Session of 2007

HOUSE BILL No. 2392

By Committee on Health and Human Services

2-5

AN ACT concerning registration requirements of pharmacy and wholesale distribution of drugs; amending K.S.A. 65-1655 and K.S.A. 2006 Supp. 65-1643 and repealing the existing sections.

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

Section 1. K.S.A. 2006 Supp. 65-1643 is hereby amended to read as follows: 65-1643. 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 mid-level 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 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.

(j) For any person to operate a veterinary medical teaching hospital pharmacy without first having obtained a registration to do so from the board. Such registration shall be subject to the provisions of K.S.A. 65-1662 and amendments thereto and any rules and regulations adopted pursuant thereto.

(k) For any person to sell or distribute in a pharmacy a controlled substance designated in subsection (e) or (f) of K.S.A. 65-4113, and amendments thereto, unless:

(1) (A) Such controlled substance is sold or distributed by a licensed pharmacist, a registered pharmacy technician or a pharmacy intern or clerk supervised by a licensed pharmacist; and

(B) any person purchasing, receiving or otherwise acquiring any such controlled substance produces a photo identification showing the date of birth of the person and signs a log. The log or database required by the board shall be available for inspection during regular business hours to the board of pharmacy and any law enforcement officer; or

(2) there is a lawful prescription.

(l) For any person to sell or distribute in a pharmacy four or more packages or containers of any controlled substance designated in subsection (e) or (f) of K.S.A. 65-4113, and amendments thereto, to a specific customer within any seven-day period.

(m) Except for the wholesale distribution by manufacturers of a prescription drug that has been delivered into commerce pursuant to an application approved under federal law by the food and drug administration, for any person to engage in the manufacture, repackaging, sale, delivery or holding or offering for sale any prescription drug or device that is adulterated, misbranded, counterfeit, suspected of being counterfeit or has otherwise been rendered unfit for distribution or wholesale distribution;

(n) Except for the wholesale distribution by manufacturers of a prescription drug that has been delivered into commerce pursuant to an application approved under federal law by the food and drug administration, for any person to engage in the adulteration, misbranding or counterfeiting of any prescription drug or device;

(o) For any person to receive any prescription drug or device that is adulterated, misbranded, stolen, obtained by fraud or deceit, counterfeit, or suspected of being counterfeit, or the delivery or proffered delivery of such prescription drug or device for pay or otherwise;

(p) For any person to engage in the alteration, mutilation, destruction, obliteration or removal of the whole or any part of the product labeling of a prescription drug or device or the commission of any other

act with respect to a prescription drug or device that results in the prescription drug or device being misbranded;

(q) For any person to engage in the forging, counterfeiting, simulating or falsely representing of any prescription drug or device without the authority of the manufacturer, or using any mark, stamp, tag, label or other identification device without the authorization of the manufacturer;

(r) For any person to purchase or receive a prescription drug or device from a person that is not licensed to wholesale distribute prescription drugs or devices to that purchaser or recipient;

(s) For any person to sell or transfer a prescription drug or device to a person who is not legally authorized to receive a prescription drug or device;

(t) For any person to fail to maintain or provide records as required by this act and rules and regulations adopted thereunder;

(u) For any person to provide the board or any of its representatives or any state or federal official with false or fraudulent records or making false or fraudulent statements regarding any matter within the provisions of this act and rules and regulations adopted thereunder;

(v) For any person to engage in the wholesale distribution of any prescription drug or device that was:

(1) Purchased by a public or private hospital or other health care entity;

(2) donated or supplied at a reduced price to a charitable organization; or

(3) stolen or obtained by fraud or deceit.

(w) For any person to fail to obtain a license or operating without a valid license when a license is required;

(x) For any person to obtain or attempt to obtain a prescription drug or device by fraud, deceit, misrepresentation or engaging in misrepresentation or fraud in the distribution or wholesale distribution of a prescription drug or device;

(y) For any person to distribute a prescription drug or device to the patient without a prescription or prescription order from a practitioner licensed by law to use or prescribe the prescription drug or device;

(z) For any person to fail to obtain, authenticate or pass on a pedigree when required under these rules and regulations adopted thereunder;

(aa) For any person to receive a prescription drug or device pursuant to a wholesale distribution without first receiving a pedigree, when required, that was attested to as accurate and complete by the wholesale distributor;

(bb) For any person to distribute or distribute by wholesale a prescription drug or device that was previously dispensed by a pharmacy or distributed by a practitioner;

(cc) For any person to fail to report any prohibited act as listed in these rules and regulations adopted thereunder; or

(dd) For any person to fail to exercise due diligence as provided in K.S.A. 65-1655(i), and amendments thereto, (due diligence) of these regulations.

Sec. 2. K.S.A. 65-1655 is hereby amended to read as follows: 65-1655. (a) *For the purposes of this act:*

(1) "Adulterated" means: a drug or device shall be deemed to be adulterated:

(A) If:

(i) It consists in whole or in part of any filthy, putrid, or decomposed substance; or

(ii) it has been produced, prepared, packed, or held under unsanitary conditions whereby it may have been contaminated with filth, or whereby it may have been rendered injurious to health; or if the methods used in, or the facilities or controls used for, its manufacture, processing, packing, or holding do not conform to or are not operated or administered in conformity with current good manufacturing practices to assure that the drug or device meets the requirements of this paragraph as to safety and has the identity and strength, and meets the quality and purity characteristics that it purports or is represented to possess; or

(iii) its container is composed, in whole or in part, of any poisonous or deleterious substance that may render the contents injurious to health; or

(iv) it bears or contains, for purposes of coloring only, a color additive that is unsafe within the meaning of the federal food, drug and cosmetic act (federal act); or it is a color additive, the intended use of which is for purposes of coloring only, and is unsafe within the meaning of the federal act;

(B) if it purports to be or is represented as a drug, the name of which is recognized in an official compendium, and its strength differs from, or its quality or purity falls below, the standard set forth in the compendium. Such a determination as to strength, quality, or purity shall be made in accordance with the tests or methods of assay set forth in the compendium, or in the absence of or inadequacy of these tests or methods of assay, those prescribed under authority of the federal act. No drug defined in an official compendium shall be deemed to be adulterated under this paragraph because it differs from the standard of strength, quality, or purity therefore set forth in the compendium, if its difference in strength, quality, or purity from that standard is plainly stated on its label. Whenever a drug is recognized in both the United States pharmacopeia (USP) and the homeopathic pharmacopoeia of the United States it shall be subject to the requirements of the USP unless it is labeled and offered for sale as a

homeopathic drug, in which case it shall be subject to the homeopathic pharmacopoeia of the United States and not those of the USP;

(C) if it is not subject to paragraph (2) and its strength differs from, or its purity or quality falls below, that which it purports or is represented to possess; or

(D) if it is a drug and any substance has been mixed or packed therewith so as to reduce its quality or strength; or substituted wholly or in part therefore.

