Approved: 3-11-99
Date

MINUTES OF THE HOUSE COMMITTEE ON HEALTH AND HUMAN SERVICES.

The meeting was called to order by Chairperson Garry Boston at 1:30 p.m. on March 10 in Room 423-S of the Capitol.

All members were present except: Representative David Haley, Excused
Representative Peggy Long, Excused

Committee staff present: Emalene Correll, Kansas Legislative Research
Norman Furse, Revisor of Statutes
June Evans, Secretary

Conferees appearing before the committee: Larry Froelich, Executive Director, Kansas State Board of Pharmacy
Barb Hinton, Legislative Post Audit

Others attending: See Attached Sheet

The Chairperson opened the hearing on **SB 267 - Pharmacy act amendments including board of pharmacy procedures and definition of prescription-only drugs.**

Staff gave a briefing on **SB 267.**

Larry Froelich, Executive Director, Kansas State Board of Pharmacy, a proponent to **SB 267**, stated the current federal definition of prescription-only drug is changing from using the "caution" legend to "Rx only". Although this definition and description on prescription products is being phased in over several years (by the year 2002), the Board of requesting changing the Kansas definition to follow that which the 21 *United States Code Annotated* defines prescription drug. (See Attachment #1)

The Chairperson closed the hearing on **SB 267.**

Representative Morrison moved and Representative Wells seconded to move **SB 267** out favorably and put on the consent calendar. The motion carried.

The Chairperson opened the hearing on **SB 128 - Child care - civil fines.**

Staff gave a briefing on **SB 128** stating this was a clarification.

Barb Hinton, Legislative Post Auditor, testified this bill, as introduced by the Legislative Post Audit committee, would clearly specify the authority the Department of Health and Environment has in applying fines for violations of the State's child-care regulations

This legislation addresses a recommendation made in our performance audit report, *Reviewing the Department of Health and Environment's Regulation of Child Care Facilities and Family Day Care Homes.* In that audit, it was noted that State law subjects child-care providers to fines when they've violated regulations that "significantly and adversely" affect the health, safety, or sanitation of children.

In cases reviewed, serious violations were found where child-care providers sometimes hadn't corrected those violations even after repeated warnings and re-inspections. For these situations, the law wasn't clear about whether the maximum fine that could be levied was $500 per day, per violation, or per incident.

SB 128 would allow (but not require) the Department to assess a civil fine of up to $500 for each violation that could significantly affect children's safety or well-being. For continuing violations, every day the violation continues counts as a separate violation. (See Attachment #2)

The Chairperson stated that written testimony supporting **SB 128** had been distributed by Senator Lana Oleen. (See Attachment #3)

MINUTES OF THE HOUSE COMMITTEE ON HEALTH AND HUMAN SERVICES, Room 423-S of the Capitol at 1:30 p.m. on March 10, 1999.

The Chairperson closed the hearing on **SB 128.**

Representative Geringer moved and Representative Bethell seconded to move **SB 128** out favorably and place on the consent calendar. The motion carried.

The meeting adjourned at 2:05 p.m. The next meeting will be March 11.

HUMAN AND HEALTH SERVICES

DATE March 10, 1999

NAME	REPRESENTING
RANDY FORBES	Pharmacy Bd.
LARRY FROELICH	PHARMACY BOARD
Beth LeCuyer	Social Welfare
Wendy Lopez	University of Kansas / Social Welfare
Stephanie Frohock	University of Kansas / Social Welfare
Ruth Gillum	Kansas Midwest
KEITH R LANDIS	EXHIBITION SCIENCE COMMITTEE ON PUBLICATION FOR KANSAS
Jane Weiler	SRS-Childhood Services
Vicki Schmidt	KS. Bd. of Pharmacy
Alisa Crawford	Leadership Newton
Cyndi Beckman	" "
Lisa Elliott	" "
Nickala Sindelar	" "
[illegible]	" "
BOB ALDERSON	KANSAS PHARMACISTS ASSOC.

Kansas State Board of Pharmacy

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STATE OF KANSAS

BILL GRAVES
GOVERNOR

EXECUTIVE DIRECTOR
LARRY FROELICH

1999 KANSAS LEGISLATIVE SESSION
SENATE BILL No. 267

PHARMACY PRACTICE ACT

House Committee on Health and Human Services
Representative Garry Boston, Chairman
Committee Members

The Kansas Board of Pharmacy requests favorable passage of **SB 267**.

SB 267 has two distinct areas that are addressed:

1.) Changing the definition of prescription-only drug:

The current Federal definition of prescription-only drug is changing from using the "caution" legend to "Rx only". Although this definition and description on prescription products is being phased in over several years (by the year 2002), the Board is requesting changing the Kansas definition to follow that which the *21 United States Code Annotated* defines prescription drug. In the event that subsequent changes are done federally, Kansas Law will already include that definition.

2.) Additional administrative avenues that the Board may utilize:

A.) The Board is requesting the power of a subpoena in obtaining records during investigations. The Kansas Administrative Procedures Act (KAPA) allows for subpoenas after filling a notice of hearing. There are instances when the subpoenas are needed during an investigation. The Board currently relies upon the Attorney General's Office or associated agencies.

B.) Adding verbiage to discipline a pharmacist who fails to furnish information that is legally requested by the Board, and

C.) Additional language to suspend or limit a pharmacists' license under KAPA if the Board believes there is a danger to public health and safety.

3.) The amendments offered by the Senate committee will reconcile two versions of a Statute (K.S.A. 65-1627 & K.S.A. 65-1627i).

The Kansas Board of Pharmacy respectfully requests **favorable passage of SB 267**.

H&HSvcs
3-10-99
Atch #1

As Amended by Senate Committee

Session of 1999

SENATE BILL No. 267

By Committee on Public Health and Welfare

2-8

AN ACT concerning the pharmacy act of the state of Kansas; board procedures; prescription-only drugs; amending K.S.A. 1998 Supp. 65-1626, 65-1627, 65-1635 and 65-1643 and repealing the existing sections; ***also repealing K.S.A. 1998 Supp. 65-1627i.***

Be it enacted by the Legislature of the State of Kansas:

Section 1. K.S.A. 1998 Supp. 65-1626 is hereby amended to read as follows: 65-1626. For the purposes of this act:

(a) "Administer" means the direct application of a drug, whether by injection, inhalation, ingestion or any other means, to the body of a patient or research subject by:

(1) A practitioner or pursuant to the lawful direction of a practitioner, or

(2) the patient or research subject at the direction and in the presence of the practitioner.

(b) "Agent" means an authorized person who acts on behalf of or at the direction of a manufacturer, distributor or dispenser but shall not include a common or contract carrier, public warehouseman or employee of the carrier or warehouseman when acting in the usual and lawful course of the carrier's or warehouseman's business.

(c) "Board" means the state board of pharmacy created by K.S.A. 74-1603 and amendments thereto.

(d) "Brand exchange" means the dispensing of a different drug product of the same dosage form and strength and of the same generic name than the brand name drug product prescribed.

(e) "Brand name" means the registered trademark name given to a drug product by its manufacturer, labeler or distributor.

(f) "Deliver" or "delivery" means the actual, constructive or attempted transfer from one person to another of any drug whether or not an agency relationship exists.

(g) "Direct supervision" means the process by which the responsible pharmacist shall observe and direct the activities of a pharmacy student or pharmacy technician to a sufficient degree to assure that all such activities are performed accurately, safely and without risk or harm to pa-

tients, and complete the final check before dispensing.

(h) "Dispense" means to deliver prescription medication to the ultimate user or research subject by or pursuant to the lawful order of a practitioner.

(i) "Dispenser" means a practitioner or pharmacist who dispenses prescription medication.

(j) "Distribute" means to deliver, other than by administering or dispensing, any drug.

(k) "Distributor" means a person who distributes a drug.

