

Kansas Administrative Regulations

State Board of Pharmacy

Article 20.—Controlled Substances

68-20-10. Requirements of registration.

(a) Persons required to register. Every person who manufactures, distributes, or dispenses any controlled substances within this state, or who proposes to engage in the manufacture, distribution, or dispensing of any controlled substance in this state shall obtain annually a registration unless exempted by law or pursuant to subsections (d) through (g) of this regulation. Only persons actually engaged in these activities in this state shall be required to obtain a registration.

(b) Separate registration for independent activities.

(1) The following six groups of activities shall be deemed to be independent of each other:

(A) Manufacturing controlled substances;

(B) distributing controlled substances;

(C) dispensing, conducting research, other than research described in paragraph (b)(1)(D), with, and conducting instructional activities with, controlled substances listed in schedules II through V;

(D) conducting research with narcotic drugs listed in schedules II through V for the purpose of continuing the dependence on these drugs of a narcotic drug-dependent person in the course of conducting an authorized clinical investigation in the development of a narcotic addict rehabilitation program pursuant to a notice of claimed investigational exemption for a new drug approved by the food and drug administration;

(E) conducting research and instructional activities with controlled substances listed in schedule I; and

(F) conducting chemical analysis with controlled substances listed in any schedule.

(2) Every person who engages in more than one group of independent activities shall obtain a separate registration for each group of activities, except as provided in this subsection (b). Any person, when registered to engage in the group of activities

described in each paragraph in this subsection, shall be authorized to engage in the coincident activities described in that paragraph without obtaining a registration to engage in such coincident activities if, unless specifically exempted, the person complies with all requirements and duties prescribed by law for the following persons registered to engage in the coincident activities:

(A) A person registered to manufacture any controlled substance or basic class of controlled substance shall be authorized to distribute that substance or class, but no other substance or class that the person is not registered to manufacture.

(B) A person registered to manufacture any controlled substance listed in schedules II through V shall be authorized to conduct chemical analysis and preclinical research, including quality control analysis, with narcotic and nonnarcotic controlled substances listed in those schedules in which the person is authorized to manufacture.

(C) A person registered to conduct research with a basic class of controlled substances listed in schedule I shall be authorized to manufacture this class if and to the extent that the manufacture is set forth in the research protocol filed with the application for registration and to distribute this class to other persons registered to conduct research with this class or to conduct chemical analysis.

(D) A person registered to conduct chemical analysis with controlled substances shall be authorized to perform the following:

- (i) Manufacture and import these substances for analytical or instructional purposes;
- (ii) distribute these substances to other persons registered to conduct chemical analysis or instructional activities, to persons registered or authorized to conduct research with these substances, and to persons exempted from registration pursuant to subsection (c);
- (iii) export these substances to persons in other countries performing chemical analysis or enforcing laws relating to controlled substances or drugs in those countries; and
- (iv) conduct instructional activities with controlled substances.

(E) A person registered or authorized to conduct research, other than the research described in paragraph (b)(2)(C), with controlled substances listed in schedules II through V shall be authorized to perform the following:

(i) Conduct chemical analysis with controlled substances listed in those schedules in which the person is authorized to conduct research to manufacture is set forth in a statement filed with the application for registration;

(ii) distribute these substances to other persons registered or authorized to conduct chemical analysis, instructional activities, or research with these substances and to persons exempted from registration pursuant to subsection (c); and

(iii) conduct instructional activities with controlled substances.

(F) A person registered to dispense under the pharmacy act, or to conduct research, other than research described in paragraph (b)(2)(D), with controlled substances listed in schedules II through V shall be authorized to dispense and to conduct research and to conduct instructional research with those substances.

(3) A single registration to engage in any group of independent activities may include one or more controlled substances listed in the schedules authorized in that group of independent activities. A person registered to conduct research with controlled substances listed in schedule I may conduct research with any substance listed in schedule I for which the person has filed and had approved a research protocol.

(c) Separate registrations for separate locations.

(1) A separate registration shall be required for each principal place of business or professional practice at one general physical location where controlled substances are manufactured, distributed, or dispensed by a person.

(2) The following locations shall be deemed not to be places where controlled substances are manufactured, distributed, or dispensed:

(A) A warehouse where controlled substances are stored by or on behalf of a registered person, unless these substances are distributed directly from the warehouse to registered locations other than the registered location from which the substances were delivered or to persons not required to register by virtue of the pharmacy act, K.S.A. 65-4116 and amendments thereto;

(B) an office used by agents of a registrant where sales of controlled substances are solicited, made, or supervised but which neither contains these substances, other than substances for display purposes only, nor serves as a distribution point for filling sales orders; and

(C) an office used by a practitioner or mid-level practitioner who is registered at another location where controlled substances are prescribed but neither administered nor otherwise dispensed as a regular part of the professional practice of the practitioner or mid-level practitioner at this office, and where no supplies of controlled substances are maintained.

(d) Exemption of agents and employees; affiliated practitioners.

(1) Practitioners, mid-level practitioners, pharmacists, and other persons required to register under this act shall not be exempt from registration because of their status as an agent or employee of a person who is already registered to engage in any group of independent activities. The requirements of registration, however, shall be waived for any agent or employee of a person who is registered to engage in any group of independent activities, if the agent or employee is acting in the usual course of his business or employment.

