

CHAPTER 9
HOUSE BILL No. 2578

AN ACT concerning health care; relating to the inspector general of the Kansas health policy authority; enacting the utilization of unused medications act; duties of the state department of health and environment and the state department on aging; amending K.S.A. 2007 Supp. 75-7427 and repealing the existing section.

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

New Section 1. (a) Sections 1 through 8, and amendments thereto, shall be known and may be cited as the “utilization of unused medications act”.

(b) The provisions of the utilization of unused medications act shall not apply to any drug, prescription drug or medication purchased or provided with moneys provided under title XIX of the federal social security act, 42 U.S.C. 1396 et seq., and amendments thereto, or title XXI of the federal social security act, section 4901 of public law 105-33, 42 U.S.C. 1397aa et seq., and amendments thereto.

New Sec. 2. As used in the utilization of unused medications act:

(a) “Adult care home” has the same meaning as such term is defined in K.S.A. 39-923, and amendments thereto.

(b) “Community mental health center” has the same meaning as such term is defined in K.S.A. 75-3307c, and amendments thereto.

(c) “Donating entities” means adult care homes, mail service pharmacies and medical care facilities who elect to participate in the program.

(d) “Drug” has the same meaning as such term is defined in K.S.A. 65-1626, and amendments thereto.

(e) “Federally qualified health center” means a center which meets the requirements for federal funding under 42 U.S.C. section 1396d(1) of the public health service act, and which has been designated as a “federally qualified health center” by the federal government.

(f) “Indigent health care clinic” has the same meaning as such term is defined in K.S.A. 75-6102, and amendments thereto.

(g) “Mail service pharmacy” means a licensed Kansas pharmacy located within the state that ships, mails or delivers by any lawful means a lawfully dispensed medication in tamper-resistant packaging to residents of this state or another state.

(h) “Medical care facility” has the same meaning as such term is defined in K.S.A. 65-425, and amendments thereto.

(i) “Medically indigent” has the same meaning as such term is defined in K.S.A. 75-6102, and amendments thereto.

(j) “Medication” means a prescription drug or drug as defined by this section.

(k) “Mid-level practitioner” has the same meaning as such term is defined in K.S.A. 65-1626, and amendments thereto.

(l) “Practitioner” has the same meaning as such term is defined in K.S.A. 65-1626, and amendments thereto.

(m) “Prescription drug” means a drug which may be dispensed only upon prescription of a practitioner or mid-level practitioner authorized by law and which is approved for safety and effectiveness as a prescription drug under section 505 or 507 of the federal food, drug and cosmetic act (52 Stat. 1040 (1938), 21 U.S.C.A., section 301).

(n) “Qualifying center or clinic” means an indigent health care clinic, federally qualified health center or community mental health center.

New Sec. 3. (a) The board of pharmacy shall establish and implement a program consistent with public health and safety through which unused drugs, other than drugs defined as controlled substances, may be transferred from donating entities that elect to participate in the program for the purpose of distributing the unused medications to Kansas residents who are medically indigent.

(b) A qualifying center or clinic in consultation with a pharmacist shall establish procedures necessary to implement the program established by the utilization of unused medications act.

(c) The state board of pharmacy shall provide technical assistance to entities who may wish to participate in the program.

New Sec. 4. The following criteria shall be used in accepting unused medications for use under the utilization of unused medications act:

(a) The medications shall have come from a controlled storage unit

of a donating entity;

(b) only medications in their original or pharmacist sealed unit dose packaging or hermetically sealed by the pharmacy in tamper evident packaging, unit of use or sealed, unused injectables shall be accepted and dispensed pursuant to the utilization of unused medications act;

(c) expired medications shall not be accepted;

(d) a medication shall not be accepted or dispensed if the person accepting or dispensing the medication has reason to believe that the medication is adulterated;

(e) no controlled substances shall be accepted; and

(f) subject to the limitation specified in this section, unused medications dispensed for purposes of a medical assistance program or drug product donation program may be accepted and dispensed under the utilization of unused medications act.

