the reporting of any Schedule II***
24 ***controlled substance dispensed by a practitioner at a facility licensed by the***
25 ***cabinet and a Schedule II through Schedule V controlled substance regardless of***
26 ***dosage when dispensed by the emergency department of a hospital to an***
27 ***emergency department patient.***~~[except that reporting]~~***Reporting*** shall not be

1 required for:

2 (a) A drug administered directly to a patient in a hospital, a resident of a health
3 care facility licensed under KRS Chapter 216B, a resident of a child-caring
4 facility as defined by KRS 199.011, or an individual in a jail, correctional
5 facility, or juvenile detention facility;

6 (b) A Schedule III through Schedule V controlled substance dispensed by a
7 practitioner at a facility licensed by the cabinet provided that the quantity
8 dispensed is limited to an amount adequate to treat the patient for a
9 maximum of forty-eight (48) hours and is not dispensed by the emergency
10 department of a hospital; or

11 [~~A drug, other than any Schedule II controlled substance or a Schedule III~~
12 ~~controlled substance containing hydrocodone, dispensed by a practitioner at a~~
13 ~~facility licensed by the cabinet, provided that the quantity dispensed is limited~~
14 ~~to an amount adequate to treat the patient for a maximum of forty eight (48)~~
15 ~~hours; or]~~

16 (c) A drug administered or dispensed to a research subject enrolled in a research
17 protocol approved by an institutional review board that has an active
18 federalwide assurance number from the United States Department of Health
19 and Human Services, Office for Human Research Protections, where the
20 research involves single, double, or triple blind drug administration or is
21 additionally covered by a certificate of confidentiality from the National
22 Institutes of Health.

23 (4) In addition to the data required by subsection (5) of this section, a Kentucky-
24 licensed acute care hospital or critical access hospital shall report to the cabinet
25 all positive toxicology screens that were performed by the hospital's emergency
26 department to evaluate the patient's suspected drug overdose.

27 (5) Data for each controlled substance that is administered or dispensed shall include

1 but not be limited to the following:

- 2 (a) Patient identifier;
- 3 (b) National drug code of the drug dispensed;
- 4 (c) Date of dispensing;
- 5 (d) Quantity dispensed;
- 6 (e) Prescriber; and
- 7 (f) Dispenser.

8 ~~(6)~~⁽⁵⁾ The data shall be provided in the electronic format specified by the Cabinet
9 for Health and Family Services unless a waiver has been granted by the cabinet to
10 an individual dispenser. The cabinet shall establish acceptable error tolerance rates
11 for data. Dispensers shall ensure that reports fall within these tolerances. Incomplete
12 or inaccurate data shall be corrected upon notification by the cabinet if the dispenser
13 exceeds these error tolerance rates.

14 ~~(7)~~⁽⁶⁾ The Cabinet for Health and Family Services shall only disclose data to
15 persons and entities authorized to receive that data under this section. Disclosure to
16 any other person or entity, including disclosure in the context of a civil action where
17 the disclosure is sought either for the purpose of discovery or for evidence, is
18 prohibited unless specifically authorized by this section. The Cabinet for Health and
19 Family Services shall be authorized to provide data to:

- 20 (a) A designated representative of a board responsible for the licensure,
21 regulation, or discipline of practitioners, pharmacists, or other person who is
22 authorized to prescribe, administer, or dispense controlled substances and who
23 is involved in a bona fide specific investigation involving a designated person;
- 24 (b) Employees of the Office of the Inspector General of the Cabinet for Health
25 and Family Services who have successfully completed training for the
26 electronic system and who have been approved to use the system, *federal*
27 *prosecutors*, Kentucky Commonwealth's attorneys and assistant

