PRESCRIPTION MONITORING PROGRAM STATE PROFILES – KENTUCKY

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KENTUCKY

http://chfs.ky.gov/os/oig/KASPER.htm
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- Status of Program – operational
- Housing Entity – Cabinet for Health and Family Services
- Advisory Commission – yes
- Funding – grants
- Drugs Monitored – Schedules II – V
- Who's Required to Report Dispensing Information – every dispenser licensed, permitted, or otherwise authorized to prescribe or dispense a controlled substance
- Exemptions from Reporting – drug administered directly to a patient in a hospital, a resident of a health care facility, a resident of a child-caring facility, or an individual in a jail, correctional facility, or a juvenile detention facility; a drug, other than any Schedule II controlled substance or a Schedule III substance containing hydrocodone, dispensed by a practitioner provided that the quantity is limited to an amount adequate to treat the patient for a maximum of 48 hours; a drug dispensed to a research subject
- Nonresident Pharmacies Required to Report – yes
- Veterinarians Required to Report – no
- Data Collection Interval – daily/24 hours
- Notice to Consumers - no
- Interstate Sharing – with other PMPs and authorized users in other states
- Persons Authorized to Receive Information – county coroners and/or medical examiners; law enforcement and judicial/prosecutorial officials; licensing/regulatory boards; state-operated Medicaid program; patient or parent of minor child; health care agent; prescribers; dispensers; judge or probation and/or parole officers administering a diversion or probation program of a criminal defendant
- Delegates Allowed – yes
- De-identified Data Provided – yes
- Unsolicited Reports – to licensing boards
- Training Required – yes for employees of the Cabinet for Health and Family Services only
- Mandatory Enrollment – yes; practitioners and pharmacists
- Mandatory Access – yes; multiple circumstances; see States that Require Prescribers and/or Dispensers to Access PMP in Certain Circumstances, compilation of statutes, on NAMSDL's website for further information

Baldwin's Kentucky Revised Statutes Annotated (2014)
Title XVIII. Public Health
Chapter 218A. Controlled Substances

§ 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 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;

(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.

Baldwin's Kentucky Revised Statutes Annotated (2014)
Title XVIII. Public Health
Chapter 218A. Controlled Substances

§ 218A.202 Electronic system for monitoring controlled substances; required registration and reporting; penalty for illegal use of system; pilot or continuing project; continuing education programs; reports of failure to comply with section; administrative regulations

(1) The Cabinet for Health and Family Services shall establish an electronic system for monitoring Schedules II, III, IV, and V controlled substances that are dispensed within the Commonwealth by a practitioner or pharmacist or dispensed to an address within the Commonwealth by a pharmacy that has obtained a license, permit, or other authorization to operate from 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 dispenser within the Commonwealth who is licensed, permitted, or otherwise authorized to prescribe or dispense a controlled substance to a person in Kentucky shall report to the Cabinet for Health and Family Services the data required by this section, except that 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 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) Data for each controlled substance that is 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.

(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.

(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, 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 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 (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 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.

(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.

(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 (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 (6)(b) of this section authorized to receive data or a report if the persons specified in subsection (6)(b) of this section are working on a bona fide specific investigation involving a designated person. Both the person providing and the person receiving the data or report under this paragraph shall document in writing each person to whom the data or report has been given or received and the day, month, and year that the data or report has been given or received. This document shall be maintained in a file by each 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 (6)(a) of this section, or with a law enforcement officer designated in subsection (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 (6)(e) of this section may share the report with the patient or person authorized to act on the patient's behalf and place the report in the patient's medical record, with that individual report then 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.

(9) The Cabinet for Health and Family Services, all peace officers specified in subsection (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.

(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.

(11) Intentional failure by a dispenser to transmit data to the cabinet as required by subsection (3), (4), or (5) of this section shall be a Class B misdemeanor for the first offense and a Class A misdemeanor for each subsequent offense.

(12) Intentional disclosure of transmitted data to a person not authorized by subsection (6) to subsection (8) of this section or authorized by KRS 315.121, or obtaining information under this section not relating to a bona fide specific investigation, shall be a Class B misdemeanor for the first offense and a Class A misdemeanor for each subsequent offense.

(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.

(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.

(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.

(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 (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.

Baldwin's Kentucky Revised Statutes Annotated (2014)
Title XVIII. Public Health
Chapter 218A. Controlled Substances

§ 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(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.

Baldwin's Kentucky Revised Statutes Annotated (2014)
Title XVIII. Public Health
Chapter 218A. Controlled Substances

§ 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 with an organization administering the exchange of interstate data on behalf of the prescription monitoring program of one (1) or more states, to share prescription drug monitoring information if the other state's prescription drug monitoring program or the organization's data exchange program is compatible with the program in Kentucky. If the secretary elects to evaluate the prescription drug monitoring program of another state or organization as authorized by this section, priority shall be given to a state that is contiguous with the borders of the Commonwealth or an organization that offers connectivity with a contiguous state.

(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 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.

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Title XVIII. Public Health
Chapter 218A. Controlled Substances

§ 218A.390 Prescription Monitoring Program Compact

The Prescription Monitoring Program compact is hereby enacted into law and entered into with all other jurisdictions legally joining therein in the form substantially as follows:

ARTICLE I

PURPOSE

The purpose of this interstate compact is to provide a mechanism for state prescription monitoring programs to securely share prescription data to improve public health and safety. This interstate compact is intended to:

A. Enhance the ability of state prescription monitoring programs, in accordance with state laws, to provide an efficient and comprehensive tool for:

1. Practitioners to monitor patients and support treatment decisions;

2. Law enforcement to conduct diversion investigations where authorized by state law;

3. Regulatory agencies to conduct investigations or other appropriate reviews where authorized by state law; and

4. Other uses of prescription drug data authorized by state law for purposes of curtailing drug abuse and diversion; and

B. Provide a technology infrastructure to facilitate secure data transmission.

ARTICLE II

DEFINITIONS

As used in this compact, unless the context clearly requires a different construction:

A. “Authentication” means the process of verifying the identity and credentials of a person before authorizing access to prescription data;

B. “Authorize” means the process by which a person is granted access privileges to prescription data;

C. “Bylaws” means those bylaws established by the interstate commission pursuant to Article VIII for its governance, or for directing or controlling its actions and conduct;

D. “Commissioner” means the voting representative appointed by each member state pursuant to Article VI of this compact;

E. “Interstate commission” or “commission” means the interstate commission created pursuant to Article VI of this compact;

F. “Member state” means any state that has adopted a prescription monitoring program and has enacted the enabling compact legislation;

G. “Practitioner” means a person licensed, registered or otherwise permitted to prescribe or dispense a prescription drug;

H. “Prescription data” means data transmitted by a prescription monitoring program that contains patient, prescriber, dispenser, and prescription drug information;

I. “Prescription drug” means any drug required to be reported to a state prescription monitoring program and which includes but is not limited to substances listed in the federal Controlled Substances Act;

J. “Prescription Monitoring Program” means a program that collects, manages, analyzes, and provides prescription data under the auspices of a state;

K. “Requestor” means a person authorized by a member state who has initiated a request for prescription data;

L. “Rule” means a written statement by the interstate commission promulgated pursuant to Article VII of this compact that is of general applicability, implements, interprets or prescribes a policy or provision of the compact, or an organizational, procedural, or practice requirement of the commission, and has the force and effect of statutory law in a member state, and includes the amendment, repeal, or suspension of an existing rule;

M. “State” means any state, commonwealth, district, or territory of the United States;

N. “Technology infrastructure” means the design, deployment, and use of both individual technology based components and the systems of such components to facilitate the transmission of information and prescription data among member states; and

O. “Transmission” means the release, transfer, provision, or disclosure of information or prescription data among member states.

ARTICLE III

AUTHORIZED USES AND RESTRICTIONS ON THE PRESCRIPTION DATA

A. Under the Prescription Monitoring Program compact a member state:

1. Retains its authority and autonomy over its prescription monitoring program and prescription data in accordance with its laws, regulations and policies;

2. May provide, restrict or deny prescription data to a requestor of another state in accordance with its laws, regulations and policies;

3. May provide, restrict or deny prescription data received from another state to a requestor within that state; and

4. Has the authority to determine which requestors shall be authorized.

B. Prescription data obtained by a member state pursuant to this compact shall have the following restrictions:

1. Be used solely for purposes of providing the prescription data to a requestor; and

2. Not be stored in the state's prescription monitoring program database, except for stored images, nor in any other database.

C. A state may limit the categories of requestors of another member state that will receive prescription data.

D. The commission shall promulgate rules establishing standards for requestor authentication.

1. Every member state shall authenticate requestors according to the rules established by the commission.

2. A member state may authorize its requestors to request prescription data from another member state only after such requestor has been authenticated.

3. A member state that becomes aware of a requestor who violated the laws or regulations governing the appropriate use of prescription data shall notify the state that transmitted the prescription data.

ARTICLE IV

TECHNOLOGY AND SECURITY

A. The commission shall establish security requirements through rules for the transmission of prescription data.

B. The commission shall foster the adoption of open (vendor- and technology-neutral) standards for the technology infrastructure.

C. The commission shall be responsible for acquisition and operation of the technology infrastructure.

ARTICLE V

FUNDING

A. The commission, through its member states, shall be responsible to provide for the payment of the reasonable expenses for establishing, organizing and administering the operations and activities of the interstate compact.

B. The interstate commission may levy on and collect annual dues from each member state to cover the cost of operations and activities of the interstate commission and its staff which must be in a total amount sufficient to cover the interstate commission's annual budget as approved each year. The aggregate annual dues amount shall be allocated in an equitable manner and may consist of a fixed fee component as well as a variable fee component based upon a formula to be determined by the interstate commission, which shall promulgate a rule binding upon all member states. Such a formula shall take into account factors including, but not limited to the total number of practitioners or licensees within a member state. Fees established by the commission may be recalculated and assessed on an annual basis.

C. Notwithstanding the above or any other provision of law, the interstate commission may accept non-state funding, including grants, awards and contributions to offset, in whole or in part, the costs of the annual dues required under Article V, Section B.

D. The interstate commission shall not incur obligations of any kind prior to securing the funds adequate to meet the same; nor shall the interstate commission pledge the credit of any of the member states, except by and with the authority of the member states.

E. The interstate commission shall keep accurate accounts of all receipts and disbursements subject to the audit and accounting procedures established under its bylaws. All receipts and disbursements of funds handled by the interstate commission shall be audited annually by a certified or licensed public accountant and the report of the audit shall be included in and become part of the annual report of the interstate commission.

ARTICLE VI

INTERSTATE COMMISSION

The member states hereby create the Interstate Prescription Monitoring Program Commission. The Prescription Monitoring Program compact shall be governed by an interstate commission

comprised of the member states and not by a third-party group or federal agency. The activities of the commission are the formation of public policy and are a discretionary state function.

A. The commission shall be a body corporate and joint agency of the member states and shall have all the responsibilities, powers and duties set forth herein, and such additional powers as may be conferred upon it by a subsequent concurrent action of the respective legislatures of the member states in accordance with the terms of this compact.

B. The commission shall consist of one (1) voting representative from each member state who shall be that state's appointed compact commissioner and who is empowered to determine statewide policy related to matters governed by this compact. The compact commissioner shall be a policymaker within the agency that houses the state's Prescription Monitoring Program.

C. In addition to the state commissioner, the state shall appoint a non-voting advisor who shall be a representative of the state Prescription Monitoring Program.

D. In addition to the voting representatives and non-voting advisor of each member state, the commission may include persons who are not voting representatives, but who are members of interested organizations as determined by the commission.

E. Each member state represented at a meeting of the commission is entitled to one vote. A majority of the member states shall constitute a quorum for the transaction of business, unless a larger quorum is required by the bylaws of the commission. A representative shall not delegate a vote to another member state. In the event the compact commissioner is unable to attend a meeting of the commission, the appropriate appointing authority may delegate voting authority to another person from their state for a specified meeting. The bylaws may provide for meetings of the commission to be conducted by electronic communication.

F. The commission shall meet at least once each calendar year. The chairperson may call additional meetings and, upon the request of a simple majority of the compacting states, shall call additional meetings.

G. The commission shall establish an executive committee, which shall include officers, members, and others as determined by the bylaws. The executive committee shall have the power to act on behalf of the commission, with the exception of rulemaking. During periods when the commission is not in session the executive committee shall oversee the administration of the compact, including enforcement and compliance with the provisions of the compact, its bylaws and rules, and other such duties as deemed necessary.

H. The commission shall maintain a robust committee structure for governance (i.e., policy, compliance, education, technology, etc.) and shall include specific opportunities for stakeholder input.

I. The commission's bylaws and rules shall establish conditions and procedures under which the commission shall make its information and official records available to the public for inspection

or copying. The commission may exempt from disclosure information or official records that would adversely affect personal privacy rights or proprietary interests.

J. The commission shall provide public notice of all meetings and all meetings shall be open to the public, except as set forth in the rules or as otherwise provided in the compact. The commission may close a meeting, or portion thereof, where it determines by a two-thirds (2/3) vote of the members present that an open meeting would be likely to:

1. Relate solely to the commission's internal personnel practices and procedures;

2. Discuss matters specifically exempted from disclosure by federal and state statute;

3. Discuss trade secrets or commercial or financial information which is privileged or confidential;

4. Involve accusing a person of a crime, or formally censuring a person;

5. Discuss information of a personal nature where disclosure would constitute a clearly unwarranted invasion of personal privacy;

6. Discuss investigative records compiled for law enforcement purposes; or

7. Specifically relate to the commission's participation in a civil action or other legal proceeding.

K. For a meeting, or portion of a meeting, closed pursuant to this provision, the commission's legal counsel or designee shall certify that the meeting may be closed and shall reference each relevant exemptive provision. The commission shall keep minutes which shall fully and clearly describe all matters discussed in a meeting and shall provide a full and accurate summary of actions taken, and the reasons therefore, including a description of the views expressed and the record of a roll call vote. All documents considered in connection with an action shall be identified in such minutes. All minutes and documents of a closed meeting shall remain under seal, subject to release by a majority vote of the commission.

