TEAM KENTUCKY®

CABINET FOR HEALTH AND FAMILY SERVICES

KASPER

Kentucky Revised Statutes and Kentucky Administrative Regulations

Pertaining to an

Electronic System for Monitoring Controlled Substances

(KASPER)

Compiled July 20, 2018

KASPER Statutes and Administrative Regulation

218A.172 Administrative regulations on prescribing or dispensing of Schedule II controlled substance or Schedule III controlled substance containing hydrocodone -- Continuing course of treatment -- Recordkeeping -- Exemptions.

(1) Administrative regulations promulgated under KRS 218A.205(3) shall require that, prior to the initial prescribing or dispensing of any Schedule II controlled substance or a Schedule III controlled substance containing hydrocodone to a human patient, a practitioner shall:

(a) Obtain a medical history and conduct a physical or mental health examination of the patient, as appropriate to the patient's medical complaint, and document the information in the patient's medical record;

(b) Query the electronic monitoring system established in KRS 218A.202 for all available data on the patient for the twelve (12) month period immediately preceding the patient encounter and appropriately utilize that data in the evaluation and treatment of the patient;

(c) Make a written plan stating the objectives of the treatment and further diagnostic examinations required;

(d) Discuss the risks and benefits of the use of controlled substances with the patient, the patient's parent if the patient is an unemancipated minor child, or the patient's legal guardian or health care surrogate, including the risk of tolerance and drug dependence; and

(e) Obtain written consent for the treatment.

(2) (a) Administrative regulations promulgated under KRS 218A.205(3) shall require that a practitioner prescribing or dispensing additional amounts of Schedule II controlled substances or Schedule III controlled substances containing hydrocodone for the same medical complaint and related symptoms shall:

1. Review, at reasonable intervals based on the patient's individual circumstances and course of treatment, the plan of care;
2. Provide to the patient any new information about the treatment; and
3. Modify or terminate the treatment as appropriate.

(b) If the course of treatment extends beyond three (3) months, the administrative regulations shall also require that the practitioner:

1. Query the electronic monitoring system established in KRS 218A.202 no less than once every three (3) months for all available data on the patient for the twelve (12) month period immediately preceding the query; and
2. Review that data before issuing any new prescription or refills for the patient for any Schedule II controlled substance or a Schedule III controlled substance containing hydrocodone.

(3) Administrative regulations promulgated under KRS 218A.205(3) shall require that, for each patient for whom a practitioner prescribes any Schedule II controlled substance or a Schedule III controlled substance containing hydrocodone, the practitioner shall keep accurate, readily accessible, and complete medical records which include, as appropriate:

(a) Medical history and physical or mental health examination;

(b) Diagnostic, therapeutic, and laboratory results;

(c) Evaluations and consultations;

(d) Treatment objectives;
(e) Discussion of risk, benefits, and limitations of treatments;
(f) Treatments;
(g) Medications, including date, type, dosage, and quantity prescribed or dispensed;
(h) Instructions and agreements; and
(i) Periodic reviews of the patient's file.

(4) Administrative regulations promulgated under KRS 218A.205(3) may exempt, in whole or in part, compliance with the mandatory diagnostic, treatment, review, and other protocols and standards established in this section for:

(a) A licensee prescribing or administering a controlled substance immediately prior to, during, or within the fourteen (14) days following an operative or invasive procedure or a delivery if the prescribing or administering is medically related to the operative or invasive procedure or the delivery and the medication usage does not extend beyond the fourteen (14) days;
(b) A licensee prescribing or administering a controlled substance necessary to treat a patient in an emergency situation;
(c) A licensed pharmacist or other person licensed by the Kentucky Board of Pharmacy to dispense drugs or a licensed pharmacy;
(d) A licensee prescribing or dispensing a controlled substance:

1. For administration in a hospital or long-term-care facility if the hospital or long-term-care facility with an institutional account, or a practitioner in those hospitals or facilities where no institutional account exists, queries the electronic monitoring system established in KRS 218A.202 for all available data on the patient or resident for the twelve (12) month period immediately preceding the query within twelve (12) hours of the patient's or resident's admission and places a copy of the query in the patient's or resident's medical records during the duration of the patient's stay at the facility;
2. As part of the patient's hospice or end-of-life treatment;
3. For the treatment of pain associated with cancer or with the treatment of cancer;
4. In a single dose to relieve the anxiety, pain, or discomfort experienced by a patient submitting to a diagnostic test or procedure;
5. Within seven (7) days of an initial prescribing or dispensing under subsection (1) of this section if the prescribing or dispensing:
    a. Is done as a substitute for the initial prescribing or dispensing;
    b. Cancels any refills for the initial prescription; and
    c. Requires the patient to dispose of any remaining unconsumed medication;
6. Within ninety (90) days of an initial prescribing or dispensing under subsection (1) of this section if the prescribing or dispensing is done by another practitioner in the same practice or in an existing coverage arrangement, if done for the same patient for the same medical condition; or
7. To a research subject enrolled in a research protocol approved by an institutional review board that has an active federal wide 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;

(e) The prescribing of a Schedule III, IV, or V controlled substance by a licensed optometrist to a patient in accordance with the provisions of KRS 320.240; or

(f) The prescribing of a three (3) day supply of a Schedule III controlled substance following the performance of oral surgery by a dentist licensed pursuant to KRS Chapter 313.

(5) (a) A state licensing board promulgating administrative regulations under KRS 218A.205(3) may promulgate an administrative regulation authorizing exemptions supplemental or in addition to those specified in subsection (4) of this section. Prior to exercising this authority, the board shall:

1. Notify the Kentucky Office of Drug Control Policy that it is considering a proposal to promulgate an administrative regulation authorizing exemptions supplemental or in addition to those specified in subsection (4) of this section and invite the office to participate in the board meeting at which the proposal will be considered;

2. Make a factual finding based on expert testimony as well as evidence or research submitted to the board that the exemption demonstrates a low risk of diversion or abuse and is supported by the dictates of good medical practice; and

3. Submit a report to the Governor and the Legislative Research Commission of its actions, including a detailed explanation of the factual and policy basis underlying the board's action. A copy of this report shall be provided to the regulations compiler.

(b) Within one (1) working day of promulgating an administrative regulation authorizing an exemption under this section, the promulgating board shall e-mail to the Kentucky Office of Drug Control Policy:

1. A copy of the administrative regulation as filed, and all attachments required by KRS 13A.230(1); and

2. A request from the board that the office review the administrative regulation in the same manner as would the Commission on Small Business Advocacy under KRS 11.202(1)(e), and submit its report or comments in accordance with the deadline established in KRS 13A.270(1)(c). A copy of the report or comments shall be filed with the regulations compiler.

Effective:March 4, 2013
History: Amended 2013 Ky. Acts ch. 2, sec. 1, effective March 4, 2013. – Created 2012 (1st Extra. Sess.) Ky. Acts ch. 1, sec. 3, effective July 20, 2012.

218A.202 Electronic system for monitoring controlled substances – Required registration and reporting -- Penalty for illegal use of system -- Continuing education programs -- Reports of failure to comply with section -- Quarterly reviews to identify patterns of improper prescribing or dispensing -- Administrative regulations -- Collection and retention of drug conviction data.

(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. 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 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. 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

(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 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) 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) 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 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) 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 certifies that the requested information is for the purpose of:

1. Providing medical or pharmaceutical treatment to a bona fide current or prospective patient;
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) 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) 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)(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)(b) of this section authorized to receive data or a report if the persons specified in subsection (7)(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)(a) of this section, or with a law enforcement officer designated in subsection (7)(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)(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 place the report in the patient's medical record, in which case the individual report shall then be 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) The Cabinet for Health and Family Services, all peace officers specified in subsection (7)(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) 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) Intentional failure to comply with the reporting requirements of this section shall be a Class B misdemeanor for the first offense and a Class A misdemeanor for each subsequent offense.

(13) Intentional disclosure of transmitted data to a person not authorized by subsections (7) to (9) 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) 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) (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) 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) The Cabinet for Health and Family Services, Office of Inspector General, shall conduct quarterly reviews to identify patterns of potential improper, inappropriate, or illegal prescribing or dispensing of a controlled substance. The Office of Inspector General may independently investigate and submit findings and recommendations to the appropriate boards of licensure or other reporting agencies.