- 1 Commonwealth's attorneys, county attorneys and assistant county attorneys, a
2 peace officer certified pursuant to KRS 15.380 to 15.404, a certified or full-
3 time peace officer of another state, or a federal **agent**~~[peace officer]~~ whose
4 duty is to enforce the laws of this Commonwealth, of another state, or of the
5 United States relating to drugs and who is engaged in a bona fide specific
6 investigation involving a designated person;
- 7 (c) A state-operated Medicaid program in conformity with subsection **(8)**~~[(7)]~~ of
8 this section;
- 9 (d) A properly convened grand jury pursuant to a subpoena properly issued for the
10 records;
- 11 (e) A practitioner or pharmacist, or employee of the practitioner's or pharmacist's
12 practice acting under the specific direction of the practitioner or pharmacist,
13 who~~[requests information and]~~ certifies that the requested information is for
14 the purpose of:
- 15 1. Providing medical or pharmaceutical treatment to a bona fide current or
16 prospective patient;~~[or]~~
 - 17 2. **Reviewing data on controlled substances that have been administered**
18 **or dispensed to the birth mother of an infant who is currently being**
19 **treated by the practitioner for neonatal abstinence syndrome, or has**
20 **symptoms that suggest prenatal drug exposure; or**
 - 21 **3.** Reviewing and assessing the individual prescribing or dispensing
22 patterns of the practitioner or pharmacist or to determine the accuracy
23 and completeness of information contained in the monitoring system;
- 24 (f) The chief medical officer of a hospital or long-term-care facility, an employee
25 of the hospital or long-term-care facility as designated by the chief medical
26 officer and who is working under his or her specific direction, or a physician
27 designee if the hospital or facility has no chief medical officer, if the officer,

1 employee, or designee certifies that the requested information is for the
2 purpose of providing medical or pharmaceutical treatment to a bona fide
3 current or prospective patient or resident in the hospital or facility;

4 (g) In addition to the purposes authorized under paragraph (a) of this subsection,
5 the Kentucky Board of Medical Licensure, for any physician who is:

- 6 1. Associated in a partnership or other business entity with a physician who
7 is already under investigation by the Board of Medical Licensure for
8 improper prescribing or dispensing practices;
- 9 2. In a designated geographic area for which a trend report indicates a
10 substantial likelihood that inappropriate prescribing or dispensing may
11 be occurring; or
- 12 3. In a designated geographic area for which a report on another physician
13 in that area indicates a substantial likelihood that inappropriate
14 prescribing or dispensing may be occurring in that area;

15 (h) In addition to the purposes authorized under paragraph (a) of this subsection,
16 the Kentucky Board of Nursing, for any advanced practice registered nurse
17 who is:

- 18 1. Associated in a partnership or other business entity with a physician who
19 is already under investigation by the Kentucky Board of Medical
20 Licensure for improper prescribing or dispensing practices;
- 21 2. Associated in a partnership or other business entity with an advanced
22 practice registered nurse who is already under investigation by the Board
23 of Nursing for improper prescribing practices;
- 24 3. In a designated geographic area for which a trend report indicates a
25 substantial likelihood that inappropriate prescribing or dispensing may
26 be occurring; or
- 27 4. In a designated geographic area for which a report on a physician or

1 another advanced practice registered nurse in that area indicates a
2 substantial likelihood that inappropriate prescribing or dispensing may
3 be occurring in that area;

4 (i) A judge or a probation or parole officer administering a diversion or probation
5 program of a criminal defendant arising out of a violation of this chapter or of
6 a criminal defendant who is documented by the court as a substance abuser
7 who is eligible to participate in a court-ordered drug diversion or probation
8 program; or

9 (j) A medical examiner engaged in a death investigation pursuant to KRS 72.026.

10 ~~(8)(7)~~ The Department for Medicaid Services shall use any data or reports from the
11 system for the purpose of identifying Medicaid providers or recipients whose
12 prescribing, dispensing, or usage of controlled substances may be:

13 (a) Appropriately managed by a single outpatient pharmacy or primary care
14 physician; or

15 (b) Indicative of improper, inappropriate, or illegal prescribing or dispensing
16 practices by a practitioner or drug seeking by a Medicaid recipient.

