

KENTUCKY

CONTROLLED SUBSTANCES

ASSOCIATED ADMINISTRATIVE REGULATIONS



CABINET FOR HEALTH AND FAMILY SERVICES
OFFICE OF THE INSPECTOR GENERAL
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902 KAR 55 Controlled Substances

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KENTUCKY ADMINISTRATIVE REGULATIONS
TITLE 902
CHAPTER 55
CONTROLLED SUBSTANCES

902 KAR 55:015. Schedules of controlled substances.

RELATES TO: KRS 217.005 -217.215, 218A.010, 218A.020, 218A.040, 218A.060, 218A.080, 218A.100, 218A.120, 218A.200, 21 C.F.R. 1308.11, 1308.12, 1308.13, 1308.14, 1308.15, 1308.35, 1308.49, 21 U.S.C. 301 – 399f, 801-971

STATUTORY AUTHORITY: KRS 218A.020(1), (3)

NECESSITY, FUNCTION, AND CONFORMITY: KRS 218A.020(1) authorizes the Cabinet for Health and Family Services to promulgate administrative regulations in order to add, delete, or reschedule substances enumerated in KRS Chapter 218A. KRS 218A.020(3) authorizes the Cabinet for Health and Family Services to promulgate administrative regulations to control substances at the state level in the same numerical schedule corresponding to the federal schedule or control a substance in a more restrictive schedule than the federal schedule. This administrative regulation designates Schedule I, II, III, IV, and V drugs. This administrative regulation differs from the federal regulation, 21 C.F.R. 1308.14, because it designates pentazocine, barbital, methylphenobarbital, and phenobarbital as a Schedule III controlled substance. The federal regulation designates these substances as a Schedule IV controlled substance. The Cabinet for Health and Family Services recognizes that pentazocine and derivatives of barbituric acid or its salts have significant abuse potential, and inclusion on Kentucky's Schedule III list will help reduce the risk to public health. This administrative regulation further differs from the federal regulation, 21 C.F.R. 1308.14-1308.15, because it designates nalbuphine as a Schedule IV controlled substance and gabapentin as a Schedule V controlled substance. The Cabinet for Health and Family Services recognizes that nalbuphine and gabapentin have significant abuse potential, and inclusion on Kentucky's controlled substances schedules will help reduce the risk to public health.

Section 1. Schedule I Controlled Substances.

(1) Each substance that is scheduled or designated as a Schedule I controlled substance under 21 C.F.R. 1308.11, including a substance temporarily scheduled or designated under 21 C.F.R. 1308.11(h) or 1308.49, shall be scheduled or designated at the state level as a Schedule I controlled substance.

(2) The following shall be exempt from control as a Schedule I substance:

- (a) Cannabis plant material, and products made therefrom, that contain tetrahydrocannabinols pursuant to the exemption established in 21 C.F.R. 1308.35; and
- (b) Any substance or product exempt from the definition of marijuana pursuant to KRS 218A.010(27)(a) – (f).

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Section 2. Schedule II Controlled Substances.

Each substance that is scheduled or designated as a Schedule II controlled substance under 21 C.F.R. 1308.12 shall be scheduled or designated at the state level as a Schedule II controlled substance.

Section 3. Schedule III Controlled Substances

(1) Except as provided by subsection (2) of this section, each substance that is scheduled or designated as a Schedule III controlled substance under 21 C.F.R. 1308.13 shall be scheduled or designated at the state level as a Schedule III controlled substance.

(2) The Cabinet for Health and Family Services designates the following as Schedule III controlled substances:

- (a) Pentazocine;
- (b) Barbitol;
- (c) Methylphenobarbital; and
- (d) Phenobarbital.

(3) This section shall not apply to any material, compound, mixture, or preparation containing any quantity of an anabolic steroid substance, or any isomer, ester, salt, or derivative thereof that is:

- (a) Expressly intended for administration through implant to livestock or other nonhuman species; and
- (b) Approved by the United States Food and Drug Administration for use as described in this subsection.

Section 4. Schedule IV Controlled Substances.

(1) Except as provided by subsection (2) of this section and Section 3(2) of this administrative regulation, each substance that is scheduled or designated as a Schedule IV controlled substance under 21 C.F.R. 1308.14 shall be scheduled or designated at the state level as a Schedule IV controlled substance.

(2) The Cabinet for Health and Family Services designates the following as a Schedule IV controlled substance: nalbuphine.

Section 5. Schedule V Controlled Substances

(1) Except as provided by subsection (2) of this section, each substance that is scheduled or designated as a Schedule V controlled substance under 21 C.F.R. 1308.15 shall be scheduled or designated at the state level as a Schedule V controlled substance.

(2) The Cabinet for Health and Family Services designates the following as a Schedule V controlled substance: gabapentin.

Section 6 Dispensing Without Prescription.

A controlled substance listed in Schedule V, which is not a prescription drug under the Federal Food, Drug, and Cosmetic Act, 21 U.S.C. 301 to 399f, may be dispensed by a pharmacist without a prescription to a purchaser at retail, if:

(1) The medicinal preparation contains, in addition to the controlled substances, some drug or drugs conferring upon it medicinal qualities other than those possessed by the controlled substances alone;

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- (2) Not more than 240cc (eight (8) ounces) or more than forty-eight (48) dosage units of any controlled substance containing opium is dispensed at retail to the same purchaser in any given forty-eight (48) hour period;
- (3) The labeling and packaging is in accordance with the current requirements of KRS 217.005 to 217.215, 21 U.S.C. 301 to 399f, and the United States Pharmacopeia;
- (4) The preparation is dispensed or sold in good faith as a medicine and not for the purpose of evading the provisions of KRS Chapter 218A;
- (5) The preparation is not displayed in areas open to the public;
- (6) The dispensing is made only by a pharmacist and not by a nonpharmacist employee even if under the supervision of a pharmacist. After the pharmacist has fulfilled his or her professional and legal responsibilities as set forth in this section, the actual cash, credit transaction, or delivery may be completed by a nonpharmacist;
- (7) The purchaser is at least eighteen (18) years of age;
- (8) The pharmacist requires every purchaser of a controlled substance under this section not known to the pharmacist to furnish suitable identification, including proof of age if appropriate; and
- (9) The dispensing of exempt controlled substances under this administrative regulation is recorded in a bound book that shall be maintained in accordance with the recordkeeping requirements of KRS 218A.200 and contain the:
 - (a) Name and address of the purchaser;
 - (b) Name and quantity of controlled substance purchased;
 - (c) Date of each purchase; and
 - (d) Name or initials of the pharmacist who dispensed the substance to the purchaser.

(Recodified from 901 KAR 1:015, 4-14-1982; Am. 11 Ky.R. 1674; eff. 6-4-1985; 12 Ky.R. 266; eff. 9-10-1985; 1175; eff. 2-4-1986; 13 Ky.R. 1944; eff. 6-9-1987; 15 Ky.R. 863; eff. 11-4-1988; 20 Ky.R. 659; eff. 10-21-1993; 39 Ky.R. 1789; 2032; eff. 5-3-2013; 42 Ky.R. 1972; eff. 3-4-2016; 43 Ky.R. 1068, 1381; eff. 3-3-2017; 44 Ky.R. 143, 531; eff. 9-20-2017.)