(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) of this section to request the correction of inaccurate information contained in the system relating to that patient; and

(b) A requirement that data be reported to the system under subsection (3) of this section within one (1) day of dispensing.

(19) Before July 1, 2018, the Administrative Office of the Courts shall forward data regarding any felony or Class A misdemeanor conviction that involves the

trafficking or possession of a controlled substance or other prohibited acts under KRS Chapter 218A for the previous five (5) calendar years to the cabinet for inclusion in the electronic monitoring system established under this section. On or after July 1, 2018 such data shall be forwarded by the Administrative Office of the Courts to the cabinet on a continuing basis. The cabinet shall incorporate the data received into the system so that a query by patient name indicates any prior drug conviction.

Effective: June 29, 2017

History: Amended 2017 Ky. Acts ch. 120, sec. 1, effective June 29, 2017; ch. 138, sec. 1, effective June 29, 2017; and ch. 168, sec. 10, effective June 29, 2017. -- Amended 2013 Ky. Acts ch. 2, sec. 3, effective March 4, 2013. -- Amended 2012 (1st Extra. Sess.) Ky. Acts ch. 1, sec. 4, effective July 20, 2012. -- Amended 2010 Ky. Acts ch. 85, sec. 43, effective July 15, 2010. -- Amended 2007 Ky. Acts ch. 85, sec. 252, effective June 26, 2007; and ch. 124, sec. 4, effective June 26, 2007. -- Amended 2006 Ky. Acts ch. 5, sec. 5, effective July 12, 2006. -- Amended 2005 Ky. Acts ch. 85, sec. 627, effective June 20, 2005; and ch. 99, sec. 543, effective June 20, 2005. -- Amended 2004 Ky. Acts ch. 68, sec. 1, effective July 13, 2004; and ch. 107, sec. 1, effective July 13, 2004. -- Amended 2002 Ky. Acts ch. 295, sec. 1, effective April 9, 2002. -- Created 1998 Ky. Acts ch. 301, sec. 13, effective July 15, 1998.

Legislative Research Commission Note (6/29/2017). This statute was amended by 2017 Ky. Acts chs. 120, 138, and 168, which do not appear to be in conflict and have been codified together.

Legislative Research Commission Note (7/13/2004). This section was amended by 2004 Ky. Acts chs. 68 and 107. Where these Acts are not in conflict, they have been codified together. Where a conflict exists, Acts ch. 107, which was last enacted by the General Assembly, prevails under KRS 446.250.

218A.205 Reports of improper, inappropriate, or illegal prescribing or dispensing of controlled substances -- Administrative regulations for prescribing and dispensing protocols and licensure actions and requirements -- Presumption of medical necessity -- Complaint procedure -- Criminal record check.

(1) As used in this section:

(a) "Reporting agency" includes:

1. The Department of Kentucky State Police;
2. The Office of the Attorney General;
3. The Cabinet for Health and Family Services; and
4. The applicable state licensing board; and

(b) "State licensing board" means:

1. The Kentucky Board of Medical Licensure;
2. The Kentucky Board of Nursing;
3. The Kentucky Board of Dentistry;
4. The Kentucky Board of Optometric Examiners;
5. The State Board of Podiatry; and
6. Any other board that licenses or regulates a person who is entitled to prescribe or dispense controlled substances to humans.

(2) (a) When a reporting agency or a law enforcement agency receives a report of improper, inappropriate, or illegal prescribing or dispensing of a controlled substance it may, to the extent otherwise allowed by law, send a copy of the report within three (3) business days to every other reporting agency.

(b) A county attorney or Commonwealth's attorney shall notify the Office of the Attorney General and the appropriate state licensing board within three (3) business days of an indictment or a waiver of indictment becoming public in his or her jurisdiction charging a licensed person with a felony offense relating to the manufacture of, trafficking in, prescribing, dispensing, or possession of a controlled substance.