New Sec. 5. (a) Participation in the utilization of unused medications act by residents of adult care homes and donating entities shall be voluntary. Nothing in the utilization of unused medications act shall require any resident of an adult care home or any donating entity to participate in the program.

(b) A qualifying center or clinic which meets the eligibility requirements established in the utilization of unused medications act may:

(1) Dispense medications donated under the utilization of unused medications act to persons who are medically indigent residents of Kansas; and

(2) charge persons receiving donated medications a handling fee not to exceed 200% of the medicaid dispensing fee.

(c) A qualifying center or clinic which meets the eligibility requirements established and authorized by the utilization of unused medications act which accepts donated medications shall:

(1) Comply with all applicable federal and state laws related to the storage and distribution of medications;

(2) inspect all medications prior to dispensing the medications to determine that such medications are not adulterated; and

(3) dispense prescription drugs only pursuant to a prescription issued by a practitioner or mid-level practitioner.

(d) Medications donated under the utilization of unused medications act shall not be resold but are available for transfer to another qualifying center or clinic.

(e) For purposes of the utilization of unused medications act, medications dispensed by qualifying centers or clinics shall not be considered resale of such medications.

New Sec. 6. (a) For matters related only to the lawful donation, acceptance or dispensing of medications under the utilization of unused medications act, the following persons and entities, in compliance with the utilization of unused medications act, in the absence of bad faith or gross negligence, shall not be subject to criminal or civil liability for injury other than death, or loss to person or property, or professional disciplinary action:

(1) The state board of pharmacy;

(2) the department of health and environment;

(3) the department on aging;

(4) any governmental entity or donating entity donating medications under the utilization of unused medications act;

(5) any qualifying center or clinic that accepts or dispenses medications under the utilization of unused medications act; and

(6) any qualifying center or clinic that employs a practitioner or mid-level practitioner who accepts or can legally dispense prescription drugs under the utilization of unused medications act and the pharmacy act of the state of Kansas.

(b) For matters related to the donation, acceptance or dispensing of a medication manufactured by the prescription drug manufacturer that is donated by any entity under the utilization of unused medications act, a prescription drug manufacturer shall not, in the absence of bad faith or gross negligence, be subject to criminal or civil liability for injury other than for death, or loss to person or property including, but not limited to, liability for failure to transfer or communicate product or consumer information or the expiration date of the donated prescription drug.

(c) Any person who in good faith donates medications without charge under the utilization of unused medications act, which medications are

in compliance with such act at the time donated, shall not be subject to criminal or civil liability arising from any injury or death due to the condition of such medications unless such injury or death is a direct result of the willful, wanton, malicious or intentional misconduct of such person.

New Sec. 7. (a) The state board of pharmacy shall adopt rules and regulations by December 1, 2008, to implement the utilization of unused medications act. Such rules shall:

(1) Include standards and procedures for transfer, acceptance and safe storage of donated medications;

(2) include standards and procedures for inspecting donated medications to ensure that the medications are in compliance with the utilization of unused medications act and to ensure that, in the professional judgment of a pharmacist, the medications meet all federal and state standards for product integrity;

(3) establish standards for acceptance of unused medications from donating entities; and

(4) establish, in consultation with the department of health and environment and the department on aging, any additional rules and regulations, and standards and procedures it deems appropriate or necessary to implement the provisions of the utilization of unused medications act.

(b) In accordance with the rules and regulations and procedures of the program established pursuant to this section, a resident of an adult care home, or the representative or guardian of a resident may donate unused medications, other than prescription drugs defined as controlled substances, for dispensation to medically indigent persons.

New Sec. 8. The secretary of health and environment shall maintain records of program participation including the number of donating entities donating medications, recipient locations, the amount of medications received and the number of clients served.

Sec. 9. K.S.A. 2007 Supp. 75-7427 is hereby amended to read as follows: 75-7427. (a) As used in this section:

(1) "Attorney general" means the attorney general, employees of the attorney general or authorized representatives of the attorney general.