ARTICLE VII

POWERS AND DUTIES OF THE INTERSTATE COMMISSION

The commission shall have the following powers and duties:

A. To oversee and maintain the administration of the technology infrastructure;

B. To promulgate rules and take all necessary actions to effect the goals, purposes and obligations as enumerated in this compact, provided that no member state shall be required to create an advisory committee. The rules shall have the force and effect of statutory law and shall be binding in the member states to the extent and in the manner provided in this compact;

C. To establish a process for member states to notify the commission of changes to a state's prescription monitoring program statutes, regulations, or policies. This applies only to changes that would affect the administration of the compact;

D. To issue, upon request of a member state, advisory opinions concerning the meaning or interpretation of the interstate compact, its bylaws, rules and actions;

E. To enforce compliance with the compact provisions, the rules promulgated by the interstate commission, and the bylaws, using all necessary and proper means, including but not limited to the use of judicial process;

F. To establish and maintain one (1) or more offices;

G. To purchase and maintain insurance and bonds;

H. To borrow, accept, hire or contract for personnel or services;

I. To establish and appoint committees including, but not limited to, an executive committee as required by Article VI, Section G, which shall have the power to act on behalf of the interstate commission in carrying out its powers and duties hereunder;

J. To elect or appoint such officers, attorneys, employees, agents, or consultants, and to fix their compensation, define their duties and determine their qualifications; and to establish the interstate commission's personnel policies and programs relating to conflicts of interest, rates of compensation, and qualifications of personnel;

K. To seek and accept donations and grants of money, equipment, supplies, materials, and services, and to utilize or dispose of them;

L. To lease, purchase, accept contributions or donations of, or otherwise to own, hold, improve or use any property, real, personal, or mixed;

M. To sell, convey, mortgage, pledge, lease, exchange, abandon, or otherwise dispose of any property, real, personal or mixed;

N. To establish a budget and make expenditures;

O. To adopt a seal and bylaws governing the management and operation of the interstate commission;

P. To report annually to the legislatures, Governors and Attorneys General of the member states concerning the activities of the interstate commission during the preceding year. Such reports shall also include any recommendations that may have been adopted by the interstate commission and shall be made publically available;

Q. To coordinate education, training and public awareness regarding the compact, its implementation and operation;

R. To maintain books and records in accordance with the bylaws;

S. To perform such functions as may be necessary or appropriate to achieve the purposes of this compact; and

T. To provide for dispute resolution among member states.

ARTICLE VIII

ORGANIZATION AND OPERATION OF THE INTERSTATE COMMISSION

A. The interstate commission shall, by a majority of the members present and voting, within twelve (12) months after the first interstate commission meeting, adopt bylaws to govern its conduct as may be necessary or appropriate to carry out the purposes of the compact, including but not limited to:

1. Establishing the fiscal year of the interstate commission;

2. Establishing an executive committee, and such other committees as may be necessary for governing any general or specific delegation of authority or function of the interstate commission;

3. Providing procedures for calling and conducting meetings of the interstate commission, and ensuring reasonable notice of each such meeting;

4. Establishing the titles and responsibilities of the officers and staff of the interstate commission; and

5. Providing a mechanism for concluding the operations of the interstate commission and the return of surplus funds that may exist upon the termination of the compact after the payment and reserving of all of its debts and obligations.

B. The interstate commission shall, by a majority of the members present, elect annually from among its members a chairperson, a vice-chairperson, and a treasurer, each of whom shall have such authority and duties as may be specified in the bylaws. The chairperson or, in the chairperson's absence or disability, the vice-chairperson, shall preside at all meetings of the interstate commission. The officers so elected shall serve without compensation or remuneration from the interstate commission; provided that, subject to the availability of budgeted funds, the officers shall be reimbursed for ordinary and necessary costs and expenses incurred by them in the performance of their responsibilities as officers of the interstate commission.

C. Executive Committee, Officers and Staff

1. The executive committee shall have such authority and duties as may be set forth in the bylaws, including but not limited to:

a. Managing the affairs of the interstate commission in a manner consistent with the bylaws and purposes of the interstate commission;

b. Overseeing an organizational structure within, and appropriate procedures for the interstate commission to provide for the administration of the compact; and

c. Planning, implementing, and coordinating communications and activities with other state, federal and local government organizations in order to advance the purpose of the interstate commission.

2. The executive committee may, subject to the approval of the interstate commission, appoint or retain an executive director for such period, upon such terms and conditions and for such compensation, as the interstate commission may deem appropriate. The executive director shall serve as secretary to the interstate commission, but shall not be a member of the interstate commission. The executive director shall hire and supervise such other persons as may be authorized by the interstate commission.

D. The interstate commission's executive director and its employees shall be immune from suit and liability, either personally or in their official capacity, for a claim for damage to or loss of property or personal injury or other civil liability caused or arising out of or relating to an actual or alleged act, error, or omission that occurred, or that such person had a reasonable basis for believing occurred, within the scope of interstate commission employment, duties, or responsibilities; provided, that such person shall not be protected from suit or liability for damage, loss, injury, or liability caused by the intentional or willful and wanton misconduct of such person.

1. The liability of the interstate commission's executive director and employees or interstate commission representatives, acting within the scope of such person's employment or duties for acts, errors, or omissions occurring within such person's state may not exceed the limits of liability set forth under the constitution and laws of that state for state officials, employees, and agents. The interstate commission is considered to be an instrumentality of the states for the purposes of any such action. Nothing in this subsection shall be construed to protect such person from suit or liability for damage, loss, injury, or liability caused by the intentional or willful and wanton misconduct of such person.

2. The interstate commission shall defend the executive director, its employees, and subject to the approval of the Attorney General or other appropriate legal counsel of the member state represented by an interstate commission representative, shall defend such interstate commission representative in any civil action seeking to impose liability arising out of an actual or alleged act, error or omission that occurred within the scope of interstate commission employment, duties or responsibilities, or that the defendant had a reasonable basis for believing occurred within the scope of interstate commission employment, duties, or responsibilities, provided that

the actual or alleged act, error, or omission did not result from intentional or willful and wanton misconduct on the part of such person.

3. To the extent not covered by the state involved, member state, or the interstate commission, the representatives or employees of the interstate commission shall be held harmless in the amount of a settlement or judgment, including attorney's fees and costs, obtained against such persons arising out of an actual or alleged act, error, or omission that occurred within the scope of interstate commission employment, duties, or responsibilities, or that such persons had a reasonable basis for believing occurred within the scope of interstate commission employment, duties, or responsibilities, provided that the actual or alleged act, error, or omission did not result from intentional or willful and wanton misconduct on the part of such persons.

ARTICLE IX

RULEMAKING FUNCTIONS OF THE INTERSTATE COMMISSION

A. Rulemaking Authority--The interstate commission shall promulgate reasonable rules in order to effectively and efficiently achieve the purposes of this compact. Notwithstanding the foregoing, in the event the interstate commission exercises its rulemaking authority in a manner that is beyond the scope of the purposes of this compact, or the powers granted hereunder, then such an action by the interstate commission shall be invalid and have no force or effect. Any rules promulgated by the commission shall not override the state's authority to govern prescription drugs or each state's Prescription Monitoring Program.

B. Rulemaking Procedure--Rules shall be made pursuant to a rulemaking process that substantially conforms to the "Model State Administrative Procedure Act," of 1981 Act, Uniform Laws Annotated, Vol. 15, p.1 (2000) as amended, as may be appropriate to the operations of the interstate commission.

C. Not later than thirty (30) days after a rule is promulgated, any person may file a petition for judicial review of the rule; provided, that the filing of such a petition shall not stay or otherwise prevent the rule from becoming effective unless the court finds that the petitioner has a substantial likelihood of success. The court shall give deference to the actions of the interstate commission consistent with applicable law and shall not find the rule to be unlawful if the rule represents a reasonable exercise of the interstate commission's authority.

ARTICLE X

OVERSIGHT, ENFORCEMENT, AND DISPUTE RESOLUTION

A. Oversight

1. The executive, legislative and judicial branches of state government in each member state shall enforce this compact and shall take all actions necessary and appropriate to effectuate the compact's purposes and intent. The provisions of this compact and the rules promulgated

hereunder shall have standing as statutory law but, shall not override the state's authority to govern prescription drugs or the state's Prescription Monitoring Program.

2. All courts shall take judicial notice of the compact and the rules in any judicial or administrative proceeding in a member state pertaining to the subject matter of this compact which may affect the powers, responsibilities or actions of the interstate commission.

3. The interstate commission shall be entitled to receive all service of process in any such proceeding, and shall have standing to intervene in the proceeding for all purposes. Failure to provide service of process to the interstate commission shall render a judgment or order void as to the interstate commission, this compact or promulgated rules.

B. Default, Technical Assistance, Suspension and Termination--If the interstate commission determines that a member state has defaulted in the performance of its obligations or responsibilities under this compact, or the bylaws or promulgated rules, the interstate commission shall:

1. Provide written notice to the defaulting state and other member states, of the nature of the default, the means of curing the default and any action taken by the interstate commission. The interstate commission shall specify the conditions by which the defaulting state must cure its default.

2. Provide remedial training and specific technical assistance regarding the default.

3. If the defaulting state fails to cure the default, the defaulting state shall be terminated from the compact upon an affirmative vote of a majority of the member states and all rights, privileges and benefits conferred by this compact shall be terminated from the effective date of termination. A cure of the default does not relieve the offending state of obligations or liabilities incurred during the period of the default.

4. Suspension or termination of membership in the compact shall be imposed only after all other means of securing compliance have been exhausted. Notice of intent to suspend or terminate shall be given by the interstate commission to the Governor, the majority and minority leaders of the defaulting state's legislature, and each of the member states.

5. The state which has been suspended or terminated is responsible for all dues, obligations and liabilities incurred through the effective date of suspension or termination including obligations, the performance of which extends beyond the effective date of suspension or termination.

6. The interstate commission shall not bear any costs relating to any state that has been found to be in default or which has been suspended or terminated from the compact, unless otherwise mutually agreed upon in writing between the interstate commission and the defaulting state.

7. The defaulting state may appeal the action of the interstate commission by petitioning the United States District Court for the District of Columbia or the federal district where the

interstate commission has its principal offices. The prevailing party shall be awarded all costs of such litigation including reasonable attorney's fees.

C. Dispute Resolution

1. The interstate commission shall attempt, upon the request of a member state, to resolve disputes which are subject to the compact and which may arise among member states.

2. The interstate commission shall promulgate a rule providing for both mediation and binding dispute resolution as appropriate.

D. Enforcement

1. The interstate commission, in the reasonable exercise of its discretion, shall enforce the provisions and rules of this compact.

2. The interstate commission, may by majority vote of the members, initiate legal action in the United States District Court for the District of Columbia or, at the discretion of the interstate commission, in the federal district where the interstate commission has its principal offices, to enforce compliance with the provisions of the compact, its promulgated rules and bylaws, against a member state in default. The relief sought may include both injunctive relief and damages. In the event judicial enforcement is necessary the prevailing party shall be awarded all costs of such litigation including reasonable attorney's fees.

3. The remedies herein shall not be the exclusive remedies of the interstate commission. The interstate commission may avail itself of any other remedies available under state law or the regulation of a profession.

ARTICLE XI

MEMBER STATES, EFFECTIVE DATE AND AMENDMENT

A. Any state that has enacted Prescription Monitoring Program legislation through statute or regulation is eligible to become a member state of this compact.

B. The compact shall become effective and binding upon legislative enactment of the compact into law by no less than six (6) of the states. Thereafter it shall become effective and binding on a state upon enactment of the compact into law by that state. The Governors of non-member states or their designees shall be invited to participate in the activities of the interstate commission on a non-voting basis prior to adoption of the compact by all states.

C. The interstate commission may propose amendments to the compact for enactment by the member states. No amendment shall become effective and binding upon the interstate commission and the member states unless and until it is enacted into law by unanimous consent of the member states.

ARTICLE XII

WITHDRAWAL AND DISSOLUTION

A. Withdrawal

1. Once effective, the compact shall continue in force and remain binding upon each and every member state; provided that a member state may withdraw from the compact by specifically repealing the statute which enacted the compact into law.

2. Withdrawal from this compact shall be by the enactment of a statute repealing the same, but shall not take effect until one (1) year after the effective date of such statute and until written notice of the withdrawal has been given by the withdrawing state to the Governor of each other member state.

3. The withdrawing state shall immediately notify the chairperson of the interstate commission in writing upon the introduction of legislation repealing this compact in the withdrawing state. The interstate commission shall notify the other member states of the withdrawing state's intent to withdraw within sixty (60) days of its receipt thereof.

4. The withdrawing state is responsible for all dues, obligations and liabilities incurred through the effective date of withdrawal, including obligations, the performance of which extend beyond the effective date of withdrawal.

5. Reinstatement following withdrawal of a member state shall occur upon the withdrawing state reenacting the compact or upon such later date as determined by the interstate commission.

B. Dissolution of the Compact

1. This compact shall dissolve effective upon the date of the withdrawal or default of the member state which reduces the membership in the compact to one (1) member state.