(3) Each state licensing board shall, in consultation with the Kentucky Office of Drug Control Policy, establish the following by administrative regulation for those licensees authorized to prescribe or dispense controlled substances:

(a) Mandatory prescribing and dispensing standards related to controlled substances, the requirements of which shall include the diagnostic, treatment, review, and other protocols and standards established for Schedule II controlled substances and Schedule III controlled substances containing hydrocodone under KRS 218A.172 and which may include the exemptions authorized by KRS 218A.172(4);

(b) In accord with the CDC Guideline for Prescribing Opioids for Chronic Pain published in 2016, a prohibition on a practitioner issuing a prescription for a Schedule II controlled substance for more than a three (3) day supply of a Schedule II controlled substance if the prescription is intended to treat pain as an acute medical condition, with the following exceptions:

1. The practitioner, in his or her professional judgment, believes that more than a three (3) day supply of a Schedule II controlled substance is medically necessary to treat the patient's pain as an acute medical condition and the practitioner adequately documents the acute medical condition and lack of alternative treatment options which justifies deviation from the three (3) day supply limit established in this subsection in the patient's medical records;

2. The prescription for a Schedule II controlled substance is prescribed to treat chronic pain;
3. The prescription for a Schedule II controlled substance is prescribed to treat pain associated with a valid cancer diagnosis;
4. The prescription for a Schedule II controlled substance is prescribed to treat pain while the patient is receiving hospice or end-of-life treatment;
5. The prescription for a Schedule II controlled substance is prescribed as part of a narcotic treatment program licensed by the Cabinet for Health and Family Services;
6. The prescription for a Schedule II controlled substance is prescribed to treat pain following a major surgery or the treatment of significant trauma, as defined by the state licensing board in consultation with the Kentucky Office of Drug Control Policy;
7. The Schedule II controlled substance is dispensed or administered directly to an ultimate user in an inpatient setting; or
8. Any additional treatment scenario deemed medically necessary by the state licensing board in consultation with the Kentucky Office of Drug Control Policy.

Nothing in this paragraph shall authorize a state licensing board to promulgate regulations which expand any practitioner's prescriptive authority beyond that which existed prior to June 29, 2017;

(c) A prohibition on a practitioner dispensing greater than a forty-eight (48) hour supply of any Schedule II controlled substance or a Schedule III controlled substance containing hydrocodone unless the dispensing is done as part of a narcotic treatment program licensed by the Cabinet for Health and Family Services;

(d) A procedure for temporarily suspending, limiting, or restricting a license held by a named licensee where a substantial likelihood exists to believe that the continued unrestricted practice by the named licensee would constitute a danger to the health, welfare, or safety of the licensee's patients or of the general public;

(e) A procedure for the expedited review of complaints filed against their licensees pertaining to the improper, inappropriate, or illegal prescribing or dispensing of controlled substances that is designed to commence an investigation within seven (7) days of a complaint being filed and produce a charging decision by the board on the complaint within one hundred twenty (120) days of the receipt of the complaint, unless an extension for a definite period of time is requested by a law enforcement agency due to an ongoing criminal investigation;

(f) The establishment and enforcement of licensure standards that conform to the following:

1. A permanent ban on licensees and applicants convicted after July 20, 2012, in this state or any other state of any felony offense relating to controlled substances from prescribing or dispensing a controlled substance;
2. Restrictions short of a permanent ban on licensees and applicants convicted in this state or any other state of any misdemeanor offense relating to prescribing or dispensing a controlled substance;
3. Restrictions mirroring in time and scope any disciplinary limitation placed on a licensee or applicant by a licensing board of another state if

the disciplinary action results from improper, inappropriate, or illegal prescribing or dispensing of controlled substances; and

4. A requirement that licensees and applicants report to the board any conviction or disciplinary action covered by this subsection with appropriate sanctions for any failure to make this required report;

(g) A procedure for the continuous submission of all disciplinary and other reportable information to the National Practitioner Data Bank of the United States Department of Health and Human Services;

(h) If not otherwise required by other law, a process for submitting a query on each applicant for licensure to the National Practitioner Data Bank of the United States Department of Health and Human Services to retrieve any relevant data on the applicant; and

(i) Continuing education requirements beginning with the first full educational year occurring after July 1, 2012, that specify that at least seven and one-half percent (7.5%) of the continuing education required of the licensed practitioner relate to the use of the electronic monitoring system established in KRS 218A.202, pain management, or addiction disorders.

