CABINET FOR HEALTH AND FAMILY SERVICES
Office of Inspector General
Division of Audits and Investigations
(Amendment)

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

RELATES TO: KRS 218A.010(11), 218A.202, 218A.240, 42 C.F.R. Part 2
STATUTORY AUTHORITY: KRS 194A.050, 218A.202(1), (18)[~~(17)~~], 218A.250
NECESSITY, FUNCTION, AND CONFORMITY: KRS 218A.202(1) directs the Cabinet for Health and Family Services to establish and maintain an electronic system for monitoring Schedule II, III, IV, and V controlled substances. KRS 218A.250 requires the cabinet to promulgate administrative regulations pursuant to KRS Chapter 13A for carrying out the provisions of KRS Chapter 218A. This administrative regulation establishes criteria for reporting prescription data, establishes procedures to correct errors, and allows for disclosure of data[~~providing reports~~] to authorized persons[~~, and a waiver for a dispenser who does not have an automated recordkeeping system~~].

Section 1. Definitions.
(1) "Branch" means the Drug Enforcement and Professional Practices Branch in the Division of Audits and Investigations, Office of Inspector General, Cabinet for Health and Family Services.
(2) "Cabinet personnel" means an individual who:
(a)
1. Is directly employed by the Cabinet for Health and Family Services; or
2. Is employed by an agent or contractor of the cabinet;
(b) Has undergone KASPER training; and
(c) Has been approved to use the KASPER system.
(3) "Central registry" is an entity defined by 908 KAR 1:374, Section 1(3) that may report information to KASPER on behalf of a narcotic treatment program.
(4) "Dispenser" is defined by KRS 218A.010(12)[~~218A.010(11)~~], and shall:
(a) Include a dispenser who has a DEA (Drug Enforcement Administration) number or is a pharmacist who owns or is employed by a facility that operates a pharmacy that has a DEA number;[~~ and~~]
(b) Include a narcotic treatment program licensed pursuant to 908 KAR 1:374, and
(c) Not include an individual licensed to practice veterinary medicine under KRS Chapter 321.
(5) [~~(4)~~] "Health facility" is defined by KRS 216B.015(13).
(6) [~~(5)~~] "KASPER" means Kentucky All-Schedule Prescription Electronic Reporting System.
(7) [~~(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.
(8) [~~(7)~~] "Practitioner" is defined by KRS 218A.010(40)[~~218A.010(39)~~].
(9) [~~(8)~~] "Report" means a compilation of data concerning a patient, dispenser, practitioner, or controlled substance.
(10) [~~(9)~~] "Suspected drug overdose" means an acute condition that:
(a) May include physical illness, coma, mania, or hysteria that is the result of consumption or use of a controlled substance, or another substance with which a

controlled substance was combined; and

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

1. T40;
2. T42; or
3. T43.

Section 2. Data Reporting.

(1) A dispenser or a health facility that has a DEA number shall report all dispensed Schedule II, III, IV, or V controlled substances, except:

(a) During the circumstances specified in KRS 218A.202(3)(a) through (c); or[.]

(b) If the controlled substance is dispensed by a narcotic treatment program for use to treat substance use disorder and the patient has not provided written consent that meets the requirements of 42 C.F.R. 2.31.

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

(a) Patient identifier;
(b) National drug code of the drug dispensed;
(c) Metric quantity of the drug dispensed;
(d) Date of dispensing;
(e) Estimated days the supply of dispensed medication will last;
(f) Drug Enforcement Administration registration number of the prescriber;
(g) Prescription number or dispensing identification number assigned by the dispenser or health facility; and
(h) The Drug Enforcement Administration registration number of the dispenser.

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

(4)

(a) An extension may be granted if the dispenser, health facility, or central registry:

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) To request an extension, a written request shall:[dispenser shall apply to the branch in writing for an extension]

1. Be submitted to the branch:

a. [listed in paragraph (a) of this subsection]Within twenty-four (24) hours of discovery of the circumstances necessitating the request; or

b. If state offices are closed, on the next day that[date] state offices are open for business[,] following [the]discovery of the circumstances necessitating the request; and

2. Provide a [. An application for an extension shall state the] justification for the extension, including the length[and the period] of time [for which]the extension is necessary.

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

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

(a) An electronic device compatible with the receiving device of the cabinet or the cabinet's agent;
(b) Secure File Transfer Protocol;

(c) https protocol; or

(d) Secure Virtual Private Network connection.