902 KAR 55:040. Excluded nonnarcotic substances.

RELATES TO: KRS 218A.020-218A.120, 21 C.F.R. 1308.22, 21 U.S.C. 301-399f, 801-971

STATUTORY AUTHORITY: KRS 218A.020(4), 218A.250

NECESSITY, FUNCTION, AND CONFORMITY: KRS 218A.020(4) requires the Cabinet for Health and Family Services to exclude any nonnarcotic substance from a schedule if the substance may be lawfully sold over the counter without prescription under the provisions of the Federal Food, Drug and Cosmetic Act (21 U.S.C. 301-399f), the Federal Comprehensive Drug Abuse Prevention and Control Act of 1970 (21 U.S.C. 801-971), or KRS Chapter 218A. KRS 218A.250 requires the Cabinet for Health and Family Services to promulgate administrative regulations to carry out the provisions of KRS Chapter 218A. This administrative regulation excludes certain nonnarcotic substances from scheduling pursuant to KRS 218A.020(4).

Section 1. Excluded Substances.

The Cabinet for Health and Family Services shall exclude from all state schedules established in accordance with KRS 218A.020(1), (3) and 902 KAR 55:015 any nonnarcotic substance that may be lawfully sold over-the-counter without a prescription if the substance has been excluded from all federal schedules pursuant to 21 U.S.C. 811(g)(1) and as listed in 21 C.F.R. 1308.22.

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(Recodified from 901 KAR 1:040, 4-14-1982; Am. 11 Ky.R. 1679; eff. 6-4-1985; 18 Ky.R. 1471; eff. 2-7-1992; 19 Ky.R. 1665; 2251; eff. 3-17-1993; 20 Ky.R. 863; eff. 12-6-1993; 21 Ky.R. 1393; eff. 1-9-1995; 23 Ky.R. 3985; 24 Ky.R. 126; eff. 7-16-1997; 44 Ky.R. 147, 534; eff. 9-20-2017.)

902 KAR 55:045. Exempt prescription products.

RELATES TO: KRS 218A.020-218A.250, 21 C.F.R. 1308.31-1308.32

STATUTORY AUTHORITY: KRS 218A.020

NECESSITY, FUNCTION, AND CONFORMITY: KRS 218A.020(3) provides that if a controlled substance is designated, rescheduled, or deleted as a controlled substance under federal law and notice is given to the Cabinet for Health and Family Services, the Cabinet for Health and Family Services may similarly control the substance under KRS Chapter 218A by administrative regulation. This administrative regulation exempts prescription products from the licensing, distribution, recordkeeping, and reporting provisions of KRS Chapter 218A if the products have received approval as an exempt prescription product pursuant to 21 C.F.R. 1308.32.

Section 1. Exempt Prescription Products.

(1) Except as provided by subsection (2) of this section, the Cabinet for Health and Family Services exempts prescription products from the licensing, distribution, recordkeeping, and reporting provisions of KRS 218A.150 – 218A.172, 218A.180, 218A.200, and 218A.202 if the products have received approval as exempt prescription products pursuant to 21 C.F.R. 1308.32.

(2) All products containing butalbital shall:

- (a) Be reported to the Kentucky All-Schedule Prescription Electronic Reporting System in accordance with the requirements established in 902 KAR 55:110; and
- (b) Not be exempt from the licensing, distribution, and recordkeeping provisions of KRS 218A.150 – 218A.172, 218A.180, and 218A.200.

(Recodified from 901 KAR 1:041, 4-14-1982; Am. 11 Ky.R. 1680; eff. 6-4-1985; 18 Ky.R. 1472; eff. 2-7-1992; 19 Ky.R. 1666; 2251; eff. 3-17-1993; 20 Ky.R. 864; eff. 12-6-1993; 21 Ky.R. 1394; eff. 1-9-1995; 23 Ky.R. 4228; eff. 7-16-1997; 25 Ky.R. 629; 1631; eff. 1-19-1999; 26 Ky.R. 903; 1171; eff. 12-15-1999; 40 Ky.R. 2635; 41 Ky.R. 290; eff. 9-17-2014.)

902 KAR 55:060. Requirements for distribution of small amounts of controlled substances without manufacturer's or wholesaler's licenses.

RELATES TO: KRS 218A.010-218A.020, 218A.150-218A.200, 21 C.F.R. 1304.03, 1305.03, 1307.11

STATUTORY AUTHORITY: KRS 194.050, 218A.250

NECESSITY, FUNCTION, AND CONFORMITY: KRS 218A.250 directs the Cabinet for Human Resources to adopt rules and administrative regulations for carrying out the provisions of KRS Chapter 218A relating to controlled substances. KRS 218A.170(2) provides that all sales and distributions of controlled substances shall be in accordance with the federal controlled substances laws, including the requirements governing the use of order forms. The purpose of this administrative regulation is to provide for the distribution of small amounts of controlled substances by pharmacies to practitioners or other pharmacies, without the necessity of obtaining a state license as a manufacturer or a wholesaler, in accordance with applicable federal laws and regulations.

Section 1. Distribution of Controlled Substances by Pharmacy to Practitioner or other Pharmacy.

(1) A pharmacy may distribute a quantity of a controlled substance to a practitioner or another pharmacy, without being licensed as a manufacturer or wholesaler in Kentucky if it:

- (a) Is licensed in Kentucky;
- (b) Is registered with the U.S. Drug Enforcement Administration; and
- (c) Makes the distribution to a practitioner or pharmacy that is registered with the U.S. Drug Enforcement Administration.

(2) The distribution shall be recorded by the distributing pharmacy and by the receiving practitioner or pharmacy in accordance with KRS 218A.200;

(3) A readily retrievable record of the distribution shall be maintained showing:

- (a) Date of distribution;
- (b) Name, form and quantity of the substance distributed; and
- (c) Name, address and registration number of the purchaser.

(4) The total number of dosage units of all controlled substances distributed by a pharmacy pursuant to this administrative regulation during a twelve (12) month period shall not exceed five (5) percent of the total number of dosage units of all controlled substances distributed and dispensed by the pharmacy during the twelve (12) month period. If the five (5) percent limitation is expected to be exceeded, the pharmacy shall obtain a license to distribute controlled substances in accordance with KRS 218A.160 and 218A.170; and

(5) A prescription shall not be issued by a practitioner to obtain any controlled substance for the purpose of general dispensing, administering or office use.

(7 Ky.R. 888; eff. 6-3-1981; Recodified from 901 KAR 1:070, 4-14-1982; 11 Ky.R. 1681; eff. 6-4-1985; 18 Ky.R. 1244; 1890; eff. 11-25-1991; 20 Ky.R. 1425; eff. 1-10-1994; Crt eff. 1-11-2019.)

902 KAR 55:065. Return of prescription drugs prohibited, exceptions.

RELATES TO: KRS 217.005-217.215, 217.992

STATUTORY AUTHORITY: KRS 194.050, 211.090, 217.125

NECESSITY, FUNCTION, AND CONFORMITY: KRS 217.125 authorizes the Cabinet for Human Resources to administer the provisions of KRS 217.005 to 217.215 and 217.992. The purpose of this administrative regulation is to prevent the dispensing of prescription drugs that may be adulterated or misbranded.