(4) For the purposes of pharmacy dispensing, the medical necessity for a Schedule II controlled substance as documented by the practitioner in the patient's medical record and the prescription for more than a three (3) day supply of that controlled substance are presumed to be valid.

(5) A state licensing board shall employ or obtain the services of a specialist in the treatment of pain and a specialist in drug addiction to evaluate information received regarding a licensee's prescribing or dispensing practices related to controlled substances if the board or its staff does not possess such expertise,
to ascertain if the licensee under investigation is engaging in improper, inappropriate, or illegal practices.

(6) Any statute to the contrary notwithstanding, no state licensing board shall require that a grievance or complaint against a licensee relating to controlled substances be sworn to or notarized, but the grievance or complaint shall identify the name and address of the grievant or complainant, unless the board by administrative regulation authorizes the filing of anonymous complaints. Any such authorizing administrative regulation shall require that an anonymous complaint or grievance be accompanied by sufficient corroborating evidence as would allow the board to believe, based upon a totality of the circumstances, that a reasonable probability exists that the complaint or grievance is meritorious.

(7) Every state licensing board shall cooperate to the maximum extent permitted by law with all state, local, and federal law enforcement agencies, and all professional licensing boards and agencies, state and federal, in the United States or its territories in the coordination of actions to deter the improper, inappropriate, or illegal prescribing or dispensing of a controlled substance.

(8) Each state licensing board shall require a fingerprint-supported criminal record check by the Department of Kentucky State Police and the Federal Bureau of Investigation of any applicant for initial licensure to practice any profession authorized to prescribe or dispense controlled substances.

Effective: June 29, 2017
History: Amended 2017 Ky. Acts ch. 168, sec. 7, effective June 29, 2017. -- Amended 2013 Ky. Acts ch. 2, sec. 4, effective March 4, 2013. -- Created 2012 (1st Extra. Sess.) Ky. Acts ch. 1, sec. 2, effective July 20, 2012.

218A.240 Controlled substances -- Duties and authority of state and local officers, Cabinet for Health and Family Services, and Kentucky Board of Pharmacy -- Civil proceedings -- Identification of trends -- Identification of prescribers, dispensers, and patients for licensing board -- Review of hospital's or health care facility's prescribing and dispensing practices.

(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 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.

Effective: June 29, 2017

History: Amended 2017 Ky. Acts ch. 138, sec. 2, effective June 29, 2017. -- Amended 2012 (1st Extra. Sess.) Ky. Acts ch. 1, sec. 5, effective July 20, 2012.

-- Amended 2007 Ky. Acts ch. 85, sec. 253, effective June 26, 2007; and ch. 124, sec. 14, effective June 26, 2007. -- Amended 2005 Ky. Acts ch. 99, sec. 546, effective June 20, 2005. -- Amended 2004 Ky. Acts ch. 68, sec. 2, effective July 13, 2004; and ch. 107, sec. 2, effective July 13, 2004. -- Amended 1998 Ky. Acts ch. 301, sec. 26, effective July 15, 1998; and ch. 426, sec. 487, effective July 15, 1988. -- Amended 1992 Ky. Acts ch. 441, sec. 28, effective July 14, 2992. -- Amended 1974 Ky. Acts ch. 74, Art. VI, sec. 107(3). -- Created 1972 Ky. Acts ch. 226, sec. 26.

218A.245 Reciprocal agreements or contracts with other states or administering organization to share prescription drug monitoring information.

(1) The secretary of the Cabinet for Health and Family Services may enter into reciprocal agreements or a contract, either directly with any other state or states of the United States or any jurisdiction, county, or political subdivision thereof, or with an organization administering the exchange of interstate data on behalf of the prescription monitoring program of one (1) or more states or jurisdictions, to share prescription drug monitoring information if the other prescription drug monitoring program or data exchange program is compatible with the program in Kentucky. If the secretary elects to evaluate the prescription drug monitoring program of another state, jurisdiction, or organization as authorized by this section, priority shall be given to a state or jurisdiction that is contiguous with the borders of the Commonwealth or an organization that offers connectivity with a contiguous state or jurisdiction.