(2) "Benefit" means the receipt of money, goods, items, facilities, accommodations or anything of pecuniary value.

(3) "Claim" means an electronic, electronic impulse, facsimile, magnetic, oral, telephonic or written communication that is utilized to identify any goods, service, item, facility or accommodation as reimbursable to the state medicaid program, or its fiscal agents, the state mediKan program or the state children's health insurance program or which states income or expense.

(4) "Client" means past or present beneficiaries or recipients of the state medicaid program, the state mediKan program or the state children's health insurance program.

(5) "Contractor" means any contractor, supplier, vendor or other person who, through a contract or other arrangement, has received, is to receive or is receiving public funds or in-kind contributions from the contracting agency as part of the state medicaid program, the state mediKan program or the state children's health insurance program, and shall include any sub-contractor.

(6) "Contractor files" means those records of contractors which relate to the state medicaid program, the state mediKan program or the state children's health insurance program.

(7) "Fiscal agent" means any corporation, firm, individual, organization, partnership, professional association or other legal entity which, through a contractual relationship with the state of Kansas receives, processes and pays claims under the state medicaid program, the state mediKan program or the state children's health insurance program.

(8) "Health care provider" means a health care provider as defined under K.S.A. 65-4921, and amendments thereto, who has applied to participate in, who currently participates in, or who has previously participated in the state medicaid program, the state mediKan program or the state children's health insurance program.

(9) "Kansas health policy authority" or "authority" means the Kansas health policy authority established under K.S.A. 2007 Supp. 75-7401, and amendments thereto, or its successor agency.

(10) "Managed care program" means a program which provides coordination, direction and provision of health services to an identified group of individuals by providers, agencies or organizations.

(11) “Medicaid program” means the Kansas program of medical assistance for which federal or state moneys, or any combination thereof, are expended, or any successor federal or state, or both, health insurance program or waiver granted thereunder.

(12) “Person” means any agency, association, corporation, firm, limited liability company, limited liability partnership, natural person, organization, partnership or other legal entity, the agents, employees, independent contractors, and subcontractors, thereof, and the legal successors thereto.

(13) “Provider” means a person who has applied to participate in, who currently participates in, who has previously participated in, who attempts or has attempted to participate in the state medicaid program, the state mediKan program or the state children’s health insurance program, by providing or claiming to have provided goods, services, items, facilities or accommodations.

(14) “Recipient” means an individual, either real or fictitious, in whose behalf any person claimed or received any payment or payments from the state medicaid program, or its fiscal agent, the state mediKan program or the state children’s health insurance program, whether or not any such individual was eligible for benefits under the state medicaid program, the state mediKan program or the state children’s health insurance program.

(15) “Records” means all written documents and electronic or magnetic data, including, but not limited to, medical records, X-rays, professional, financial or business records relating to the treatment or care of any recipient; goods, services, items, facilities or accommodations provided to any such recipient; rates paid for such goods, services, items, facilities or accommodations; and goods, services, items, facilities or accommodations provided to nonmedicaid recipients to verify rates or amounts of goods, services, items, facilities or accommodations provided to medicaid recipients, as well as any records that the state medicaid program, or its fiscal agents, the state mediKan program or the state children’s health insurance program require providers to maintain. “Records” shall not include any report or record in any format which is made pursuant to K.S.A. 65-4922, 65-4923 or 65-4924, and amendments thereto, and which is privileged pursuant to K.S.A. 65-4915 or 65-4925, and amendments thereto.

(16) “State children’s health insurance program” means the state children’s health insurance program as provided in K.S.A. 38-2001 et seq., and amendments thereto.

(b) (1) There is hereby established within the Kansas health policy authority the office of inspector general. All budgeting, purchasing and related management functions of the office of inspector general shall be administered under the direction and supervision of the executive director of the Kansas health policy authority. The purpose of the office of inspector general is to establish a full-time program of audit, investigation and performance review to provide increased accountability, integrity and oversight of the state medicaid program, the state mediKan program and the state children’s health insurance program within the jurisdiction of the Kansas health policy authority and to assist in improving agency and program operations and in deterring and identifying fraud, waste, abuse and illegal acts. The office of inspector general shall be independent and free from political influence and in performing the duties of the office under this section shall conduct investigations, audits, evaluations, inspections and other reviews in accordance with professional standards that relate to the fields of investigation and auditing in government.