(l) "Drug" means: (1) Articles recognized in the official United States pharmacopoeia, or other such official compendiums of the United States, or official national formulary, or any supplement of any of them; (2) articles intended for use in the diagnosis, cure, mitigation, treatment or prevention of disease in man or other animals; (3) articles, other than food, intended to affect the structure or any function of the body of man or other animals; and (4) articles intended for use as a component of any articles specified in clause (1), (2) or (3) of this subsection; but does not include devices or their components, parts or accessories, except that the term "drug" shall not include amygdalin (laetrile) or any livestock remedy, as defined in K.S.A. 47-501 and amendments thereto, if such livestock remedy has been registered in accordance with the provisions of article 5 of chapter 47 of the Kansas Statutes Annotated.

(m) "Electronic transmission" means transmission of information in electronic form or the transmission of the exact visual image of a document by way of electronic equipment.

(n) "Generic name" means the established chemical name or official name of a drug or drug product.

(o) (1) "Institutional drug room" means any location where prescription-only drugs are stored and from which prescription-only drugs are administered or dispensed and which is maintained or operated for the purpose of providing the drug needs of:

(A) Inmates of a jail or correctional institution or facility;

(B) residents of a juvenile detention facility, as defined by the Kansas code for care of children and the Kansas juvenile justice code;

(C) students of a public or private university or college, a community college or any other institution of higher learning which is located in Kansas; or

(D) employees of a business or other employer.

(2) "Institutional drug room" does not include:

(A) Any registered pharmacy;

(B) any office of a practitioner; or

(C) a location where no prescription-only drugs are dispensed and no prescription-only drugs other than individual prescriptions are stored or

administered.

(p) "Medical care facility" shall have the meaning provided in K.S.A. 65-425 and amendments thereto, except that the term shall also include facilities licensed under the provisions of K.S.A. 75-3307b and amendments thereto except community mental health centers and facilities for the mentally retarded.

(q) "Manufacture" means the production, preparation, propagation, compounding, conversion or processing of a drug either directly or indirectly by extraction from substances of natural origin, independently by means of chemical synthesis or by a combination of extraction and chemical synthesis and includes any packaging or repackaging of the drug or labeling or relabeling of its container, except that this term shall not include the preparation or compounding of a drug by an individual for the individual's own use or the preparation, compounding, packaging or labeling of a drug by: (1) A practitioner or a practitioner's authorized agent incident to such practitioner's administering or dispensing of a drug in the course of the practitioner's professional practice; (2) a practitioner, by a practitioner's authorized agent or under a practitioner's supervision for the purpose of, or as an incident to, research, teaching or chemical analysis and not for sale; or (3) a pharmacist or the pharmacist's authorized agent acting under the direct supervision of the pharmacist for the purpose of, or incident to, the dispensing of a drug by the pharmacist.

(r) "Person" means individual, corporation, government, governmental subdivision or agency, partnership, association or any other legal entity.

(s) "Pharmacist" means any natural person licensed under this act to practice pharmacy.

(t) "Pharmacist in charge" means the pharmacist who is responsible to the board for a registered establishment's compliance with the laws and regulations of this state pertaining to the practice of pharmacy, manufacturing of drugs and the distribution of drugs. The pharmacist in charge shall supervise such establishment on a full-time or a part-time basis and perform such other duties relating to supervision of a registered establishment as may be prescribed by the board by rules and regulations. Nothing in this definition shall relieve other pharmacists or persons from their responsibility to comply with state and federal laws and regulations.

(u) "Pharmacy," "drug store" or "apothecary" means premises, laboratory, area or other place: (1) Where drugs are offered for sale where the profession of pharmacy is practiced and where prescriptions are compounded and dispensed; or (2) which has displayed upon it or within it the words "pharmacist," "pharmaceutical chemist," "pharmacy," "apothecary," "drugstore," "druggist," "drugs," "drug sundries" or any of these words or combinations of these words or words of similar import either

in English or any sign containing any of these words; or (3) where the characteristic symbols of pharmacy or the characteristic prescription sign "Rx" may be exhibited. As used in this subsection, premises refers only to the portion of any building or structure leased, used or controlled by the licensee in the conduct of the business registered by the board at the address for which the registration was issued.

(v) "Pharmacy student" means an individual, registered with the board of pharmacy, enrolled in an accredited school of pharmacy.

(w) "Pharmacy technician" means an individual who, under the direct supervision and control of a pharmacist, may perform packaging, manipulative, repetitive or other nondiscretionary tasks related to the processing of a prescription or medication order and who assists the pharmacist in the performance of pharmacy related duties, but who does not perform duties restricted to a pharmacist.

(x) "Practitioner" means a person licensed to practice medicine and surgery, dentist, podiatrist, veterinarian, optometrist licensed under the optometry law as a therapeutic licensee or diagnostic and therapeutic licensee, or scientific investigator or other person authorized by law to use a prescription-only drug in teaching or chemical analysis or to conduct research with respect to a prescription-only drug.

(y) "Preceptor" means a licensed pharmacist who possesses at least two years' experience as a pharmacist and who supervises students obtaining the pharmaceutical experience required by law as a condition to taking the examination for licensure as a pharmacist.

(z) "Prescription" means, according to the context, either a prescription order or a prescription medication.

(aa) "Prescription medication" means any drug, including label and container according to context, which is dispensed pursuant to a prescription order.

(bb) "Prescription-only drug" means any drug ~~required by the federal or state food, drug and cosmetic act to bear on its label the legend "Caution: Federal law prohibits dispensing without prescription."~~ *whether intended for use by man or animal, required by federal or state law (including 21 United States Code section 353, as amended) to be dispensed only pursuant to a written or oral prescription or order of a practitioner or is restricted to use by practitioners only.*

(cc) "Prescription order" means: (1) An order to be filled by a pharmacist for prescription medication issued and signed by a practitioner in the authorized course of professional practice; or (2) an order transmitted to a pharmacist through word of mouth, note, telephone or other means of communication directed by such practitioner.

(dd) "Probation" means the practice or operation under a temporary license, registration or permit or a conditional license, registration or per-

mit of a business or profession for which a license, registration or permit is granted by the board under the provisions of the pharmacy act of the state of Kansas requiring certain actions to be accomplished or certain actions not to occur before a regular license, registration or permit is issued.

(ee) "Professional incompetency" means:

(1) One or more instances involving failure to adhere to the applicable standard of pharmaceutical care to a degree which constitutes gross negligence, as determined by the board;

(2) repeated instances involving failure to adhere to the applicable standard of pharmaceutical care to a degree which constitutes ordinary negligence, as determined by the board; or

(3) a pattern of pharmacy practice or other behavior which demonstrates a manifest incapacity or incompetence to practice pharmacy.

(ff) "Retail dealer" means a person selling at retail nonprescription drugs which are prepackaged, fully prepared by the manufacturer or distributor for use by the consumer and labeled in accordance with the requirements of the state and federal food, drug and cosmetic acts. Such nonprescription drugs shall not include: (1) A controlled substance; (2) a ~~drug the label of which is required to bear substantially the statement "Caution: Federal law prohibits dispensing without prescription"~~ *prescription-only drug*; or (3) a drug intended for human use by hypodermic injection.

(gg) "Secretary" means the executive secretary of the board.

(hh) "Unprofessional conduct" means:

(1) Fraud in securing a registration or permit;

(2) intentional adulteration or mislabeling of any drug, medicine, chemical or poison;

(3) causing any drug, medicine, chemical or poison to be adulterated or mislabeled, knowing the same to be adulterated or mislabeled;

(4) intentionally falsifying or altering records or prescriptions;

(5) unlawful possession of drugs and unlawful diversion of drugs to others;

(6) willful betrayal of confidential information under K.S.A. 65-1654 and amendments thereto;

(7) conduct likely to deceive, defraud or harm the public;

(8) making a false or misleading statement regarding the licensee's professional practice or the efficacy or value of a drug;

(9) commission of any act of sexual abuse, misconduct or exploitation related to the licensee's professional practice; or

(10) performing unnecessary tests, examinations or services which have no legitimate pharmaceutical purpose.