(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 or dispensing;

(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 prescribing and dispensing of controlled substances in the Commonwealth.

(5) Any agreement between the cabinet and another state, jurisdiction, or organization shall prohibit the sharing of information about a Kentucky resident, practitioner, pharmacist, or other prescriber or dispenser for any purpose not otherwise authorized by this section or KRS 218A.202.

Effective: July 14, 2018

History: Amended 2018 Ky. Acts ch. 30, sec. 1, effective July 14, 2018. -- Amended 2012 (1st Extra. Sess.) Ky. Acts ch. 1, sec. 6, effective July 20, 2012. -- Amended 2005 Ky. Acts ch. 99, sec. 547, effective June 20, 2005. -- Created 2004 Ky. Acts ch. 107, sec. 3, effective July 13, 2004.

902 KAR 55:110. Monitoring system for prescription controlled substances.

RELATES TO: KRS 218A.010(11), 218A.202, 218A.240
STATUTORY AUTHORITY: KRS 194A.050, 218A.202(1), (17), 218A.250
NECESSITY, FUNCTION, AND CONFORMITY: KRS 218A.202(1) directs the Cabinet for Health and Family Services to establish and maintain an electronic system for monitoring Schedule II, III, IV, and V controlled substances. KRS 218A.250 requires the cabinet to promulgate administrative regulations pursuant to KRS Chapter 13A for carrying out the provisions of KRS Chapter 218A. This administrative regulation establishes criteria for reporting prescription data, providing reports to authorized persons, and a waiver for a dispenser who does not have an automated recordkeeping system.

Section 1. Definitions. (1) "Branch" means the Drug Enforcement and Professional Practices Branch in the Division of Audits and Investigations, Office of Inspector General, Cabinet for Health and Family Services.

(2) "Cabinet personnel" means an individual who:

(a)1. Is directly employed by the Cabinet for Health and Family Services; or

2. Is employed by an agent or contractor of the cabinet;

(b) Has undergone KASPER training; and

(c) Has been approved to use the KASPER system.

(3) "Dispenser" is defined by KRS 218A.010(11), and shall:

(a) Include a dispenser who has a DEA (Drug Enforcement Administration) number or is a pharmacist who owns or is employed by a facility that operates a pharmacy that has a DEA number; and

(b) Not include an individual licensed to practice veterinary medicine under KRS Chapter 321.

(4) "Health facility" is defined by KRS 216B.015(13).

(5) "KASPER" means Kentucky All-Schedule Prescription Electronic Reporting System.

(6) "Patient identifier" means a patient's:

(a) Full name;

(b) Address, including zip code;

(c) Date of birth; and

(d) Social Security number or an alternative identification number established pursuant to Section 5 of this administrative regulation.

(7) "Practitioner" is defined by KRS 218A.010(39).

(8) "Report" means a compilation of data concerning a patient, dispenser, practitioner, or controlled substance.

(9) "Suspected drug overdose" means an acute condition that:

(a) May include physical illness, coma, mania, or hysteria that is the result of consumption or use of a controlled substance, or another substance with which a controlled substance was combined; and

(b) Relates to injury, poisoning by, or other adverse effect of any substance corresponding to the following International Classification of Disease (ICD) version 10 (ICD-10) codes, or equivalent codes in the most recent version of the International Statistical Classification of Diseases and Related Health Problems:

1. T40;

2. T42; or

3. T43.

Section 2. Data Reporting. (1) A dispenser or a health facility that has a DEA number shall report all dispensed Schedule II, III, IV, or V controlled substances, except during the circumstances specified in KRS 218A.202(3)(a) through (c).

(2) A dispenser of a Schedule II, III, IV, or V controlled substance shall transmit or provide the following data to the cabinet or the cabinet's agent:

(a) Patient identifier;

(b) National drug code of the drug dispensed;

(c) Metric quantity of the drug dispensed;

(d) Date of dispensing;

(e) Estimated days the supply of dispensed medication will last;

(f) Drug Enforcement Administration registration number of the prescriber;

(g) Prescription number assigned by the dispenser; and

(h) The Drug Enforcement Administration registration number of the dispenser.