2. Upon the dissolution of this compact, the compact becomes null and void and shall be of no further force or effect, and the business and affairs of the interstate commission shall be concluded and surplus funds shall be distributed in accordance with the bylaws.

ARTICLE XIII

SEVERABILITY AND CONSTRUCTION

A. The provisions of this compact shall be severable, and if any phrase, clause, sentence or provision is deemed unenforceable, the remaining provisions of the compact shall be enforceable.

B. The provisions of this compact shall be liberally construed to effectuate its purposes.

C. Nothing in this compact shall be construed to prohibit the applicability of other interstate compacts to which the states are members.

ARTICLE XIV

BINDING EFFECT OF COMPACT AND OTHER LAWS

A. Other Laws

1. Nothing herein prevents the enforcement of any other law of a member state that is not inconsistent with this compact.

B. Binding Effect of the Compact

1. All lawful actions of the interstate commission, including all rules and bylaws promulgated by the interstate commission, are binding upon the member states.

2. All agreements between the interstate commission and the member states are binding in accordance with their terms.

3. In the event any provision of this compact exceeds the constitutional limits imposed on the legislature of any member state, such provision shall be ineffective to the extent of the conflict with the constitutional provision in question in that member state.

Baldwin's Kentucky Revised Statutes Annotated (2014)
Title XVIII. Public Health
Chapter 218A. Controlled Substances

§ 218A.391 Gubernatorial appointments to Prescription Monitoring Program Compact

The Governor shall be the appointing authority for those appointments Kentucky is entitled to make under KRS 218A.390, provided that all such appointments shall be subject to confirmation by the Senate.

Kentucky Administrative Regulations (2014)
Title 201. General Government Cabinet
Chapter 5. Board of Optometric Examiners

201 KAR 5:130. Controlled substances

Section 1. Prescribing Standards. (1) A Kentucky licensed optometrist authorized to prescribe controlled substances for humans shall:

(a) Have a current and valid DEA number;

(b) Register with Kentucky All Schedule Prescription Electronic Reporting (KASPER);

(c) Prescribe controlled substances only for the treatment or relief of pain for a condition of the eye and its appendages;

(d) Prescribe only Schedule III, IV, or V controlled substances;

(e) Prescribe controlled substances for a quantity therapeutically sufficient, up to seventy-two (72) hours;

(f) Examine the patient face-to-face and in-person prior to prescribing a controlled substance;

(g) Verify the fact that the patient that is prescribed a controlled substance is who the patient claims to be;

(h) Establish a documented diagnosis through the use of accepted medical practices; and

(i) Keep accurate, readily accessible medical records which shall include:

1. History and eye examination;

2. Diagnostic, therapeutic, and laboratory results;

3. Evaluations and consultations;

4. Treatment objectives;

5. Discussions of risk, benefits, and limitations of treatments;

6. Treatments;

7. Medication including date, type, dosage, and quantity prescribed; and

8. Instructions and agreements.

(2) A Kentucky licensed optometrist authorized to prescribe controlled substances for humans shall not:

(a) Dispense any controlled substances;

(b) Write a prescription for a controlled substance that is refillable; and

(c) Prescribe:

1. With the intent or knowledge that a medication will be used, or is likely to be used, for other than a medicinal or an accepted therapeutic purpose; or

2. With the intent to evade any law with respect to sale, use, or disposition of the medication.

Section 2. Temporary Suspension, Limit, or Restriction of License. (1) The board may, without benefit of a hearing, temporarily suspend, limit, or restrict the license of an optometrist authorized to prescribe controlled substances if the board finds on the basis of reasonable evidence that the licensee has violated a statute or administrative regulation the board is empowered to enforce, and continued unrestricted practice by the licensee would constitute a danger to the health, welfare, or safety of the licensee's patients or of the general public.

(2) The temporary suspension, limit, or restriction of a license shall take effect upon receipt by the licensee of written notice, delivered by certified mail or in person, specifying the statute or administrative regulation violated. At the time the temporary suspension, limit, or restriction order issues, the board shall schedule a disciplinary hearing to be held in accordance with the provisions of KRS Chapter 13B within ten (10) days.

Section 3. Complaints. (1) The board shall consider all written complaints and sufficient anonymous complaints pertaining to the improper, inappropriate, or illegal prescribing of controlled substances. An anonymous complaint shall be considered sufficient if it is 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 is meritorious.

(2) Upon receipt of a complaint pertaining to the improper, inappropriate, or illegal prescribing of controlled substances, the board shall:

(a) Send a copy of the complaint to the Office of the Attorney General, the Department of the Kentucky State Police, and the Cabinet for Health and Family Services within three (3) business days;

(b) Commence an investigation within seven (7) business days of the complaint; and

(c) Produce a charging decision within 120 days of the complaint, unless an extension for a definite time period is requested in writing by a law enforcement agency due to an ongoing criminal investigation.

Section 4. Penalties. (1) Pursuant to the provisions of KRS 218A.205(3):

(a) A licensee convicted of a felony offense related to prescribing a controlled substance shall, at a minimum, have a lifetime revocation on prescribing any and all controlled substances;

(b) The board shall impose restrictions short of a permanent ban from prescribing controlled substances on a licensee convicted of a misdemeanor offense related to the prescribing of controlled substances. A licensee who has been convicted of any misdemeanor offense after July 20, 2012 relating to prescribing or dispensing controlled substances in any state shall have his or her authority to prescribe controlled substances suspended for at least three (3) months, and shall be further restricted as determined by the board; and

(c) A licensee disciplined by a licensing board of another state related to the improper, inappropriate, or illegal prescribing of controlled substances shall, at a minimum, have the same disciplinary action imposed by the licensing board of the other state.

(2) A licensee who is authorized to prescribe controlled substances shall be subject to discipline by the board if:

(a) A licensee who is required to register for an account with KASPER fails to do so or does not maintain continuous registration during the licensee's term of licensure; or

(b) A licensee or applicant fails to report to the board, within thirty (30) days of the action:

1. Any conviction involving controlled substances; or

2. Disciplinary action taken by another licensure board involving controlled substances.

(3) Pursuant to the provisions of KRS 218A.205(3)(f), the board shall submit all disciplinary actions to the National Practitioner Data Bank of the United States Department of Health and Human Services either directly or through a reporting agent.

Kentucky Administrative Regulations (2014)
Title 201. General Government Cabinet
Chapter 8. Board of Dentistry

201 KAR 8:540. Dental practices and prescription writing

Section 1. Definitions. (1) “Invasive procedure” means a procedure that penetrates hard or soft tissue.

(2) “Oral surgery” means any manipulation or cutting of hard or soft tissues of the oral or maxillofacial area and associated procedures, by any means, as defined by the American Dental Association, utilized by a dentist licensed by 201 KAR Chapter 8 and within the dentist's scope of training and practice.

Section 2. Minimum Documentation Standards for all Dental Patients. (1) Each patient's dental records shall be kept by the dentist for a minimum of:

(a) Seven (7) years from the date of the patient's last treatment;

(b) Seven (7) years after the patient's eighteenth (18) birthday, if the patient was seen as a minor; or

(c) Two (2) years following the patient's death.

(2) Each dentist shall comply with KRS 422.317 regarding the release of patient records.

(3) The dentist shall keep accurate, readily accessible, and complete records which include:

(a) The patient's name;

(b) The patient's date of birth;

(c) The patient's medical history and documentation of the physical exam of the oral and perioral tissues;

(d) The date of treatment;

(e) The tooth number, surfaces, or areas to be treated;

(f) The material used in treatment;

(g) Local or general anesthetic used, the type, and the amount;

(h) Sleep or sedation dentistry medications used, the type, and the amount;

(i) Diagnostic, therapeutic, and laboratory results, if any;

(j) The findings and recommendations of the dentist and a description of each evaluation or consultation, if any;

(k) Treatment objectives;

(l) All medications, including date, type, dosage, and quantity prescribed or dispensed; and

(m) Any post treatment instructions.

Section 3. Prescription Writing Privileges. (1) In accordance with KRS 313.035, a dentist may prescribe any drug necessary within the scope of the dentist's practice if the dentist:

(a) Is licensed pursuant to 201 KAR 8:532;

(b) Has obtained a license from the Drug Enforcement Administration; and

(c) Has enrolled with and utilizes the Kentucky All Schedule Prescription Electronic Reporting System as required by KRS 218A.202.

(2) A dentist shall not compound any scheduled drugs or dispense any Schedule I, Schedule II, or Schedule III controlled substances containing Hydrocodone for use by the patient outside the office setting.

Section 4. Prescribing of Controlled Substances by Dentist. (1) Prior to the initial prescribing of any controlled substance, each dentist shall:

(a) Except as provided in subsection (2) of this section, and review a KASPER report for all available data on the patient;

(b) Document relevant information in the patient's record;

(c) Consider the available information to determine if it is medically appropriate and safe to prescribe a controlled substance;

(d) Obtain a complete medical history and conduct a physical examination of the oral or maxillofacial area of the patient and document the information in the patient's medical record;

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

(f) 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

(g) Obtain written consent for the treatment.

(2) A dentist shall not be required to obtain and review a KASPER report if:

(a)1. The dentist prescribes a Schedule III controlled substance or one (1) of the Schedule IV controlled substances listed in subsection (3) of this section after the performance of oral surgery; and

2. No more than a seventy-two (72) hour supply of the controlled substance is prescribed;

(b) The dentist prescribes or dispenses a Schedule IV or V controlled substance not listed in subsection (3) of this section; or

(c)1. The dentist prescribes pre-appointment medication for the treatment of procedure anxiety; and

2. The prescription is limited to a two (2) day supply and has no refills.

(3) A dentist shall obtain and review a KASPER report before initially prescribing any of the following Schedule IV controlled substances:

(a) Ambien;

(b) Anorexics;

(c) Ativan;

(d) Klonopin;

(e) Librium;

(f) Nubain;

(g) Oxazepam;

(h) Phentermine;

(i) Soma;

(j) Stadol;

(k) Stadol NS;

(l) Tramadol;

(m) Versed; and

(n) Xanax.

(4) A dentist may provide one (1) refill within thirty (30) days of the initial prescription for the same controlled substance for the same amount or less or prescribe a lower schedule drug for the same amount without a clinical reevaluation of the patient by the dentist.

(5) A patient who requires additional prescriptions for a controlled substance shall be clinically reevaluated by the dentist and the provisions of this section, shall be followed.

Section 5. Penalties and Investigations. (1) A licensee convicted of a felony offense related to prescribing and dispensing of a controlled substance shall, at a minimum be permanently banned from prescribing or dispensing a controlled substance.

(2) A licensee convicted of a misdemeanor offense relating to the prescribing of a controlled substance shall, at a minimum, have a five (5) year ban from prescribing or dispensing a controlled substance.

(3) A licensee disciplined by a licensing board of another state relating to the improper, inappropriate, or illegal prescribing or dispensing of controlled substances shall, at a minimum, have the same disciplinary action imposed by this state or the disciplinary action prescribed in subsection (1) or (2) of this section, whichever is greater.

(4) A licensee who is disciplined in another state or territory who holds a Kentucky license and fails to notify the board in writing of the disciplinary action within thirty (30) days of the finalization of the action shall be subject to a fine of $1,000 for each failure to report.

(5) A licensee who fails to register for an account with the Kentucky All schedule Prescription Electronic Reporting System or who fails to meet the requirements of Section 4 of this administrative regulation shall receive a private admonishment from the board and be given no more than thirty (30) days to become compliant after which time the dentist shall be fined a minimum of $500 to a maximum of $10,000.

(6) The Law Enforcement Committee of the Board shall produce a charging decision on the complaint within 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.

Section 6. Infection Control Compliance. (1) Each licensed dentist in the Commonwealth of Kentucky shall:

(a) Adhere to the standard precautions outlined in the Guidelines for Infection Control in Dental Health-Care Settings published by the Centers for Disease Control and Prevention; and

(b) Ensure that any person under the direction, control, supervision, or employment of a licensee whose activities involve contact with patients, teeth, blood, body fluids, saliva, instruments, equipment, appliances, or intra-oral devices adheres with those same standard precautions.

(2) The board or its designee shall perform an infection control inspection of a dental practice utilizing the Infection Control Inspection Checklist.

(3)(a) Any dentist who is found deficient upon an initial infection control inspection shall have thirty (30) days to be in compliance with the guidelines and submit a written plan of correction to the board.

(b) The dentist may receive a second inspection after the thirty (30) days have passed.

(c) If the dentist fails the second inspection, he or she shall be immediately temporarily suspended pursuant to KRS 313.085 until proof of compliance is provided to the board and the dentist pays the fine as prescribed in 201 KAR 8:520.

(4) Any licensed dentist, licensed dental hygienist, registered dental assistant, or dental assistant in training for registration who performs invasive procedures may seek counsel from the board if he or she tests seropositive for the human immunodeficiency virus or the hepatitis B virus.

(5) Upon the request of a licensee or registrant, the executive director of the board or designee shall convene a confidential expert review panel to offer counsel regarding under what circumstances, if any, the individual may continue to perform invasive procedures.

Section 7. Termination of a Patient-Doctor Relationship. In order for a licensed dentist to terminate the patient-doctor relationship, the dentist shall:

(1) Provide written notice to the patient of the termination;

(2) Provide emergency treatment for the patient for thirty (30) days from the date of termination; and

(3) Retain a copy of the letter of termination in the patient records.

Section 8. Incorporation by Reference. (1) The following material is incorporated by reference:

(a) "Guidelines for Infection Control in Dental Health-Care Settings" December 2003; and

(b) "Infection Control Inspection Checklist" July 2010.