New Sec. 2. (a) In all investigative and disciplinary matters pending

before the board, the board shall have the power to issue subpoenas and compel the attendance of witnesses and the production of all necessary papers, books and records, documentary evidence and materials. Any person failing or refusing to appear or testify regarding any matter about which such person may be lawfully questioned or to produce any papers, books, records, documentary evidence or materials in the matter to be heard, after having been required by order of the board or by a subpoena of the board to do so, upon application to any district judge of the state of Kansas, may be ordered to comply with such subpoena, and upon failure to comply with the order of the district judge, the court may compel obedience by attachment as for contempt as in the case of disobedience of a similar order or subpoena issued by the court. A subpoena may be served upon any person named therein, anywhere within the state of Kansas with the same fees and mileage by any officer authorized to serve subpoenas in civil actions in the same manner as is prescribed by the code of civil procedure for subpoenas issued out of the district courts of this state.

(b) This section shall be part of and supplemental to the pharmacy act of the state of Kansas.

Sec. 3. K.S.A. 1998 Supp. 65-1627 is hereby amended to read as follows: 65-1627. (a) The board may revoke, suspend, place in a probationary status or deny a renewal of any license of any pharmacist upon a finding that:

(1) The license was obtained by fraudulent means;

(2) the licensee has been convicted of a felony and the licensee fails to show that the licensee has been sufficiently rehabilitated to warrant the public trust;

(3) the licensee is found by the board to be guilty of unprofessional conduct or professional incompetency;

(4) the licensee is addicted to the liquor or drug habit to such a degree as to render the licensee unfit to practice the profession of pharmacy;

(5) the licensee has violated a provision of the federal or state food, drug and cosmetic act, the uniform controlled substances act of the state of Kansas, or any rule and regulation adopted under any such act;

(6) the licensee is found by the board to have filled a prescription not in strict accordance with the directions of the practitioner;

(7) the licensee is found to be mentally or physically incapacitated to such a degree as to render the licensee unfit to practice the profession of pharmacy;

(8) the licensee has violated any of the provisions of the pharmacy act of the state of Kansas or any rule and regulation adopted by the board pursuant to the provisions of such pharmacy act;

(9) the licensee has failed to comply with the requirements of the

board relating to the continuing education of pharmacists;

(10) the licensee as a pharmacist in charge or consultant pharmacist under the provisions of subsection (c) or (d) of K.S.A. 65-1648 and amendments thereto has failed to comply with the requirements of subsection (c) or (d) of K.S.A. 65-1648 and amendments thereto;

(11) the licensee has knowingly submitted a misleading, deceptive, untrue or fraudulent misrepresentation on a claim form, bill or statement;

(12) the licensee has had a license to practice pharmacy revoked, suspended or limited, has been censured or has had other disciplinary action taken, or voluntarily surrendered the license after formal proceedings have been commenced, or has had an application for license denied, by the proper licensing authority of another state, territory, District of Columbia or other country, a certified copy of the record of the action of the other jurisdiction being conclusive evidence thereof; ~~or~~

(13) the licensee has self-administered any controlled substance without a practitioner's prescription order.; ~~or~~

(14) the licensee has assisted suicide in violation of K.S.A. 21-3406 and amendments thereto as established by any of the following:

(A) A copy of the record of criminal conviction or plea of guilty for a felony in violation of K.S.A. 21-3406 and amendments thereto.

(B) A copy of the record of a judgment of contempt of court for violating an injunction issued under K.S.A. 1998 Supp. 60-4404 and amendments thereto.

(C) A copy of the record of a judgment assessing damages under K.S.A. 1998 Supp. 60-4405 and amendments thereto; or

~~(14)~~ ***(15)*** *the licensee has failed to furnish the board, its investigators or its representatives any information legally requested by the board.*

(b) In determining whether or not the licensee has violated subsection (a)(3), (a)(4), (a)(7) or (a)(13), the board upon reasonable suspicion of such violation has authority to compel a licensee to submit to mental or physical examination or drug screen, or any combination thereof, by such persons as the board may designate. To determine whether reasonable suspicion of such violation exists, the investigative information shall be presented to the board as a whole. Information submitted to the board as a whole and all reports, findings and other records shall be confidential and not subject to discovery by or release to any person or entity. The licensee shall submit to the board a release of information authorizing the board to obtain a report of such examination or drug screen, or both. A person affected by this subsection shall be offered, at reasonable intervals, an opportunity to demonstrate that such person can resume the competent practice of pharmacy with reasonable skill and safety to patients. For the purpose of this subsection, every person licensed to prac-

tice pharmacy and who shall accept the privilege to practice pharmacy in this state by so practicing or by the making and filing of a renewal application to practice pharmacy in this state shall be deemed to have consented to submit to a mental or physical examination or a drug screen, or any combination thereof, when directed in writing by the board and further to have waived all objections to the admissibility of the testimony, drug screen or examination report of the person conducting such examination or drug screen, or both, at any proceeding or hearing before the board on the ground that such testimony or examination or drug screen report constitutes a privileged communication. In any proceeding by the board pursuant to the provisions of this subsection, the record of such board proceedings involving the mental and physical examination or drug screen, or any combination thereof, shall not be used in any other administrative or judicial proceeding.

(c) The board may temporarily suspend or temporarily limit the license of any licensee in accordance with the emergency adjudicative proceedings under the Kansas administrative procedure act if the board determines that there is cause to believe that grounds exist for disciplinary action under subsection (a) against the licensee and that the licensee's continuation in practice would constitute an imminent danger to the public health and safety.

~~(c)~~ *(d)* The board may suspend, revoke, place in a probationary status or deny a renewal of any retail dealer's permit issued by the board when information in possession of the board discloses that such operations for which the permit was issued are not being conducted according to law or the rules and regulations of the board.

~~(d)~~ *(e)* The board may revoke, suspend, place in a probationary status or deny a renewal of the registration of a pharmacy upon a finding that: (1) Such pharmacy has been operated in such manner that violations of the provisions of the pharmacy act of the state of Kansas or of the rules and regulations of the board have occurred in connection therewith; (2) the owner or any pharmacist employed at such pharmacy is convicted, subsequent to such owner's acquisition of or such employee's employment at such pharmacy, of a violation of the pharmacy act or uniform controlled substances act of the state of Kansas, or the federal or state food, drug and cosmetic act; (3) the owner or any pharmacist employed by such pharmacy has fraudulently claimed money for pharmaceutical services; or (4) the registrant has had a registration revoked, suspended or limited, has been censured or has had other disciplinary action taken, or an application for registration denied, by the proper registering authority of another state, territory, District of Columbia or other country, a certified copy of the record of the action of the other jurisdiction being conclusive evidence thereof.

~~(e)~~ *(f)* A registration to manufacture or to distribute at wholesale a drug or a registration for the place of business where any such operation is conducted may be suspended, revoked, placed in a probationary status or the renewal of such registration may be denied by the board upon a finding that the registrant or the registrant's agent: (1) Has materially falsified any application filed pursuant to or required by the pharmacy act of the state of Kansas; (2) has been convicted of a felony under any federal or state law relating to the manufacture or distribution of drugs; (3) has had any federal registration for the manufacture or distribution of drugs suspended or revoked; (4) has refused to permit the board or its duly authorized agents to inspect the registrant's establishment in accordance with the provisions of K.S.A. 65-1629 and amendments thereto; (5) has failed to keep, or has failed to file with the board or has falsified records required to be kept or filed by the provisions of the pharmacy act of the state of Kansas or by the board's rules and regulations; or (6) has violated the pharmacy act of the state of Kansas or rules and regulations adopted by the state board of pharmacy under the pharmacy act of the state of Kansas or has violated the uniform controlled substances act or rules and regulations adopted by the state board of pharmacy under the uniform controlled substances act.

~~(f)~~ *(g)* Orders under this section, and proceedings thereon, shall be subject to the provisions of the Kansas administrative procedure act.

Sec. 4. K.S.A. 1998 Supp. 65-1635 is hereby amended to read as follows: 65-1635. (a) Nothing contained in the pharmacy act of the state of Kansas shall prohibit any duly licensed practitioner from purchasing and keeping drugs, from compounding prescriptions or from administering, supplying or dispensing to such practitioner's patients such drugs as may be fit, proper and necessary. Except as provided in subsection (b) or (c), such drugs shall be dispensed by such practitioner and shall comply with the Kansas food, drug and cosmetic act and be subject to inspection as provided by law.

