

CABINET FOR HEALTH AND FAMILY SERVICES

Office of Inspector General

Division of Audits and Investigations

(Amended at ARRS Committee)

902 KAR 55:095. Prescription for Schedule II controlled substance – authorization of oral prescriptions for immediate administration, 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

CERTIFICATION STATEMENT:

NECESSITY, FUNCTION, AND CONFORMITY: KRS 194A.050 *requires the secretary of the Cabinet for Health and Family Services to promulgate administrative regulations necessary under applicable state laws to protect, develop, and maintain the health, personal dignity, integrity, and sufficiency of the individual citizens of the Commonwealth; operate the programs and fulfill the responsibilities vested in the cabinet; implement programs mandated by federal law; 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 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 ~~authorizes/determines the following criteria exists for the purposes of authorizing~~ an oral prescription for a Schedule II controlled substance, pursuant to KRS 218A.180(1):

(a) Immediate administration of the controlled substance is necessary for proper treatment of the intended ultimate user;

(b) ~~An~~ ~~Not~~ appropriate alternative treatment is not 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), ~~excludes/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;
 - (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 or electronic 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, 902 KAR 55:105 and 902 KAR 55:130, 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 or electronic 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
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 ~~or~~ real time ~~or~~ 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.]~~
- ~~(5)~~ ~~[(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.

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