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

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

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

Section 3. Compliance. A dispenser may presume that the patient identification information ~~[established in Section 5 of this administrative regulation and]~~provided by the patient or the patient's agent in accordance with Section 5 of this administrative regulation 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) A request for a KASPER provider report made by a law enforcement or prosecutorial official~~[peace officer]~~ authorized to receive data under KRS 218A.202, or a designated representative of a board responsible for the licensure, regulation, or discipline of prescribing practitioners shall be made by written application on the KASPER Report Request for Law Enforcement and Licensure Boards, Form DCB-20L.

(b) If the request made by a law enforcement or prosecutorial official authorized to receive data under KRS 218A.202 is for KASPER data on dispensing of controlled substances by a narcotic treatment program to treat substance use disorder, a report shall not be disclosed to the official unless there is a valid court order requiring the release of the information and all other applicable provisions of 42 C.F.R. Subpart E are met.

(4) A medical examiner engaged in a death investigation pursuant to KRS 72.026 may query KASPER for a report on the decedent.

Section 5. Patient Identification Number.

(1) A patient or the person obtaining the controlled substance on behalf of the patient shall disclose to the dispenser the patient's Social Security number for purposes of the dispenser's mandatory reporting to KASPER.

(2) If a patient is an adult who does not have a Social Security number, the patient's driver's license number shall be disclosed.

(3) If a patient is an adult who has not been assigned a Social Security number or a driver's license number, the number 000-00-0000 shall be used in the Social Security field.

(4) If a patient is a child who does not have a Social Security number or a driver's license number, the number "000-00-0000" shall be used in the Social Security field.

(5) If a patient is an animal, the number "000-00-0000" shall be used in the Social Security number field.

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

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

Section 8. Error Resolution.

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

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

(b) Request that the dispenser correct the information.

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

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

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

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

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

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

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

Section 10. Disclosure of Data or Report.

(1) The cabinet shall only disclose data to:

(a) The persons and entities authorized to receive that data under KRS 218A.202(7); and[.]

(b) The persons and entities authorized to receive data pursuant to 42 C.F.R. Part 2, Subparts C, D, and E if the data to be disclosed includes information on controlled substances dispensed by a narcotic treatment program for use to treat substance use disorder.

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

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

1. Proper use of the KASPER system;

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

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

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

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

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

(3)

(a) An individual authorized to receive data under KRS 218A.202(7) shall not provide the data to any other entity except:

1. As provided in KRS 218A.202(9); and

2. For substance use disorder treatment data, as provided in 42 C.F.R. 2.32; or

(b) As provided in paragraph (c)[(b)] of this subsection.

(c) [(b)] In addition to the purposes authorized under KRS 218A.202(9)(e), and pursuant to KRS 218A.205(2)(a) and (6), a practitioner or pharmacist who obtains KASPER data or a report under KRS 218A.202(7)(e)1. or who in good faith believes that any person, including a patient, has violated the law in attempting to obtain a prescription for a controlled substance, may report suspected improper or illegal use of a controlled substance to law enforcement or the appropriate licensing board.

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

Section 11. Incorporation by Reference.

[(1)] [The following material is incorporated by reference:]

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

(1) [(b)] "KASPER Report Request for Law Enforcement and Licensure Boards", Form DCB-20L, October 2022[2017], is hereby incorporated by reference.

(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. This material may also be viewed on the Office of Inspector General's Web site at: https://chfs.ky.gov/agencies/os/oig/dai/deppb/Pages/kasper.aspx.

ADAM MATHER, Inspector General
ERIC C. FRIEDLANDER, Secretary

APPROVED BY AGENCY: November 1, 2022
FILED WITH LRC: November 9, 2022 at 2:10 p.m.
PUBLIC HEARING AND COMMENT PERIOD: A public hearing on this administrative regulation shall, if requested, be held on January 23, 2023, at 9:00 a.m. using the CHFS Office of Legislative and Regulatory Affairs Zoom meeting room. The Zoom

invitation will be emailed to each requestor the week prior to the scheduled hearing. Individuals interested in attending this hearing shall notify this agency in writing by January 16, 2023, five (5) workdays prior to the hearing, of their intent to attend. If no notification of intent to attend the hearing is received by that date, the hearing may be canceled. This hearing is open to the public. Any person who attends will be given an opportunity to comment on the proposed administrative regulation. A transcript of the public hearing will not be made unless a written request for a transcript is made. If you do not wish to be heard at the public hearing, you may submit written comments on this proposed administrative regulation until January 31, 2023. Send written notification of intent to attend the public hearing or written comments on the proposed administrative regulation to the contact person. In the event of an emergency, the public hearing will be held using the CHFS Office of Legislative and Regulatory Affairs Zoom meeting room. The Zoom invitation will be emailed to each requestor in advance of the scheduled hearing. Pursuant to KRS 13A.280(8), copies of the statement of consideration and, if applicable, the amended after comments version of the administrative regulation shall be made available upon request.