(2) "Authenticate" means to affirmatively verify before any wholesale distribution that each transaction listed on the pedigree and any other accompanying documentation has occurred, in accordance with the rules of the board.

(3) "Authorized distributor of record" means a wholesale distributor with whom a manufacturer has established an ongoing relationship to distribute the manufacturer's prescription drug. An ongoing relationship is deemed to exist between such wholesale distributor and a manufacturer when the wholesale distributor, including any affiliated group of the wholesale distributor, as defined in section 1504 of the internal revenue code, complies with any one of the following: (1) The wholesale distributor has a written agreement currently in effect with the manufacturer evidencing such ongoing relationship; and (2) the wholesale distributor is listed on the manufacturer's current list of authorized distributors of record, which is updated by the manufacturer on no less than a monthly basis.

(4) "Centralized prescription processing" means the processing by a pharmacy of a request from another pharmacy to fill or refill a prescription drug order or to perform processing functions such as dispensing, drug regimen review (DRR), claims adjudication, refill authorizations, and therapeutic interventions.

(5) "Closed pharmacy" means a pharmacy that purchases drugs or devices for a limited patient population and is not open for dispensing to the general patient population and cannot operate or be licensed as a wholesale distributor.

(6) "Chain pharmacy warehouse" means a permanent physical location for drugs and devices that acts as a central warehouse and performs intracompany sales and transfers of prescription drugs or devices to chain pharmacies, which are members of the same affiliated group, under common ownership and control. Chain pharmacy warehouses must be licensed as wholesale distributors.

(7) "Co-licensee" means a pharmaceutical manufacturer that has entered into an agreement with another pharmaceutical manufacturer to engage in a business activity or occupation related to the manufacture or distribution of a prescription drug and the national drug code on the drug

product label shall be used to determine the identity of the drug manufacturer.

(8) "Contraband drug" means a drug which is counterfeit, stolen, misbranded, obtained by fraud, purchased by a nonprofit institution for its own use and placed in commerce in violation of the own use agreement for that drug, or for which a pedigree (if required) does not exist, or for which the pedigree in existence has been forged, counterfeited, falsely created, or contains any altered, false, or misrepresented information.

(9) "Counterfeit drug" means a drug which, or the container, shipping container, seal, or product labeling of which, without authorization, bears the trademark, trade name, or other identifying mark, imprint, or device, or any likeness thereof, of a manufacturer, processor, packer, or distributor other than the person or persons who in fact manufactured, processed, packed, distributed, or wholesale distributed such drug and which thereby falsely purports or is represented to be the product of, or to have been packed, distributed, or wholesale distributed by, such other manufacturer, processor, packer, or distributor.

(10) "Designated representative" means an individual designated by the wholesale distributor who will serve as the responsible individual of the wholesale distributor with the board who is actively involved in and aware of the actual daily operation of the wholesale distributor.

(11) "Distribute" or "distribution" means to sell, offer to sell, deliver, offer to deliver, broker, give away, or transfer a drug, whether by passage of title, physical movement, or both. The term does not include:

(A) To dispense or administer;

(B) delivering or offering to deliver a drug by a common carrier in the usual course of business as a common carrier; or

(C) providing a drug sample to a patient by a practitioner licensed to prescribe such drug; a health care professional acting at the direction and under the supervision of a practitioner; or the 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 in accordance with the act and regulations to administer or dispense.

(12) "Drop shipment" means the sale, by a manufacturer, that manufacturer's co-licensee, that manufacturer's third party logistics provider, or that manufacturer's exclusive distributor, of the manufacturer's prescription drug, to a wholesale distributor whereby the wholesale distributor takes title but not possession of such prescription drug and the wholesale distributor invoices the pharmacy, the chain pharmacy warehouse, or other designated person authorized by law to dispense or administer such prescription drug, and the pharmacy, the chain pharmacy warehouse, or other designated person authorized by law to dispense or administer such prescription drug receives delivery of the prescription drug

directly from the manufacturer, that manufacturer's co-licensee, that manufacturer's third party logistics provider, or that manufacturer's exclusive distributor, of such prescription drug. Drop shipments shall be part of the "normal distribution channel".

(13) "Emergency medical reasons" include, but are not limited to, transfers of a prescription drug between a wholesale distributor or pharmacy to alleviate a temporary shortage of a prescription drug arising from delays in or interruption of regular distribution schedules; sales to nearby emergency medical services, such as ambulance companies and firefighting organizations in the same state or same marketing or service area, or nearby licensed practitioners of prescription drugs for use in the treatment of acutely ill or injured persons; provision of minimal emergency supplies of prescription drugs to nearby nursing homes for use in emergencies or during hours of the day when necessary prescription drugs cannot be obtained; and transfers of prescription drugs by a retail pharmacy to another retail pharmacy to alleviate a temporary shortage.

(14) "Exclusive distributor" means an entity that:

(A) Contracts with a manufacturer to provide or coordinate warehousing, wholesale distribution, or other services on behalf of a manufacturer and who takes title to that manufacturer's prescription drug, but who does not have general responsibility to direct the sale or disposition of the manufacturer's prescription drug;

(B) is licensed as a wholesale distributor under this act; and

(C) to be considered part of the normal distribution channel, must also be an authorized distributor of record.

(15) "FDA" means food and drug administration, a federal agency within the United States department of health and human services, established to set safety and quality standards for drugs, food, cosmetics, and other consumer products.

(16) "Federal act" means the federal food, drug, and cosmetic act.

(17) "Health care entity" means any person that provides diagnostic, medical, surgical, dental treatment, or rehabilitative care but does not include any retail pharmacy or wholesale distributor.

(18) "Immediate container" means a container and does not include package liners.

(19) "Intracompany transaction" means any transaction, or transfer between a division, subsidiary, parent, or affiliated or related company under the common ownership and control of a corporate entity.

(20) "Label" means a display of written, printed, or graphic matter upon the immediate container of any drug or device.

(21) "Manufacturer" means a person licensed or approved by the FDA to engage in the manufacture of drugs and devices.

(22) "Misbranded" means a drug or device shall be deemed to be

misbranded if the label is false or misleading in any particular; or the label does not bear the name and address of the manufacturer, packer, or distributor and does not have an accurate statement of the quantities of the active ingredients in the case of a drug; or the label does not show an accurate monograph for prescription drugs.