(2) This material may be inspected, copied, or obtained, subject to applicable copyright law, at the Kentucky Board of Dentistry, 312 Whittington Parkway, Suite 101, Louisville, Kentucky 40222, Monday through Friday, 8 a.m. through 4:30 p.m. This material is also available on the board's Web site at http://dentistry.ky.gov.

Adopted on an emergency basis effective July 15, 2010; Amended effective February 4, 2011; Amended effective February 1, 2013.

Kentucky Administrative Regulations (2014)
Title 201. General Government Cabinet
Chapter 9. Board of Medical Licensure

201 KAR 9:016. Restrictions on use of amphetamine and amphetamine-like anorectic controlled substances

Section 1. Definitions. (1) “Board” is defined in KRS 311.550(1).

(2) “Body mass index” means the weight of the patient in kilograms divided by the height in meters, squared.

(3) “Schedule II amphetamine or amphetamine-like controlled substance” means:

(a) Amphetamine, its salts, optical isomers, and salts of optical isomers; or

(b) Methylphenidate.

(4) “Schedule III or IV amphetamine-like controlled substance” means a drug classified as a stimulant pursuant to:

(a) 902 KAR 55:025, Section 2; or

(b) 902 KAR 55:030 Section 1.

Section 2. Prior to prescribing, ordering, dispensing, administering, selling, supplying, or giving a Schedule II, III or IV amphetamine or amphetamine-like controlled substance, a physician shall take into account the:

(1) Drug's potential for abuse;

(2) Possibility that a drug may lead to dependence;

(3) Possibility a patient will obtain the drug for a nontherapeutic use;

(4) Possibility a patient will distribute it to others; and

(5) Potential illicit market for the drug.

Section 3. Schedule II Amphetamine or Amphetamine-like Controlled Substances. (1) The patient's record shall denote the diagnosis that justifies treatment with a Schedule II amphetamine or amphetamine-like controlled substance.

(2) A Schedule II amphetamine or amphetamine-like controlled substance shall be used to treat only:

(a) Narcolepsy;

(b) Attention deficit/hyperactive disorder;

(c) Resistant depressive disorder in combination with other antidepressant medications, or if alternative antidepressants and other therapeutic modalities are contraindicated;

(d) Drug-induced brain dysfunction; or

(e) A diagnosis for which the clinical use of the Schedule II amphetamine or amphetamine-like controlled substance is investigational and the investigative protocol has been submitted, reviewed, and approved by the board prior to the clinical use of the drug.

(3) A Schedule II amphetamine or amphetamine-like controlled substance shall not be utilized to treat obesity.

Section 4. Treatment of Obesity with a Schedule III or IV Amphetamine-like Controlled Substance. (1) Prior to prescribing, administering, dispensing, ordering, selling, supplying, or giving a Schedule III or IV amphetamine-like controlled substance to treat obesity in a patient sixteen (16) years of age or older, the physician shall:

(a) Establish a physician/patient relationship;

(b) Determine that the patient is obese or overweight with medical risk factors and is a proper candidate for weight reduction treatment;

(c) Determine and record the extent of prior anorectics or other controlled substances used by the patient. The prescribing physician shall obtain and review a KASPER report for the twelve (12) month period immediately preceding the patient encounter, before prescribing or dispensing controlled substances to the patient;

(d) Determine that the patient has either:

1. A body mass index of twenty-seven (27) or more, unless the body mass index is twenty-five (25) to twenty-seven (27) and the patient has a co-morbidity such as a cardiovascular disease, diabetes mellitis, dyslipidemia, hypertension, or sleep apnea;

2. Body fat greater than or equal to thirty (30) percent in females or greater than or equal to twenty-five (25) percent in males;

3. Current body weight greater than or equal to 120 percent of a well documented, long-standing, healthy weight that the patient maintained after age eighteen (18);

4. A waist-hip ratio or waist circumference at a level indicating that the individual is known to be at increased cardiovascular or co-morbidity risk because of abdominal visceral fat; or

5. Presence of a co-morbid condition or conditions aggravated by the patient's excessive adiposity; and

(e) Provide the patient with carefully prescribed diet, together with counseling on exercise, behavior modification, and other appropriate supportive and collateral therapies.

(2) During treatment for obesity, a physician shall:

(a) Maintain a physician/patient relationship throughout the treatment process;

(b) Maintain an adequate patient record in accordance with subsection (4) of this section; and

(c) Justify in the patient record the use of any Schedule III or IV amphetamine-like controlled substance beyond three (3) months. Before the physician continues the use of a substance beyond three (3) months, the physician shall obtain and review a current KASPER report.

(3) A physician shall terminate the use of Schedule III or IV amphetamine-like controlled substances if:

(a) The patient does not demonstrate weight loss and does not attempt to comply with exercise and dietary changes;

(b) The body mass index of the patient without a co-morbid condition is less than twenty-seven (27) and the percentage of body fat is normal at less than thirty (30) percent in females or less than twenty-five (25) percent in males;

(c) The body mass index of the patient with a co-morbid condition is less than twenty-five (25) and the percentage of body fat is normal at less than thirty (30) percent in females or less than twenty-five (25) percent in males;

(d) The patient has regained the weight lost, using sympathomimetics as part of a complete program and reuse of the medication does not produce loss of the weight gain to help maintain a minimum of five (5) percent weight loss; or

(e) The patient has obtained a Schedule III or IV amphetamine-like controlled substance from another physician without the prescriber's knowledge and consent.

(4) The board shall consider the following factors in reviewing the adequacy of a patient record:

(a) Medical history, including:

1. Illnesses, with particular emphasis on cardiovascular diseases;

2. Surgery;

3. Lifestyle;

4. Medications, including controlled substances;

5. Eating habits;

6. Exercise;

7. Weight gain or loss;

8. Prior efforts at weight control or reduction;

9. Prior treatment compliance;

10. Menstruation or pregnancy; and

11. Psychiatric history with particular reference to depression, paranoia, psychosis, or chemical dependency;

(b) Social history;

(c) Family history;

(d) Complete physical examination;

(e) Evaluation of laboratory tests including:

1. CBC;

2. Fasting blood sugar;

3. Thyroid panel or TSH;

4. Lipid profile;

5. Serum potassium;

6. Liver function test; and

7. Renal function test;

(f) An informed consent signed by the patient that cites the limitations and risk of anorectic treatment including potential dependency or psychiatric illness;

(g)1. A signed agreement that the patient has voluntarily agreed to:

a. Have one (1) prescribing physician for controlled substances;

b. Use one (1) pharmacy to fill prescriptions for controlled substances;

c. Not have early refills on the prescriptions for controlled substances; and

d. Provide full disclosure of other medications taken; or

2. Documentation that:

a. The physician requested the patient sign an agreement meeting the requirements of subparagraph 1 of this paragraph;

b. The patient declined to sign the agreement; and

c. Indicates the physician's clinical reasons for prescribing, or continuing to prescribe, a Schedule III or IV amphetamine-like controlled substance to the patient, in light of the patient's refusal to sign the agreement; and

(h) A record of each office visit, including:

1. The patient's weight;

2. The patient's blood pressure;

3. The patient's pulse;

4. The presence or absence of medication side effects or complications;

5. The doses of medications prescribed;

6. The patient's body mass index; and

7. Evaluation of the patient's compliance with the total treatment regimen.

Section 5. Waiver. For a legitimate medical purpose, a physician may apply in writing for a written waiver of any requirement in this administrative regulation. The board may issue a waiver with terms and conditions it deems appropriate.

Section 6. Failure to comply with the requirements of this administrative regulation shall constitute dishonorable, unethical, or unprofessional conduct by a physician which is apt to deceive, defraud, or harm the public under KRS 311.595(9) and 311.597.

Kentucky Administrative Regulations (2014)
Title 201. General Government Cabinet
Chapter 9. Board of Medical Licensure

201 KAR 9:230. Required registration in the KASPER system; legal requirements for prescribing controlled substances in the Commonwealth of Kentucky; enforcement

Section 1. (1) In order to lawfully prescribe or dispense a controlled substance within the Commonwealth of Kentucky, a licensee shall:

(a) Hold a valid DEA permit to do so; and

(b) Be registered to use the KASPER system as required by KRS 218A.202.

(2) Prescribing or dispensing a controlled substance without a valid DEA permit or KASPER registration, as required by subsection (1) of this section, shall constitute a violation of KRS 311.595(9) and (12) which constitutes an immediate danger to the public health, safety, or welfare, for the purposes of KRS 311.592 and 13B.125.

(3)(a) If the board receives documentation from the Cabinet for Health and Family Services that a licensee holds a valid DEA permit to prescribe or dispense controlled substances to humans within the Commonwealth of Kentucky, but is not currently registered with the cabinet to use the KASPER system as required by KRS 218A.202, the board shall immediately send written notice, by certified mail return receipt requested, to the physician that the physician is required to register with the Cabinet for Health and Family Services to use the KASPER system within seven (7) days of receipt of the written notice.

(b) At the end of the seven (7) day period, the board shall confirm with the Cabinet for Health and Family Services that the physician registered with the cabinet to use the KASPER system.

(c) If the physician failed to register with the Cabinet for Health and Family Services to use the KASPER system within the seven (7) days following receipt of the written notice, the appropriate inquiry panel or its chair shall promptly issue an emergency order restricting that licensee from prescribing or dispensing controlled substances within the Commonwealth of Kentucky until the licensee has registered with the cabinet to use the KASPER system.

(4)(a) An emergency order restricting a licensee from prescribing or dispensing controlled substances within the Commonwealth of Kentucky issued pursuant to subsection (3)(c) of this section shall remain valid and in effect until the board has received written verification from the cabinet that the licensee has registered with the cabinet to use the KASPER system.

(b) Upon receipt of the written verification, the panel or its chair shall immediately issue an order terminating the emergency order issued pursuant to subsection (3)(c) of this section.

(5) If a licensee who is affected by an emergency order issued pursuant to subsection (3)(c) of this section requests an emergency hearing pursuant to KRS 13B.125(3), the hearing officer conducting the emergency hearing shall affirm the emergency order of restriction if presented with a written notification on cabinet letterhead stating that the affected licensee holds a valid DEA permit but is not registered with the cabinet to use the KASPER system as required by KRS 218A.202.

Section 2. If a licensee prescribes or dispenses a controlled substance within the Commonwealth of Kentucky during any period when the licensee is not registered with the cabinet to use the KASPER system, each instance of prescribing or dispensing shall constitute a separate violation of KRS 311.595(12) and (9), as illustrated by KRS 311.597(1)(b) and shall serve as the basis for disciplinary sanctions pursuant to KRS 311.595.

Kentucky Administrative Regulations (2014)
Title 201. General Government Cabinet
Chapter 9. Board of Medical Licensure

201 KAR 9:250. Registration and oversight of pain management facilities

Section 1. Definitions. (1) “Board” is defined by KRS 311.550(1).

(2) “In good standing” means an active license to practice medicine or osteopathy that is not currently subject to any final order imposing any disciplinary sanction authorized by KRS 311.595, agreed order, or letter of agreement issued by or entered into with the board.

(3) “Pain management facility” is defined by KRS 218A.175(1), and each separate operating location of a physician's practice that meets the criteria established by this definition shall be considered a separate pain management facility.

(4) “Practitioner” means a licensed or certified health care practitioner who is legally authorized to prescribe or dispense controlled substances.

Section 2. Ownership or Investment Interest. (1)(a) A physician who has an ownership or investment interest in a pain management facility during any period when the physician is not licensed to practice medicine or osteopathy within the Commonwealth of Kentucky shall be deemed to be:

1. In violation of KRS 311.595(12); and

2. Practicing medicine without a license and subject to criminal sanctions.

(b) If the board determines that a physician has maintained an ownership or investment interest in a pain management facility during a period when that physician was not licensed to practice medicine or osteopathy within the Commonwealth of Kentucky, it may deny an application for licensing filed by that physician or may take appropriate disciplinary action against a license previously issued to the physician.

(2) A physician who maintains an ownership or investment interest in a pain management facility during any period when the physician's Kentucky license is not in good standing shall be in violation of KRS 311.595(12) and subject to disciplinary action by the Board.

Section 3. Divestiture of Ownership or Investment Interest. (1) A physician who has an ownership or investment interest in a pain management facility shall immediately divest that ownership or investment interest if:

(a) The physician's Kentucky license is no longer active for any reason; or

(b) The physician's Kentucky license becomes subject to any final order imposing any disciplinary sanction authorized by KRS 311.595, agreed order, or letter of agreement issued by or entered into with the board.

(2)(a) If a physician fails to immediately divest the ownership or investment interest in the pain management facility as required by subsection (1) of this section, the board may institute an action for injunctive relief pursuant to KRS 311.605(3) and (4) to require the physician to immediately divest the ownership or investment interest in the pain management facility.

(b) An unlawful ownership or investment interest in a pain management facility shall be considered the unlawful practice of medicine and shall be considered to cause irreparable injury to the Commonwealth, acting through this board.