(b) Nothing contained in the pharmacy act of the state of Kansas shall be construed to prohibit any nurse or other person, acting under the direction of a duly licensed practitioner, from administering drugs to a patient.

(c) Nothing contained in the pharmacy act of the state of Kansas shall be construed to prohibit any registered nurse, acting under the supervision of a person who is licensed to practice medicine and surgery as of July 1, 1982, from dispensing drugs to patients of such person so long as the principal office of such person is, and as of July 1, 1982, was, located in a city not having a registered pharmacy within its boundaries. For the purposes of this subsection (c), "supervision" means guidance and direction of the dispensing of drugs by the person licensed to practice medicine

and surgery who shall be physically present in the general location at which the drugs are being dispensed.

(d) Nothing contained in the pharmacy act of the state of Kansas shall be construed to prohibit a duly registered wholesaler from distributing a ~~drug labeled, "Caution: Federal law restricts this drug to use by or on the order of a licensed veterinarian,"~~ *prescription-only drug* pursuant to a veterinarian practitioner's written prescription or order, where a valid veterinarian-client-patient relationship, VCPR, as defined in K.S.A. 47-816, and amendments thereto, exists, to the layman responsible for the control of the animal.

Sec. 5. K.S.A. 1998 Supp. 65-1643 is hereby amended to read as follows: 65-1643. On and after the effective date of this act, it shall be unlawful:

(a) For any person to operate, maintain, open or establish any pharmacy within this state without first having obtained a registration from the board. Each application for registration of a pharmacy shall indicate the person or persons desiring the registration, including the pharmacist in charge, as well as the location, including the street name and number, and such other information as may be required by the board to establish the identity and exact location of the pharmacy. The issuance of a registration for any pharmacy shall also have the effect of permitting such pharmacy to operate as a retail dealer without requiring such pharmacy to obtain a retail dealer's permit. On evidence satisfactory to the board: (1) That the pharmacy for which the registration is sought will be conducted in full compliance with the law and the rules and regulations of the board; (2) that the location and appointments of the pharmacy are such that it can be operated and maintained without endangering the public health or safety; (3) that the pharmacy will be under the supervision of a pharmacist, a registration shall be issued to such persons as the board shall deem qualified to conduct such a pharmacy.

(b) For any person to manufacture within this state any drugs except under the personal and immediate supervision of a pharmacist or such other person or persons as may be approved by the board after an investigation and a determination by the board that such person or persons is qualified by scientific or technical training or experience to perform such duties of supervision as may be necessary to protect the public health and safety; and no person shall manufacture any such drugs without first obtaining a registration so to do from the board. Such registration shall be subject to such rules and regulations with respect to requirements, sanitation and equipment, as the board may from time to time adopt for the protection of public health and safety.

(c) For any person to distribute at wholesale any drugs without first obtaining a registration so to do from the board.

(d) For any person to sell or offer for sale at public auction or private sale in a place where public auctions are conducted, any drugs without first having obtained a registration from the board so to do, and it shall be necessary to obtain the permission of the board in every instance where any of the products covered by this section are to be sold or offered for sale.

(e) For any person to in any manner distribute or dispense samples of any drugs without first having obtained a permit from the board so to do, and it shall be necessary to obtain permission from the board in every instance where the samples are to be distributed or dispensed. Nothing in this subsection shall be held to regulate or in any manner interfere with the furnishing of samples of drugs to duly licensed practitioners, to pharmacists or to medical care facilities.

(f) Except as otherwise provided in this subsection (f), for any person operating a store or place of business to sell, offer for sale or distribute any drugs to the public without first having obtained a registration or permit from the board authorizing such person so to do. No retail dealer who sells 12 or fewer different nonprescription drug products shall be required to obtain a retail dealer's permit under the pharmacy act of the state of Kansas or to pay a retail dealer new permit or permit renewal fee under such act. It shall be lawful for a retail dealer who is the holder of a valid retail dealer's permit issued by the board or for a retail dealer who sells 12 or fewer different nonprescription drug products to sell and distribute nonprescription drugs which are prepackaged, fully prepared by the manufacturer or distributor for use by the consumer and labeled in accordance with the requirements of the state and federal food, drug and cosmetic acts. Such nonprescription drugs shall not include: (1) A controlled substance; (2) ~~a drug product the label of which is required to bear substantially the statement: "Caution: Federal law prohibits dispensing without prescription"~~ *a prescription-only drug*; or (3) a drug product intended for human use by hypodermic injection; but such a retail dealer shall not be authorized to display any of the words listed in subsection (u) of K.S.A. 65-1626 and amendments thereto, for the designation of a pharmacy or drugstore.

(g) For any person to sell any drugs manufactured and sold only in the state of Kansas, unless the label and directions on such drugs shall first have been approved by the board.

(h) For any person to operate an institutional drug room without first having obtained a registration to do so from the board. Such registration shall be subject to the provisions of K.S.A. 65-1637a and amendments thereto and any rules and regulations adopted pursuant thereto.

(i) For any person to be a pharmacy student without first obtaining a registration to do so from the board, in accordance with rules and reg-

ulations adopted by the board, and paying a pharmacy student registration fee of $25 to the board.

Sec. 6. K.S.A. 1998 Supp. 65-1626, 65-1627, ***65-1627i,*** 65-1635 and 65-1643 are hereby repealed.

Sec. 7. This act shall take effect and be in force from and after its publication in the statute book.

UNITED STATES CODE ANNOTATED

Title 21
Food and Drugs
§§ 1 to 800

1998

Supplementary Pamphlet

Covering Years 1973 to 1997

Replacing 1997 Supplementary Pamphlet

Includes the Laws of the
105th CONGRESS, First Session (1997)

For close of Notes of Decisions
See page III

For Later Laws and Cases
Consult
USCA
Interim Pamphlet Service

WEST GROUP
ST. PAUL, MINN.

OU RECYCLE POCKET PARTS?

are printed on recyclable paper and can be cled with newspapers. Staples do not have ause recycling companies use magnets to ing the recycling process.

EXPLANATION

This Cumulative Annual Pocket Part or Supplementary Pamphlet contains the laws of a general and permanent nature enacted by Congress through the final law of the First Session of the 105th Congress. This Pocket Part or Supplementary Pamphlet also includes Executive Orders, Proclamations and Reorganization Plans affecting such general and permanent laws.

The laws are classified to the United States Code. Under the same classification will be found the annotations from the decisions of the State and Federal courts, the Comptroller General, and the United States Merit Systems Protection Board, and from the formal opinions of the Attorney General and the informal opinions of the Office of Legal Counsel of the Department of Justice construing the statutes.

The annotations close with the following:

Supreme Court Reporter	118 S.Ct. 463
Federal Reporter, Third Series	119 F.3d 17
Federal Supplement	968 F.Supp. 743
Federal Rules Decisions	175 F.R.D. 61
Atlantic Reporter, Second Series	696 A.2d 943
California Reporter, Second Series	66 Cal.Rptr.2d 121
New York Supplement, Second Series	660 N.Y.S.2d 105
North Eastern Reporter, Second Series	682 N.E.2d 44
North Western Reporter, Second Series	566 N.W.2d 502
Pacific Reporter, Second Series	940 P.2d 708
South Eastern Reporter, Second Series	487 S.E.2d 599
Southern Reporter, Second Series	696 So.2d 1069
South Western Reporter, Second Series	948 S.W.2d 387
Opinions Attorney General	43 Op.Atty.Gen. (part)
Opinions of Office of Legal Counsel of the Department of Justice	6 Op.O.L.C. 847
Decisions Comptroller General	65 Comp.Gen. 1111
United States Merit Systems Protection Board Reporter	76 M.S.P.R. 269
Claims Court Reporter	26 Cl.Ct. 1492
Federal Claims Reporter	38 Fed.Cl. 799
Court of International Trade	21 C.I.T. (part)
United States Tax Court	108 T.C. 99
Military Justice Reporter	47 M.J.
	#5 C.A.A.F. 145
	#5 C.C.A. 595
Bankruptcy Reporter	210 B.R. 492
Veterans Appeals Reporter	10 Vet.App. 445
Veterans' Administration General Counsel	O.G.C. PREC 12-1996

Other Standard Reports

For subsequent judicial constructions, pending the publication of the next supplementary service, see Table of Statutes Construed in the

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Extent to which special consideration should be given to persons who have difficulty with English language, in formulating tort standard as to what warnings manufacturer must place on nonprescription drug, is matter of public policy for consideration by appropriate legislative bodies and not by courts. Ramirez v. Plough, Inc., Cal.1993, 863 P.2d 167, 25 Cal.Rptr.2d 97, 6 Cal.4th 539, rehearing denied.