(23) "Normal distribution channel" means a chain of custody for a prescription drug that goes from a manufacturer of the prescription drug, the manufacturer's co-licensee, the manufacturer's third-party logistics provider, or the manufacturer's exclusive distributor to:

(A) a wholesale distributor, to a pharmacy to a patient or other designated persons authorized by law to dispense or administer such prescription drug to a patient; or

(B) a wholesale distributor, to a chain pharmacy warehouse to that chain pharmacy warehouse's intracompany pharmacy to a patient or other designated persons authorized by law to dispense or administer such prescription drug to a patient; or

(C) a chain pharmacy warehouse to that chain pharmacy warehouse's intracompany pharmacy to a patient or other designated persons authorized by law to dispense or administer such prescription drug to a patient; or

(D) a pharmacy to a patient;

(E) other designated persons authorized by law to dispense or administer such prescription drug to a patient;

(F) as prescribed by the board's regulations.

(24) "Pedigree" means a statement or record in a written form or electronic form, approved by the board, that records each wholesale distribution of any given prescription drug, excluding veterinary prescription drugs, which leaves the normal distribution channel. The pedigree shall minimally include the following information for each transaction:

(A) The source of the prescription drug, including the name and principal address of the seller;

(B) the proprietary and established name of the prescription drug, the amount of the prescription drug, the national drug code number, its dosage form and dosage strength, the date of the purchase, the sales invoice number, container size, number of containers, expiration date, and lot number or control number of the prescription drug;

(C) the business name and address of each owner of the prescription drug and its shipping information, including the name and address of the facility of each person certifying delivery or receipt of the prescription drug;

(D) information that states that the wholesale distributor has conducted due diligence of the wholesale distributor from which the wholesale distributor purchased; and

(E) a certification from the designated representative of the wholesale distributor that the information contained therein is true and accurate under penalty of perjury.

(F) other items as prescribed by the board's regulations.

(25) "Prescription drug" or "legend drug" means a drug which is required under federal law to be labeled with either of the following statements prior to being dispensed or delivered: (A) "Rx Only"; or (B) "Caution: Federal law restricts this drug to use by, or on the order of, a licensed veterinarian"; or (C) a drug which is required by any applicable federal or state law or rule to be dispensed pursuant only to a prescription drug order or is restricted to use by practitioners only.

(26) "Product labeling" means all labels and other written, printed, or graphic matter upon any article or any of its containers or wrappers, or accompanying such article.

(27) "Repackage" means changing the container, wrapper, quantity, or product labeling of a drug or device to further the distribution of the drug or device.

(28) "Repackager" means a person who repackages.

(29) "Sales unit" means the unit of measure the manufacturer uses to invoice its customer for the particular product.

(30) "Third party logistics provider" means an entity that:

(A) Provides or coordinates warehousing, distribution, or other services on behalf of a manufacturer, but does not take title to the prescription drug or have general responsibility to direct the prescription drug's sale or disposition;

(B) is licensed as a wholesale distributor under this chapter; and

(C) to be considered part of the normal distribution channel, must also be an authorized distributor of record.

(31) "USP standards" means standards published in the current official United States pharmacopeia or national formulary.

(32) "Wholesale distribution" means the distribution of prescription drugs or devices by wholesale distributors to persons other than consumers or patients, and includes the transfer of prescription drugs by a pharmacy to another pharmacy if the value of the goods transferred exceeds 5% of total prescription drug sales revenue of either the transferor or transferee pharmacy during any consecutive 12-month period. Wholesale distribution does not include:

(A) The sale, purchase or trade of a prescription drug or device, an offer to sell, purchase, or trade a prescription drug or device or the dispensing of a prescription drug or device pursuant to a prescription;

(B) the sale, purchase or trade of a prescription drug or device or an offer to sell, purchase, or trade a prescription drug or device for emergency medical reasons;

(C) intracompany transactions, unless in violation of own use provisions;

(D) the sale, purchase or trade of a prescription drug or device or an offer to sell, purchase or trade a prescription drug or device among hospitals, chain pharmacy warehouses, pharmacies or other health care entities that are under common control;

(E) the sale, purchase or trade of a prescription drug or device or the offer to sell, purchase or trade a prescription drug or device by a charitable organization described in 503(c)(3) of the internal revenue code of 1954 to a nonprofit affiliate of the organization to the extent otherwise permitted by law;

(F) the purchase or other acquisition by a hospital or other similar health care entity that is a member of a group purchasing organization of a prescription drug or device for its own use from the group purchasing organization or from other hospitals or similar health care entities that are members of these organizations;

(G) the transfer of prescription drugs or devices between pharmacies pursuant to a centralized prescription processing agreement;

(H) the sale, purchase or trade of blood and blood components intended for transfusion;

(I) the return of recalled, expired, damaged or otherwise non-salable prescription drugs, when conducted by a hospital, health care entity, pharmacy or charitable institution in accordance with the board's regulations; or

(J) the sale, transfer, merger or consolidation of all or part of the business of a retail pharmacy or pharmacies from or with another retail pharmacy or pharmacies, whether accomplished as a purchase and sale of stock or business assets, in accordance with the board's regulations.

(K) the distribution of drug samples by manufacturers' and authorized distributors' representatives;

(L) the sale of minimal quantities of drugs by retail pharmacies to licensed practitioners for office use.

(33) "Wholesale distributor" means any person engaged in wholesale distribution of prescription drugs or devices in or into the state, including but not limited to, manufacturers, repackagers, own-label distributors, private-label distributors, jobbers, brokers, warehouses, including manufacturers' and distributors' warehouses, co-licensees, exclusive distributors, third party logistics providers, chain pharmacy warehouses, and wholesale drug warehouses, independent wholesale drug traders, and retail pharmacies that conduct wholesale distributions. To be considered part of the normal distribution channel, such wholesale distributor must also be an authorized distributor of record.