Section 1. Return of Prescription Drugs Prohibited; Exceptions. (1) No pharmacist, practitioner, or agent thereof shall accept the return of a prescription drug for reuse or resale unless:

- (a) The drug is in a sealed container by which it can be readily determined by a pharmacist employed by the dispensing pharmacy or by the dispensing practitioner that entry or attempted entry by any means has not been made;
- (b) The drug container meets the standards of the United States Pharmacopoeia for storage conditions including temperature, light sensitivity, moisture, chemical, and physical stability;
- (c) The drug labeling and packaging has not been altered or defaced and the identity of the drug, its potency, lot number, and expiration date are legible;
- (d) The drug does not require refrigeration; and

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(e) The drug is returned to a pharmacist employed by the dispensing pharmacy or to the dispensing practitioner within fourteen (14) days.

(2) Subsection (1) (d) and (e) of this section shall be waived if all other conditions are met and if:

(a) The drug was dispensed for a patient in a health care facility licensed by the Cabinet for Human Resources;

(b) The drug has not come into the physical possession of the person for whom it was pre-scribed;

(c) The drug has been under the continuous control of personnel in the health care facility who are trained and knowledgeable in the storage and administration of drugs;

(d) The drug has been properly stored in an area which is regularly inspected by a pharmacist; and

(e) The drug is not expired.

(3) Drugs distributed within an acute care facility shall be exempt from the provisions of sub-section

(1) (a), (d) and (e) of this section.

(4) Nothing in this administrative regulation shall be construed to require a pharmacist or practitioner to accept the return of a prescription drug.

(15 Ky.R. 1618; 1853; eff. 3-15-1989; 20 Ky.R. 2226; eff. 3-14-1994; Crt eff. 1-11-2019.)

902 KAR 55:070 Emergency medication kit in certain long-term care facilities.

RELATES TO: KRS 13B.050, 13B.080, 13B.090, 13B.110, 13B.120, 218A.010 (39), 218A.200 (6), 315.335

STATUTORY AUTHORITY: KRS 194A.050 (1), 218A.250

NECESSITY, FUNCTION, AND CONFORMITY: KRS 194A.050(1) requires the Secretary of the Cabinet for Health and Family Service to promulgate administrative regulations necessary to implement programs mandated by federal law, or to qualify for the receipt of federal funds and cooperate with other state and federal agencies for the proper administration of the cabinet and its programs. KRS 218A.250 requires the Cabinet for Health and Family Services to promulgate administrative regulations for carrying out the provisions of KRS Chapter 218A. This administrative regulation establishes requirements related to the placement of emergency medication kits with controlled substances in long-term care facilities.

Section 1. Definitions.

(1) "Emergency medication kit" or "EMK" is defined by 201KAR 2:370, Section 1(3).

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

Section 2. Storage of Controlled Substances in an EMK.

(1) A pharmacy provider may place one (1) EMK that contains controlled substances in:

(a) A residential hospice facility licensed in accordance with 902 KAR 20:380;

(b) A nursing home licensed in accordance with 902 KAR 20:048;

(c) A nursing facility licensed in accordance with 902 KAR 20:300;

(d) An intermediate care facility licensed in accordance with 902 KAR 20:051;

(e) A personal care home pursuant to 201 KAR 2:370, Section 2(4)(i); or

(f) An intermediate care facility for individuals with intellectual disabilities licensed in accordance with 902 KAR 20:086.

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- (2) A long-term care facility with an EMK shall:
 - (a) Implement and maintain on-site a copy of written policies and procedures developed in consultation with the pharmacy provider, including responsibilities specific to the facility and the pharmacy as it relates to procuring, using, storing, securing, and replacing controlled substances in the kit;
 - (b) Maintain a complete and accurate record of all controlled substances to be kept in the EMK, including the disposition of the controlled substances; and
 - (c) Ensure that the EMK is stored in a limited access area such as a securely locked:
 1. Substantially constructed cabinet; or
 2. Room with restricted access.
- (3) Controlled substances in the EMK shall be the property of the pharmacy provider.
- (4) The pharmacy provider shall:
 - (a) Implement and maintain a copy of the written policies and procedures required by subsection (2)(a) of this section;
 - (b) Maintain a complete and accurate record of all controlled substances to be kept in the EMK, including the disposition of the controlled substances;
 - (c) Be responsible for the labeling, storage, security, and accountability of all controlled substances in the EMK;
 - (d) Document completion of a physical inventory of the controlled substances no less than one (1) time per month; and
 - (e) Report theft or loss of controlled substances from the EMK pursuant to:
 1. KRS 218A.200 (6);
 2. KRS 315.335; and
 3. 201 KAR 2:205, Section 2(3) (g).
- (5) Controlled substances stored in the EMK shall be selected by the facility's:
 - (a) Medical director or other physician;
 - (b) Consultant pharmacist; and
 - (c) Director of nursing.
- (6) Controlled substances in the EMK shall not exceed six (6) individual doses each of ten (10) different controlled substances, plus two (2) multi-dose packages in the smallest unit that is commercially available.
- (7) A controlled substance from the EMK shall be administered only upon the prescription order of an authorized practitioner who determines that the resident has an immediate medical need.
- (8) Access to a controlled substance in the EMK shall be limited to a:
 - (a) Practitioner;
 - (b) Registered nurse; or
 - (c) Other person authorized by law in this state to access and administer the prescribed medication.
- (9) If an EMK is opened for any reason, the facility shall notify the pharmacy provider within twenty-four (24) hours after the kit has been opened for the pharmacy to restock and reseal the kit promptly, if necessary.

Section 3. Adverse Action.

- (1) The Cabinet for Health and Family Services shall deny, suspend, or revoke the privilege of supplying or possessing an EMK if the cabinet finds substantial noncompliance with Section 2 of this administrative regulation.

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- (2) The pharmacy provider or facility may file an appeal with the cabinet within (10) calendar days of the cabinet’s notice of denial, suspension, or revocation.
- (3) If the pharmacy provider or facility requests an administrative hearing, the cabinet shall:
 - (a) Appoint a hearing officer; and
 - (b) Proceed pursuant to KRS 13B.050.
- (4) The administrative hearing shall be conducted by a hearing officer appointed by the secretary and held in accordance with KRS 13B.080, 13B.090, and 13B.110.
- (5) The secretary shall issue a final order in accordance with KRS 13B.120. (15 Ky.R. 1352; eff. 12-13-1988; 20 Ky.R. 2227; eff. 3-14-1994; 22 Ky.R. 2481; eff. 8-1-1996; 33 Ky.R. 2218; 2973; eff. 4-6-2007; Crt eff. 05-07-2019; 46 Ky.R. 270; eff. 11-18-2019.)

902 KAR 55:080. Written prescriptions to be signed by practitioner.

RELATES TO: KRS Chapter 218A

STATUTORY AUTHORITY: KRS 194.050, 218A.250

NECESSITY, FUNCTION, AND CONFORMITY: KRS 218A.250 directs the Cabinet for Human Resources to adopt rules and administrative regulations for carrying out the provisions of KRS Chapter 218A relating to controlled substances. The purpose of this administrative regulation is to clarify who is authorized to sign a prescription for controlled substances and the form of the signature, which must be in accordance with federal regulation.

Section 1. A written prescription for a controlled substance shall be signed only by a practitioner who is authorized to prescribe controlled substances under the laws of the jurisdiction in which he is licensed to practice his profession.

Section 2. A written prescription for a controlled substance shall be written with ink, indelible pencil or typewriter and may be prepared by an agent for the practitioner's signature. The prescription shall be manually signed by the practitioner which may be in the same manner as he would sign a check or legal document. (17 Ky.R. 3607; eff. 7-17-91.; Crt eff. 1-11-2019.)