CONTACT PERSON: Krista Quarles, Policy Specialist, Office of Legislative and Regulatory Affairs, 275 East Main Street 5 W-A, Frankfort, Kentucky 40621; phone 502-564-6746; fax 502-564-7091; email CHFSregs@ky.gov.

REGULATORY IMPACT ANALYSIS AND TIERING STATEMENT

Contact Person:Krista Quarles

(1) Provide a brief summary of:

(a) What this administrative regulation does:
This administrative regulation establishes criteria for reporting prescription data, establishes procedures to correct errors, and allows for disclosure of data to authorized persons.

(b) The necessity of this administrative regulation:
This administrative regulation is necessary to comply with KRS 218A.202 and 42 C.F.R Part 2.

(c) How this administrative regulation conforms to the content of the authorizing statutes:
This administrative regulation conforms to the content of KRS 218A.202 by establishing criteria for reporting prescription data and establishing related procedures and protections of the data.

(d) How this administrative regulation currently assists or will assist in the effective administration of the statutes:
This administrative regulation assists in the effective administration of the statutes by establishing the Kentucky All-Schedule Prescription Electronic Reporting System (KASPER) and related procedures and data protections.

(2) If this is an amendment to an existing administrative regulation, provide a brief summary of:

(a) How the amendment will change this existing administrative regulation:
This amendment makes needed changes to reflect amendments to the federal law, 42 C.F.R. Part 2, that now allows the reporting of controlled substances dispensed for use to treat substance use disorder (SUD) to state prescription drug monitoring programs. Such reporting was prohibited by federal regulations until July 2020.

(b) The necessity of the amendment to this administrative regulation:
This amendment is necessary to reflect changes in the federal law and the expansion of KASPER to allow reporting of controlled substances used to treat SUDs.

(c) How the amendment conforms to the content of the authorizing statutes:
KRS 218A.202 requires the cabinet to establish and maintain an electronic prescription drug monitoring program to monitor dispensing of all controlled substances.

(d) How the amendment will assist in the effective administration of the statutes:
This amendment will make needed changes to require the reporting of all controlled substances to KASPER, including those dispensed for use in SUD treatment. Including in KASPER all controlled substances a patient is taking will allow providers to give individuals with SUD more comprehensive, safe, and effective treatment, and it will reduce the possibility of diversion, misuse, and abuse of controlled substances.

(3) List the type and number of individuals, businesses, organizations, or state and local governments affected by this administrative regulation:
This administrative regulation affects licensed narcotic treatment programs (NTPs) and the central registry used by narcotic treatment programs to report data. There are thirty-

two (32) full-service NTPs and three (3) medication stations in Kentucky and one (1) central registry.

(4) Provide an analysis of how the entities identified in question (3) will be impacted by either the implementation of this administrative regulation, if new, or by the change, if it is an amendment, including:

(a) List the actions that each of the regulated entities identified in question (3) will have to take to comply with this administrative regulation or amendment:

In accordance with existing Kentucky law and a change in federal regulations, narcotic treatment programs will be required to report certain data regarding dispensed controlled substances to KASPER. They will be required to comply with the same reporting requirements that are already in place for other dispensers of controlled substances.

(b) In complying with this administrative regulation or amendment, how much will it cost each of the entities identified in question (3):

NTPs will have to obtain an electronic device and any software necessary to allow them to transmit the required data.

(c) As a result of compliance, what benefits will accrue to the entities identified in question (3):

NTPs will be able to access and share information regarding their patients' access to controlled substances, giving NTPs and all prescribers a more comprehensive picture of patients' treatment and promoting safer, more effective treatment.

(5) Provide an estimate of how much it will cost the administrative body to implement this administrative regulation:

(a) Initially:

The Office of Inspector General (OIG) is using existing staff to manage the project and consult with developers regarding changes that will be needed for KASPER as well as providing outreach and training to providers. OIG will have to pay developers an estimated $180,000 to make the necessary system changes.