17 ~~(9)(8)~~ A person who receives data or any report of the system from the cabinet shall
18 not provide it to any other person or entity except as provided in this section, in
19 another statute, or by order of a court of competent jurisdiction and only to a person
20 or entity authorized to receive the data or the report under this section, except that:

21 (a) A person specified in subsection ~~(7)(6)~~(b) of this section who is authorized
22 to receive data or a report may share that information with any other persons
23 specified in subsection ~~(7)(6)~~(b) of this section authorized to receive data or
24 a report if the persons specified in subsection ~~(7)(6)~~(b) of this section are
25 working on a bona fide specific investigation involving a designated person.
26 Both the person providing and the person receiving the data or report under
27 this paragraph shall document in writing each person to whom the data or

- 1 report has been given or received and the day, month, and year that the data or
2 report has been given or received. This document shall be maintained in a file
3 by each agency engaged in the investigation;
- 4 (b) A representative of the Department for Medicaid Services may share data or
5 reports regarding overutilization by Medicaid recipients with a board
6 designated in subsection ~~(7)(6)~~(a) of this section, or with a law enforcement
7 officer designated in subsection ~~(7)(6)~~(b) of this section;
- 8 (c) The Department for Medicaid Services may submit the data as evidence in an
9 administrative hearing held in accordance with KRS Chapter 13B;
- 10 (d) If a state licensing board as defined in KRS 218A.205 initiates formal
11 disciplinary proceedings against a licensee, and data obtained by the board is
12 relevant to the charges, the board may provide the data to the licensee and his
13 or her counsel, as part of the notice process required by KRS 13B.050, and
14 admit the data as evidence in an administrative hearing conducted pursuant to
15 KRS Chapter 13B, with the board and licensee taking all necessary steps to
16 prevent further disclosure of the data; and
- 17 (e) A practitioner, pharmacist, or employee who obtains data under subsection
18 ~~(7)(6)~~(e) of this section may share the report with the patient or person
19 authorized to act on the patient's behalf, **Any practitioner, pharmacist, or**
20 **employee who obtains data under subsection (7)(e) of this section may** ~~and~~
21 place the report in the patient's medical record, **in which case the** ~~with that~~
22 individual report **shall** then **be** ~~being~~ deemed a medical record subject to
23 disclosure on the same terms and conditions as an ordinary medical record in
24 lieu of the disclosure restrictions otherwise imposed by this section.
- 25 ~~(10)(9)~~ The Cabinet for Health and Family Services, all peace officers specified in
26 subsection ~~(7)(6)~~(b) of this section, all officers of the court, and all regulatory
27 agencies and officers, in using the data for investigative or prosecution purposes,

1 shall consider the nature of the prescriber's and dispenser's practice and the
2 condition for which the patient is being treated.

3 ~~(11)~~~~(10)~~ The data and any report obtained therefrom shall not be a public record,
4 except that the Department for Medicaid Services may submit the data as evidence
5 in an administrative hearing held in accordance with KRS Chapter 13B.

6 ~~(12)~~~~(11)~~ Intentional failure to comply with the reporting requirements of this
7 section~~[by a dispenser to transmit data to the cabinet as required by subsection (3),~~
8 ~~(4), or (5) of this section]~~ shall be a Class B misdemeanor for the first offense and a
9 Class A misdemeanor for each subsequent offense.

10 ~~(13)~~~~(12)~~ Intentional disclosure of transmitted data to a person not authorized by
11 subsections~~[subsection] (7)~~~~(6)~~ to~~[subsection] (9)~~~~(8)~~ of this section or authorized
12 by KRS 315.121, or obtaining information under this section not relating to a bona
13 fide current or prospective patient or a bona fide specific investigation, shall be a
14 Class B misdemeanor for the first offense and a Class A misdemeanor for each
15 subsequent offense.