(b) Wholesale distributors that provide services within this state,

whether the wholesale distributor is located within this state or outside this state, shall be licensed by the board and shall renew their license with the board using an application provided by the board. Wholesale distributors cannot operate from a place of residence. Where wholesale distribution operations are conducted at more than one location, each such location shall be licensed by the board of pharmacy. Manufacturers engaged in wholesale distribution need only satisfy the minimum federal requirements for licensure provided in FDA regulations 21 CFR part 205, and need not demonstrate or submit the following for licensure to provide wholesale distribution services: social security numbers or dates of birth (section (b)(1)(E)); designation of a designated representative (section (b)(1)(C)); a listing of any state licenses, registrations or permits (section (b)(1)(G)); and a copy of the deed, information regarding product liability insurance and a description of import and export activities (section (b)(1)(J, K and L)). The board shall require an applicant for registration to distribute at wholesale any *prescription* drugs under K.S.A. 65-1643 and amendments thereto, or an applicant for renewal of such a registration, to provide the following information:

(1) The name, full business address and telephone number of the applicant;

(2) all trade or business names used by the applicant *which cannot be identical to the name used by another unrelated wholesale distributor licensed to purchase prescription drugs or devices in the state*;

(3) addresses, telephone numbers, and the names of ~~contact persons for all facilities used by the applicant for the storage, handling and~~ *a person(s) to serve as the designated representative for each facility of the wholesale distributor used for the wholesale* distribution of prescription drugs;

(4) the type of ownership or operation of the applicant;

(5) the name of the owner or operator, or both, of the applicant, including:

(A) If a person, the name of the person*, business address, social security number and date of birth*;

(B) if a partnership, the name*, business address, social security number and date of birth* of each partner, and the name of the partnership *and the federal employer identification number*;

(C) if a corporation, the name*, business address, social security number, date of birth* and title of each corporate officer and director, the corporate names and the name of the state of incorporation *federal employer identification number and the name of the parent company, if any; the name, business address, and social security number of each shareholder owning 10% or more of the voting stock of the corporation, including over-the-counter (OTC) stock, unless the stock is traded on a*

major stock exchange and not OTC;

(D) if a sole proprietorship, the full name of the sole proprietor ~~and the name of the business entity; and~~, *business address, social security number and date of birth of the sole proprietor and the name and federal employer identification number of the business entity; and*

(E) if a limited liability company, the name of the limited liability company and federal employer identification number and the name of the state in which the limited liability company was organized.

~~(6)~~ *(F)* such other information as the board deems appropriate. Changes in any information in this ~~subsection (a)~~ *section* shall be submitted to the board as required by such board.

(G) a list of all state and federal licenses, registrations or permits, including the license, registration or permit numbers issued to the wholesale distributor by any other state and federal authority that authorizes the wholesale distributor to purchase, possess and wholesale distribute prescription drugs;

(H) a list of all disciplinary actions by state and federal agencies relating to wholesale distribution against the wholesale distributor as well as any such actions against principals, owners, directors or officers;

(I) a full description of each facility and warehouse, including all locations utilized for prescription drug storage or wholesale distribution, or both. The description should include the following:

(i) Square footage;

(ii) security and alarm system descriptions;

(iii) terms of lease or ownership;

(iv) address; and

(v) temperature and humidity controls.

(J) A copy of the deed for the property on which the wholesale distributor's establishment is located, if the property is owned by the wholesale distributor or a copy of the wholesale distributor's lease for the property on which the establishment is located that has an original term of not less than one calendar year, if the establishment is not owned by the wholesale distributor;

(K) information regarding general and product liability insurance, including copies of relevant policies;

(L) a description of the wholesale distributor's drug import and export activities; and

(M) a copy of the wholesale distributor's written policies and procedures as required in KSA 65-1655 (l), and amendments thereto.

(N) The information collected pursuant to subparagraphs (I) and (M) shall be made available only to the board, a third party recognized by the board, and to state and federal law enforcement officials. The board shall make provisions for protecting the confidentiality of the information col-

lected under this section.

(2) A "surety" bond of not less than $100,000, or other equivalent means of security acceptable to the board or a third party recognized by the board such as insurance, an irrevocable letter of credit or funds deposited in a trust account or financial institution, to secure payment of any administrative penalties imposed by the board and any fees or costs incurred by the board regarding that licensee when those penalties, fees or costs are authorized under state law and the licensee fails to pay 30 days after the penalty, fee or costs becomes final. A separate surety bond or other equivalent means of security is not required for each company's separate locations or for affiliated companies or groups when such separate locations or affiliated companies or groups are required to apply for or renew their wholesale distributor license with the board. The board may make a claim against such bond or other equivalent means of security until one year after the wholesale distributor's license ceases to be valid or until 60 days after any administrative or legal proceeding before or on behalf of the board that involves the wholesale distributor is concluded, including any appeal, whichever occurs later. Manufacturers shall be exempt from securing a "surety" bond or other equivalent means of security acceptable to the board or a third party recognized by the board. The board may waive the bond requirement, if the wholesale distributor has previously obtained a comparable surety bond or other equivalent means of security for the purpose of licensure in another state, where the wholesale distributor possesses a valid license in good standing.

(3) Every wholesale distributor who engages in wholesale distribution shall submit a reasonable fee to be determined by the board.

(4) Each facility that engages in wholesale distribution must undergo an inspection by the board or a third party recognized by the board for the purpose of inspecting the wholesale distribution operations prior to initial licensure and periodically thereafter in accordance with a schedule to be determined by the board but not less than once every three years. Manufacturing facilities are exempt from inspection by the board if the manufacturing facilities are currently registered with the food and drug administration in accordance with section 510 of the federal act.

(5) All wholesale distributors must publicly display or have readily available all licenses and the most recent inspection report administered by the board.

(6) Changes in any information in this section shall be submitted to the board, or to a third party recognized by the board, within 30 days of such change, unless otherwise noted.

(7) Information submitted by the wholesale distributor to the board or a third party recognized by the board that is considered trade secret or proprietary information, as defined under this state's privacy and trade

secret or proprietary statutes, shall be maintained by the board or a third party recognized by the board as private or trade secret or proprietary information and be exempt from public disclosure.

~~(b)~~ *(c) (1)* In reviewing the qualifications for applicants for initial registration or renewal of registration to distribute at wholesale any drugs, the board shall consider the following factors:

~~(1)~~ *(A)* Any convictions of the applicant under any federal, state or local laws relating to drug samples, wholesale or retail drug distribution or distribution of controlled substances;

~~(2)~~ *(B)* any felony convictions of the applicant under federal or state laws;

~~(3)~~ *(C)* the applicant's past experience in the manufacture or distribution of prescription drugs, including controlled substances;

~~(4)~~ *(D)* the furnishing by the applicant of false or fraudulent material in any application made in connection with drug manufacturing or distribution;

~~(5)~~ *(E)* suspension or revocation by federal, state or local government of any license or registration currently or previously held by the applicant for the manufacture or distribution of any drugs, including controlled substances;

~~(6)~~ *(F)* compliance with registration requirements under previously granted registrations, if any;

~~(7)~~ *(G)* compliance with requirements to maintain or make available to the board or to federal state or local law enforcement officials those records required by federal food, drug and cosmetic act, and rules and regulations adopted pursuant thereto; and

~~(8)~~ *(H)* any other factors or qualifications the board considers relevant to and consistent with the public health and safety.