Section 4. Registration; Amended Registration; Fee; New Facility Registration. (1) On or before September 1, 2012 and September 1 of each succeeding year, every pain management facility operating as the private office or clinic of a physician within the Commonwealth of Kentucky shall register with the board, providing the following specific information in writing:

(a) The name, business address, profession, current professional licensing status and nature and extent of ownership or investment interest of each person who has or maintains an ownership or investment interest in the pain management facility;

(b) The names and addresses of every pain management facility in which the person has an ownership or investment interest;

(c) The hours of operation of every pain management facility in which the person has an ownership or investment interest;

(d) The names and professional status of each employee at each practice location owned and operated by that pain management facility;

(e) The name, professional license number, and practice address of the qualified physician owner or owner's physician designee who will be physically present practicing medicine in the pain management facility for at least fifty (50) percent of the time patients are present at the facility. The facility shall also state its plan for ensuring that the designated physician owner or owner's physician designee will be physically present practicing medicine in the facility and, if the facility owns and operates multiple practice locations, the plan to ensure that a physician owner or owner's physician designee is physically present practicing medicine in each practice location for at least fifty (50) percent of the time that patients are seen at each pain management facility;

(f) For each owner's physician designee who will fulfill the oversight responsibility, an attestation that the physician designee is employed by the owner and the plan for owner supervision of the physician designee; and

(g) An attestation by the physician owner that the owner or owner's physician designee:

1. Meets one (1) of the requirements established in KRS 218A.175(3) and specifying each qualification met by the physician owner or owner's physician designee; or

2. Was an owner of that specific pain management facility prior to and continuing through July 20, 2012 and meets one (1) of the following qualifications:

a. Successfully completed a residency program in physical medicine and rehabilitation, anesthesiology, addiction medicine, neurology, neurosurgery, family practice, preventive medicine, internal medicine, surgery, orthopedics or psychiatry approved by the Accreditation Council for Graduate Medical Education (ACGME) or American Osteopathic Association Bureau of Osteopathic Specialists (AOABOS); or

b.(i) Registered the ownership or investment interest in that pain management facility with this board on or before September 1, 2012;

(ii) Is eligible for and has provided the board with written verification that the licensee has registered to complete the certification examination offered by the American Board of Pain Medicine or the American Board of Interventional Pain Physicians in April 2013; and

(iii) Becomes certified by the American Board of Pain Medicine or by the American Board of Interventional Pain Physicians by September 1, 2013.

(2) If the physician fails the certification examination or fails to become certified by the American Board of Pain Medicine or the American Board of Interventional Pain Physicians by September 1, 2013, the physician shall meet one (1) of the requirements established in KRS 218A.175(3), to continue to be qualified to provide the on-site supervision required by Section 6 of this administrative regulation.

(3) At the time of filing of the registration required by subsection (1) of this section, each pain management facility operating as the private office or clinic of a physician shall pay an annual fee of $500 for each pain management facility to the board to defray the costs of registration and enforcement of this administrative regulation.

(4) If, during the effective period of the annual registration, a new or different physician obtains an ownership or investment interest in the pain management facility, or there is a change in the physician owner or physician designee who will practice on-site at least fifty (50) percent of the time the facility is open to patients, the facility shall file an amended registration with the board identifying these physicians and providing the information required by subsection (1) of this section about the new or different physicians, within fourteen (14) calendar days of that change.

(5) Failure to file the required registration or to pay the annual fee on or before September 1 of each year shall constitute a violation of KRS 311.595(12) and shall serve as a basis for discipline by the board against the license of any physician who has an ownership or investment interest in the facility that failed to file the required registration.

(6) If a new pain management facility operating as the private office or clinic of a physician comes into existence after September 1 of a calendar year but before September 1 of the following calendar year, that new pain management facility shall register with the board within fourteen (14) calendar days of its legal formation, and shall meet each of the registration requirements of this section.

Section 5. Identification and Qualifications of Prescribers Employed by the Facility; Notification of Changes. (1) As part of its initial or annual registration, the facility shall identify each practitioner, who is employed by the facility in any capacity, who will be prescribing or dispensing controlled substances to patients of the facility.

(2) Each licensed physician who will prescribe or dispense controlled substances to patients of the facility as part of the employment arrangement with the facility shall successfully complete a minimum of ten (10) hours of Category I continuing medical education in pain management during each registration period throughout the employment agreement with the facility. This continuing medical education requirement shall satisfy the requirement of 201 KAR 9:310.

(3) A licensed physician shall not prescribe or dispense controlled substances to patients of the facility if the physician has:

(a) Had an application for a license or certificate to prescribe, dispense, or administer controlled substances denied in any jurisdiction or by any governmental agency;

(b) Had a Drug Enforcement Administration permit to prescribe, dispense, or administer controlled substances revoked;

(c) Had the professional ability or authority to prescribe or dispense controlled substances revoked, restricted, or limited in any manner by a licensing authority of any state, except as provided by subsection (4) of this section; or

(d) Been convicted of or entered a plea of guilt, nolo contendere, or Alford plea, regardless of adjudication, to any felony or misdemeanor relating to controlled substances, in any state or federal court.

(4) The prohibition established in subsection (3)(c) of this section shall not apply if:

(a) The conduct requiring the revocation, restriction, or limitation was directly related to the physician's impairment as a result of controlled substance abuse or dependence;

(b) The order imposing the revocation, restriction, or limitation is no longer in effect;

(c) The physician has achieved a level of recovery which provides the licensing authority sufficient assurance that the physician will not likely engage in similar conduct while practicing at the pain management facility; and

(d) The board or its panel has specifically approved the physician to practice in that specific pain management facility.

(5) The facility shall notify the board in writing within fourteen (14) days of each change in physician staffing of the facility.

Section 6. On-site Supervision. (1) If the physician owner or qualified designee is not present in each practice location of a pain management facility for at least fifty (50) percent of the time that patients are present at the practice location for any given calendar week as required by KRS 218A.175(3), the facility shall immediately notify the board of that fact in writing and include the reasons.

(2) Any violation of KRS 218A.175(3) or this section shall constitute a violation of KRS 311.595(12) and (9), as illustrated by KRS 311.595(3) and (4) by the physician owner and, if applicable, the qualified designee who was responsible for being present at the practice location during that period.

Section 7. Record-Keeping; Inspection. (1) Each pain management facility shall document on a weekly basis that a physician owner or an owner's physician designee who is employed by and under the direct supervision of the owner was physically present practicing medicine in the facility for at least fifty (50) percent of the time that patients were present in the facility during that week. This documentation shall include:

(a) The name, practice address, and phone number of the physician owner or physician designee who fulfilled this oversight function for that specific week;

(b) The practice address of each practice location owned and operated by that pain management facility;

(c) The days and hours each practice location of the pain management facility was open to patients during that specific week; and

(d) The days and hours the physician owner or physician designee was present in each practice location for the pain management facility for that specific week.

(2) Each pain management facility shall maintain appropriate records of the patients receiving treatment at that facility so that the board may determine the identity and number of patients treated during any given time period.

(3) The pain management facility shall maintain the weekly reports required by subsection (1) of this section and any daily sign-in sheets maintained by the practice on site in a readily accessible location for a minimum period of six (6) years.

(4) Upon request by an employee or agent of the board, the pain management facility shall permit the board employee or agent to inspect and copy the weekly reports and daily sign-in sheets maintained on site.

(5) For the purpose of enforcing the provisions of this administrative regulation, an agent of the board shall have the power and authority to:

(a) Enter upon professional premises during periods when those premises are otherwise open to patients or the public;

(b) Obtain evidence, including psychiatric or nonpsychiatric patient records, by consent or pursuant to a subpoena or search warrant;

(c) Interview all persons including owners, employees, or patients; and

(d) Require the production of books, papers, documents, or other documentary evidence either by consent or pursuant to a subpoena or search warrant.

Section 8. Proof of Operation of a Pain Management Facility. (1) The board may establish sufficient proof that a clinic, practice, or facility is a pain management facility subject to the provisions of this administrative regulation by establishing that:

(a) The facility has filed a registration with the board as a pain management facility; or

(b) 1. For any selected thirty (30) day period, the majority of patients receiving medical treatment from the clinic, practice, or facility received controlled substances or a prescription for controlled substances during that period; and

2. One (1) of the following additional conditions was present during that thirty (30) day period as required by KRS 218A.175(1)(a):

a. A primary component of the practice was the treatment of pain; or

b. The facility advertised in any medium for any type of pain management services.

(2) The board may establish sufficient proof that the majority of patients treated in the facility for any specified thirty (30) day period received controlled substances or a prescription for controlled substances on their visit by comparing the names on the sign-in sheet to the KASPER report for that thirty (30) day period.

Section 9. Violations; Enforcement; Emergency Action. (1) Any violation of the requirements of this administrative regulation shall constitute a violation of KRS 311.595(12) and (9), as illustrated by KRS 311.597(4) and may constitute a violation of KRS 311.595(9), as illustrated by KRS 311.597(3) given the circumstances.

(2) In order to lawfully prescribe or dispense controlled substances within the Commonwealth of Kentucky while practicing at a pain management facility, a licensee shall practice in a lawful pain management facility.

(3) A pain management facility shall be considered an unlawful pain management facility if it:

(a) Permits an unqualified person to gain or maintain an ownership or investment interest in the pain management facility; or

(b) Fails to ensure that a qualified physician owner or physician designee is physically present practicing medicine in the facility for at least fifty (50) percent of the time that patients are present in the facility.

(4) Prescribing or dispensing controlled substances within the Commonwealth of Kentucky while employed by or practicing in an unlawful pain management facility within the Commonwealth of Kentucky shall constitute a violation of KRS 311.595(9) and (12) which constitutes an immediate danger to the public health, safety, or welfare of the public, for the purposes of KRS 311.592 and 13B.125.

(5) If the board receives proof that a licensed physician is prescribing or dispensing a controlled substance while employed by or practicing in an unlawful pain management facility within the Commonwealth of Kentucky, the appropriate inquiry panel or its chair shall promptly issue an emergency order restricting that licensee from prescribing or dispensing a controlled substance within the Commonwealth of Kentucky until the licensee has provided sufficient proof that the licensee is no longer employed by or practicing in an unlawful pain management facility.

(6) An emergency order restricting a licensee from prescribing or dispensing a controlled substance within the Commonwealth of Kentucky issued pursuant to subsection (5) of this section shall remain valid and in effect until the board has received sufficient proof that the licensee is no longer employed by or practicing in an unlawful pain management facility. Upon receipt of that proof, the panel or its chair shall immediately issue an order terminating the emergency order issued pursuant to subsection (5) of this section.

(7) If a licensee who is affected by an emergency order issued pursuant to subsection (5) of this section requests an emergency hearing pursuant to KRS 13B.125(3), the hearing officer conducting the emergency hearing shall affirm the emergency order if presented with substantial evidence that the licensee was prescribing or dispensing controlled substances within an unlawful pain management facility.

(8) If a licensee prescribes or dispenses a controlled substance within the Commonwealth of Kentucky during any period when the licensee is employed by or practicing in an unlawful facility, each instance of prescribing or dispensing shall constitute a separate violation of KRS 311.595(12) and (9), as illustrated by KRS 311.597(1)(b) and shall serve as the basis for disciplinary sanctions pursuant to KRS 311.595.

Section 10. Periodic KASPER Reviews. (1) The board shall have the authority pursuant to KRS 218A.202 and 218A.240 to obtain KASPER reports and analyses for each practitioner practicing in a pain management facility.

(2) At least once each year, the board shall obtain a KASPER review and analysis for each physician who has or maintains an ownership or investment interest in, or is employed by, or practices in, a pain management facility to determine whether improper, inappropriate, or illegal prescribing is occurring. If the board determines that there is evidence to indicate that improper, inappropriate, or illegal prescribing is occurring, it shall initiate an investigation of that physician and notify the appropriate agencies of its investigation.

Kentucky Administrative Regulations (2014)
Title 201. General Government Cabinet
Chapter 9. Board of Medical Licensure

201 KAR 9:260. Professional standards for prescribing and dispensing controlled substances

Section 1. Applicability. (1) A physician who is authorized to prescribe or dispense a controlled substance shall comply with the standards of acceptable and prevailing medical practice for prescribing and dispensing a controlled substance established in this administrative regulation.

(2) The professional standards established in this administrative regulation shall not apply to a physician prescribing or dispensing a controlled substance:

(a) To a patient as part of the patient's hospice or end-of-life treatment;

(b) To a patient admitted to a licensed hospital as an inpatient, outpatient, or observation patient, during and as part of a normal and expected part of the patient's course of care at that hospital;

(c) To a patient for the treatment of pain associated with cancer or with the treatment of cancer;

(d) To a patient who is a registered resident of a long-term-care facility as defined in KRS 216.510;

(e) During the effective period of any period of disaster or mass casualties which has a direct impact upon the physician's practice;

(f) In a single dose prescribed or dispensed to relieve the anxiety, pain, or discomfort experienced by that patient submitting to a diagnostic test or procedure; or

(g) That has been classified as a Schedule V controlled substance.

Section 2. Professional Standards for Documentation of Patient Assessment, Education, Treatment Agreement and Informed Consent, Action Plans, Outcomes and Monitoring. (1) Each physician prescribing or dispensing a controlled substance shall obtain and document all relevant information in a patient's medical record in a legible manner and in sufficient detail to enable the board to determine whether the physician is conforming to professional standards for prescribing or dispensing controlled substances and other relevant professional standards.

(2) If a physician is unable to conform to professional standards for prescribing or dispensing controlled substances due to circumstances beyond the physician's control, or the physician makes a professional determination that it is not appropriate to comply with a specific standard, based upon the individual facts applicable to a specific patient's diagnosis and treatment, the physician shall document those circumstances in the patient's record and only prescribe or dispense a controlled substance to the patient if the patient record appropriately justifies the prescribing or dispensing of a controlled substance under the circumstances.