48. Packaging, complying with standard of

Pharmaceutical company's practices, including placing inert brown beads similar in appearance to those used in amphetamine capsules in pharmaceutical company's capsules, and marketing capsules and tablets bearing markings and imprints deceptively similar to imprints on controlled substances, supported finding that pharmaceutical company intentionally induced others to misbrand drugs in interstate commerce. U.S. v. Articles of Drug, C.A.8 (Neb.) 1987, 825 F.2d 1238.

Since the Eighth Circuit in Stromsodt expressly held that the package insert of the drug Quadrigen was inadequate, and since that holding in no way depended on the "Phemerol causes leakage" theory discounted by the New York Appellate Division in Tinnerholm because of the purported discovery of new scientific evidence, Vincent did not bar reliance on Stromsodt to collaterally estop the manufacturer of Quadrigen from denying that the package inserts were inadequate in failing to apprise doctors administering the vaccine of the known hazards attendant upon such use. Exagui v. Dow Chemical Corp., C.A.2 (N.Y.) 1979, 598 F.2d 727.

Where ampules of Vitamin K for injection were not completely sealed, the lots of ampules failed to comply with standard of packaging for sterile drugs for injection prescribed by the National Formulary and such ampules would be deemed to be misbranded. U. S. v. Dianovin Pharmaceuticals, Inc., D.C.Puerto Rico 1971, 342 F.Supp. 724, affirmed 476 F.2d 100, certiorari denied 94 S.Ct. 60, 414 U.S. 830, 38 L.Ed.2d 65.

49. Use by physician

Because doctors holding drugs for use in their practices are clearly one part of distribution process, doctors may hold drugs for sale and may be held liable for misbranding drugs. U. S. v. Evers, C.A.5 (Ala.) 1981, 643 F.2d 1043.

A physician may, as part of practice of medicine, lawfully prescribe a different dosage for his patient or may otherwise vary conditions of use from those approved in package insert without informing or obtaining approval of Food and Drug Administration. U. S. v. Evers, M.D.Ala. 1978, 453 F.Supp. 1141, affirmed 643 F.2d 1043.

A physician must be free to use a drug for an indication not in the package insert when such usage is part of the practice of medicine and for the benefit of the patient. U. S. v. Evers, M.D.Ala.1978, 453 F.Supp. 1141, affirmed 643 F.2d 1043.

50. Dangerous when used as prescribed

Labeling of automatic external defibrillators was not inaccurate or improper such that these devices were misbranded within meaning of Federal Food, Drug and Cosmetic Act section providing that device is misbranded if it is dangerous to health when used in dosage or manner or with frequency or duration prescribed, recommended or suggested in the labeling thereof. U.S. v. Laerdal Mfg. Corp., D.Or.1994, 853 F.Supp. 1219, affirmed 73 F.3d 852.

§ 353. Exemptions and consideration for certain drugs, devices, and biological products

[See main volume for text of (a)]

(b) Prescription by physician; exemption from labeling and prescription requirements; misbranded drugs; compliance with narcotic and marihuana laws

(1) A drug intended for use by man which—

(A) because of its toxicity or other potentiality for harmful effect, or the method of its use, or the collateral measures necessary to its use, is not safe for use except under the supervision of a practitioner licensed by law to administer such drug; or

(B) is limited by an approved application under section 355 of this title to use under the professional supervision of a practitioner licensed by law to administer such drug,

(C) Redesignated (B)

[See main volume for text of (1)]

(2) Any drug dispensed by filling or refilling a written or oral prescription of a practitioner licensed by law to administer such drug shall be exempt from the requirements of section 352 of this title, except paragraphs (a), (i)(2) and (3), (k), and (*l*), and the packaging requirements of paragraphs (g), (h), and (p), if the drug bears a label containing the name and address of the dispenser, the serial number and date of the prescription or of its filling, the name of the prescriber, and, if stated in the prescription, the name of the patient, and the directions for use and cautionary statements, if any, contained in such prescription. This exemption shall not apply to any drug dis[illegible] in

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the course of the conduct of a business of dispensing drugs pursuant to diagnosis by mail, or to a drug dispensed in violation of paragraph (1) of this subsection.

(3) The Secretary may by regulation remove drugs subject to section 355 of this title from the requirements of paragraph (1) of this subsection when such requirements are not necessary for the protection of the public health.

(4)(A) A drug that is subject to paragraph (1) shall be deemed to be misbranded if at any time prior to dispensing the label of the drug fails to bear, at a minimum, the symbol "Rx only".

(B) A drug to which paragraph (1) does not apply shall be deemed to be misbranded if at any time prior to dispensing the label of the drug bears the symbol described in subparagraph (A).

[See main volume for text of (3) to (5)]

(c) Sales restrictions

(1) No person may sell, purchase, or trade or offer to sell, purchase, or trade any drug sample. For purposes of this paragraph and subsection (d) of this section, the term "drug sample" means a unit of a drug, subject to subsection (b) of this section, which is not intended to be sold and is intended to promote the sale of the drug. Nothing in this paragraph shall subject an officer or executive of a drug manufacturer or distributor to criminal liability solely because of a sale, purchase, trade, or offer to sell, purchase, or trade in violation of this paragraph by other employees of the manufacturer or distributor.

(2) No person may sell, purchase, or trade, offer to sell, purchase, or trade, or counterfeit any coupon. For purposes of this paragraph, the term "coupon" means a form which may be redeemed, at no cost or at a reduced cost, for a drug which is prescribed in accordance with subsection (b) of this section.

(3)(A) No person may sell, purchase, or trade, or offer to sell, purchase, or trade, any drug—

(i) which is subject to subsection (b) of this section, and

(ii)(I) which was purchased by a public or private hospital or other health care entity, or

(II) which was donated or supplied at a reduced price to a charitable organization described in section 501(c)(3) of Title 26.

(B) Subparagraph (A) does not apply to—

(i) the purchase or other acquisition by a hospital or other health care entity which is a member of a group purchasing organization of a drug for its own use from the group purchasing organization or from other hospitals or health care entities which are members of such organization,

(ii) the sale, purchase, or trade of a drug or an offer to sell, purchase, or trade a drug by an organization described in subparagraph (A)(ii)(II) to a nonprofit affiliate of the organization to the extent otherwise permitted by law,

(iii) a sale, purchase, or trade of a drug or an offer to sell, purchase, or trade a drug among hospitals or other health care entities which are under common control,

(iv) a sale, purchase, or trade of a drug or an offer to sell, purchase, or trade a drug for emergency medical reasons, or

(v) a sale, purchase, or trade of a drug, an offer to sell, purchase, or trade a drug, or the dispensing of a drug pursuant to a prescription executed in accordance with subsection (b) of this section.

For purposes of this paragraph, the term "entity" does not include a wholesale distributor of drugs or a retail pharmacy licensed under State law and the term "emergency medical reasons" includes transfers of a drug between health care entities or from a health care entity to a retail pharmacy undertaken to alleviate temporary shortages of the drug arising from delays in or interruptions of regular distribution schedules.

(d) Distribution of drug samples

(1) Except as provided in paragraphs (2) and (3), no person may distribute any drug sample. For purposes of this subsection, the term "distribute" does not include the providing of a drug sample to a patient by a—

(A) practitioner licensed to prescribe such drug,

(B) health care professional acting at the direction and under the supervision of such a practitioner, or

(C) pharmacy of a hospital or of another health care entity that is acting at the direction of such a practitioner and that received such sample pursuant to paragraph (2) or (3).