(2) The board shall consider the results of a criminal and financial background check of the applicant, including but not limited to all key personnel involved in the operations of the wholesale distributor, including the most senior person responsible for facility operations, purchasing, and inventory control and the person or persons they report to; and all company officers, key management, principals, and owners with 10% or greater ownership interest in the company, applying to non-publicly held companies only, to determine if an applicant or others associated with the ownership, management, or operations of the wholesale distributor have committed criminal acts that would constitute grounds for denial of licensure. The background check will be conducted in compliance with any applicable state and federal laws, at the applicant's expense, and will be sufficient to include all states of residence since the person has been an adult. Manufacturers shall be exempt from criminal and financial background checks.

(3) The applicant shall provide, and attest to, a statement providing a complete disclosure of any past criminal convictions and violations of the state and federal laws regarding drugs or devices or an affirmation and attestation that the applicant has not been involved in, or convicted of, any criminal or prohibited acts.

~~(c)~~ *(4)* After consideration of the qualifications for applicants for registration to distribute at wholesale any drugs, the board may deny an initial application for registration or application for renewal of a registration if the board determines that the granting of such registration would not be in the public interest. The authority of the board under this subsection to deny a registration to distribute at wholesale any drugs shall be in addition to the authority of the board under subsection (e) of K.S.A. 65-1627 and amendments thereto or subsection (e) of K.S.A. 65-1645 and amendments thereto.

(d) Each person that is issued an initial or renewal license as a wholesale distributor, whether in state or out of state, must designate in writing on a form required by the board a person for each facility to serve as the designated representative of the wholesale distributor. A wholesale distributor must report a change in designated representative for the facility to the board or a third party recognized by the board within 30 days of such change.

(1) To be certified as a designated representative, a person must:

(A) Submit an application on a form furnished by the board and provide information that includes, but is not limited to:

(i) Information required to complete the criminal and financial background checks required under subsection (c)(2);

(ii) date and place of birth;

(iii) occupations, positions of employment, and offices held during the past seven years;

(iv) principal business and address of any business corporation, or other organization in which each such office of the person was held or in which each such occupation or position of employment was carried on;

(v) whether the person, during the past seven years, has been enjoined, either temporarily or permanently, by a court of competent jurisdiction from violating any federal or state law regulating the possession, control or wholesale distribution of prescription drugs or devices, together with details of such events;

(vi) description of any involvement by the person with any business, including any investments, other than the ownership of stock in a publicly traded company or mutual fund, during the past seven years, which manufactured, administered, prescribed, wholesale distributed, or stored prescription drugs and devices in which such businesses were named as a party in a lawsuit;

(vii) description of any criminal offense, not including minor traffic violations, of which the person, as an adult, was found guilty, regardless of whether adjudication of guilt was withheld or whether the person pled guilty or nolo contendere. If the person indicates that a criminal conviction is under appeal and submits a copy of the notice of appeal of the criminal offense, the applicant must, within 15 days after the disposition of the appeal, submit to the board a copy of the final written order of disposition;

(viii) photograph of the person taken within the previous 30 days under procedures as specified by the board;

(ix) name, address, occupation, and date and place of birth for each member of the person's immediate family, unless the person is employed by a wholesale distributor that is a publicly held company. As used in this subparagraph, the term "member of the immediate family" includes the person's spouse, children, parents, siblings, the spouses of the person's children, and the spouses of the person's siblings; and

(x) any other information the board deems relevant.

(B) have a minimum of two years of verifiable full-time managerial or supervisory experience in a pharmacy or wholesale distributor licensed in this state or another state, where the person's responsibilities included but were not limited to recordkeeping, storage, and shipment of prescription drugs or devices;

(C) may serve as the designated representative for only one wholesale distributor at any one time, except where more than one licensed wholesale distributor is co-located in the same facility and such wholesale distributors are members of an affiliated group, as defined in section 1504 of the internal revenue code;

(D) be actively involved in and aware of the actual daily operations of the wholesale distributor:

(i) Employed full-time in a managerial position by the wholesale distributor;

(ii) physically present at the wholesale distributor during normal business hours, except for time periods when absent due to illness, family illness or death, scheduled vacation or other authorized absence; and

(iii) aware of, and knowledgeable about, all policies and procedures pertaining to the operations of the wholesale distributor.

(2) The information collected pursuant to subsection (d)(1) shall be made available only to the board, a third party recognized by the board, and to state and federal law enforcement officials. The board and a third party recognized by the board shall make provisions for protecting the confidentiality of the information collected under this section.

(3) Each licensed wholesale distributor located outside of this state that wholesale distributes prescription drugs or devices in this state shall

designate a registered agent in this state for service of process. Any licensed wholesale distributor that does not so designate a registered agent shall be deemed to have designated the secretary of state of this state to be its true and lawful attorney, upon who may be served all legal processes in any action or proceeding against such licensed wholesale distributor growing out of or arising from such wholesale distribution. A copy of any such service of process shall be mailed to such wholesale distributor by the board by certified mail, return receipt requested, postage prepaid, at the address such licensed wholesale distributor has designated on its application for licensure in this state. If any such wholesale distributor is not licensed in this state, service on the secretary of state only shall be sufficient service.

(4) A designated representative must complete:

(A) Continuing education programs specified by the board regarding federal and state laws in regard to the wholesale distribution, handling and storage of prescription drugs or devices; or

(B) if no formal continuing education is specified by the board, training programs that address applicable federal and state laws and are provided by qualified in-house specialists, outside counsel or consulting specialists with capabilities to help ensure compliance.

(e) The following are required for the storage, handling, transport and shipment of prescription drugs or devices and for the establishment and maintenance of wholesale distribution records by wholesale distributors and their officers, agents, representatives and employees.