902 KAR 55:090. Exempt anabolic steroid products.

RELATES TO: KRS 218A.010-218A.250, 21 C.F.R. 1308.13, 1308.33-1308.34, 21 U.S.C. 801, 812

STATUTORY AUTHORITY: KRS 218A.020

NECESSITY, FUNCTION, AND CONFORMITY: KRS 218A.020 authorizes the Cabinet for Health and Family Services to add, delete, or reschedule substances enumerated in KRS Chapter 218A. This administrative regulation exempts certain anabolic steroid products from the licensing, distribution, recordkeeping, and reporting provisions of KRS Chapter 218A if the products have received approval as an exempt anabolic steroid product pursuant to 21 C.F.R. 1308.34.

Section 1. Exempt Anabolic Steroid Products.

The Cabinet for Health and Family Services exempts anabolic steroid products from the licensing, distribution, recordkeeping, and reporting provisions of KRS 218A.150 – 218A.172, 218A.180, 218A.200, and 218A.202 if the products have received approval as exempt anabolic steroid products pursuant to 21 C.F.R. 1308.34.

(19 Ky.R. 2207; eff. 4-21-1993; Am. 21 Ky.R. 1395; eff. 1-9-1995; 23 Ky.R. 3986; eff. 7-16-1997; 26 Ky.R. 907; 1174; eff. 12-15-1999; 29 Ky.R. 820; 1278; eff. 10-16-2002; 40 Ky.R. 2639; eff. 9-17-2014.)

902 KAR 55:095. Prescription for Schedule II controlled substance - facsimile transmission or partial filling.

RELATES TO: KRS 216.510(1), 216B.042, 218A.060, 218A.180, 218A.200, 21 C.F.R. 290.10, 1306.05, 1306.11-1306.14

STATUTORY AUTHORITY: KRS 194A.050, 218A.180(1), 218A.250

NECESSITY, FUNCTION, AND CONFORMITY: KRS 218A.250 requires the Cabinet for Health and Family Services to promulgate administrative regulations for carrying out the provisions of KRS Chapter 218A relating to controlled substances. This administrative regulation permits the transmission of prescriptions for Schedule II controlled substances between the prescriber and dispenser via oral authorization for immediate administration or by facsimile to facilitate the delivery of medications to certain patients whose need for medication shall be initiated or changed quickly. This administrative regulation also permits the partial filling of prescriptions for Schedule II controlled substances if requested by the patient or prescribing practitioner to patients whose medication needs may be long term but who wish to store limited quantities or in situations where the pharmacy is unable to supply the full quantity prescribed.

Section 1. Definitions.

(1) "Hospice" means a hospice program licensed pursuant to KRS 216B.042.

(2) "Immediate administration" means an emergency situation in which the prescribing practitioner determines the following criteria exists for the purposes of authorizing an oral prescription for a Schedule II controlled substance:

- (a) Immediate administration of the controlled substance is necessary for proper treatment of the intended ultimate user;
- (b) No appropriate alternative treatment is available, including administration of a drug that is not a Schedule II controlled substance; and
- (c) It is not reasonably possible for the prescribing practitioner to provide a written prescription to be presented to the person dispensing the substance prior to the dispensing.

(3) "Long-term care facility" or "LTCF" is defined by KRS 216.535(1)(a) and, pursuant to KRS 218A.180(1), shall not include a family care home or personal care home.

Section 2. Oral Prescription Only for Immediate Administration.

(1) A pharmacist may dispense a Schedule II controlled substance upon receiving oral authorization from a prescribing practitioner under the following conditions:

- (a) Pursuant to KRS 218A.180(1), the prescription shall be needed for immediate administration to a patient enrolled in a hospice program or a resident of a long-term care facility;

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- (b) The quantity prescribed and dispensed shall be limited to the amount adequate to treat the patient or resident during the period in which immediate administration is necessary; and
 - (c) The prescribing practitioner personally communicates the oral prescription.
- (2) Except for the signature of the prescribing practitioner, the prescription shall:
- (a) Be immediately reduced to writing by the pharmacist in accordance with KRS 218A.180(6); and
 - (b) Contain all information required by KRS 218A.180(5) and 21 C.F.R. 1306.05.
- (3) If the prescribing practitioner is not known to the pharmacist, the pharmacist shall make a reasonable effort to determine that the oral authorization came from a registered practitioner, which may include:
- (a) A callback to the prescribing practitioner using the practitioner's phone number as listed in the telephone directory; or
 - (b) Other good faith efforts to ensure the practitioner's identity.
- (4) Within seven (7) days after authorizing an oral prescription for immediate administration, the prescribing practitioner shall cause a written prescription for the emergency quantity prescribed to be delivered to the dispensing pharmacist and demonstrate compliance with the requirements established in this subsection.
- (a) In addition to conforming to the requirements of KRS 218A.180(5) and 21 C.F.R. 1306.05, the prescription shall:
 - 1. Have written on its face "Authorization for Emergency Dispensing" and the date of the oral order; and
 - 2. Be delivered to the pharmacist:
 - a. In person;
 - b. By mail; or
 - c. Electronically pursuant to paragraph (d) of this subsection.
 - (b) If delivered by mail, the prescription shall be postmarked within seven (7) days of the date of the oral prescription for immediate administration.
 - (c) Upon receipt, the dispensing pharmacist shall attach the paper prescription to the oral prescription for immediate administration that was earlier reduced to writing.
 - (d) For electronic prescriptions, the pharmacist shall annotate the record of the prescription with the:
 - 1. Original authorization; and
 - 2. Date of the oral order.
 - (e) If the prescribing practitioner fails to deliver a written prescription to the pharmacist in accordance with this subsection, the pharmacist shall notify the nearest Drug Enforcement Administration (DEA) office.
 - (f) Failure of the pharmacist to comply with paragraph (e) of this subsection shall void the authority conferred by this subsection to dispense without a written prescription of a prescribing practitioner.
- (5) A central fill pharmacy shall not be authorized under subsection (4) of this section to prepare prescriptions for a Schedule II controlled substance upon receiving an oral authorization from a retail pharmacist or a prescribing practitioner.
- (6) Dispensing a Schedule II controlled substance beyond the period necessary for immediate administration shall be pursuant to a written prescription signed by the prescribing practitioner.

Section 3. Transmission by Facsimile of a Prescription for a Schedule II Controlled Substance.

(1) A prescription prepared in accordance with KRS 218A.180, 21 C.F.R. 1306.05, 902 KAR 55:080, and 902 KAR 55:105, Section 2, for a Schedule II narcotic substance to be compounded for the direct administration to a patient by parenteral, intravenous, intramuscular, subcutaneous, or intraspinal infusion may be transmitted by a practitioner or the practitioner's agent to the dispensing pharmacy by facsimile.

(2) A prescription prepared in accordance with KRS 218A.180, 21 C.F.R. 1306.05, 902 KAR 55:080, and 902 KAR 55:105, Section 2, for a Schedule II controlled substance for a resident of a long-term care facility may be transmitted by a practitioner or the practitioner's agent to the dispensing pharmacy by facsimile.

(3) (a) A prescription prepared in accordance with KRS 218A.180, 21 C.F.R. 1306.05, 902 KAR 55:080, and 902 KAR 55:105, Section 2, for a Schedule II controlled substance for a hospice patient may be transmitted by a practitioner or the practitioner's agent to the dispensing pharmacy by facsimile.