(2)(A) The manufacturer or authorized distributor of record of a drug subject to subsection (b) of this section may, in accordance with this paragraph, distribute drug samples by mail or common carrier to practitioners licensed to prescribe such drugs or, at the request of a licensed practitioner, to pharmacies of hospitals or other health care entities. Such a distribution of drug samples may only be made—

(i) in response to a written request for drug samples made on a form which meets the requirements of subparagraph (B), and

(ii) under a system which requires the recipient of the drug sample to execute a written receipt for the drug sample upon its delivery and the return of the receipt to the manufacturer or authorized distributor of record.

(B) A written request for a drug sample required by subparagraph (A)(i) shall contain—

(i) the name, address, professional designation, and signature of the practitioner making the request,

(ii) the identity of the drug sample requested and the quantity requested,

(iii) the name of the manufacturer of the drug sample requested, and

(iv) the date of the request.

(C) Each drug manufacturer or authorized distributor of record which makes distributions by mail or common carrier under this paragraph shall maintain, for a period of 3 years, the request forms submitted for such distributions and the receipts submitted for such distributions and shall maintain a record of distributions of drug samples which identifies the drugs distributed and the recipients of the distributions. Forms, receipts, and records required to be maintained under this subparagraph shall be made available by the drug manufacturer or distributor to Federal and State officials engaged in the regulation of drugs and in the enforcement of laws applicable to drugs.

(3) The manufacturer or distributor of a drug subject to subsection (b) of this section may, by means other than mail or common carrier, distribute drug samples only if the manufacturer or distributor makes the distributions in accordance with subparagraph (A) and carries out the activities described in subparagraphs (B) through (F) as follows:

(A) Drug samples may only be distributed—

(i) to practitioners licensed to prescribe such drugs if they make a written request for the drug samples, or

(ii) at the written request of such a licensed practitioner, to pharmacies of hospitals or other health care entities.

A written request for drug samples shall be made on a form which contains the practitioner's name, address, and professional designation, the identity of the drug sample requested, the quantity of drug samples requested, the name of the manufacturer or distributor of the drug sample, the date of the request and signature of the practitioner making the request.

(B) Drug manufacturers or authorized distributors of record shall store drug samples under conditions that will maintain their stability, integrity, and effectiveness and will assure that the drug samples will be free of contamination, deterioration, and adulteration.

(C) Drug manufacturers or authorized distributors of record shall conduct, at least annually, a complete and accurate inventory of all drug samples in the possession of representatives of the manufacturer or distributor. Drug manufacturers or authorized distributors of record shall maintain lists of the names and address of each of their representatives who distribute drug samples and of the sites where drug samples are stored. Drug manufacturers or authorized bu-

tors of record shall maintain records for at least 3 years of all drug samples distributed, destroyed, or returned to the manufacturer or distributor, of all inventories maintained under this subparagraph, of all thefts or significant losses of drug samples, and of all requests made under subparagraph (A) for drug samples. Records and lists maintained under this subparagraph shall be made available by the drug manufacturer or distributor to the Secretary upon request.

(D) Drug manufacturers or authorized distributors of record shall notify the Secretary of any significant loss of drug samples and any known theft of drug samples.

(E) Drug manufacturers or authorized distributors of record shall report to the Secretary any conviction of their representatives for violations of subsection (c)(1) of this section or a State law because of the sale, purchase, or trade of a drug sample or the offer to sell, purchase, or trade a drug sample.

(F) Drug manufacturers or authorized distributors of record shall provide to the Secretary the name and telephone number of the individual responsible for responding to a request for information respecting drug samples.

(e) Wholesale distributors; guidelines for licensing; definitions

(1)(A) Each person who is engaged in the wholesale distribution of a drug subject to subsection (b) of this section and who is not the manufacturer or an authorized distributor of record of such drug shall, before each wholesale distribution of such drug (including each distribution to an authorized distributor of record or to a retail pharmacy), provide to the person who receives the drug a statement (in such form and containing such information as the Secretary may require) identifying each prior sale, purchase, or trade of such drug (including the date of the transaction and the names and addresses of all parties to the transaction).

(B) Each manufacturer of a drug subject to subsection (b) of this section shall maintain at its corporate offices a current list of the authorized distributors of record of such drug; and

(2)(A) No person may engage in the wholesale distribution in interstate commerce of drugs subject to subsection (b) of this section in a State unless such person is licensed by the State in accordance with the guidelines issued under subparagraph (B).

(B) The Secretary shall by regulation issue guidelines establishing minimum standards, terms, and conditions for the licensing of persons to make wholesale distributions in interstate commerce of drugs subject to subsection (b) of this section. Such guidelines shall prescribe requirements for the storage and handling of such drugs and for the establishment and maintenance of records of the distributions of such drugs.

(3) For the purposes of this subsection and subsection (d) of this section—

(A) the term "authorized distributors of record" means those distributors with whom a manufacturer has established an ongoing relationship to distribute such manufacturer's products, and

(B) the term "wholesale distribution" means distribution of drugs subject to subsection (b) of this section to other than the consumer or patient but does not include intracompany sales and does not include distributions of drugs described in subsection (c)(3)(B) of this section.

(f) Veterinary prescription drugs

(1)(A) A drug intended for use by animals other than man, other than a veterinary feed directive drug intended for use in animal feed or an animal feed bearing or containing a veterinary feed directive drug, which—

(i) because of its toxicity or other potentiality for harmful effect, or the method of its use, or the collateral measures necessary for its use, is not safe for animal use except under the professional supervision of a licensed veterinarian, or

(ii) is limited by an approved application under subsection (b) of section 512 to use under the professional supervision of a licensed veterinarian,

shall be dispensed only by or upon the lawful written or oral order of a licensed veterinarian in the course of the veterinarian's professional practice.

(B) For purposes of subparagraph (A), an order is lawful if the order—

(i) is a prescription or other order authorized by law,

(ii) is, if an oral order, promptly reduced to writing by the person lawfully filling the order, and filed by that person, and

(iii) is refilled only if authorized in the original order or in a subsequent oral order promptly reduced to writing by the person lawfully filling the order, and filed by that person.

(C) The act of dispensing a drug contrary to the provisions of this paragraph shall be deemed to be an act which results in the drug being misbranded while held for sale.

(2) Any drug when dispensed in accordance with paragraph (1) of this subsection—

(A) shall be exempt from the requirements of section 352 of this title, except paragraphs (a), (g), (h), (i)(2), (i)(3), and (p) of such section, and

(B) shall be exempt from the packaging requirements of paragraphs (g), (h), and (p) of such section, if—

(i) when dispensed by a licensed veterinarian, the drug bears a label containing the name and address of the practitioner and any directions for use and cautionary statements specified by the practitioner, or

(ii) when dispensed by filling the lawful order of a licensed veterinarian, the drug bears a label containing the name and address of the dispenser, the serial number and date of the order or of its filling, the name of the licensed veterinarian, and the directions for use and cautionary statements, if any, contained in such order.

The preceding sentence shall not apply to any drug dispensed in the course of the conduct of a business of dispensing drugs pursuant to diagnosis by mail.

(3) The Secretary may by regulation exempt drugs for animals other than man subject to section 512 from the requirements of paragraph (1) when such requirements are not necessary for the protection of the public health.

(4) A drug which is subject to paragraph (1) shall be deemed to be misbranded if at any time prior to dispensing its label fails to bear the statement "Caution: Federal law restricts this drug to use by or on the order of a licensed veterinarian.". A drug to which paragraph (1) does not apply shall be deemed to be misbranded if at any time prior to dispensing its label bears the statement specified in the preceding sentence.

(g) Combinations of drugs, devices, or biological products

(1) The Secretary shall designate a component of the Food and Drug Administration to regulate products that constitute a combination of a drug, device, or biological product. The Secretary shall determine the primary mode of action of the combination product. If the Secretary determines that the primary mode of action is that of—

(A) a drug (other than a biological product), the persons charged with premarket review of drugs shall have primary jurisdiction,

(B) a device, the persons charged with premarket review of devices shall have primary jurisdiction, or

(C) a biological product, the persons charged with premarket review of biological products shall have primary jurisdiction.

(2) Nothing in this subsection shall prevent the Secretary from using any agency resources of the Food and Drug Administration necessary to ensure adequate review of the safety, effectiveness, or substantial equivalence of an article.