(2) (A) The inspector general shall be appointed by the Kansas health policy authority with the advice and consent of the senate and subject to confirmation by the senate as provided in K.S.A. 75-4315b, and amendments thereto. Except as provided in K.S.A. 46-2601, and amendments thereto, no person appointed to the position of inspector general shall exercise any power, duty or function of the inspector general until confirmed by the senate. The inspector general shall be selected without regard to political affiliation and on the basis of integrity and capacity for effectively carrying out the duties of the office of inspector general. The inspector general shall possess demonstrated knowledge, skills, abilities and experience in conducting audits or investigations and shall be familiar with the programs subject to oversight by the office of inspector general.

(B) No former or current executive or manager of any program or

agency subject to oversight by the office of inspector general may be appointed inspector general within two years of that individual's period of service with such program or agency. The inspector general shall hold at time of appointment, or shall obtain within one year after appointment, certification as a certified inspector general from a national organization that provides training to inspectors general.

(C) The term of the person first appointed to the position of inspector general shall expire on January 15, 2009. Thereafter, a person appointed to the position of inspector general shall serve for a term which shall expire on January 15 of each year in which the whole senate is sworn in for a new term.

(D) The inspector general shall be in the classified service and shall receive such compensation as is determined by law, except that such compensation may be increased but not diminished during the term of office of the inspector general. The inspector general may be removed from office prior to the expiration of the inspector general's term of office in accordance with the Kansas civil service act. The inspector general shall exercise independent judgment in carrying out the duties of the office of inspector general under subsection (b). Appropriations for the office of inspector general shall be made to the Kansas health policy authority by separate line item appropriations for the office of inspector general. The inspector general shall report to the ~~executive director of the~~ Kansas health policy authority.

(E) The inspector general shall have general managerial control over the office of the inspector general and shall establish the organization structure of the office as the inspector general deems appropriate to carry out the responsibilities and functions of the office.

(3) Within the limits of appropriations therefor, the inspector general may hire such employees in the unclassified service as are necessary to administer the office of the inspector general. Such employees shall serve at the pleasure of the inspector general. Subject to appropriations, the inspector general may obtain the services of certified public accountants, qualified management consultants, professional auditors, or other professionals necessary to independently perform the functions of the office.

(c) (1) In accordance with the provisions of this section, the duties of the office of inspector general shall be to oversee, audit, investigate and make performance reviews of the state medicaid program, the state mediKan program and the state children's health insurance program, which programs are within the jurisdiction of the Kansas health policy authority.

(2) In order to carry out the duties of the office, the inspector general shall conduct independent and ongoing evaluation of the Kansas health policy authority and of such programs administered by the Kansas health policy authority, which oversight includes, but is not limited to, the following:

(A) Investigation of fraud, waste, abuse and illegal acts by the Kansas health policy authority and its agents, employees, vendors, contractors, consumers, clients and health care providers or other providers.

(B) Audits of the Kansas health policy authority, its employees, contractors, vendors and health care providers related to ensuring that appropriate payments are made for services rendered and to the recovery of overpayments.

(C) Investigations of fraud, waste, abuse or illegal acts committed by clients of the Kansas health policy authority or by consumers of services administered by the Kansas health policy authority.

(D) Monitoring adherence to the terms of the contract between the Kansas health policy authority and an organization with which the authority has entered into a contract to make claims payments.

(3) Upon finding credible evidence of fraud, waste, abuse or illegal acts, the inspector general shall report its findings to the Kansas health policy authority and refer the findings to the attorney general.