16 ~~(14)~~~~(13)~~ ~~(a) The Commonwealth Office of Technology, in consultation with the~~
17 ~~Cabinet for Health and Family Services, may submit an application to the United~~
18 ~~States Department of Justice for a drug diversion grant to fund a pilot or continuing~~
19 ~~project to study, create, or maintain a real-time electronic monitoring system for~~
20 ~~Schedules II, III, IV, and V controlled substances.~~

21 ~~(b) The pilot project shall:~~

- 22 1. ~~Be conducted in two (2) rural counties that have an interactive real-time electronic~~
23 ~~information system in place for monitoring patient utilization of health and social~~
24 ~~services through a federally funded community access program; and~~
- 25 2. ~~Study the use of an interactive system that includes a relational data base with query~~
26 ~~capability.~~

27 ~~(c) Funding to create or maintain a real-time electronic monitoring system for~~

1 ~~Schedules II, III, IV, and V controlled substances may be sought for a statewide~~
2 ~~system or for a system covering any geographic portion or portions of the state.~~

3 ~~(14) Provisions in this section that relate to data collection, disclosure, access, and~~
4 ~~penalties shall apply to the pilot project authorized under subsection (13) of this~~
5 ~~section.~~

6 ~~(15)~~ The Cabinet for Health and Family Services may, by promulgating an
7 administrative regulation, limit the length of time that data remain in the electronic
8 system. Any data removed from the system shall be archived and subject to retrieval
9 within a reasonable time after a request from a person authorized to review data
10 under this section.

11 ~~(15)~~~~(16)~~ (a) The Cabinet for Health and Family Services shall work with each board
12 responsible for the licensure, regulation, or discipline of practitioners,
13 pharmacists, or other persons who are authorized to prescribe, administer, or
14 dispense controlled substances for the development of a continuing education
15 program about the purposes and uses of the electronic system for monitoring
16 established in this section.

17 (b) The cabinet shall work with the Kentucky Bar Association for the
18 development of a continuing education program for attorneys about the
19 purposes and uses of the electronic system for monitoring established in this
20 section.

21 (c) The cabinet shall work with the Justice and Public Safety Cabinet for the
22 development of a continuing education program for law enforcement officers
23 about the purposes and uses of the electronic system for monitoring
24 established in this section.

25 ~~(16)~~~~(17)~~ If the cabinet becomes aware of a prescriber's or dispenser's failure to comply
26 with this section, the cabinet shall notify the licensing board or agency responsible
27 for licensing the prescriber or dispenser. The licensing board shall treat the

1 notification as a complaint against the licensee.

2 ~~(17)~~~~(18)~~ The cabinet shall promulgate administrative regulations to implement the
3 provisions of this section. Included in these administrative regulations shall be:

4 (a) An error resolution process allowing a patient to whom a report had been
5 disclosed under subsection ~~(9)~~~~(8)~~ of this section to request the correction of
6 inaccurate information contained in the system relating to that patient; and

7 ~~(b) [Beginning July 1, 2013,]~~A requirement that data be reported to the system
8 under subsection (3) of this section within one (1) day of dispensing.

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

10 (1) All police officers and deputy sheriffs directly employed full-time by state, county,
11 city, urban-county, or consolidated local governments, the Department of Kentucky
12 State Police, the Cabinet for Health and Family Services, their officers and agents,
13 and of all city, county, and Commonwealth's attorneys, and the Attorney General,
14 within their respective jurisdictions, shall enforce all provisions of this chapter and
15 cooperate with all agencies charged with the enforcement of the laws of the United
16 States, of this state, and of all other states relating to controlled substances.

17 (2) For the purpose of enforcing the provisions of this chapter, the designated agents of
18 the Cabinet for Health and Family Services shall have the full power and authority
19 of peace officers in this state, including the power of arrest and the authority to bear
20 arms, and shall have the power and authority to administer oaths; to enter upon
21 premises at all times for the purpose of making inspections; to seize evidence; to
22 interrogate all persons; to require the production of prescriptions, of books, papers,
23 documents, or other evidence; to employ special investigators; and to expend funds
24 for the purpose of obtaining evidence and to use data obtained under KRS
25 218A.202~~(7)~~ in any administrative proceeding before the cabinet.