(3) The Secretary shall promulgate regulations to implement market clearance procedures in accordance with paragraphs (1) and (2) not later than 1 year after November 28, 1990.

(4) As used in this subsection:

(A) The term "biological product" has the meaning given the term in section 262(i) of Title 42.

(B) The term "market clearance" includes—

(i) approval of an application under section 355, 357, 360e, or 360j(g),

(ii) a finding of substantial equivalence under this subchapter, and

(iii) approval of a biologics license application under subsection (a) of section 262 of Title 42.

(As amended Apr. 22, 1988, Pub.L. 100–293, §§ 4 to 6, 102 Stat. 96 to 98; Nov. 16, 1988, Pub.L. 100–670, Title I, § 105, 102 Stat. 3983; Nov. 28, 1990, Pub.L. 101–629, § 16(a), 104 Stat. 4526; Aug. 17, 1991, Pub.L. 102–108, § 2(d), 105 Stat. 550; June 16, 1992, Pub.L. 102–300, § 6(d), 106 Stat. 240; Aug. 26, 1992, Pub.L. 102–353, §§ 2(a) to (c), 4, 106 Stat. 941, 942; Oct. 9, 1996, Pub.L. 104–250, § 5(a), 110 Stat. 3155; Nov. 21, 1997, Pub.L. 105–115, Title I, §§ 123(e), 126(a), (c)(1), (2), 111 Stat. 2324, 2327, 2328.)

Enactment of Subsec. (e)(2)(A)

Pub.L. 100–293, § 8(b)(2), Apr. 22, 1988, 102 Stat. 100, set out as a note below, provided that the Secretary of Health and Human Services by regulation issue the guidelines required by subsec. (e)(2)(B) of this section not later than 180 days after Apr. 22, 1988, and subsec. (e)(2)(A) of this section take effect upon the expiration of 2 years after the date such regulations are promulgated and take effect.

HISTORICAL AND STATUTORY NOTES

References in Text

Title 26, referred to in subsec. (c)(3)(A)(ii)(II), was in the original a reference to the Internal Revenue Code of 1954. Section 2 of Pub.L. 99–514, set out as a note preceding section 1 of Title 26, redesignated the Internal Revenue Code of 1954 as the Internal Revenue Code of 1986 and provided that any reference to the 1954 Code be deemed a reference to the 1986 Code.

Codification

Section 126(c)(2) of Pub.L. 105–115, which directed that subsec. (b)(3) be amended by striking "section 352(d) and", was executed by substituting "section 355 of this title" for "sections 352(d) and 355 of this title", as the probable intent of Congress.

1997 Amendments

Subsec. (b)(1)(A). Pub.L. 105–115, § 126(c)(1), redesignated former subpars. (B) and (C) as (A) and (B), respectively, and struck out former subpar. (A), which read: "is a habit-forming drug to which section 352(d) of this title applies; or".

Subsec. (b)(3). Pub.L. 105–115, § 126(c)(2), substituted "section 355 of this title" for "sections 352(d) and 355 of this title". See Codification note under this section.

Subsec. (b)(4). Pub.L. 105–115, § 126(a), rewrote par. (4), which formerly read: "A drug which is subject to paragraph (1) of this subsection shall be deemed to be misbranded if at any time prior to dispensing its label fails to bear the statement 'Caution: Federal law prohibits dispensing without prescription'. A drug to which paragraph (1) of this subsection does not apply shall be deemed to be misbranded if at any time prior to dispensing its label bears the caution statement quoted in the preceding sentence.".

Subsec. (g)(4)(A). Pub.L. 105–115, § 123(e)(1), substituted "section 262(i)" for "section 262(a)" and made a technical correction to directory language, requiring no change in text.

Subsec. (g)(4)(B)(iii). Pub.L. 105–115, § 123(e)(2), substituted "biologics license application under subsection (a)" for "product or establishment license under subsection (a) or (d)".

1992 Amendments

Subsec. (d)(1). Pub.L. 102–353, § 4(1), added sentence directing that the term "distribute" does not include the providing of a drug sample by practitioners, health care professionals, and pharmacies.

Subsec. (d)(2). Pub.L. 102–353, § 4(2), substituted "authorized distributor of record" for "distributor" wherever appearing.

Subsec. (d)(3). Pub.L. 102–353, § 4(2), substituted "authorized distributor of record" for "distributor" and "authorized distributors of record" for "distributors", respectively, wherever appearing.

Subsec. (e)(1). Pub.L. 102–353, § 4(3), designated the first sentence of existing par. (1) as subpar. (A) and the second sentence of existing par. (1) as subpar. (B), added requirements that, before each wholesale distribution of a drug to an authorized distributor of record or to a retail pharmacy, persons engaged the wholesale distribution of drugs provide to the person who receives the drug a statement identifying each prior sale, purchase, or trade of such drug, and substituted reference to "authorized distributors of record" for "authorized distributors".

Subsec. (e)(2)(A). Pub.L. 102–353, § 2(a), effective for the period through September 13, 1994, inserted "or has registered with the Secretary in accordance with paragraph (3)". See Effective and Termination Date of 1992 Amendments note set out under this section.

Subsec. (e)(3). Pub.L. 102–353, § 2(b), effective for the period through September 13, 1994, added par. (3). Former par. (3) was redesignated (4). See Effective and Termination Date of 1992 Amendments note set out under this section.

Subsec. (e)(4). Pub.L. 102–353, § 2(b), effective for the period through September 13, 1994, redesignated par. (3) as (4). See Effective and Termination Date of 1992 Amendments note set out under this section.

Pub.L. 102–353, § 4(4), inserted "and subsection (d) of this section" after "For purposes of this subsection".

Subsec. (f)(1)(B). Pub.L. 102–353, § 2(c), directed that "an order" be substituted for "and order", resulting in no change in the text as codified.

SESSION OF 1999

SUPPLEMENTAL NOTE ON SENATE BILL NO. 267

As Amended by Senate Committee on
Public Health and Welfare

Brief*

S.B. 267 amends five of the statutes in the Pharmacy Act of the State of Kansas to redefine the terms, "prescription-only drug" and "retail dealer"; to add to the grounds for which the Board of Pharmacy may take disciplinary action against a licensed pharmacist; to allow the Board to temporarily suspend or limit the license of a pharmacist without notice and hearing if the Board has cause to believe grounds exist for disciplinary action and that the continued practice of the licensee constitutes an eminent danger to the public health and safety; to redefine the reference to the type of drugs that may be distributed to veterinarians; and to make changes in the reference to prescription-only drugs as the term is used to define the type of drugs that may not be sold by the holder of a retail dealers permit issued by the Board.

S.B. 267 also adds a new statute that is made a part of and supplemental to the Pharmacy Act of the State of Kansas that gives the Board the power to issue subpoenas and compel the attendance of witnesses in investigative and disciplinary matters before the Board of Pharmacy.

The Senate Committee amendments to K.S.A. 1998 Supp. 65-1627 do not change existing law. They reconcile two versions of the statute enacted in 1998, one of which, K.S.A. 1998 Supp. 65-1627i, is repealed by S.B. 267.

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*Supplemental notes are prepared by the Legislative Research Department and do not express legislative intent. The supplemental note and fiscal note for this bill may be accessed on the Internet at http://www.ink.org/public/legislative/bill_search.html.

Background

The introduction of S.B. 267 was requested by a representative of the Board of Pharmacy who also supported passage of the bill during the Senate Committee hearing. The Committee was told the change in definition of those drugs that require a prescription has been made in the federal Food, Drug and Cosmetic Act and will be phased in for the labeling of such drugs over a three-year period. The Senate Committee amendment was suggested as a cleanup of the Pharmacy Act of the State of Kansas.

The fiscal note on S.B. 267 states there will be no fiscal impact from passage of S.B. 267.

Testimony for the
House Health and Human Services Committee
SENATE BILL 128

Barb Hinton, Legislative Post Auditor
March 10, 1999

Mr. Chairman and members of the Committee, I'm appearing before your Committee today on behalf of Senate Bill 128. This bill, as introduced by the Legislative Post Audit Committee, would clearly specify the authority the Department of Health and Environment has in applying fines for violations of the State's child-care regulations.