(d) The inspector general shall have access to all pertinent information, confidential or otherwise, and to all personnel and facilities of the Kansas health policy authority, their employees, vendors, contractors and health care providers and any federal, state or local governmental agency that are necessary to perform the duties of the office as directly related to such programs administered by the authority. Access to contractor or health care provider files shall be limited to those files necessary to verify the accuracy of the contractor's or health care provider's invoices or their

compliance with the contract provisions or program requirements. No health care provider shall be compelled under the provisions of this section to provide individual medical records of patients who are not clients of the state medicaid program, the state mediKan program or the state children's health insurance program. State and local governmental agencies are authorized and directed to provide to the inspector general requested information, assistance or cooperation.

(e) Except as otherwise provided in this section, the inspector general and all employees and former employees of the office of inspector general shall be subject to the same duty of confidentiality imposed by law on any such person or agency with regard to any such information, and shall be subject to any civil or criminal penalties imposed by law for violations of such duty of confidentiality. The duty of confidentiality imposed on the inspector general and all employees and former employees of the office of inspector general shall be subject to the provisions of subsection (f), and the inspector general may furnish all such information to the attorney general, Kansas bureau of investigation or office of the United States attorney in Kansas pursuant to subsection (f). Upon receipt thereof, the attorney general, Kansas bureau of investigation or office of the United States attorney in Kansas and all assistants and all other employees and former employees of such offices shall be subject to the same duty of confidentiality with the exceptions that any such information may be disclosed in criminal or other proceedings which may be instituted and prosecuted by the attorney general or the United States attorney in Kansas, and any such information furnished to the attorney general, the Kansas bureau of investigation or the United States attorney in Kansas under subsection (f) may be entered into evidence in any such proceedings.

(f) All investigations conducted by the inspector general shall be conducted in a manner that ensures the preservation of evidence for use in criminal prosecutions or agency administrative actions. If the inspector general determines that a possible criminal act relating to fraud in the provision or administration of such programs administered by the Kansas health policy authority has been committed, the inspector general shall immediately notify the office of the Kansas attorney general. If the inspector general determines that a possible criminal act has been committed within the jurisdiction of the office, the inspector general may request the special expertise of the Kansas bureau of investigation. The inspector general may present for prosecution the findings of any criminal investigation to the office of the attorney general or the office of the United States attorney in Kansas.

(g) To carry out the duties as described in this section, the inspector general and the inspector general's designees shall have the power to compel by subpoena the attendance and testimony of witnesses and the production of books, electronic records and papers as directly related to such programs administered by the Kansas health policy authority. Access to contractor files shall be limited to those files necessary to verify the accuracy of the contractor's invoices or its compliance with the contract provisions. No health care provider shall be compelled to provide individual medical records of patients who are not clients of the authority.

(h) The inspector general shall report all convictions, terminations and suspensions taken against vendors, contractors and health care providers to the Kansas health policy authority and to any agency responsible for licensing or regulating those persons or entities. If the inspector general determines reasonable suspicion exists that an act relating to the violation of an agency licensure or regulatory standard has been committed by a vendor, contractor or health care provider who is licensed or regulated by an agency, the inspector general shall immediately notify such agency of the possible violation.

(i) The inspector general shall make annual reports, findings and recommendations regarding the office's investigations into reports of fraud, waste, abuse and illegal acts relating to any such programs administered by the Kansas health policy authority to the executive director of the Kansas health policy authority, the legislative post auditor, the committee on ways and means of the senate, the committee on appropriations of the house of representatives, the joint committee on health policy oversight and the governor. These reports shall include, but not be limited to, the following information:

- (1) Aggregate provider billing and payment information;
- (2) the number of audits of such programs administered by the Kan-

sas health policy authority and the dollar savings, if any, resulting from those audits;

(3) health care provider sanctions, in the aggregate, including terminations and suspensions; and

(4) a detailed summary of the investigations undertaken in the previous fiscal year, which summaries shall comply with all laws and rules and regulations regarding maintaining confidentiality in such programs administered by the Kansas health policy authority.