(1) All facilities at which prescription drugs and devices are received, stored, warehoused, handled, held, offered, marketed, displayed or transported from shall:

(A) Be of suitable construction to ensure that all prescription drugs and devices in the facilities are maintained in accordance with the product labeling of such prescription drugs and devices, or in compliance with official compendium standards such as the United States pharmacopeia-USP/NF;

(B) be of suitable size and construction to facilitate cleaning, maintenance and proper wholesale distribution operations;

(C) have adequate storage areas to provide adequate lighting, ventilation, temperature, sanitation, humidity, space, equipment and security conditions;

(D) have a quarantine area for storage of prescription drugs and devices that are outdated, damaged, deteriorated, misbranded or adulterated, counterfeit or suspected of being counterfeit, otherwise unfit for distribution or wholesale distribution or that are in immediate or sealed secondary containers that have been opened;

(E) be maintained in a clean and orderly condition;

(F) be free from infestation of any kind;

(G) be a commercial location and not a personal dwelling or residence;

(H) provide for the secure and confidential storage of information with restricted access and policies and procedures to protect the integrity and confidentiality of the information;

(I) provide and maintain appropriate inventory controls in order to detect and document any theft, counterfeiting or diversion of prescription drugs or devices; and

(J) provide to another wholesale distributor or pharmacy pedigrees for prescription drugs that leave the normal distribution channel before wholesale distribution to such other wholesale distributor or pharmacy in accordance with subsection (k). Effective at a date set by the board, pedigrees shall electronically record, for all prescription drugs, each wholesale distribution starting with the sale by a manufacturer through acquisition and sale by any wholesale distributor, until final sale to a pharmacy or other authorized person administering or dispensing the prescription drug. Consideration must be given, however, to the large-scale implementation of this technology across the supply chain and the technology must be proven to have no negative impact on the safety and efficacy of the pharmaceutical product. Nevertheless, implementation should not be unnecessarily delayed. Until such date set by the board, manufacturers are exempt from this section, unless the manufacturer is performing the manufacturing operation of repackaging prescription drugs.

(2) Wholesale distributors involved in the wholesale distribution of controlled substances shall be duly registered with drug enforcement administration (DEA) and appropriate state controlled substance agency and in compliance with all applicable laws and rules for the storage, handling, transport, shipment and wholesale distribution of controlled substances.

(f) (1) All facilities used for wholesale distribution shall be secure from unauthorized entry:

(A) access from outside the premises shall be kept to a minimum and be well-controlled;

(B) the outside perimeter of the premises shall be well-lighted; and

(C) entry into areas where prescription drugs or devices are held shall be limited to authorized personnel; all facilities shall be equipped with an alarm system to detect entry after hours.

(2) All facilities shall be equipped with a security system that will provide suitable protection against theft and diversion. When appropriate, the security system shall provide protection against theft or diversion that is facilitated or hidden by tampering with computers or electronic records.

(3) All facilities shall be equipped with inventory management and control systems that protect against, detect, and document any instances of theft, diversion or counterfeiting.

(4) All facilities shall be equipped with security systems to protect the integrity and confidentiality of data and documents and make such data and documents readily available to the board and other state and federal law enforcement officials.

(5) Authentication of pedigrees:

(A) Wholesale distributors that acquire prescription drugs from other wholesale distributors outside the normal distribution channel shall authenticate the pedigrees of at least 10% of all such prescription drugs, unless an electronic pedigree and track and trace system or other acceptable means, which documents each transaction, is in place; and

(B) wholesale distributors and manufacturers from whom wholesale distributors have acquired prescription drugs shall cooperate with pedigree authentication efforts and provide the requested information in a timely manner. The board shall provide authentication standards and procedures.

(C) Each wholesale distributor that has distributed a prescription drug for which an acquiring wholesale distributor is conducting a pedigree authentication, shall provide to the acquiring wholesale distributor, upon request, detailed information regarding its acquisition of the prescription drug, including:

(i) Date of acquisition;

(ii) national drug code number and lot number or control number;

(iii) acquisition invoice number; and

(iv) name, address, telephone number and e-mail address, if available, of the manufacturer or wholesale distributor from which the prescription drug was acquired.

(D) If the wholesale distributor attempting to authenticate the pedigree of the prescription drug is unable to authenticate the pedigree, the wholesale distributor shall quarantine the prescription drug and file a report with the board and FDA within three business days after completing the attempted authentication; and

(E) if the wholesale distributor attempting to authenticate the pedigree of the prescription drug is able to authenticate the pedigree, the wholesale distributor shall maintain records of the authentication for three years, and shall produce them to the board upon request.

(g) All prescription drugs and devices shall be stored at appropriate temperatures and under appropriate conditions in accordance with requirements, if any, in the product labeling of such prescription drugs and devices, or with requirements in the current edition of an official compendium such as the USP-NF.

(1) If no storage requirements are established for a prescription drug, the prescription drug may be held at "controlled" room temperature, as defined in an official compendium such as USP-NF, to help ensure that its identity, strength, quality, and purity are not adversely affected.

(2) Appropriate manual, electromechanical, or electronic temperature and humidity recording equipment or logs shall be utilized to document proper storage of prescription drugs and devices.

(3) Packaging of the prescription drugs and devices should be in accordance with an official compendium such as USP-NF and identify any compromise in the integrity of the prescription drugs or devices due to tampering or adverse storage conditions.

(4) Controlled substance drugs should be isolated from non-controlled substance drugs and stored in a secure area in accordance with DEA security requirements and standards.

(5) The recordkeeping requirements in subsection (k) shall be followed for the wholesale distribution of all prescription drugs and devices.

(h) (1) Upon receipt, each shipping container shall be visually examined for identity and to determine if it may contain contaminated, contraband, counterfeit, suspected of being counterfeit or contraband, or damaged prescription drugs or devices, or prescription drugs or devices that are otherwise unfit for wholesale distribution. This examination shall be adequate to reveal container damage that would suggest possible contamination, adulteration, misbranding, counterfeiting, contraband, suspected of being counterfeit or contraband or other damage to the contents.

(2) The prescription drugs or devices found to be unacceptable under paragraph 1 should be quarantined from the rest of stock until the examination and determination that the prescription drugs and devices are not outdated, damaged, deteriorated, misbranded, counterfeited, contraband or adulterated and the determination that they are fit for human use.

(3) Each outgoing shipment shall be carefully inspected for identity of the prescription drugs or devices and to ensure that there is no delivery of prescription drugs or devices that have been damaged in storage or held under improper conditions.

(4) Upon receipt, a wholesale distributor must review records for the acquisition of prescription drugs or devices for accuracy and completeness, considering the total facts and circumstances surrounding the transactions and the wholesale distributors involved.

(5) The recordkeeping requirements in subsection (k) shall be followed for all incoming and outgoing prescription drugs and devices.

(i) (1) Appropriate documentation shall be completed and any necessary notations made to the pedigree if any prescription drug that was ordered in excess of need by the wholesale distributor, if identified as such,

and which the integrity has been maintained, that is returned to the manufacturer or wholesale distributor from which it was acquired.