Section 3. Professional Standards for the Prescribing or Dispensing of Controlled Substances for the Treatment of Pain and Related Symptoms Associated with a Primary Medical Complaint. Prior to the initial prescribing or dispensing of any controlled substance for pain or other symptoms associated with the same primary medical complaint, the first physician prescribing or dispensing a controlled substance shall:

(1) Obtain an appropriate medical history relevant to the medical complaint, including a history of present illness, and:

(a) If the complaint does not relate to a psychiatric condition, conduct a physical examination of the patient relevant to the medical complaint and related symptoms and document the information in the patient's medical record; or

(b) If the complaint relates to a psychiatric condition, perform, or have performed by a psychiatrist or other designated mental health provider, an evaluation appropriate to the presenting complaint and document the relevant findings;

(2) Obtain and review a KASPER report for that patient for the twelve (12) month period immediately preceding the patient encounter, and appropriately utilize that information in the evaluation and treatment of the patient;

(3) After examining the benefits and risks of prescribing or dispensing a controlled substance to the patient, including nontreatment or other treatment, make a deliberate decision that it is medically appropriate to prescribe or dispense the controlled substance in the amount specified;

(4) Not prescribe or dispense a long-acting or controlled-release opioid (e.g. OxyContin, fentanyl patches, or methadone) for acute pain that is not directly related to and close in time to a specific surgical procedure;

(5) Explain to the patient that a controlled substance used to treat an acute medical complaint is for time-limited use, and that the patient should discontinue the use of the controlled substance when the condition requiring the controlled substance use has resolved; and

(6) Explain to the patient how to safely use and properly dispose of any unused controlled substance.

Section 4. Professional Standards for Commencing Long Term Use of Prescribing or Dispensing of Controlled Substances for the Treatment of Pain and Related Symptoms Associated with a Primary Medical Complaint. (1) Before a physician commences to prescribe or dispense any controlled substance to a patient sixteen (16) years or older for pain or other symptoms associated with the same primary medical complaint for a total period of longer than three (3) months, the physician shall comply with the mandatory professional standards established in subsection (2) of this section. These standards may be accomplished by different licensed practitioners in a single group practice at the direction of or on behalf of the prescribing physician if:

(a) Each practitioner involved has lawful access to the patient's medical record;

(b) There is compliance with all applicable standards; and

(c) Each practitioner performing an action to meet the required standards is acting within the practitioner's legal scope of practice.

(2)(a) The physician shall obtain the following information from the patient and record all relevant information in the patient's medical record:

1. History of present illness;

2. Past medical history;

3. History of substance use and any prior treatment for that use by the patient, and history of substance abuse by first degree relatives of the patient;

4. Past family history of relevant illnesses and treatment; and

5. Psychosocial history.

(b) The physician shall conduct an appropriate physical examination of the patient sufficient to support the medical indications for prescribing or dispensing a controlled substance on a long-term basis.

(c) The physician shall perform appropriate baseline assessments to establish beginning values to assist in establishing and periodically evaluating the functional goals of any treatment plan.

(d) If a specific or specialized evaluation is necessary for the formulation of a working diagnosis or treatment plan, the physician shall only continue the use of a controlled substance after determining that continued use of the controlled substance is safe and medically appropriate in the absence of that information.

(e) If the physician determines that the patient has previously received medical treatment for the presenting medical complaint or related symptoms and that review of the prior treatment records is necessary to justify long-term prescribing of a controlled substance, the physician shall obtain those prior medical records and incorporate the information therein into the evaluation and treatment of the patient.

(f)1. Based upon consideration of all information available, the physician shall promptly formulate and document a working diagnosis of the source of the patient's medical complaint and related symptoms without simply describing or listing the related symptoms.

2. If the physician is unable, despite best efforts, to formulate a working diagnosis, the physician shall consider the usefulness of additional information, such as a specialized evaluation or

assessment, referral to an appropriate specialist, and the usefulness of further observation and evaluation, before attempting again to formulate a working diagnosis.

3. If the physician is unable to formulate a working diagnosis, despite the use of an appropriate specialized evaluation or assessment, the physician shall only prescribe long term use of a controlled substance after establishing that its use at a specific level is medically indicated and appropriate.

(g)1. To the extent that functional improvement is medically expected based upon the patient's condition, the physician shall formulate an appropriate treatment plan.

2. The treatment plan shall include specific and verifiable goals of treatment, with a schedule for periodic evaluations.

(h)1. The physician shall utilize appropriate screening tools to screen each patient to determine if the patient:

a. Is presently suffering from another medical condition which may impact the prescribing or dispensing of a controlled substance; or

b. Presents a significant risk for illegal diversion of a controlled substance.

2. If, after screening, the physician determines that there is a reasonable likelihood that the patient suffers from substance abuse or dependence, or a psychiatric or psychological condition, the physician shall take the necessary actions to facilitate a referral to an appropriate treatment program or provider. The physician shall appropriately incorporate the information from the treatment program or provider into the evaluation and treatment of the patient.

3. If, after screening, the physician determines that there is a risk that the patient may illegally divert a controlled substance, but determines to continue long term prescribing of the controlled substance, the physician shall use a prescribing agreement that meets professional standards. The prescribing agreement and informed consent document may be combined into one (1) document.

4. The physician shall obtain and document a baseline drug screen.

5. If, after screening, the physician determines that the controlled substance prescribed to the patient will be used or is likely to be used other than medicinally or other than for an accepted therapeutic purpose, the physician shall not prescribe any controlled substance to that patient.

(i) After explaining the risks and benefits of long-term use of a controlled substance, the physician shall obtain the written informed consent of the patient in a manner that meets professional standards.

(j) The physician shall initially attempt, to the extent possible, or establish and document a previous attempt by another physician, of a trial of noncontrolled modalities and lower doses of a

controlled substance in increasing order to treat the pain and related symptoms associated with the primary medical complaint, before continuing with long term prescribing of a controlled substance at a given level.

Section 5. Professional Standards for Continuing Long Term Prescribing or Dispensing of Controlled Substances for the Treatment of Pain and Related Symptoms Associated with a Primary Medical Complaint. (1) If a physician continues to prescribe or dispense a controlled substance beyond three (3) months to a patient sixteen (16) years or older for pain and related symptoms associated with the primary medical complaint, the physician shall comply with the professional standards established in subsection (2) of this section. These standards may be accomplished by different licensed practitioners in a single group practice at the direction of or on behalf of the prescribing physician as established in Section 4(1) of this administrative regulation.

(2)(a)1. The physician shall ensure that the patient is seen at least once a month initially for evaluation and review of progress. The physician may determine that the patient is to be evaluated less frequently, on a schedule determined by the physician's professional judgment after the physician has determined:

a. The controlled substance prescribed or dispensed has been titrated to the level appropriate and necessary to treat the medical complaint and related symptoms;

b. The controlled substance prescribed or dispensed is not causing unacceptable side effects; and

c. There is sufficient monitoring in place to minimize the likelihood that the patient will use the controlled substance in an improper or inappropriate manner or divert it for an improper or inappropriate use.

(b) At appropriate intervals, the physician shall:

1. Ensure that a current history is obtained from the patient;

2. Ensure that a focused physical examination is considered, and performed, if appropriate; and

3. Perform appropriate measurable examinations as indicated in the treatment plan.

(c) At appropriate intervals, the physician shall evaluate the working diagnosis and treatment plan based upon the information gained to determine whether there has been functional improvement or any change in baseline measures. The physician shall modify the diagnosis, treatment plan, or controlled substance therapy, as appropriate.

(d) If the physician determines that the patient presents a significant risk of diversion or improper use of a controlled substance, the physician shall discontinue the use of the controlled substance or justify its continued use in the patient record.

(e) If the medical complaint and related symptoms continue with no significant improvement in function despite treatment with a controlled substance, and if improvement is medically expected, the physician shall obtain appropriate consultative assistance to determine whether there are undiagnosed conditions to be addressed in order to resolve the medical complaint.

(f) For a patient exhibiting symptoms suggestive of a mood, anxiety, or psychotic disorder, the physician shall obtain a psychiatric or psychological consultation for intervention if appropriate.

(g) If a patient reports experiencing episodes of breakthrough pain, the physician shall:

1. Attempt to identify the trigger or triggers for each episode;

2. Determine whether the breakthrough pain may be adequately treated through noncontrolled treatment; and

3. If the physician determines that the nonmedication treatments do not adequately address the triggers, and after considering the risks and benefits, determines to add an as-needed controlled substance to the regimen, take appropriate steps to minimize the improper or illegal use of the additional controlled substance.

(h) At least once a year, the physician shall perform or shall ensure that the patient's primary treating physician performs a preventive health screening and physical examination appropriate to the patient's gender, age, and medical condition.

(i)1. At least once every three (3) months, the physician shall obtain and review a current KASPER report, for the twelve (12) month period immediately preceding the request, and appropriately use that information in the evaluation and treatment of the patient.

2. If the physician obtains or receives specific information that the patient is not taking the controlled substance as directed, is diverting a controlled substance, or is engaged in any improper or illegal use of a controlled substance, the physician shall immediately obtain and review a KASPER report and appropriately use the information in the evaluation and treatment of the patient.

3. If a KASPER report discloses that the patient is obtaining a controlled substance from another practitioner without the physician's knowledge and approval, in a manner that raises suspicion of illegal diversion, the physician shall promptly notify the other practitioner of the relevant information from the KASPER review.

4. The physician shall obtain consultative assistance from a specialist if appropriate.

(j) If appropriate, the physician shall conduct random pill counts and appropriately use that information in the evaluation and treatment of the patient.

(k)1. During the course of long-term prescribing or dispensing of a controlled substance, the physician shall utilize drug screens, appropriate to the controlled substance and the patient's condition, in a random and unannounced manner at appropriate times. If the drug screen or other information available to the physician indicates that the patient is noncompliant, the physician shall:

a. Do a controlled taper;

b. Stop prescribing or dispensing the controlled substance immediately; or

c. Refer the patient to an addiction specialist, mental health professional, pain management specialist, or drug treatment program, depending upon the circumstances.

2. The physician shall discontinue controlled substance treatment or refer the patient to addiction management if:

a. There has been no improvement in function and response to the medical complaint and related symptoms, if improvement is medically expected;

b. Controlled substance therapy has produced significant adverse effects; or

c. The patient exhibits inappropriate drug-seeking behavior or diversion.

Section 6. Professional Standards for the Prescribing and Dispensing of Controlled Substances in an Emergency Department. In addition to complying with the standards for the initial prescribing or dispensing of a controlled substance as established in Sections 3 and 7 of this administrative regulation, a physician prescribing or dispensing a controlled substance for a specific medical complaint and related symptoms to a patient in an emergency department shall not routinely:

(1) Administer an intravenous controlled substance for the relief of acute exacerbations of chronic pain, unless intravenous administration is the only medically appropriate means of delivery;

(2) Provide a replacement prescription for a controlled substance that was lost, destroyed, or stolen;

(3) Provide a replacement dose of methadone, suboxone, or subutex for a patient in a treatment program;

(4) Prescribe a long-acting or controlled-release controlled substance, such as OxyContin, fentanyl patches, or methadone or a replacement dose of that medication;

(5) Administer Meperidine to the patient; or

(6) Prescribe or dispense more than the minimum amount medically necessary to treat the patient's medical condition until the patient can be seen by the primary treating physician or another physician, with no refills. If the controlled substance prescription exceeds seven (7) days in length, the patient record shall justify the amount of the controlled substance prescribed.

Section 7. Professional Standards for the Prescribing and Dispensing of Controlled Substances for the Treatment of Other Conditions. (1) Before initially prescribing or dispensing a controlled substance to a patient for a condition other than pain, the physician shall:

(a) Obtain an appropriate medical history relevant to the medical complaint, including a history of present illness, and:

1. If the complaint does not relate to a psychiatric condition, conduct a physical examination of the patient relevant to the medical complaint and related symptoms and document the information in the patient's medical record; or

2. If the complaint relates to a psychiatric condition, perform, or have performed by a psychiatrist or other designated mental health provider, an evaluation appropriate to the presenting complaint and document the relevant findings;

(b) Obtain and review a KASPER report for that patient, for the twelve (12) month period immediately preceding the patient encounter, and appropriately utilize that information in the evaluation and treatment of the patient;

(c) After examining the benefits and risks of prescribing or dispensing a controlled substance to the patient, including nontreatment or other treatment, make a deliberate decision that it is medically appropriate to prescribe or dispense the controlled substance in the amount specified;

(d) Avoid providing more controlled substances than necessary by prescribing or dispensing only the amount of a controlled substance needed to treat the specific medical complaint;

(e) Explain to the patient that a controlled substance used to treat an acute medical complaint is for time-limited use, and that the patient should discontinue the use of a controlled substance when the condition requiring the controlled substance use has resolved; and

(f) Explain to the patient how to safely use and properly dispose of any unused controlled substance.

(2) If the physician continues to prescribe or dispense a controlled substance to a patient for the same medical complaint and related symptoms, the physician shall fully conform to the standards of acceptable and prevailing practice for treatment of that medical complaint and for the use of the controlled substance.

(3) If a physician receives a request from an established patient to prescribe or dispense a limited amount of a controlled substance to assist the patient in responding to the anxiety or depression resulting from a nonrecurring single episode or event, the physician shall:

(a) Obtain and review a KASPER report for that patient for the twelve (12) month period immediately preceding the patient request and appropriately utilize the information obtained in the evaluation and treatment of the patient;

(b) Make a deliberate decision that it is medically appropriate to prescribe or dispense the controlled substance in the amount specified, with or without requiring a personal encounter with the patient to obtain a more detailed history or to conduct a physical examination; and

(c) If the decision is made that it is medically appropriate to prescribe or dispense the controlled substance, prescribe or dispense the minimum amount of the controlled substance to appropriately treat the situational anxiety or depression.

Section 8. Responsibility to Educate Patients Regarding the Dangers of Controlled Substance Use. (1) A physician prescribing or dispensing a controlled substance shall take appropriate steps to educate a patient receiving a controlled substance.

(2) Educational materials relating to these subjects may be found on the board's Web site, www.kbml.ky.gov.