(j) Based upon the inspector general's findings under subsection (c), the inspector general may make such recommendations to the Kansas health policy authority or the legislature for changes in law, rules and regulations, policy or procedures as the inspector general deems appropriate to carry out the provisions of law or to improve the efficiency of such programs administered by the Kansas health policy authority. The inspector general shall not be required to obtain permission or approval from any other official or authority prior to making any such recommendation.

(k) (1) The inspector general shall make provision to solicit and receive reports of fraud, waste, abuse and illegal acts in such programs administered by the Kansas health policy authority from any person or persons who shall possess such information. The inspector general shall not disclose or make public the identity of any person or persons who provide such reports pursuant to this subsection unless such person or persons consent in writing to the disclosure of such person's identity. Disclosure of the identity of any person who makes a report pursuant to this subsection shall not be ordered as part of any administrative or judicial proceeding. Any information received by the inspector general from any person concerning fraud, waste, abuse or illegal acts in such programs administered by the Kansas health policy authority shall be confidential and shall not be disclosed or made public, upon subpoena or otherwise, except such information may be disclosed if (A) release of the information would not result in the identification of the person who provided the information, (B) the person or persons who provided the information to be disclosed consent in writing prior to its disclosure, (C) the disclosure is necessary to protect the public health, or (D) the information to be disclosed is required in an administrative proceeding or court proceeding and appropriate provision has been made to allow disclosure of the information without disclosing to the public the identity of the person or persons who reported such information to the inspector general.

(2) No person shall:

(A) Prohibit any agent, employee, contractor or subcontractor from reporting any information under subsection (k)(1); or

(B) require any such agent, employee, contractor or subcontractor to give notice to the person prior to making any such report.

(3) Subsection (k)(2) shall not be construed as:

(A) Prohibiting an employer from requiring that an employee inform the employer as to legislative or auditing agency requests for information or the substance of testimony made, or to be made, by the employee to legislators or the auditing agency, as the case may be, on behalf of the employer;

(B) permitting an employee to leave the employee's assigned work areas during normal work hours without following applicable rules and regulations and policies pertaining to leaves, unless the employee is requested by a legislator or legislative committee to appear before a legislative committee or by an auditing agency to appear at a meeting with officials of the auditing agency;

(C) authorizing an employee to represent the employee's personal opinions as the opinions of the employer; or

(D) prohibiting disciplinary action of an employee who discloses information which (A) the employee knows to be false or which the employee discloses with reckless disregard for its truth or falsity, (B) the employee knows to be exempt from required disclosure under the open records act, or (C) is confidential or privileged under statute or court rule.

(4) Any agent, employee, contractor or subcontractor who alleges that disciplinary action has been taken against such agent, employee, contractor or subcontractor in violation of this section may bring an action for any damages caused by such violation in district court within 90 days after the occurrence of the alleged violation.

(5) Any disciplinary action taken against an employee of a state agency

or firm as such terms are defined under subsection (b) of K.S.A. 75-2973, and amendments thereto, for making a report under subsection (k)(1) shall be governed by the provisions of K.S.A. 75-2973, and amendments thereto.

(l) The scope, timing and completion of any audit or investigation conducted by the inspector general shall be within the discretion of the inspector general. Any audit conducted by the inspector general's office shall adhere and comply with all provisions of generally accepted governmental auditing standards promulgated by the United States government accountability office.

(m) Nothing in this section shall limit investigations by any state department or agency that may otherwise be required by law or that may be necessary in carrying out the duties and functions of such agency.

(n) The Kansas health policy authority, in accordance with K.S.A. 75-4319, and amendments thereto, may recess for a closed, executive meeting under the open meetings act, K.S.A. 75-4317 through 75-4320a, and amendments thereto, to discuss with the inspector general any information, records or other matters that are involved in any investigation or audit under this section. All information and records of the inspector general that are obtained or received under any investigation or audit under this section shall be confidential, except as required or authorized pursuant to this section.

Sec. 10. K.S.A. 2007 Supp. 75-7427 is hereby repealed.

Sec. 11. This act shall take effect and be in force from and after its publication in the Kansas register.

Approved March 20, 2008.

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