(2) Any prescription drug or device that is outdated, damaged, deteriorated, misbranded, counterfeited, contraband, suspected of being counterfeited or contraband, adulterated, or otherwise deemed unfit for human consumption shall be quarantined and physically separated from other prescription drugs and devices until it is destroyed or returned to either the manufacturer or wholesale distributor from which it was acquired. When prescription drugs and devices are adulterated, counterfeited, contraband, misbranded, or suspected of being adulterated, counterfeit, contraband, or misbranded, notice of the adulteration, counterfeiting, contrabandage, misbranding, or suspected adulteration, counterfeiting, contrabandage, or misbranding shall be provided within three business days of that determination to the board, FDA, and manufacturer or wholesale distributor from which they were acquired. Any prescription drug or device returned to a manufacturer or wholesale distributor shall be kept under proper conditions for storage, handling, transport, shipment, and documentation showing that proper conditions were maintained and shall be provided to the manufacturer or wholesale distributor to which the prescription drugs or devices are returned.

(3) Any prescription drug or device whose immediate or sealed outer or secondary containers or product labeling are adulterated, misbranded, counterfeited, contraband, or suspect of being counterfeit or contraband shall be quarantined and physically separated from other prescription drugs or devices until it is destroyed or returned to either the manufacturer or wholesale distributor from which it was acquired. When the immediate or sealed outer or secondary containers or product labeling of any prescription drug or device are adulterated, misbranded, counterfeited, contraband, or suspect of being counterfeit or contraband, notice of the adulteration, misbranding, counterfeiting, contrabandage, or suspected counterfeiting or contrabandage shall be provided within three business days of that determination to the board, FDA, and manufacturer or wholesale distributor from which it was acquired.

(4) Any prescription drug or device that has been opened or used, but is not adulterated, misbranded, counterfeited, contraband, or suspect of being counterfeit or contraband, shall be identified as such, and shall be quarantined and physically separated from other prescription drugs or devices until it is destroyed or returned to the manufacturer or wholesale distributor from which acquired.

(5) If the conditions under which a prescription drug or device has been returned cast doubt on the prescription drug's or device's safety, identity, strength, quality, or purity, then the prescription drug or device shall be destroyed, or returned to the supplier, unless examination, testing,

or other investigation proves that the prescription drug or device meets appropriate standards of safety, identity, strength, quality, and purity. In determining whether the conditions under which a prescription drug or device has been returned cast doubt on the prescription drug's or device's safety, identity, strength, quality, or purity, the wholesale drug distributor shall consider, among other things, the conditions under which the prescription drug or device has been held, stored, or shipped before or during its return and the condition of the prescription drug and its container, carton, or product labeling as a result of storage or shipping.

(6) Contraband, counterfeit, or suspected to be counterfeit or contraband drugs and devices, other evidence of criminal activity, and accompanying documentation shall be retained and not destroyed until its disposition is authorized by the board and FDA.

(7) The shipping, immediate, or sealed outer or secondary container or product labeling, and accompanying documentation, suspected of or determined to be counterfeit, contraband or otherwise fraudulent shall not be destroyed until its disposition is authorized by the board and FDA.

(8) The recordkeeping requirements in subsection (k) of this act shall be followed for all outdated, damaged, deteriorated, counterfeit, contraband, misbranded, or adulterated prescription drugs.

(j) If a wholesale distributor is licensed in accordance with this act or provides documentation that the due diligence procedures are in place and monitored by the board or a third party recognized by the board, then the following due diligence requirements may be waived by the board:

(1) Prior to the initial wholesale distribution or acquisition of prescription drugs to or from any wholesale distributor or prior to any wholesale distribution to a wholesale distributor by a manufacturer, the distributing wholesale distributor or manufacturer shall provide the following information to the acquiring wholesale distributor:

(A) A list of states in which the wholesale distributor is licensed, and into which it ships prescription drugs;

(B) copies of all state and federal regulatory licenses and registrations;

(C) the wholesale distributor's most recent facility inspection reports;

(D) information regarding general and product liability insurance, including copies of relevant policies;

(E) a list of other names under which the wholesale distributor is doing business, or was formerly known;

(F) a list of corporate officers;

(G) a list of managerial employees directly involved in the day-to-day operations of wholesale distribution;

(H) a list of all owners of the wholesale distributor that own more than 10% of the wholesale distributor, unless the wholesale distributor is

publicly traded;

(I) a list of all disciplinary actions by state and federal agencies;

(J) a description, including the address, dimensions, and other relevant information, of each facility or warehouse used for prescription drug storage and wholesale distribution;

(K) a description of prescription drug import and export activities of the wholesale distributor;

(L) a description of the wholesale distributor's policies and procedures to comply with this act; and

(2) prior to the initial wholesale distribution or acquisition of prescription drugs to or from any wholesale distributor, the distributing or acquiring wholesale distributor shall:

(A) Conduct a criminal background check of all of the wholesale distributor's personnel, shareholders, and owners involved in operations and management as specified in subsection (c)(2) (minimum qualifications); or

(B) verify that the wholesale distributor has been accredited by a third party recognized by the board.

(3) If a wholesale distributor's facility has not been inspected by the board or a third party recognized by the board within three years of the contemplated transaction, any wholesale distributor choosing to do business with that facility shall conduct an inspection of the former wholesale distributor's facility prior to the first transaction to ensure compliance with applicable laws and regulations relating to the storage and handling of prescription drugs or devices. A third party may be engaged to conduct the site inspection on behalf of the latter wholesale distributor. If the wholesale distributor's facility has been inspected by the board or a third party recognized by the board, within a three-year time period, the inspection report is sufficient to meet the requirements of this subsection.

(4) At least annually, a wholesale distributor that wholesale distributes or acquires prescription drugs to or from another wholesale distributor shall update the information set forth in subsection (k).

(5) At least once every three years, a wholesale distributor that wholesale distributes or acquires prescription drugs to or from another wholesale distributor shall inspect or engage a third party to inspect, the premises of the facility or facilities of the wholesale distributor to or from whom it is distributing or acquiring prescription drugs. If the distributing or acquiring wholesale distributor's facility has been inspected by the board or a third party recognized by the board within the three-year time period, the inspection report is sufficient to meet the requirements of this subsection.

(6) Wholesale distributors are exempt from inspecting and obtaining the information from manufacturers of prescription drugs as required in

subsection (b)(4) (due diligence) when the manufacturer is registered with FDA in accordance with section 510 of the federal act.