Section 9. Additional Standards for Prescribing or Dispensing Schedule II Controlled Substances or Schedule III Controlled Substances Containing Hydrocodone. (1) In addition to the other standards established in this administrative regulation, prior to the initial prescribing or dispensing of a Schedule II controlled substance or a Schedule III controlled substance containing hydrocodone to a human patient, a physician 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 KASPER 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) In addition to the other standards established in this administrative regulation, a physician prescribing or dispensing additional amounts of a Schedule II controlled substance or a Schedule III controlled substance 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 physician shall:

1. Query KASPER 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) To the extent not already required by the standards established in this administrative regulation, for each patient for whom a physician prescribes or dispenses a Schedule II controlled substance or a Schedule III controlled substance containing hydrocodone, the physician 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) The additional standards for prescribing or dispensing a Schedule II controlled substance or a Schedule III controlled substance containing hydrocodone established in this section shall not apply to:

(a) A physician prescribing or administering that 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 delivery and the medication usage does not extend beyond the fourteen (14) days; or

(b) A physician prescribing or dispensing that 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 physician in those hospitals or facilities if no institutional account exists, queries KASPER 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 for use 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 physician 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 federalwide assurance number from the United States Department for Health and Human Services, Office for Human Research Protections if 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.

Section 10. Violations. (1) Any violation of the professional standards established in this administrative regulation shall constitute a violation of KRS 311.595(12) and (9), which may result in the imposition of disciplinary sanctions by the board, pursuant to KRS 311.595.

(2) Each violation of the professional standards established in this administrative regulation shall be established by expert testimony by one (1) or more physicians retained by the board, following a review of the licensee's patient records and other available information including KASPER reports.

Kentucky Administrative Regulations (2014)
Title 201. General Government Cabinet
Chapter 20. Board of Nursing

201 KAR 20:057. Scope and standards of practice of advanced practice registered nurses

Section 1. Definitions. (1) “Collaboration” means the relationship between the advanced practice registered nurse and a physician in the provision of prescription medication, including both autonomous and cooperative decision-making, with the advanced practice registered nurse and the physician contributing their respective expertise.

(2) “Collaborative Agreement for the Advanced Practice Registered Nurse's Prescriptive Authority for Controlled Substances” or “CAPA-CS” means the written document pursuant to KRS 314.042(9).

(3) “Collaborative Agreement for the Advanced Practice Registered Nurse's Prescriptive Authority for Nonscheduled Legend Drugs” or “CAPA-NS” means the written document pursuant to KRS 314.042(8).

Section 2. The practice of the advanced practice registered nurse shall be in accordance with the standards and functions defined in the following scope and standards of practice statements for each specialty area:

(1) Scope and Standards of Psychiatric-Mental Health Nursing Practice;

(2) Nursing: Scope and Standards of Practice;

(3) Scope and Standards for Nurse Anesthesia Practice;

(4) Standards for Office-based Anesthesia Practice;

(5) Standards for the Practice of Midwifery;

(6) The Women's Health Nurse Practitioner: Guidelines for Practice and Education;

(7) Pediatric Nursing: Scope and Standards of Practice;

(8) Standards of Practice for Nurse Practitioners;

(9) Scope of Practice for Nurse Practitioners;

(10) Scope and Standards of Practice for the Acute Care Nurse Practitioner;

(11) Neonatal Nursing: Scope and Standards of Practice;

(12) Scope and Standards for Acute and Critical Care Clinical Nurse Specialist Practice; and

(13) Statement on the Scope and Standards of Advanced Practice Nursing in Oncology.

Section 3. In the performance of advanced practice registered nursing, the advanced practice registered nurse shall seek consultation or referral in those situations outside the advanced practice registered nurse's scope of practice.

Section 4. Advanced practice registered nursing shall include prescribing medications and ordering treatments, devices, and diagnostic tests which are consistent with the scope and standard of practice of the advanced practice registered nurse.

Section 5. Advanced practice registered nursing shall not preclude the practice by the advanced practice registered nurse of registered nursing practice as defined in KRS 314.011(5).

Section 6. (1) A CAPA-NS shall include the name, address, phone number, and license number of both the advanced practice registered nurse and each physician who is a party to the agreement. It shall also include the specialty area of practice of the advanced practice registered nurse. An advanced practice registered nurse shall, upon request, furnish to the board or its staff, a copy of the CAPA-NS.

(2) To notify the board of the existence of a CAPA-CS pursuant to KRS 314.042(9)(a), the APRN shall file with the board the "Notification of a Collaborative Agreement for the Advanced Practice Registered Nurse's Prescriptive Authority for Controlled Substances (CAPA-CS)"

(3) For purposes of the CAPA-CS, in determining whether the APRN and the collaborating physician are qualified in the same or a similar specialty, the board shall be guided by the facts of each particular situation and the scope of the APRN's and the physician's actual practice.

(4)(a) An APRN with a CAPA-CS shall report all of his or her United States Drug Enforcement Agency (DEA) Controlled Substance Registration Certificate numbers to the board when issued to the APRN by mailing a copy of the registration certificate to the board within thirty (30) days of issuance.

(b) Any change in the status of the DEA Controlled Substance Registration Certificate number shall be reported in writing to the board within thirty (30) days.

Section 7. Prescribing medications without a CAPA-NS or a CAPA-CS shall constitute a violation of KRS 314.091(1).

Section 8. The board may make an unannounced monitoring visit to an advanced practice registered nurse to determine if the advanced practice registered nurse's practice is consistent with the requirements established by 201 KAR Chapter 20, and patient and prescribing records shall be made available for immediate inspection.

Section 9. Prescribing Standards for Controlled Substances. (1)(a) This section shall apply to an APRN with a CAPA-CS if prescribing a controlled substance other than a Schedule II controlled substance or a Schedule III controlled substance containing hydrocodone.

(b) The APRN shall practice according to the applicable scope and standards of practice for the APRN's role and population focus.

(2) This section shall not apply to:

(a) An APRN 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) An APRN prescribing or administering a controlled substance necessary to treat a patient in an emergency situation; or

(c) An APRN prescribing a controlled substance:

1. For administration in a hospital or long-term-care facility with an institutional account, or an APRN in a hospital or facility without an institutional account, if the hospital, long-term-care facility, or licensee queries KASPER 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 pursuant to subsection (1) of this section if the prescribing:

a. Is done as a substitute for the initial prescribing;

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 pursuant to subsection (1) of this section if the prescribing is done by another licensee in the same practice or in an existing coverage arrangement, if done for the same patient for the same medical condition;

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 if 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;

8. During the effective period of any disaster or situation with mass casualties that have a direct impact on the APRN's practice;

9. Administering or prescribing controlled substances to prisoners in a state, county, or municipal correctional facility;

10. Prescribing a Schedule IV controlled substance for no longer than three (3) days for an established patient to assist the patient in responding to the anxiety of a nonrecurring event; or

11. That has been classified as a Schedule V controlled substance.

(3) The APRN shall, prior to initially prescribing a controlled substance for a medical complaint for a patient:

(a) Obtain the patient's medical history and conduct an examination of the patient and document the information in the patient's medical record. An APRN certified in psychiatric/mental health shall obtain a medical and psychiatric history, perform a mental health assessment, and document the information in the patient's medical record;

(b) Query KASPER for all available data on the patient;

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

(d) Discuss 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:

1. The risks and benefits of the use of controlled substances, including the risk of tolerance and drug dependence;

2. That the controlled substance should be discontinued when the condition requiring its use has resolved; and

3. Document that the discussion occurred and that the patient consented to the treatment.

(4) The treatment plan shall include an exit strategy, if appropriate, including potential discontinuation of the use of controlled substances.

(5) For subsequent or continuing long-term prescriptions of a controlled substance for the same medical complaint, the APRN shall:

(a) Update the patient's medical history and document the information in the patient's medical record;

(b) Modify the treatment plan as clinically appropriate; and

(c) Discuss the risks and benefits of any new controlled substances prescribed 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.

(6) During the course of treatment, the APRN shall query KASPER no less than once every three (3) months for all available data on the patient before issuing a new prescription or a refill for a controlled substance.

(7) These requirements may be satisfied by other licensed practitioners in a single group practice if:

(a) Each licensed practitioner involved has lawful access to the patient's medical record;

(b) Each licensed practitioner performing an action to meet these requirements is acting within the scope of practice of his or her profession; and

(c) There is adequate documentation in the patient's medical record reflecting the actions of each practitioner.

(8) If prescribing a controlled substance for the treatment of chronic, noncancer pain, the APRN, in addition to the requirements of this section, shall obtain a baseline drug screen or further random drug screens if the APRN:

(a) Deems a drug screen to be clinically appropriate; or

(b) Believes that it is appropriate to determine whether or not the controlled substance is being taken by the patient.

(9) If prescribing a controlled substance for the treatment of a mental health condition, the APRN shall meet the requirements of this section.

(10) If prescribing a controlled substance for a patient younger than sixteen (16) years of age, the APRN shall obtain and review an initial KASPER report. If prescribing a controlled substance for an individual sixteen (16) years of age or older, the requirements of this section shall apply.

(11) Prior to prescribing a controlled substance for a patient in the emergency department of a hospital that is not an emergency situation as specified in subsection (2) of this section, the APRN shall:

(a) Obtain the patient's medical history, conduct an examination of the patient and document the information in the patient's medical record. An APRN certified in psychiatric/mental health shall obtain a medical and psychiatric history, perform a mental health assessment, and document the information in the patient's medical record;

(b) Query KASPER for all available data on the patient;

(c) Make a written treatment 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 document that the discussion occurred and that the patient consented to the treatment.

Section 10. Prescribing Standards for Controlled Substances from Schedule II and Schedule III Containing Hydrocodone. (1)(a) This section shall apply to an APRN with a CAPA-CS if prescribing a controlled substance from Schedule II or Schedule III controlled substance containing hydrocodone.

(b) The APRN shall practice according to the applicable scope and standards of practice for the APRN's role and population focus.

(2) This section shall not apply to:

(a) An APRN 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) An APRN prescribing or administering a controlled substance necessary to treat a patient in an emergency situation; or

(c) An APRN prescribing a controlled substance:

1. For administration in a hospital or long-term-care facility with an institutional account, or an APRN in a hospital or facility without an institutional account, if the hospital, long-term-care facility, or licensee queries KASPER 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 pursuant to subsection (1) of this section if the prescribing or dispensing:

a. Is done as a substitute for the initial prescribing;

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 pursuant to subsection (1) of this section if the prescribing is done by another licensee 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 if 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.

(3) Prior to the initial prescribing of a Schedule II controlled substance or a Schedule III controlled substance containing hydrocodone to a human patient, an APRN 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.

(4)(a) An APRN prescribing an additional amount of a Schedule II controlled substance or Schedule III controlled substance containing hydrocodone for the same medical complaint and related symptoms shall:

1. Review the plan of care at reasonable intervals based on the patient's individual circumstances and course of treatment;

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 licensee shall:

1. Query KASPER 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.

(5) For each patient for whom an APRN prescribes a Schedule II controlled substance or a Schedule III controlled substance containing hydrocodone, the licensee 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;

(h) Instructions and agreements; and

(i) Periodic reviews of the patient's file.

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

(a) "Scope and Standards of Psychiatric-Mental Health Nursing Practice" 2007 Edition, American Nurses' Association;

(b) “Nursing: Scope and Standards of Practice” 2010 Edition, American Nurses' Association;

(c) “Standards for Office-based Anesthesia Practice” 2010 Edition, American Association of Nurse Anesthetists;

(d) “Scope and Standards for Nurse Anesthesia Practice” 2010 Edition, American Association of Nurse Anesthetists;

(e) “Standards for the Practice of Midwifery” 2011 Edition, American College of Nurse-midwives;

(f) “The Women's Health Nurse Practitioner: Guidelines for Practice and Education” 2008 Edition, Association of Women's Health, Obstetric and Neonatal Nurses and National Association of Nurse Practitioners in Women's Health;

(g) “Pediatric Nursing: Scope and Standards of Practice” 2008 Edition, National Association of Pediatric Nurse Practitioners;

(h) “Standards of Practice for Nurse Practitioners” 2010 Edition, American Academy of Nurse Practitioners;

(i) “Scope of Practice for Nurse Practitioners” 2010 Edition, American Academy of Nurse Practitioners;

(j) “Scope and Standards of Practice for the Acute Care Nurse Practitioner” 2006 Edition. American Association of Critical Care Nurses;

(k) “Neonatal Nursing: Scope and Standards of Practice” 2004 Edition, American Nurses Association/National Association of Neonatal Nurses;

(l) “Scope and Standards for Acute and Critical Care Clinical Nurse Specialist Practice” 2010 Edition, American Association of Critical-Care Nurses;

(m) “Statement on the Scope and Standards of Advanced Practice Nursing in Oncology” 2003 Edition, Oncology Nursing Society; and

(n) “Notification of a Collaborative Agreement for the Advanced Practice Registered Nurse's Prescriptive Authority for Controlled Substances (CAPA-CS)” 6/2010, Kentucky Board of Nursing.

(2) This material may be inspected, copied, or obtained, subject to applicable copyright law, at the Kentucky Board of Nursing, 312 Whittington Parkway, Suite 300, Louisville, Kentucky 40222, Monday through Friday, 8 a.m. to 4:30 p.m.