(3) The data identified in subsection (2) of this section shall be transmitted no later than close of business on the business day immediately following the dispensing unless the cabinet grants an extension as provided in subsection (4) or (5) of this section.

(4)(a) An extension may be granted if:

1. The dispenser suffers a mechanical or electronic failure; or

2. The dispenser cannot meet the deadline established by subsection (3) of this section because of reasons beyond his or her control.

(b) A dispenser shall apply to the branch in writing for an extension listed in paragraph (a) of this subsection within twenty-four (24) hours of discovery of the circumstances necessitating the request or on the next date state offices are open for business, following the discovery. An application for an extension shall state the justification for the extension and the period of time for which the extension is necessary.

(5) An extension shall be granted to a dispenser if the cabinet or its agent is unable to receive electronic reports transmitted by the dispenser.

(6) Except as provided in subsection (8) of this section, the data shall be transmitted by:

(a) An electronic device compatible with the receiving device of the cabinet or the cabinet's agent;

(b) Secure File Transfer Protocol;

(c) https protocol; or

(d) Secure Virtual Private Network connection.

(7) The data shall be transmitted in the telecommunications format for controlled substances established by the Implementation Guide,ASAP Standard for Prescription Monitoring Programs, developed by the American Society for Automation in Pharmacy, Version 4.2, or a comparable format approved by the branch.

(8) A dispenser who does not have an automated recordkeeping system capable of producing an electronic report in the telecommunications format for controlled substances established by the Implementation Guide, ASAP Standard for Prescription Monitoring Programs shall report the data identified in subsection (2) of this section using an Internet accessible web portal designated by the cabinet.

(9) To meet the reporting requirement of KRS 218A.202(4), a hospital shall report to the cabinet all positive toxicology screens ordered by the hospital's emergency department to evaluate a patient's suspected drug overdose via the Kentucky Health Information Exchange.

Section 3. Compliance. A dispenser may presume that the patient identification information established in Section 5 of this administrative regulation and provided by the patient or the patient's agent is correct.

Section 4. Request for Report. (1) A written or electronic request shall be filed with the cabinet prior to the release of a report, except for a subpoena issued by a grand jury or an appropriate court order issued by a court of competent jurisdiction.
(2) A request for a KASPER patient report shall be made electronically at www.chfs.ky.gov/KASPER.
(3) A request for a KASPER provider report made by a peace officer authorized to receive data under KRS 218A.202, or a designated representative of a board responsible for the licensure, regulation, or discipline of prescribing practitioners shall be made by written application on the KASPER Report Request for Law Enforcement and Licensure Boards, Form DCB-20L.
(4) A medical examiner engaged in a death investigation pursuant to KRS 72.026 may query KASPER for a report on the decedent.

Section 5. Patient Identification Number. (1) A patient or the person obtaining the controlled substance on behalf of the patient shall disclose to the dispenser the patient's Social Security number for purposes of the dispenser's mandatory reporting to KASPER.
(2) If a patient is an adult who does not have a Social Security number, the patient's driver's license number shall be disclosed.
(3) If a patient is an adult who has not been assigned a Social Security number or a driver's license number, the number 000-00-0000 shall be used in the Social Security field.
(4) If a patient is a child who does not have a Social Security number or a driver's license number, the number "000-00-0000" shall be used in the Social Security field.
(5) If a patient is an animal, the number "000-00-0000" shall be used in the Social Security number field.

Section 6. KASPER Data and Trend Reports. Cabinet personnel shall have authorized access to the data obtained from the KASPER system and trend reports in accordance with KRS 218A.240(7)(a).

Section 7. Data Retention. Data shall be maintained in KASPER according to the Office of Inspector General's retention schedule on file with the State Archives and Records Commission.

Section 8. Error Resolution. (1) A patient, patient's representative, practitioner, pharmacist, health facility, or private practitioner's office or clinic to whom a report has been disclosed under KRS 218A.202(9) or this administrative regulation may request that information contained in KASPER be corrected if the patient, patient's representative, practitioner, pharmacist, health facility, or private practitioner's office or clinic believes that any information is inaccurate. The patient, patient's representative, practitioner, pharmacist, health facility, or private practitioner's office or clinic shall:

(a) Contact the dispenser who reported the information required by Section 2(2) of this administrative regulation; and

(b) Request that the dispenser correct the information.