This legislation addresses a recommendation we made in our performance audit report, *Reviewing the Department of Health and Environment's Regulation of Child Care Facilities and Family Day Care Homes*. In that audit, we noted that State law subjects child-care providers to fines when they've violated regulations that "significantly and adversely" affect the health, safety, or sanitation of children.

In the cases we reviewed, we found examples where serious violations had occurred, and where child-care providers sometimes hadn't corrected those violations even after repeated warnings and re-inspections. For these situations, the law wasn't clear about whether the maximum fine that could be levied was $500 per day, per violation, or per incident.

In the few instances we saw where fines were assessed, the amount of fine levied generally was per "provider." Unfortunately, this approach creates little incentive for problem child-care providers to come into compliance. For example, even after the Department found multiple and repeated violations by a provider in inspection after inspection, over a long period of time, it was applying the maximum $500 fine to the "provider." When we looked at examples of other State agencies' fining authority, we found that most were for each violation, not each violator.

The bill before you would allow (but not require) the Department to assess a civil fine of up to $500 for <u>each</u> violation that could significantly affect children's safety or well-being. For continuing violations, <u>every day</u> the violation continues counts as a separate violation.

HHS
3-10-99
Atch #2

I've included three brief attachments with my testimony that can provide your Committee with additional information in considering this bill:

- a copy of a letter from former-Secretary Mitchell supporting the legislation
- a summary of the fining authority we identified for a variety of other State agencies (this list was not meant to be all-inclusive)
- a summary of our audit findings in this area, including the types of violations being identified. Some of those violations appeared to be relatively minor, while others appeared to pose significant risks for children.

Thank you for giving me the opportunity to appear before you today.

KANSAS
DEPARTMENT OF HEALTH & ENVIRONMENT
BILL GRAVES, GOVERNOR
Gary R. Mitchell, Secretary

December 10, 1998

Barbara J. Hinton
Legislative Post Auditor
Mercantile Bank Tower
Jackson Street, Suite 1200
Topeka, Kansas 66612-2212

Dear Ms. Hinton:

Thank you for allowing us time to review the draft legislation being proposed by the Legislative Post Audit Committee regarding an audit of the Child Care Regulation in 1997.

We find the language of the proposed bill appropriate to clarify whether the fine amount applies on a per provider, per violation, and per day basis.

Should you have any further questions or concerns, please feel free to contact me at 296-0461.

Sincerely,

Gary R. Mitchell
Secretary

c: grm hinton

Capitol Tower
400 SW 8th Street, Suite 200
(785) 296-0461

Topeka, KS 66603-3930
FAX (785) 368-6368

Examples of other agencies' fining authority:

State Agency	Type of Fraud/Violation	Fine or Penalty Provision
Board of Accountancy	Fraud or deceit in obtaining a certificate to practice accounting or in practicing accounting; willful violation of rules of professional conduct, etc.	...an administrative fine not exceeding $1,000, for **any one or any combination of the following causes**...
Board of Cosmetology	Failure to comply with any provision of the Act, with rules and regulations of the Board, etc.	...a fine not to exceed $1,000 **per violation**...
Securities Commissioner	Violation of the Securities Act or any rule, regulation, or order of the Commissioner.	...a civil penalty up to a maximum of $5,000 for **each** violation
Board of Healing Arts	Violations of the Kansas Healing Arts Act *(misdemeanor penalties)*	...a fine of not less than $50 nor more than $200 **for each separate** offense...
	Violations of the Kansas Healing Arts Act *(administrative fines)*	...a fine...not to exceed $5,000 for the first violation, $10,000 for the second violation, and $15,000 for the third violation and for **each** subsequent violation
KCC (Gas Pipelines)	Violation of any rule or regulation adopted pursuant to the Gas Pipeline Safety Act, or any regulation adopted by the KCC.	...a civil penalty not to exceed $25,000 **for each violation for each day the violation persists**. not to exceed $500,000 for any related series of violations.
KCC (Common Carriers)	Violation of any provision of the Motor Carrier Act, failure to uphold KCC order or final judgment by court.	...for **every such** violation, failure, or refusal, forfeit and pay to the State Treasurer...not less than $100 and not more than $1,000 for such offense.
KDHE (Hazardous Waste)	Violation of any provision of the Hazardous Waste Act.	...in the case of a continuing violation, **every day such violation continues shall be deemed a separate violation**.

Reviewing the Department of Health and Environment's Regulation of Child Care Facilities and Family Day Care Homes

Audit finding: KDHE can fine providers up to $500 for violating child care regulations that "affect significantly and adversely the health, safety, or sanitation" of children. However, State law doesn't specify whether this fine applies on a per-day, per-violation, or per-incident basis. KDHE is applying that fine on a per-provider basis.

Impact: Reinspections sometimes showed homes and facilities didn't take corrective action, and continued to violate child care regulations. In these cases, providers have little incentive to come into compliance, and KDHE has little recourse to force compliance. Children's safety and well-being can be affected.

Draft legislation: Allows KDHE to assess a civil fine of up to $500, after proper notice and hearing, for each violation that could significantly affect children's safety or well-being. For continuing violations, every day the violation continues counts as a separate violation. (KDHE still has discretion as to when to assess a fine, and by how much.)

We reviewed 40 "enforcement" actions taken when violations were identified during an annual licensing inspection or complaint investigation. Most violations resulted in "notices of noncompliance" (KDHE advised provider of problem, gave 5 days to correct). Each notice can contain multiple violations. The most common ones we saw:

- **Violations regarding treatment of children.** Examples: Corporal punishment. Verbal abuse. Inappropriate discipline methods (withholding food from children as punishment).

- **Violations regarding the provider's "environment."** Examples: Matches, knives, cleaning products, etc., within children's reach. Dangerous equipment in children's play area. Guns not locked away; medication accessible. Outlets uncovered. Stairs not gated. Bannister rails too wide.

- **Violations regarding child supervision.** Examples: Provider caring for more children than authorized. Children playing outside unsupervised. Child not supervised in bathroom. Infants in playpen outside provider's hearing range. Infant left 1 hour without toys.

- **Violations regarding paperwork.** Examples: No background checks for employees. No proof of provider's training and qualifications. Missing health assessments for children and provider. Children had no paperwork, and provider didn't know their last name.

In 8 instances, a reinspection showed the provider hadn't corrected one or more of the violations identified. These violations were:

1. not supervising children
2. stairway not gated
3. unanchored swing set, hazardous personal products within reach, missing paperwork
4. children sleeping in basement
5. children left outside unsupervised
6. missing training docs and health assessments
7. missing KBI report, licensing fee not paid, relicensing paperwork not completed
8. no working telephone on premises

STATE OF KANSAS

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KANSAS SENTENCING COMMISSION

SENATE CHAMBER

TESTIMONY BEFORE THE HOUSE HEALTH AND HUMAN SERVICES COMMITTEE ON SENATE BILL 128

Senator Lana Oleen, Vice-Chair
Legislative Post Audit Committee
March 10, 1999, 1:30 p.m., Room 423-S

Mister Chairman and members of the Committee, thank you for allowing me the opportunity to address you on Senate Bill 128. I was Chair of the Legislative Post Audit Committee when this bill was approved for introduction, and I'm speaking on behalf of the Committee in support of this bill.

This legislation addresses a recommendation Legislative Post Audit made in its report about the Department of Health and Environment's regulation of child-care providers. That recommendation called for the Legislature to clarify State law regarding civil fines for providers who violate child-care regulations.

At issue is whether the maximum fine the Department can levy for serious or repeat violations that affect children's health and safety is $500 per day, per violation, or per incident. This bill would allow that fine to be levied for each violation. For continuing violations, every day the violation continues counts as a separate violation.

The Post Audit Committee introduced this bill so that the Department has both the legislative guidance and the enforcement tools it needs to help bring problem providers into compliance. We think this bill also can help make sure that children in State-licensed child-care facilities are safer from harm.

I am supportive of this bill, and would urge the Committee to give it favorable consideration.

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