(b) The practitioner or the practitioner's agent shall note on the prescription that the patient is a hospice patient.

(4) The facsimile prescription shall:

(a) Serve as the original written prescription for the purposes of subsections (1) to (3) of this section and as allowed by KRS 218A.180(1) for the dispensing of a Schedule II controlled substance; and

(b) Be maintained in the same manner as an original prescription.

Section 4. Partial Filling of a Prescription for a Schedule II Controlled Substance.

(1) Except as provided in subsections (2) and (3) of this section, a pharmacist may partially fill a prescription for a controlled substance listed in Schedule II if the pharmacist:

(a) Is unable to dispense the full quantity called for in a written prescription or oral prescription for immediate administration as authorized by Section 2 of this administrative regulation;

(b) Makes a notation of the quantity dispensed:

1. On the face of the written prescription;

2. In the written record of the oral prescription for immediate administration; or

3. In the electronic prescription record; and

(c) Dispenses the remaining portion of the prescription within seventy-two (72) hours of the first partial filling. If the remaining portion is not or cannot be filled within the seventy-two (72) hour period, the pharmacist shall notify the prescribing practitioner. No further quantity shall be dispensed without a new written prescription.

(2) A prescription for a Schedule II controlled substance written for a patient in a long-term care facility or for a patient with a documented terminal illness may be dispensed in partial quantities, including individual dosage units, if:

(a) The pharmacist records on the prescription whether the patient is "terminally ill" or an "LTCF patient";

(b) The pharmacist records on the back of the written prescription or on another appropriate record, uniformly maintained and readily retrievable, the following data:

1. The date of the partial dispensing;

2. The quantity dispensed;

3. The remaining quantity authorized to be dispensed; and

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4. The identification of the dispensing pharmacist;
 - (c) The pharmacist contacts the practitioner prior to dispensing the partial quantity if there is any question whether the patient is terminally ill because both the pharmacist and the prescribing practitioner have a corresponding responsibility to assure that the controlled substance is for a terminally ill patient;
 - (d) The total quantity dispensed in all partial dispensings does not exceed the quantity prescribed;
 - (e) The partial dispensing occurs at the pharmacy where the original prescription is on file; and
 - (f) No dispensing occurs beyond sixty (60) days from date of issuance of the prescription.
- (3) For a patient who is not terminally ill or a resident of a long-term care facility, a written prescription for a Schedule II controlled substance may be dispensed in partial quantities in accordance with the requirements established in this subsection.
- (a) The partial dispensing shall be requested by the patient or the prescribing practitioner who issued the prescription.
 - (b) Dispensing shall not occur beyond thirty (30) days from the date of issuance of the prescription.
 - (c) The pharmacist shall comply with requirements established in subsection (2)(b), (d), and (e) of this section.
- (4) The information required by this section pertaining to current Schedule II prescriptions may be maintained in a computerized system if the system has the capability to permit:
- (a) Output (display or printout) of the:
 1. Original prescription number;
 2. Date of issue;
 3. Identification of the prescribing practitioner;
 4. Identification of the patient;
 5. Address of the long-term care facility, hospital, or residence of the patient, if applicable;
 6. Identification of medication authorized, including:
 - a. Dosage;
 - b. Form;
 - c. Strength; and
 - d. Quantity;
 7. Listing of the partial fillings that have been dispensed under each prescription; and
 8. Information required in 21 C.F.R. 1306.13(b);
 - (b) Immediate (real time) updating of the prescription record each time a partial filling of the prescription is conducted; and
 - (c) Retrieval of partially filled Schedule II prescription information that is the same as required by KRS 218A.180 (7) for Schedule III and IV prescription refill information.
- (5) If a record keeping system is being used that does not permit refills of Schedule II controlled substances, a new prescription number for the partial dispensing shall be permitted.
- (6) A prescription that is partially filled and does not comply with the requirements of this section shall be deemed to have been filled in violation of KRS 218A.200 (3), (4) and 21 C.F.R. 1306.13. (21 Ky.R. 2589; Am. 22 Ky.R. 291; eff. 7-26-1995; 24 Ky.R. 1165; eff. 1-12-1998; 44 Ky.R. 149, 534; eff. 9-20-2017.)

902 KAR 55:105. Controlled substance prescription blanks.

RELATES TO: KRS 218A.030-218A.140, 218A.204, 218A.170-218A.240, 218A.281, 218A.282, 218A.284, 218A.286, 218A.288

STATUTORY AUTHORITY: KRS 194A.030, 194A.050, 211.090, 218A.204, 218A.250

NECESSITY, FUNCTION, AND CONFORMITY: KRS 218A.204 requires the cabinet to promulgate administrative regulations that establish security requirements for a prescription blank used by a practitioner to write a prescription for a controlled substance. The purpose of this administrative regulation is to establish minimum requirements that will decrease the potential for forgery or alteration of a prescription or a prescription blank for a controlled substance.

Section 1. Definitions.

- (1) "Logo" means a symbol utilized by an individual, a pharmacy, professional practice, professional association, or hospital.
- (2) "Security prescription blank" means a prescription blank that complies with the requirements of Section 3 of this administrative regulation.

Section 2. Security Prescription Blanks Required.

- (1) Beginning January 1, 1999, a written prescription for a controlled substance shall be on a security prescription blank unless, pursuant to Section 7 of this administrative regulation, the cabinet has granted a waiver to the practitioner who wrote the prescription or to the pharmacy that dispenses it.
- (2) A practitioner who is licensed in Kentucky and in another state shall utilize a security prescription blank for writing a prescription for a controlled substance while practicing his profession within the Commonwealth unless, pursuant to Section 7 of this administrative regulation, the cabinet has granted a waiver to the practitioner or to the pharmacy that dispenses the controlled substance.

Section 3. Requirements of a Security Prescription Blank.

- (1) A prescription for a controlled substance shall contain the following security features:
 - (a) A latent, repetitive "void" pattern screened at five (5) percent in pantone green shall be printed across the entire front of the prescription blank. If a prescription is photocopied, the word "void" shall appear in a pattern across the entire front of the prescription;
 - (b) A watermark shall be printed on the backside of the prescription blank so that it shall only be seen at a forty-five (45) degree angle. The watermark shall consist of the words "Kentucky Security Prescription", and appear horizontally in a step-and-repeated format in five (5) lines on the back of the prescription using twelve (12) point Helvetica bold type style;
 - (c) An opaque **R** symbol shall appear in the upper right-hand corner, one-eighth (1/8) of an inch from the top of the prescription blank and five-sixteenths (5/16) of an inch from the right side of the prescription blank. The symbol shall be three-fourths (3/4) of an inch in size and disappear if the prescription copy is lightened;
 - (d) Six (6) quantity check off boxes shall be printed on the form and the following quantities shall appear:
 1. 1–24;
 2. 25–49;

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3. 50-74;
 4. 75-100;
 5. 101-150;
 6. 151 and over;
- (e) A logo may appear on the prescription blank. The upper left one (1) inch square of the prescription blank shall be reserved for a logo;
- (f) The following statement shall be printed on the bottom of the prescription blank: "Prescription is void if more than one (1) prescription is written per blank";
- (g) Refill options shall appear below any logo on the left side of the prescription blank in the following order: Refill NR 1 2 3 4 5; and
- (h) A prescription blank shall be four and one-quarter (41/4) inches high and five and one-half (51/2) inches wide.
- (2) A prescription shall bear the preprinted, stamped, typed, or manually printed name, address and telephone number of the prescribing practitioner.
- (3) A prescription blank for a controlled substance shall not contain:
- (a) An advertisement on the front or the back of the prescription blank;
 - (b) The preprinted name of a controlled substance; or
 - (c) The written, typed, or rubber-stamped name of a controlled substance until the prescription blank is signed, dated and issued to a patient.
- (4) A prescription blank for a controlled substance shall provide space for the patient's name and address, the practitioner's signature and the practitioner's DEA registration number.