(2) If, upon receipt of a request from a patient, patient's representative, practitioner, pharmacist, health facility, or private practitioner's office or clinic pursuant to subsection (1) of this section, the dispenser confirms that the information was reported in error, the dispenser shall:

(a) Transmit corrected information to update the KASPER database within seven (7) calendar days of the request for the correction; and

(b) Notify the patient, patient's representative, practitioner, pharmacist, health facility, or private practitioner's office or clinic that the corrected information has been transmitted.

(3) If a dispenser identifies a KASPER system generated error, the dispenser shall notify the branch. Upon verification of the error, the branch shall:

(a) Correct the information in the KASPER database; and

(b) Notify the patient, patient's representative, practitioner, pharmacist, health facility, private practitioner's office or clinic within five (5) working days of the correction.

Section 9. Referrals to Licensing Boards. If the cabinet becomes aware that a prescriber or dispenser has failed to comply with the reporting requirements of KRS 218A.202 and this administrative regulation, the cabinet shall notify the licensing board or agency responsible for licensing the prescriber or dispenser.

Section 10. Disclosure of Data or Report. (1) The cabinet shall only disclose data to the persons and entities authorized to receive that data under KRS 218A.202(7).

(2) As a condition precedent to the disclosure of data or a report pursuant to KRS 218A.202(7)(f), a hospital or long-term care facility shall maintain, and provide upon request by the cabinet, a copy of the hospital or long-term care facility's policy for the management of KASPER data and reports, which:

(a) Describes the hospital or long-term care facility's internal procedures for educating the designated employee or employees on the:

1. Proper use of the KASPER system;

2. Prohibition on the improper use or intentional disclosure of KASPER data to unauthorized individuals; and

3. Sanctions imposed for the improper use or intentional disclosure of KASPER data to unauthorized individuals, including criminal misdemeanor offenses; and

(b) Describes the hospital or long-term care facility's internal procedures for auditing the account, including:

1. The manner in which an employee is added to or removed from access to the account if the employee ends employment or is no longer designated to query KASPER; and

2. The actions taken if a designated employee with access to the employer's KASPER account intentionally misuses his or her privileges to KASPER data or a report, which shall include a report of the incident to the Office of Inspector General.

(4)(a) An individual authorized to receive data under KRS 218A.202(7) shall not provide the data to any other entity except as provided in KRS 218A.202(9) and paragraph (b) of this subsection.

(b) In addition to the purposes authorized under KRS 218A.202(9)(e), and pursuant to KRS 218A.205(2)(a) and (6), a practitioner or pharmacist who obtains KASPER data or a report under KRS 218A.202(7)(e)1. or who in good faith believes that any

person, including a patient, has violated the law in attempting to obtain a prescription for a controlled substance, may report suspected improper or illegal use of a controlled substance to law enforcement or the appropriate licensing board.

(5) A hospital or long-term care facility shall maintain and adhere to the entity's internal policy regarding the management of KASPER data and reports.

Section 11. Incorporation by Reference. (1) The following material is incorporated by reference:

(a) "Implementation Guide, ASAP Standard for Prescription Monitoring Programs", American Society for Automation in Pharmacy, Version 4.2, September 2011; and

(b) "KASPER Report Request for Law Enforcement and Licensure Boards", Form DCB-20L, October 2017.

(2) This material may be inspected, copied, or obtained, subject to applicable copyright law, at the Drug Enforcement and Professional Practices Branch, Office of the Inspector General, Cabinet for Health and Family Services, 275 E. Main Street, Frankfort, Kentucky 40621, Monday through Friday, 8 a.m. to 4:30 p.m. (25 Ky.R. 966; Am. 1367; eff. 12-16-1998; 32 Ky.R. 1927; 33 Ky.R. 120; eff. 7-24-2006; 34 Ky.R. 2609; 35 Ky.R. 283; eff. 9-5-2008; 2615; eff. 7-31-2009; 39 Ky.R. 629; 1218; 1413; 2033; eff. 3-4-2013; 44 Ky.R. 378, 1026, 1346; eff. 1-5-2018.)