(2) A practitioner who is an intern, resident, or foreign physician or medical graduate may dispense and prescribe controlled substances under the registration of the hospital or other institution that is registered and by whom the person is employed if all of the following conditions are met:

(A) The practitioner is authorized or permitted to do so by the laws of the state of Kansas.

(B) The dispensing or prescribing is done in the usual course of the practitioner's professional practice.

(C) The hospital or other institution by whom the person is employed has determined that the practitioner is permitted to dispense or prescribe drugs by the state of Kansas.

(D) The practitioner is acting only within the scope of employment in the hospital or institution.

(E) The hospital or other institution authorizes the intern, resident, or foreign physician or medical graduate to dispense or prescribe under the hospital registration and designates a specific internal registration code number for each intern, resident, or foreign physician or medical graduate so authorized. The code number shall consist of numbers, letters, or a combination of both and shall be a suffix to the institution's drug enforcement administration registration number, preceded by a hyphen.

(F) A current list of internal codes and the corresponding practitioners is kept by the hospital or other institution, and an updated copy is on file with the state board of pharmacy of the state of Kansas for the purposes of verifying the authority of the prescribing practitioner.

(e) Exemption of certain military and other personnel.

(1) The requirement of registration shall be waived for any official of the U.S. army, navy, marine corps, air force, coast guard, or public health service who is authorized to prescribe, dispense, or administer, but not to procure or purchase, controlled substances in the course of official duties. These officials shall follow the procedures set forth in K.A.R. 68-20-18, 68-20-19, 68-20-20, and 68-20-21, but shall state the branch of service or agency and the service identification number of the issuing official in lieu of the registration number required on prescription forms. The service identification number for a public health service employee is the person's social security identification number.

(2) If any official exempted by this subsection also engages as a private individual in any activity or group of activities for which registration is required, the official shall obtain a registration for these private activities.

(f) Exemption of law enforcement officials.

(1) The requirement of registration shall be waived for the following persons in the circumstances described in this subsection:

(A) Any officer or employee of the bureau, any officer of the U.S. bureau of customs, any officer or employee of the United States food and drug administration, and any other federal officer who is lawfully engaged in the enforcement of any federal law relating to controlled substances, drugs, or customs, and is duly authorized to possess controlled substances in the course of official duties; and

(B) any officer or employee of the state of Kansas, or any political subdivision or agency thereof, who is engaged in the enforcement of Kansas law or local law relating to controlled substances and is duly authorized to possess controlled substances in the course of official duties.

(2) Any official exempted by this subsection may, when acting in the course of official duties, possess any controlled substance and distribute any such substance to

any other official who is also exempted by this subsection and acting in the course of official duties.

(3) Any official exempted by this subsection may procure any controlled substance in the course of an inspection, in accordance with the controlled substances act, K.S.A. 65-4131(c) and amendments thereto, or in the course of any criminal investigation involving the person from whom the substance was procured.

(4) In order to enable law enforcement agency laboratories to obtain and transfer controlled substances for use as standards in chemical analysis, these laboratories shall obtain annually a registration to conduct chemical analysis. These laboratories shall be exempted from payment of a fee for registration. Laboratory personnel, when acting in the scope of their official duties, shall be deemed to be officials exempted by this subsection and within the activities described in the controlled substances act, K.S.A. 65-4115 and amendments thereto. For purposes of this subsection, laboratory activities shall not include field or other preliminary chemical tests by officials exempted by this subsection.

(g) Exemption of civil defense officials.

(1) The requirement of registration shall be waived for any official of a civil defense or disaster relief organization who, in the course of official duties, is authorized to perform either of the following:

(A) Maintain, and distribute for maintenance, controlled substances held for emergency use; or

(B) procure controlled substances for the purposes of maintaining supplies for emergency use, if all procurement is from the U.S. general services administration and in accordance with the rules of the U.S. office of emergency preparedness.

(2) The requirement of registration shall be waived for any official of a civil defense or disaster relief organization during a state of emergency or disaster within the official's jurisdiction proclaimed by the president or by a concurrent resolution of the congress, which official, in the course of official duties during this emergency or disaster, is authorized to perform either of the following:

(A) Dispense controlled substances; or

(B) procure or distribute controlled substances, if all procurement is on a special "civil defense emergency order form," as described in this subsection.

(3) Civil defense emergency order forms shall be furnished by the U.S. office of emergency preparedness and shall contain the name of the civil defense or disaster relief organization. These forms may be used and shall be valid only during a state of emergency disaster proclaimed by the president or by a concurrent resolution of the congress for the area in which the organization using the forms has civil defense or disaster relief jurisdiction, who shall state the position and the nature and legal designation of the emergency or disaster. These forms may be filled by any person registered under the controlled substances act. The organization shall, upon the execution of a civil defense emergency order form, be deemed to be registered under the controlled substances act for purposes of record keeping pursuant to K.A.R. 68-20-16.

(Authorized by K.S.A. 65-4116, as amended by L. 1999, Ch. 149, Sec. 9; implementing K.S.A. 65-4116, as amended by L. 1999, Ch. 149, Sec. 9, 65-4131; effective, E-72-24, Aug. 25, 1972; effective Jan. 1, 1973; amended Dec. 27, 1999.)

***** Authenticated Kansas Administrative Regulation *****