(k) (1) Wholesale distributors shall establish and maintain inventories and records of all transactions regarding the receipt and wholesale distribution or other disposition of prescription drugs and devices. These records shall include:

(A) Dates of receipt and wholesale distribution or other disposition of the prescription drugs and devices;

(B) pedigrees for all prescription drugs that are wholesale distributed outside the normal distribution channel; and

(C) effective at date set by the board, that shall be no sooner than July 1, 2009, pedigrees shall be maintained for each wholesale distribution of a prescription drug starting with the sale by a manufacturer through acquisition and sale by any wholesale distributor, until final sale to a pharmacy or other authorized person administering or dispensing the prescription drug. Pedigrees may be implemented through an approved and readily available system that electronically tracks and traces the prescription drug. This electronic tracking system will be deemed to be readily available only upon there being available a standardized system originating at the manufacturer and capable of being used on a wide scale across the entire healthcare industry which includes manufacturers, wholesale distributors, and pharmacies. Also, consideration must be given, however, to the large-scale implementation of this technology across the supply chain and the technology must be proven to have no negative impact on the safety and efficacy of the pharmaceutical product. Nevertheless, implementation should not be unnecessarily delayed.

(2) Such records shall include the inventories and records and shall be made available for inspection and photocopying by any authorized official of any state, federal or local governmental agency for a period of three years following their creation date.

(3) Records described in this section that are kept at the inspection site or that can be immediately retrieved by computer or other electronic means shall be readily available for authorized inspection during the retention period. Records kept at a central location apart from the inspection site and not electronically retrievable shall be made available for inspection within two working days of a request by an authorized official of any state or federal governmental agency charged with enforcement of these rules.

(4) Wholesale distributors and manufacturers shall maintain an ongoing list of persons with whom they do business.

(5) All facilities shall establish and maintain procedures for reporting counterfeit and contraband or suspected counterfeit and contraband drugs or devices or counterfeiting and contraband or suspected counter-

feiting and contraband activities to the board and FDA.

(6) Wholesale distributors shall maintain a system for the mandatory reporting of significant shortages or losses of prescription drugs and devices where it is known or suspected that diversion is occurring to the board and FDA, and, where applicable, to DEA.

(l) Wholesale distributors shall establish, maintain and adhere to written policies and procedures, which shall be followed for the receipt, security, storage, inventory, transport and shipping and wholesale distribution of prescription drugs, including policies and procedures for identifying, recording and reporting losses or thefts, for correcting all errors and inaccuracies in inventories. Wholesale distributors shall include in their written policies and procedures the following:

(1) A procedure to be followed for handling recalls and withdrawals of prescription drugs and devices. Such procedure shall be adequate to deal with recalls and withdrawals due to:

(A) Any action initiated at the request of FDA or any other federal, state, or local law enforcement or other government agency, including the board of pharmacy; or

(B) any volunteer action by the manufacturer to remove defective or potentially defective prescription drugs or devices from the market.

(2) A procedure to ensure that wholesale distributors prepare for, protect against, and handle any crisis that affects security or operation of any facility in the event of a strike, fire, flood or other natural disaster or other situations of local, state, or national emergency.

(3) A procedure to ensure that any outdated prescription drugs shall be segregated from other prescription drugs and either returned to the manufacturer or destroyed in accordance with federal and state laws, including all necessary documentation and the appropriate witnessing. This procedure shall provide for written documentation of the disposition of outdated prescription drugs. This documentation shall be maintained for two years after disposition of the outdated prescription drugs.

(4) A procedure for the destruction of outdated prescription drugs in accordance with federal and state laws, including all necessary documentation, maintained for a minimum of three years and the appropriate witnessing of the destruction of outdated prescription drugs in accordance with all applicable federal and state requirements.

(5) A procedure for the disposing and destruction of containers, labels and packaging to ensure that the containers, labels and packaging cannot be used in counterfeiting activities, including all necessary documentation, maintained for a minimum of three years, and the appropriate witnessing of the destruction of any labels, packaging, immediate containers, or containers in accordance with all applicable federal and state requirements.

(6) A procedure for identifying, investigating and reporting signifi-

cant prescription drug inventory discrepancies involving counterfeit, suspect of being counterfeit, contraband, or suspect of being contraband, in the inventory and reporting of such discrepancies within 10 business days to the board or appropriate federal or state agency upon discovery of such discrepancies.

(7) A procedure for reporting criminal or suspected criminal activities involving the inventory of prescription drugs and devices to the board, FDA, and, if applicable, DEA, within the three business days.

(8) A procedure for conducting authentication of pedigrees in accordance with subsection (f) and standards adopted by the board.

(m) Wholesale distributors shall be subject to the provisions of any applicable federal, state or local laws or rules that relate to prescription drug product salvaging or reprocessing, including chapter 21, parts 207, 210, and 211k of the code of federal regulations.

(n) The board shall have the authority to recognize a third party to inspect and accredit wholesale distributors.

(1) The board may license by reciprocity, a wholesale distributor that is licensed under the laws of another state, if:

(A) The requirements of that state are deemed by the board to be substantially equivalent; or

(B) the applicant is accredited by a third party recognized by the board.

(2) Any applicant that is denied accreditation described under paragraph (a), shall have the right of review of the accreditation body's decision, by:

(A) The accreditation body; and

(B) the board.

(3) The board recognized accreditation body shall ensure that the proprietary information obtained during the accreditation process remains confidential and privileged.

(4) The board may waive requirements of this act, by rule and regulation, for wholesale distributors that have obtained and maintain a board-approved accreditation.

~~(d)~~ *(o)* The board by rules and regulations shall require that personnel employed by persons registered to distribute at wholesale any drugs have appropriate education or experience, or both, to assume responsibility for positions related to compliance with state registration requirements.

~~(e)~~ *(p)* The board by rules and regulations may implement this section to conform to any requirements of the federal prescription drug marketing act of 1987 (21 U.S.C. 321 et seq.) in effect on the effective date of this act.

~~(f)~~ *(q)* This section shall be part of and supplemental to the pharmacy act of the state of Kansas.

New Sec. 3. (a) If a person engages in the wholesale distribution of prescription drugs in violation of this act, the person may be imprisoned for not more than 15 years or fined not more than $50,000, or both.

(b) If a person knowingly engages in wholesale distribution of prescription drugs in violation of this act, the person shall be imprisoned for not more than 20 years or fined not more than $500,000, or both.

New Sec. 4. The 2007 amendments to K.S.A. 65-1655, and amendments thereto, and K.S.A. 2006 Supp. 65-1643, and amendments thereto, shall be known and may be cited as the Kansas pharmaceutical integrity act.

Sec. 5. K.S.A. 65-1655 and K.S.A. 2006 Supp. 65-1643 are hereby repealed.

Sec. 6. This act shall take effect and be in force from and after its publication in the statute book.