Section 4. Other Requirements.

- (1) Only one (1) prescription shall be written per prescription blank.
- (2) A quantity check-off box that corresponds to the quantity prescribed shall be marked.
- (3) If a prescribed drug is a schedule III, IV or V controlled substance, a refill option shall be marked.
- (4) If a prescription for a schedule III, IV, or V controlled substance will be transmitted to a pharmacy by facsimile, the practitioner or the practitioner's agent shall, prior to transmission, write or stamp "FAXED" on the face of the original prescription along with the date and the person's initials.
- (5) If a pharmacist uses due diligence in ascertaining the validity of a prescription, a prescription for a schedule III, IV, or V controlled substance that is transmitted to a pharmacy by facsimile shall be exempt from the requirement of green ink in Section 3(1) (a) of this administrative regulation and the requirement of a watermark in Section 3(1)(b) of this administrative regulation.
- (6) If a prescription for a schedule III, IV or V controlled substance has been transmitted to a pharmacy by facsimile, the transmitting practitioner shall file the original prescription in the patient's record.

Section 5. Exceptions. A pharmacist shall not be required to use a security prescription blank to record an oral prescription or a transferred prescription for a Schedule III, IV, or V controlled substance.

Section 6. Printers, Reproducers or Distributors of Security Prescription Blanks.

- (1) A printer, reproducer or distributor of security prescription blanks shall require a written purchase order or request for security prescription blanks. A written purchase order or request shall remain on file for two (2) years.
- (2) A purchase order or request shall be signed by:
 - (a) A practitioner whose name shall be printed on the security prescription blanks; or
 - (b) The chief medical official of a health care facility or pharmacist-in-charge of a pharmacy, if the security prescription blanks are requested on behalf of a practitioner who stamps, types or manually prints his name, address, telephone number and DEA number on the security prescription blank.
- (3) The provisions of this section shall not apply to distributions between printers, reproducers, or distributors.

Section 7. Waiver of Security Prescription Blanks.

- (1) A practitioner or a pharmacy may apply in writing to the cabinet for a waiver from the requirement for security prescription blanks. A request for a waiver shall include:
 - (a) A detailed statement of the security features provided by the system proposed by the applicant for the prevention of forgery or alteration of an original prescription; or
 - (b) The format of the alternative prescription blank.
- (2) The system or prescription blank proposed by the applicant shall provide a level of security equivalent to a security prescription blank.
- (3) The cabinet shall grant or deny the application in writing within sixty (60) days after the request is received.
- (4) When a waiver has been granted, the cabinet may suspend or revoke the waiver if the alternative system or alternative prescription blank does not provide security equivalent to a security prescription blank.
- (5) Upon notification of denial, suspension, or revocation of the waiver of the requirement for a security prescription blank, the practitioner or pharmacy may request a hearing. The administrative hearing shall be conducted in accordance with 902 KAR 1:400.
(25 Ky.R. 721; Am. 1074; 1366; eff. 12-16-98; Crt eff. 1-11-2019)

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

RELATES TO: KRS 218A.010 (11) 218A.202, 218A.240

STATUTORY AUTHORITY: KRS 194A.050, 218A.202 (1), (17), 218A.250

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

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Section 1. Definitions.

- (1) "Branch" means the Drug Enforcement and Professional Practices Branch in the Division of Audits and Investigations, Office of Inspector General, Cabinet for Health and Family Services.
- (2) "Cabinet personnel" means an individual who:
 - (a) 1. Is directly employed by the Cabinet for Health and Family Services; or
2. Is employed by an agent or contractor of the cabinet;
 - (b) Has undergone KASPER training; and
 - (c) Has been approved to use the KASPER system.
- (3) "Dispenser" is defined by KRS 218A.010(11) and shall:
 - (a) Include a dispenser who has a DEA (Drug Enforcement Administration) number or is a pharmacist who owns or is employed by a facility that operates a pharmacy that has a DEA number; and
 - (b) Not include an individual licensed to practice veterinary medicine under KRS Chapter 321.
- (4) "Health facility" is defined by KRS 216B.015(13).
- (5) "KASPER" means Kentucky All-Schedule Prescription Electronic Reporting System.
- (6) "Patient identifier" means a patient's:
 - (a) Full name;
 - (b) Address, including zip code;
 - (c) Date of birth; and
 - (d) Social Security number or an alternative identification number established pursuant to Section 5 of this administrative regulation.
- (7) "Practitioner" is defined by KRS 218A.010(39).
- (8) "Report" means a compilation of data concerning a patient, dispenser, practitioner, or controlled substance.
- (9) "Suspected drug overdose" means an acute condition that:
 - (a) May include physical illness, coma, mania, or hysteria that is the result of consumption or use of a controlled substance, or another substance with which a controlled substance was combined; and
 - (b) Relates to injury, poisoning by, or other adverse effect of any substance corresponding to the following International Classification of Disease (ICD) version 10 (ICD-10) codes, or equivalent codes in the most recent version of the International Statistical Classification of Diseases and Related Health Problems:
 1. T40;
 2. T42; or
 3. T43.

Section 2. Data Reporting.

- (1) A dispenser or a health facility that has a DEA number shall report all dispensed Schedule II, III, IV, or V controlled substances, except during the circumstances specified in KRS 218A.202(3)(a) through (c).
- (2) A dispenser of a Schedule II, III, IV, or V controlled substance shall transmit or provide the following data to the cabinet or the cabinet's agent:
 - (a) Patient identifier;
 - (b) National drug code of the drug dispensed;

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- (c) Metric quantity of the drug dispensed;
 - (d) Date of dispensing;
 - (e) Estimated days the supply of dispensed medication will last;
 - (f) Drug Enforcement Administration registration number of the prescriber;
 - (g) Prescription number assigned by the dispenser; and
 - (h) The Drug Enforcement Administration registration number of the dispenser.
- (3) The data identified in subsection (2) of this section shall be transmitted no later than close of business on the business day immediately following the dispensing unless the cabinet grants an extension as provided in subsection (4) or (5) of this section.
- (4)(a) An extension may be granted if:
- 1. The dispenser suffers a mechanical or electronic failure; or
 - 2. The dispenser cannot meet the deadline established by subsection (3) of this section because of reasons beyond his or her control.
- (b) A dispenser shall apply to the branch in writing for an extension listed in paragraph (a) of this subsection within twenty-four (24) hours of discovery of the circumstances necessitating the request or on the next date state offices are open for business, following the discovery. An application for an extension shall state the justification for the extension and the period of time for which the extension is necessary.
- (5) An extension shall be granted to a dispenser if the cabinet or its agent is unable to receive electronic reports transmitted by the dispenser.
- (6) Except as provided in subsection (8) of this section, the data shall be transmitted by:
- (a) An electronic device compatible with the receiving device of the cabinet or the cabinet's agent;
 - (b) Secure File Transfer Protocol;
 - (c) Https protocol; or
 - (d) Secure Virtual Private Network connection.
- (7) The data shall be transmitted in the telecommunications format for controlled substances established by the Implementation Guide, ASAP Standard for Prescription Monitoring Programs developed by the American Society for Automation in Pharmacy, Version 4.2, or a comparable format approved by the branch.
- (8) A dispenser who does not have an automated recordkeeping system capable of producing an electronic report in the telecommunications format for controlled substances established by the Implementation Guide, ASAP Standard for Prescription Monitoring Programs shall report the data identified in subsection (2) of this section using an Internet accessible web portal designated by the cabinet.
- (9) To meet the reporting requirement of KRS 218A.202(4), a hospital shall report to the cabinet all positive toxicology screens ordered by the hospital's emergency department to evaluate a patient's suspected drug overdose via the Kentucky Health Information Exchange.