(b) On a continuing basis:

The continuing costs will be minimal as the additional data will be included in the ongoing KASPER work.

(6) What is the source of the funding to be used for the implementation and enforcement of this administrative regulation:

State general funds and agency monies will be used to implement and enforce this administrative regulation.

(7) Provide an assessment of whether an increase in fees or funding will be necessary to implement this administrative regulation, if new, or by the change if it is an amendment:

No fee is charge to providers for KASPER use and this amendment does not implement a fee.

(8) State whether or not this administrative regulation establishes any fees or directly or indirectly increases any fees:

This amendment does not establish or increase any fees.

(9) TIERING: Is tiering applied?

Tiering is not applicable as compliance with this administrative regulation applies equally to all entities regulated by it.

FISCAL NOTE

(1) What units, parts, or divisions of state or local government (including cities, counties, fire departments, or school districts) will be impacted by this administrative regulation?

This administrative regulation impacts all dispensers of controlled substances and the Cabinet for Health and Family Services, Office of Inspector General.

(2) Identify each state or federal statute or federal regulation that requires or authorizes the action taken by the administrative regulation.

KRS 218A.202, 218A.250, and 42 C.F.R. Part 2.

(3) Estimate the effect of this administrative regulation on the expenditures and revenues of a state or local government agency (including cities, counties, fire departments, or school districts) for the first full year the administrative regulation is to be in effect.

(a) How much revenue will this administrative regulation generate for the state or local government (including cities, counties, fire departments, or school districts) for the first year?

This administrative regulation will not generate revenue for state or local government.

(b) How much revenue will this administrative regulation generate for the state or local government (including cities, counties, fire departments, or school districts) for subsequent years?

This administrative regulation will not generate revenue for state or local government.

(c) How much will it cost to administer this program for the first year?

(d) How much will it cost to administer this program for subsequent years?

There will be little if any increase in continuing costs.

Note: If specific dollar estimates cannot be determined, provide a brief narrative to explain the fiscal impact of the administrative regulation.

Revenues (+/-):

Expenditures (+/-):

Other Explanation:

(4) Estimate the effect of this administrative regulation on the expenditures and cost savings of regulated entities for the first full year the administrative regulation is to be in effect.

(a) How much cost savings will this administrative regulation generate for the regulated entities for the first year?

This administrative regulation will not generate cost savings for regulated entities during the first year.

(b) How much cost savings will this administrative regulation generate for the regulated entities for subsequent years?

This administrative regulation will not generate cost savings for regulated entities during subsequent years.

(c) How much will it cost the regulated entities for the first year?

It is expected that most NTPs already have the electronic devices and software capability necessary to transmit the required data, so any costs to regulated entities are expected to be minor.

(d) How much will it cost the regulated entities for subsequent years?

It is expected that most NTPs already have the electronic devices and software capability necessary to transmit the required data, so any costs to regulated entities are expected to be minor.

Note: If specific dollar estimates cannot be determined, provide a brief narrative to explain the fiscal impact of the administrative regulation.

Cost Savings (+/-):

Expenditures (+/-):

Other Explanation:

(5) Explain whether this administrative regulation will have a major economic impact, as defined below.

"Major economic impact" means an overall negative or adverse economic impact from an administrative regulation of five hundred thousand dollars ($500,000) or more on state or local government or regulated entities, in aggregate, as determined by the promulgating administrative bodies. [KRS 13A.010(13)]. It is expected that most NTPs already have the electronic devices and software capability necessary to transmit the required data, so any costs to regulated entities are expected to be minor. The cabinet does not believe this amendment will have a major economic impact on the regulated entities.

FEDERAL MANDATE ANALYSIS COMPARISON

(1) Federal statute or regulation constituting the federal mandate.
42 C.F.R Part 2

(2) State compliance standards.
KRS 218A.202

(3) Minimum or uniform standards contained in the federal mandate.
42 C.F.R. Part 2

(4) Will this administrative regulation impose stricter requirements, or additional or different responsibilities or requirements, than those required by the federal mandate?
This administrative regulation does impose stricter requirements than federal laws or regulations. There is no federal requirement to report the dispensing of any controlled substances to prescription drug monitoring programs. The reporting requirement is in state law, KRS 218A.202.

(5) Justification for the imposition of the stricter standard, or additional or different responsibilities or requirements.
It is required by state law.