Kentucky Administrative Regulations (2014)
Title 201. General Government Cabinet
Chapter 25. Board of Podiatry

201 KAR 25:011. Approved schools; examination application; fees

Section 1. (1) The board approves the following schools or colleges of podiatry as having standards and requirements adequate to satisfy the educational requirement for taking the podiatry examination for licensure:

(a) Barry University School of Podiatric Medicine, Miami Shores, Florida;

(b) California College of Podiatric Medicine, San Francisco, California;

(c) College of Podiatric Medicine and Surgery, Des Moines, Iowa;

(d) Dr. William M. Scholl College of Podiatric Medicine, Chicago, Illinois;

(e) New York College of Podiatric Medicine, New York, New York;

(f) Ohio College of Podiatric Medicine, Cleveland, Ohio;

(g) Pennsylvania College of Podiatric Medicine, Philadelphia, Pennsylvania;

(h) Arizona Podiatric Medicine Program at Midwestern University, Glendale, Arizona.

(2) All other schools or colleges of podiatry shall have academic standards and requirements equivalent to the schools or colleges listed above as evaluated by the board in order to be approved by the board. Evaluation of the academic standards and requirements shall be made by the board after an applicant has filed an application for a license with the board.

Section 2. (1) Every applicant, otherwise eligible to take the examination pursuant to the provisions of KRS 311.420, shall file a completed Application for Examination with the board at its principal office at least forty (40) days prior to the date of the examination in order to be eligible to take the examination.

(2) The president of the board may permit a partially completed application to be filed if good cause is shown by the applicant.

(3) The fee for the examination or reexamination shall be $250 and shall be paid when the application for examination or reexamination is filed with the board. The fee shall be made payable to the Kentucky State Treasurer in United States currency by certified check, cashier's check, or postal money order and shall not be refundable.

(4) Any applicant who fails to attain a passing score as required by the board may apply to the board for reexamination.

Section 3. (1) Prior to approval for examination, an applicant shall:

(a) Submit to a nation-wide criminal background investigation by means of fingerprint check by the Department of Kentucky State Police or the Federal Bureau of Investigation;

(b) Submit to a query to the National Practitioner Data Bank of the United States Department of Health and Human Services; and

(c) Report to the board, with the Application for Examination, any conviction or disciplinary action on a license held by the applicant relating to prescribing or dispensing controlled substances.

Section 4. (1) Pursuant to KRS 218A.205(3)(e), an applicant for licensure by the board:

(a) Convicted after July 20, 2012 of any felony offense relating to controlled substances shall be permanently banned from prescribing or dispensing a controlled substance by the board;

(b) Convicted after July 20, 2012 of any misdemeanor offense relating to prescribing or dispensing a controlled substance shall have his or her authority to prescribe controlled substances suspended for at least three (3) months, and shall be further restricted as determined by the board; or

(c) Who has had any disciplinary limitation placed on an application or license by a licensing board of another state that resulted from improper, inappropriate, or illegal prescribing or dispensing of controlled substances shall be subject to a restriction on the license that is at least as restrictive in time and scope as that placed on the license by the licensing board of the other state.

(2) In addition to the actions listed in subsection (1) of this section, the Board may take any other action provided for in KRS 311.480 against a licensee or applicant that comes under the provisions of that subsection.

Section 5. Requirements for a person issued a license by the board. (1) A person who has been approved for a license from the board shall register with the Kentucky All-Schedule Prescription Electronic Reporting System (KASPER) administered by the Cabinet for Health and Family Services after issuance of the license and immediately submit proof of the registration to the board.

(2) A person who has received a license from the board shall not prescribe any controlled substance before he or she is registered with KASPER.

(3) The board shall temporarily suspend a license pursuant to 201 KAR 23:051, Section 5 of this administrative regulation, if a licensee:

(a)1. Fails to register with KASPER after the approval for licensure by the board; or

2. Prescribes a controlled substance prior to registration with KASPER.

(b) In addition to the temporary suspension, the board may take additional disciplinary action against a license pursuant to KRS 311.480.

Section 6. Incorporation by Reference. (1) "Application for Examination" 1994, is incorporated by reference.

(2) This material may be inspected, copied, or obtained, subject to applicable copyright law, at the Kentucky State Board of Podiatry, P.O. Box 174, Glasgow, Kentucky 42142-0174, Monday through Friday, 8 a.m. to 4:30 p.m.

Kentucky Administrative Regulations (2014)
Title 201. General Government Cabinet
Chapter 25. Board of Podiatry

201 KAR 25:021. Annual renewal of licenses, fees

Section 1. (1) The annual renewal fee, in the amount of $150 shall be attached to the completed annual renewal notice when the notice is returned to the board by the podiatrist seeking licensure renewal.

(2) The annual renewal fee shall be made payable to the Kentucky State Treasurer in United States currency by certified check, cashier's check, postal money order, personal check, or credit card.

(3) All information requested on the annual renewal notice form shall be furnished to the board when the completed annual renewal notice form is returned to the board, together with a statement of compliance with the continuing education administrative regulations of the board.

(4) Every renewal application shall include proof of current registration with the Kentucky All-Schedule Prescription Electronic Reporting System (KASPER) administered by the Cabinet for Health and Family Services.

Section 2. (1) Failure to complete the requirements for annual renewal of the license by July 1 of each year shall result in a delinquent penalty fee of $100.

(2) A licensee shall immediately report to the board any conviction or disciplinary action on a license held by the applicant relating to prescribing or dispensing controlled substances.

Section 3. (1) Pursuant to KRS 218A.205(3)(e), a licensee:

(a) Convicted after July 20, 2012 of any felony offense relating to controlled substances shall be permanently banned from prescribing or dispensing a controlled substance by the board;

(b) Convicted after July 20, 2012 of any misdemeanor offense relating to prescribing or dispensing a controlled substance shall have his or her authority to prescribe controlled substances suspended for at least three (3) months, and shall be further restricted as determined by the board; or

(c) Who has had any disciplinary limitation placed on a application or license by a licensing board of another state that resulted from improper, inappropriate, or illegal prescribing or dispensing of controlled substances shall be subject to a restriction on the license that is at least as restrictive in time and scope as that placed on the license by the licensing board of the other state.

(2) In addition to the actions listed in subsection (1) of this section, the board may take additional disciplinary action against a licensee pursuant to KRS 311.480.

Kentucky Administrative Regulations (2014)
Title 201. General Government Cabinet
Chapter 25. Board of Podiatry

201 KAR 25:090. Prescribing and dispensing controlled substances

Section 1. Prescribing or dispensing a controlled substance. (1) This administrative regulation governs the prescribing and dispensing of controlled substances listed in Schedule II through V as classified in KRS 218A.060, 218A.070, 218A.080, 218A.090, 218A.100, 218A.110, 218A.120, and 218A.130.

(2) If initially prescribing or dispensing a controlled substance, a licensee shall:

(a) Obtain a complete medical history and conduct a physical examination of the patient;

(b) Complete a written treatment plan which states the objectives of the treatment underlying the prescription of the controlled substance and which includes an outline of any further diagnostic examinations that may be required;

(c) Discuss the risks and benefits of the use of controlled substances with the patient or the patient's legal guardian or health care surrogate, including the risk of tolerance and drug dependence;

(d) Verify that the patient is the person that he or she has identified himself or herself as being by requiring the person to produce proper government issued identification;

(e) Query the Kentucky All-Schedule Prescription Electronic Reporting System (KASPER) for all information available on the patient if prescribing controlled substances that are included in:

1. Schedule II;

2. Schedule III; and

3. The following from Schedule IV:

a. Ambien;

b. Anorexics;

c. Ativan;

d. Klonopin;

e. Librium;

f. Nubain;

g. Oxazepam;

h. Phentermine;

i. Soma;

j. Stadol;

k. Stadol NS;

l. Tramadol;

m. Valium;

n. Versed; and

o. Xanax;

(f) Obtain consent for the treatment from the patient in writing; and

(g) Document the patient's file as required by Section 2 of this administrative regulation.

(3) If it is necessary to continue the prescription or dispensation of a controlled substance after the initial supply is completed, a licensee shall:

(a) Conduct, at reasonable intervals under the circumstances presented, all clinically indicated steps;

(b) Review the course of treatment that he initially prepared to determine if any changes are required;

(c) Provide any new information about the course of treatment or any changes made to the patient;

(d) Query KASPER for all information available on the patient no less than once every three months for all available data on the patient to review that data before issuing any new prescription or refill for the patient for controlled substance specified in subsection (2)(e) of this section; and

(e) Document the patient's file as required by Section 2 of this administrative regulation.

Section 2. Podiatric medical records for patients being prescribed controlled substance shall include at a minimum:

(1) The patient's name;

(2) The patient's date of birth;

(3) The information concerning the patient's medical history and physical examination required by Section 1 of this administrative regulation;

(4) The podiatrist's diagnosis of the patient's condition;

(5) The procedures and treatments to be undertaken and their objectives;

(6) The date of the procedures or treatments;

(7) (Whether local or general anesthetics were used, including the type and the amount administered;

(8) Diagnostic, therapeutic, and laboratory results;

(9) The findings and recommendations of any other evaluations or consultations;

(10) All medications administered or prescribed by the podiatrist, including the date, type, dosage, and quantity administered or prescribed;

(11) Any post-treatment instructions from the podiatrist; and

(12) Documentation that the KASPER query required by Section 3 of this administrative regulation was completed.

Section 3. If a prescription for a controlled substance is written, a podiatrist shall:

(1) Obtain and document in the patient's podiatric medical record the information concerning the patient's medical history and physical examination required by Section 1 of this administrative regulation;

(2) Query the Kentucky All-Scheduled Prescription Electronic Reporting System (KASPER) for all available data on the patient if the controlled substance is one specified in Section 1(2)(e) of this administrative regulation and record the results of the query in the patient's record;

(3) 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

(4) Obtain consent for the treatment from the patient in writing.

Section 4. Dispensing Schedule II or Schedule III controlled substances containing hydrocodone. (1) A licensee shall not dispense more than a forty-eight (48) hour supply of Schedule II or Schedule III controlled substances containing hydrocodone.

(2) If a patient continues to present with pain after the initial supply has been completed and the podiatrist believes that an additional prescription for a controlled substance is medically appropriate, the podiatrist shall at a minimum:

(a) Follow the requirements of Section 1 of this administrative regulation; and

(b) Prescribe only that amount of the controlled substance that is appropriate under accepted and prevailing practice standards.

Section 5. Authority to prescribe controlled substances. (1) A podiatrist licensed by the board may prescribe any medicine necessary for the treatment of a patient that comes within the practice of podiatry as defined by KRS 311.380(2), including Schedule II and Schedule III controlled substances containing hydrocodone, if the licensee:

(a) Has obtained a license number from the Drug Enforcement Administration;

(b) Registers with and utilizes the Kentucky All-Schedule Prescription Electronic Reporting System (KASPER) as required by KRS 218A.202;

(c) Follows the requirements of this administrative regulation; and

(d) Meets all the requirements for utilizing KASPER promulgated by the Cabinet as well as the requirements set forth in KRS 218A.202.

(2) A licensed podiatrist shall not prescribe or dispense:

(a) With the intent or knowledge that a medication will be used or is likely to be used for any purpose other than one that is necessary for medical treatment or therapeutic use;

(b) With the intent to evade any law governing the sale, use, or disposition of the medication;

(c) When the licensee knows or has reason to know that the abuse of the controlled substance is occurring or may result therefrom; and

(d) In amounts that the licensee knows or has reason to know, under the circumstance, that the amount prescribed is excessive under accepted and prevailing practice standards.

(3) After a hearing conducted under KRS Chapter 13B and 201 KAR 25:051, the board shall fine a licensee who otherwise has the authority to prescribe controlled substances, but who has failed

to register for an account with KASPER, an amount not less than $250 per prescription for each prescription that individual has written while not properly registered.

Kentucky Administrative Regulations (2014)
Title 902. Cabinet for Health and Family Services Department for Public Health
Chapter 55. Controlled Substances

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

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(9), 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 which 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(33).

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

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) and (b).

(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 day's supply dispensed;

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

(g) Serial number assigned by the dispenser; and

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

(3)(a) Prior to July 1, 2013, the data identified in subsection (2) of this section shall be transmitted within seven (7) days of the date of dispensing unless the cabinet grants an extension as provided in subsection (4) or (5) of this section.

(b) Prior to July 1, 2013, a dispenser that dispenses a controlled substance for the direct administration of the controlled substance to or for a patient in a licensed health facility shall not be required to transmit the data identified in subsection (2) of this section.

(c) Effective July 1, 2013, 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 format established by the "ASAP Telecommunications Format for Controlled Substances" developed by the American Society for Automation in Pharmacy, Version 4.1, 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 format established by "ASAP Telecommunications Format for Controlled Substances" shall report the data identified in subsection (2) of this section using an Internet accessible web portal designated by the cabinet.

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 "Request for KASPER Report (Law Enforcement and Licensure Boards)" Form DCB-15L.

(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 be 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 for a period of two (2) years plus the current year prior to its transfer to 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(8) 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) 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 maintains that information regarding the dispensing of a controlled substance was correctly reported to KASPER and the KASPER system generates a report with inaccurate information, the dispenser shall contact the Drug Enforcement and Professional Practices Branch (DEPPB) to identify the source of an error in the KASPER report, and the cabinet shall correct the information in the KASPER database.

(4) Upon correction of information in the KASPER database pursuant to subsection (3) of this section, cabinet staff shall 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(6).

(2) As a condition precedent to the disclosure of data or a report pursuant to KRS 218A.202(6)(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(6) shall not provide the data to any other entity except as provided in KRS 218A.202(8) and paragraph (b) of this subsection.

(b) In addition to the purposes authorized under KRS 218A.202(8)(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(6)(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) "ASAP Telecommunications Format for Controlled Substances" American Society for Automation in Pharmacy, Version 4.1, November 2009; and

(b) "Request for KASPER Report (Law Enforcement and Licensure Boards)" Form DCB-15L, 12/10.

(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.