Section 3. Compliance.

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

Section 4. Request for Report.

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

Section 5. Patient Identification Number.

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

Section 6. KASPER Data and Trend Reports.

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

Section 7. Data Retention.

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

Section 8. Error Resolution.

- (1) A patient, patient's representative, practitioner, pharmacist, health facility, or private practitioner's office or clinic to whom a report has been disclosed under KRS 218A.202(9) or this administrative regulation may request that information contained in KASPER be corrected if the patient, patient's representative, practitioner, pharmacist, health facility, or private practitioner's office or clinic believes that any information is inaccurate. The patient, patient's representative, practitioner, pharmacist, health facility, or private practitioner's office or clinic shall:
 - (a) Contact the dispenser who reported the information required by Section 2(2) of this administrative regulation; and
 - (b) Request that the dispenser correct the information.

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

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

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

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

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

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

Section 9. Referrals to Licensing Boards.

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

Section 10. Disclosure of Data or Report.

(1) The cabinet shall only disclose data to the persons and entities authorized to receive that data under KRS 218A.202 (7).

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

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

1. Proper use of the KASPER system;

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

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

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

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

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

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

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

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

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

Section 11. Incorporation by Reference.

(1) The following material is incorporated by reference:

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

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

(2) This material may be inspected, copied, or obtained, subject to applicable copyright law, at the Drug Enforcement and Professional Practices Branch, Office of the Inspector General, Cabinet for Health and Family Services, 275 E. Main Street, Frankfort, Kentucky 40621, Monday through Friday, 8 a.m. to 4:30 p.m.

(25 Ky.R. 966; Am. 1367; eff. 12-16-1998; 32 Ky.R. 1927; 33 Ky.R. 120; eff. 7-24-2006; 34 Ky.R. 2609; 35 Ky.R. 283; eff. 9-5-2008; 2615; eff. 7-31-2009; 39 Ky.R. 629; 1218; 1413; 2033; eff. 3-4-2013; 44 Ky.R. 378, 1026, 1346; eff. 1-5-2018; TAm eff. 3-20-2020)

902 KAR 55:115. Drug possession by hospice or home health agency.

RELATES TO: KRS 217.005-217.215, 217.992

STATUTORY AUTHORITY: KRS 194A.050, 211.090, 217.125, 315.300

NECESSITY, FUNCTION, AND CONFORMITY: KRS 315.300 authorizes the Cabinet for Health Services to promulgate administrative regulations that implement the possession of certain drugs by a hospice or home health agency. The purpose of this administrative regulation is to establish criteria that a pharmacy, hospice or home health agency must meet in order to insure that drugs belonging to a pharmacy, that are stored in a hospice or home health agency, are safe and effective for administration to patients.

Section 1. Authorized Employees.

A pharmacy may place a legend drug listed in KRS 315.300 with an authorized employee of a hospice or a home health agency if the pharmacy maintains a record of the license that authorizes the employee to administer legend drugs.

Section 2. Written Agreement.

Each party to a written agreement between a pharmacy and a home health agency or a pharmacy and a hospice shall maintain a copy of the written agreement.

Section 3. Protocol.

(1) A protocol required by KRS 315.300 may be included in the written agreement or may be a separate document.

(2) If the protocol is a separate document, a copy shall be maintained by the pharmacy and by the hospice or home health agency.

(3) The protocol shall be reviewed not less than annually and modified if necessary.

Section 4. Records.

(1) The pharmacy record of a drug placed with authorized employees of a hospice or home health agency shall be retained for five (5) years.

(2) The record of a drug administered by authorized employees of a hospice or home health agency shall be retained by the pharmacy for five (5) years.

(25 Ky.R. 723; Am. 1369; eff. 12-16-98; Crt eff. 1-11-2019.)

902 KAR 55:120. Disposal of prescription controlled substances.

RELATES TO: 21 C.F.R. Part 1317

STATUTORY AUTHORITY: KRS 218A.250

NECESSITY, FUNCTION, AND CONFORMITY: KRS 218A.250 requires the Cabinet for Health and Family Services to promulgate administrative regulations for carrying out the provisions of KRS Chapter 218A. This administrative regulation establishes safe, secure, and responsible methods for the disposal of unused or unwanted prescription controlled substances by long-term care facilities and other cabinet-licensed facilities with custodial control of patient-owned controlled substance medications.

Section 1. Methods of Disposal.

A long-term care facility or other cabinet-licensed facility with custodial control of patient-owned controlled substance medications shall:

(1) Dispose of all expired, abandoned, or otherwise unwanted controlled substances in accordance with 21 C.F.R. Part 1317; and

(2) Develop and implement written policies and procedures for the disposal of controlled substances. Disposal methods shall include:

(a) On-site destruction that renders the controlled substance unrecoverable and beyond reclamation so that the medication cannot be diverted; or

(b) Transfer of the controlled substance to an authorized collection receptacle maintained by a:

1. Law enforcement agency; or
2. Pharmacy.

Section 2. Procedures for Disposal.

(1) If a patient's controlled substance medication has expired, been abandoned, or is otherwise unwanted, either the facility's responsible person or the director of nursing and a witness who is employed by the facility shall perform and document:

(a) Removal of the patient's controlled substances from the medication cart or storage area;

(b) Transfer of the medications to a separate secure storage area; and

(c) Use of a disposal method established by Section 1(2) of this administrative regulation no later than thirty (30) days from the date the patient's controlled substances are removed from the medication cart or storage area.

(2) The facility shall maintain a readily retrievable record of controlled substances removed from the medication cart or other area of storage. The record shall:

(a) Be maintained for a minimum of eighteen (18) months from the date of disposal;

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- (b) Be made available upon request by the cabinet for purposes of inspection; and
 - (c) Contain the following information:
 - 1. Amount of controlled substances destroyed on-site or transferred to a collection receptacle;
 - 2. Disposal method;
 - 3. Date of disposal;
 - 4. Patient name;
 - 5. Drug name;
 - 6. Drug strength; and
 - 7. Name of the responsible person or director of nursing and witness responsible for the transfer and disposal of the medications.
- (3) Controlled substances shall not be destroyed by flushing into a sewage treatment system unless disposal by flushing is permitted by:
- (a) Instructions on the label;
 - (b) The patient information leaflet with the medication; or
 - (c) The U.S. Food and Drug Administration’s (FDA) flush list posted on the FDA webpage: <https://www.fda.gov/media/85219/download>.
- (4) The cabinet shall take adverse action against a facility’s license in accordance with 902 KAR 20:008, Section 8, or 908 KAR 1:370, Section 20, if the cabinet finds that there has been a substantial failure by the facility to comply with the provisions of this administrative regulation. (46 Ky.R. 824; eff. 11-1-2019.)