26 (3) The Kentucky Board of Pharmacy, its agents and inspectors, shall have the same
27 powers of inspection and enforcement as the Cabinet for Health and Family

1 Services.

2 (4) Designated agents of the Cabinet for Health and Family Services and the Kentucky
3 Board of Pharmacy are empowered to remove from the files of a pharmacy or the
4 custodian of records for that pharmacy any controlled substance prescription or
5 other controlled substance record upon tendering a receipt. The receipt shall be
6 sufficiently detailed to accurately identify the record. A receipt for the record shall
7 be a defense to a charge of failure to maintain the record.

8 (5) Notwithstanding the existence or pursuit of any other remedy, civil or criminal, any
9 law enforcement authority may maintain, in its own name, an action to restrain or
10 enjoin any violation of this chapter or to forfeit any property subject to forfeiture
11 under KRS 218A.410, irrespective of whether the owner of the property has been
12 charged with or convicted of any offense under this chapter.

13 (a) Any civil action against any person brought pursuant to this section may be
14 instituted in the Circuit Court in any county in which the person resides, in
15 which any property owned by the person and subject to forfeiture is found, or
16 in which the person has violated any provision of this chapter.

17 (b) A final judgment rendered in favor of the Commonwealth in any criminal
18 proceeding brought under this chapter shall estop the defendant from denying
19 the essential allegations of the criminal offense in any subsequent civil
20 proceeding brought pursuant to this section.

21 (c) The prevailing party in any civil proceeding brought pursuant to this section
22 shall recover his or her costs, including a reasonable attorney's fee.

23 (d) Distribution of funds under this section shall be made in the same manner as
24 in KRS 218A.420, except that if the Commonwealth's attorney has not
25 initiated the forfeiture action under this section, his or her percentage of the
26 funds shall go to the agency initiating the forfeiture action.

27 (6) The Cabinet for Health and Family Services shall make or cause to be made

1 examinations of samples secured under the provisions of this chapter to determine
2 whether any provision has been violated.

3 (7) (a) The Cabinet for Health and Family Services shall proactively use the data
4 compiled in the electronic system created in KRS 218A.202 for investigations,
5 research, statistical analysis, and educational purposes and shall proactively
6 identify trends in controlled substance usage and other potential problem
7 areas. Only cabinet personnel who have undergone training for the electronic
8 system and who have been approved to use the system shall be authorized
9 access to the data and reports under this subsection. The cabinet shall notify a
10 state licensing board listed in KRS 218A.205 if a report or analysis conducted
11 under this subsection indicates that further investigation about improper,
12 inappropriate or illegal prescribing or dispensing may be necessary by the
13 board. The board shall consider each report and may, after giving due
14 consideration to areas of practice, specialties, board certifications, and
15 appropriate standards of care, request and receive a follow-up report or
16 analysis containing relevant information as to the prescriber or dispenser and
17 his or her patients.

18 (b) The cabinet shall develop criteria, in collaboration with the Board of Medical
19 Licensure, the Board of Nursing, the Office of Drug Control Policy, and the
20 Board of Pharmacy, to be used to generate public trend reports from the data
21 obtained by the system. Meetings at which the criteria are developed shall be
22 meetings, as defined in KRS 61.805, that comply with the open meetings
23 laws, KRS 61.805 to 61.850. The cabinet shall, on a quarterly basis, publish
24 trend reports from the data obtained by the system. Except as provided in
25 subsection (8) of this section, these trend reports shall not identify an
26 individual prescriber, dispenser, or patient. Peace officers authorized to
27 receive data under KRS 218A.202 may request trend reports not specifically

1 published pursuant to this paragraph except that the report shall not identify an
2 individual prescriber, dispenser, or patient.

3 (8) If the cabinet deems it to be necessary and appropriate, upon the request of a state
4 licensing board listed in KRS 218A.205, the cabinet shall provide the requesting
5 board with the identity of prescribers, dispensers, and patients used to compile a
6 specific trend report.

7 (9) Any hospital or other health care facility may petition the cabinet to review data
8 from the electronic system specified in KRS 218A.202 as it relates to employees of
9 that facility to determine if inappropriate prescribing or dispensing practices are
10 occurring. The cabinet may initiate any investigation in such cases as he or she
11 determines is appropriate, and may request the assistance from the hospitals or
12 health care facilities in the investigation.