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April 3, 2024

Bradford DeYoung
Kansas Board of Pharmacy
800 SW Jackson, Suite 1414
Topeka, KS 66612

RE: **K.A.R. 68-7-18**

Dear Mr. DeYoung:

Pursuant to the Rules and Regulations Filing Act, K.S.A. 77-415, *et seq.*, we have reviewed the above-referenced regulation for legality. Finding no issues of concern, we have approved it. The stamped original regulation is enclosed.

Sincerely,

Paul Keithley
Assistant Attorney General
Legal Oversight and Government Counsel Section

PK:sb
Enclosure

cc: Sen. Kellie Warren, Chair, Joint Committee on Rules and Regulations
Rep. Barbara Wasinger, Vice Chair, Joint Committee on Rules and Regulations
Sen. Oletha Faust-Goudeau, Ranking Minority Member, Joint Committee on Rules and Regulations
Jill Shelley, Legislative Research, State Capitol, Room 68-W
Jenna Moyer, Office of Revisor, State Capitol, Room 24-E

68-7-18. Health departments ~~and~~, private not-for-profit family planning clinics, federally qualified health centers, and indigent healthcare clinics. The ~~distribution~~ supply and control of drugs provided by health departments ~~and~~, private not-for-profit family planning clinics, federally qualified health centers, and indigent healthcare clinics authorized under K.S.A. 65-1648(d)(1), and amendments thereto, shall conform to the following requirements:

(a) The approved drugs that may be stored and ~~distributed~~ supplied by health departments ~~and~~, not-for-profit family planning clinics, and indigent healthcare clinics shall be only noncontrolled drugs that are approved by the food and drug administration. ~~In determining the formulary for each health department or not-for-profit family planning clinic the pharmacist-in-charge shall consult with the medical supervisor and director of nursing for that facility. No state or federal controlled drugs shall be allowed.~~

(b) The approved drugs that may be stored and supplied by a federally qualified health center shall be only drugs that are approved by the food and drug administration.

(c)(1) ~~The pharmacist-in-charge shall review the and procedures outlined below for the distribution and control of all drugs within health department facilities, family planning clinics and shall be responsible for the following:~~

~~(A) Ensuring the development of programs for supervision of all personnel in the distribution and control of drugs;~~

~~(B) ensuring the development of a policy and procedure manual governing the storage, control, and distribution of drugs;~~

~~(C) maintaining documentation of at least quarterly checks of drug records, drug storage conditions, and drugs stored in all locations within the facility;~~

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~~(D) establishing a drug recall procedure that can be effectively implemented; and~~

~~(E) ensuring the development of written procedures for maintaining records of distribution and prepackaging of drugs.~~The pharmacist-in-charge shall ensure that health departments, family planning clinics, federally qualified health centers, and indigent healthcare clinics maintain and implement written policies and procedures for the following:

(A) Supervision of all personnel in the supply and control of drugs;

(B) storage, control, supply, labeling, and prepacking of drugs;

(C) documentation of at least quarterly checks of drug records, drug storage conditions, and drugs stored in all locations within the facility by a pharmacist;

(D) drug recall procedure that can be effectively implemented; and

(E) maintaining records of supplying and prepacking of drugs.

(2) ~~Labels for prepackaged drugs shall contain the following:~~ Drugs packaged in advance of immediate need shall meet the requirements of K.A.R. 68-7-15 and 68-7-16.

~~(A) The brand name or corresponding generic name of the drug;~~

~~(B) the name of the manufacturer or distributor of the drug, or an easily identified abbreviation of the manufacturer's or distributor's name;~~

~~(C) the strength of the drug;~~

~~(D) the contents in terms of weight, measure, or numerical count;~~

~~(E) the lot number of the drug, if the lot number is not recorded on a suitable log; and~~

~~(F) the beyond-use date of the drug~~.

~~(3) Prepackaged drugs shall be packaged in suitable containers and shall be subject to all~~

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~~other provisions of the Kansas state board of pharmacy regulations under the uniform controlled substances act of the state of Kansas and under the pharmacy act of the state of Kansas.~~

~~(c)~~(d) The procedures for the control and ~~distribution~~ supplying of drugs within health department facilities ~~and~~, family planning clinics, federally qualified health centers, and indigent healthcare clinics shall be consistent with the following requirements:

(1) Adequate records of the ~~distribution of~~ drugs supplied by the designated registered professional nurse or nurses shall be maintained and shall include the ~~physician's~~ prescriber's order or written protocol.

(A) If the ~~physician's~~ prescriber's order was given ~~orally~~ verbally, ~~electronically, or by telephone,~~ the designated registered professional nurse or nurses shall reduce that order to writing. The written copy of the order shall be ~~signed by the designated registered professional nurse and~~ maintained in a permanent patient file.

(B) The records shall include the following:

(i) The full name of the patient;

(ii) the date ~~supplied~~ ordered;

(iii) the name of the drug, strength, and the quantity supplied~~, and strength of the drug distributed~~;

(iv) the directions for use;

(v) the prescriber's name~~. The record shall include the name of the practitioner and, if involved, the name of either the physician's assistant (PA) or the advanced registered nurse practitioner (ARNP)~~ and the name of the supervising physician if the prescriber is a physician's assistant; and

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(vi) ~~the expiration date of the drug; and~~ if the order is received verbally, the first and last name of the registered professional nurse that received that order.

~~(vii) the lot number of the drug.~~

(C) The following shall be recorded in a log or accessible in a searchable database:

(i) The full name of the patient;

(ii) the name of the drug, strength, and quantity supplied;

(iii) the date supplied;

(iv) the internal ID number assigned to the supply of the drug provided.

(2) A supply of drugs shall be provided to a patient by a designated registered professional nurse or nurses pursuant to a prescriber's order. Only a designated registered professional nurse or nurses may access the pharmacy area and remove the supply of the drugs. The supply shall conform with the ~~following~~ labeling requirements of K.A.R. 68-7-14.~~:~~

~~(A) The name, address, and telephone number of the health department or family planning clinic from which the drug is supplied;~~

~~(B) the full name of the patient;~~

~~(C) adequate directions for use of the drug;~~

~~(D) the name of the prescriber. The label shall include the name of the practitioner and, if involved, the name of either the physician's assistant (PA) or the advanced registered nurse practitioner (ARNP);~~

~~(E) the date the supply was distributed;~~

~~(F) the identification number assigned to the supply of the drug distributed by the health department or family planning clinic;~~

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~~(G) the brand name or corresponding generic name of the drug;~~

~~(H) necessary auxiliary labels and storage instructions, if needed; and~~

~~(I) the beyond-use date of the drug issued~~.

~~(3) Repackaged drugs shall be packaged in suitable containers and shall be subject to all other provisions of the Kansas state board of pharmacy rules and regulations under the pharmacy act of the state of Kansas.~~

~~(d)~~(e) The ~~appointment~~ designation of ~~any Kansas licensed pharmacist as~~ a pharmacist-in-charge of a health department ~~or~~, family planning clinic, federally qualified health center, or indigent healthcare clinic shall be subject to the provisions of K.A.R. 68-1-2a and 68-7-13. (Authorized by and implementing K.S.A. 65-1648; effective, T-84-3, Feb. 10, 1983; effective May 1, 1984; amended July 23, 1999; amended April 28, 2000; amended P-_____.)

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