902 KAR 55:130. Electronic prescribing of controlled substances.

RELATES TO: KRS 13B.050, 13B.080, 13B.090, 13B.110, 13B.120, 218A.182

STATUTORY AUTHORITY: KRS 218A.182

NECESSITY, FUNCTION, AND CONFORMITY: In accordance with KRS 218A.182, which takes effect on January 1, 2021, electronic prescribing for all schedule II-V controlled substances is required by each practitioner who issues the prescription to a pharmacy. KRS 218A.182(1) identifies certain prescriptions that are exempt from the electronic prescribing mandate, including a temporary waiver for entities that demonstrate economic hardship, technological limitations, or other exceptional circumstances. KRS 218A.182(3) requires the cabinet to promulgate administrative regulations to implement the electronic prescribing mandate, including enforcement mechanisms, waivers of requirements, and the appropriate penalties for violations. This administrative regulation establishes requirements related to the electronic prescribing of controlled substances (EPCS).

Section 1. Prescription Requirements.

- (1) Beginning January 1, 2021, a prescription for a controlled substance:
 - (a) Shall be transmitted electronically to a pharmacy, except as provided by KRS 218A.182(1)(a)-(l); and
 - (b) Shall contain the:
 - 1. Full legal name, gender, address, and date of birth of the ultimate user for whom the controlled substance is intended;

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2. Name, address, Drug Enforcement Administration (DEA) registration number, telephone number, and electronic signature of the prescribing practitioner;
 3. Drug name, strength, dosage form, quantity prescribed, specific directions for use, and number of refills (if authorized); and
 4. Date upon which the prescription was issued and signed electronically by the prescribing practitioner.
- (2) In accordance with KRS 218A.182(2), a pharmacist who receives a written, oral, or faxed prescription for a controlled substance:
- (a) Shall not be required to verify that the prescription is subject to an exception provided in KRS 218A.182(1)(a)-(1); and
 - (b) May dispense a controlled substance pursuant to an otherwise valid written, oral, or fax prescription.

Section 2. Waiver from the EPCS Mandate.

- (1) A practitioner who is unable to comply with the EPCS mandate may petition the cabinet for a temporary waiver based upon:
- (a) Economic hardship;
 - (b) Technological limitations that are not reasonably within the control of the practitioner; or
 - (c) Other exceptional circumstances.
- (2) A practitioner seeking an initial waiver from the EPCS mandate shall submit a completed Temporary Exemption Form, no later than November 1, 2020.
- (3) A request for renewal of an approved waiver shall be submitted on the Temporary Exemption Form at least sixty (60) days in advance of the expiration of the waiver.
- (4) A completed Temporary Exemption Form shall include:
- (a) The name, practice address, phone number of the practice point of contact, professional license number, and Drug Enforcement Administration (DEA) registration number of the practitioner seeking the waiver;
 - (b) The practitioner's current electronic prescribing capabilities;
 - (c) The reason the practitioner is seeking the waiver;
 - (d) Supporting documentation to justify the reason for the waiver, including the following mandatory documentation:
 1. For an economic hardship exemption:
 - a. Attestation of the practitioner's current gross annual income; and
 - b. At least two (2) quotes documenting the cost to the practitioner of implementing EPCS;
 2. For a technological limitation exemption:
 - a. Documentation showing the:
 - (i) Available internet service providers;
 - (ii) Speed and bandwidth available from each provider; and
 - (iii) Any data caps imposed by the internet service provider; and
 - b. Documentation showing the minimum technological requirements from at least two (2) electronic prescribing platform vendors;
 - (e) The anticipated date of compliance with the EPCS mandate; and
 - (f) If the practitioner is requesting renewal of an approved waiver:

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1. Information relating to the practitioner's actions during the previous waiver period to work toward compliance with the EPCS mandate; or
 2. An explanation as to why no progress has been made.
- (5) Upon consideration of all information provided by the practitioner on a Temporary Exemption Form, the cabinet shall approve or deny the request for an initial or renewal waiver based on the criteria established by this subsection.
- (a) If the reason for the waiver is economic hardship and the cost, to the practitioner, of compliance with the EPCS mandate would exceed five (5) percent of the practitioner's gross annual income as self-reported, the cabinet shall approve the request.
 - (b) If the reason for the waiver is technological limitations and the internet service providers available do not have the technological capabilities required by the electronic prescribing platform, the cabinet shall approve the request.
 - (c) If the reason for the waiver is other exceptional circumstances, the cabinet shall evaluate the description of the exceptional circumstances on a case-by-case basis.
 - (d) If the practitioner seeks renewal of a previous waiver, the cabinet shall consider:
 1. Updated information as it relates to the practitioner working toward compliance with the EPCS mandate; or
 2. The explanation as to why no progress has been made.
- (6)(a) The cabinet may approve a waiver, or the renewal of a current waiver, for a specified period of time not to exceed one (1) year from the date of approval.
- (b) The cabinet shall not approve more than two (2) renewal waivers.

Section 3. Enforcement. It shall be the duty of the cabinet to enforce the provisions of this administrative regulation.

Section 4. Penalties.

- (1) The cabinet shall make a referral to the appropriate professional licensing board and impose a fine of \$1,000 against a practitioner for each violation, not to exceed \$2,000 during a twelve (12) month period, in which the cabinet substantiates that the practitioner has:
 - (a) Falsified information on the Temporary Exemption Form or the form's supporting documentation;
 - (b) Failed to request a timely waiver in accordance with KRS 218A.182(1)(i) and Section 2(1) to (4) of this administrative regulation and the practitioner is noncompliant with the EPCS mandate; or
 - (c) Failed to transmit a prescription for a controlled substance electronically to a pharmacy after expiration of the practitioner's waiver, except for prescriptions that meet the exemption criteria of KRS 218A.182(a)-(h) and (j)-(l).
 - (2) A practitioner may file an appeal with the cabinet within twenty (20) calendar days of the cabinet's written notice of the violation and fine.
 - (3) If the practitioner requests an administrative hearing, the cabinet shall:
 - (a) Appoint a hearing officer; and
 - (b) Proceed pursuant to KRS 13B.050.
 - (4) The administrative hearing shall be conducted by a hearing officer appointed by the secretary and held in accordance with KRS 13B.080, 13B.090, and 13B.110.
 - (5) The secretary shall issue a final order in accordance with KRS 13B.120.
- Section 5. Incorporation by Reference.

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(1) The OIG 55:130, "Temporary Exemption Form", October 2019 edition, is incorporated by reference.

(2) This material may be inspected, copied, or obtained, subject to applicable copyright law, at the Office of Inspector General, 275 East Main Street, Frankfort, Kentucky 40621, Monday through Friday, 8 a.m. to 4:30 p.m. (17 Ky.R. 719; eff. 10-14-1990; 20 Ky.R. 1694; eff. 2-2-1994; 22 Ky.R. 358; 725; eff. 10-5-1995; 26 Ky.R. 2320; 27 Ky.R. 962; eff. 10-16-2000; 35 Ky.R. 1894; 2223; eff. 5-1-2009; Crt eff. 7-1-2019; 46 Ky.R. 1760, 2640; eff. 6-30-2020.)