

HOUSE BILL No. 2785

By Committee on Appropriations

Requested by Representative Ballard on behalf of the Board of Pharmacy

2-18

1 AN ACT concerning health and healthcare; relating to the board of
2 pharmacy; renaming the utilization of unused medications act as the the
3 medication donation program; revising criteria for accepting donations,
4 program participation and duties of a qualifying center; authorizing the
5 board to adopt rules and regulations; amending K.S.A. 65-1668, 65-
6 1669, 65-1670, 65-1671, 65-1672, 65-1673 and 65-1674 and repealing
7 the existing sections; also repealing K.S.A. 65-1675.
8

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

10 New Section 1. (a) A donating entity may donate a drug or device to a
11 qualifying center if the drug or device meets the eligibility requirements
12 established by K.S.A. 65-1671, and amendments thereto. Any person or
13 governmental entity may facilitate the donation of drugs to the medication
14 donation program.

15 (b) A drug or device shall only be donated at a qualifying center.

16 (c) The following persons may make the decision to donate a drug or
17 device on behalf of a patient:

18 (1) A person designated by durable power of attorney or a guardian or
19 other individual responsible for the care and well-being of a patient; or

20 (2) an executor, administrator or trustee of the estate of a deceased
21 patient.

22 (d) This section shall be a part of and supplemental to the medication
23 donation program.

24 New Sec. 2. K.S.A. 65-1668 through 65-1674, and amendments
25 thereto, shall be a part of and supplemental to the pharmacy act of the state
26 of Kansas.

27 Sec. 3. K.S.A. 65-1668 is hereby amended to read as follows: 65-
28 1668. (a) K.S.A. 65-1668 through ~~65-1675~~ 65-1674, and amendments
29 thereto, and sections 1 and 2, and amendments thereto, shall be known and
30 may be cited as the "~~utilization of unused medications act~~ medication
31 donation program." *This act shall be a part of and supplemental to the*
32 *pharmacy act of the state of Kansas.*

33 (b) The provisions of the ~~utilization of unused medications act~~
34 *medication donation program* shall not apply to any drug, ~~prescription~~
35 ~~drug or medication~~ device purchased or provided with moneys provided

1 under title XIX of the federal social security act, 42 U.S.C. § 1396 et seq.,
 2 and amendments thereto, or title XXI of the federal social security act,
 3 section 4901 of public law 105-33, 42 U.S.C. § 1397aa et seq., and
 4 amendments thereto.

5 Sec. 4. K.S.A. 65-1669 is hereby amended to read as follows: 65-
 6 1669. As used in the ~~utilization of unused medications act~~ *medication*
 7 *donation program*:

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

10 (b) ~~"Community mental health center" has means the same meaning~~
 11 ~~as such term is defined in K.S.A. 39-2002, and amendments thereto.~~

12 (b) *"Controlled substance" means any drug, substance or immediate*
 13 *precursor included in any of the schedules designated in K.S.A. 65-4107,*
 14 *65-4109, 65-4111 and 65-4113, and amendments thereto, or the federal*
 15 *controlled substances act, 21 U.S.C. § 812.*

16 (c) ~~"Donating entities entity" means adult care homes, mail service~~
 17 ~~pharmacies, a patient, patient's caregiver or representative, pharmacy,~~
 18 ~~manufacturer, wholesale distributor, governmental organization,~~
 19 ~~practitioner, mid-level practitioner or institutional drug rooms and medical~~
 20 ~~care facilities who elect to participate in the program room that donates a~~
 21 ~~drug or device to a qualifying center.~~

22 (d) ~~"Drug" has the same meaning as such term is defined in K.S.A.~~
 23 ~~65-1626, and amendments thereto.~~

24 (e) "Federally qualified health center" means a center that meets the
 25 requirements for federal funding under 42 U.S.C. § 1396d(1) of the public
 26 health service act, ~~and amendments thereto, and~~ that has been designated
 27 as a "federally qualified health center" by the federal government.

28 (f)(e) "Indigent healthcare clinic" ~~has means the same meaning as~~
 29 ~~such term is defined in K.S.A. 75-6102, and amendments thereto.~~

30 (g) ~~"Institutional drug room" has the meaning as such term is defined~~
 31 ~~in K.S.A. 65-1626, and amendments thereto.~~(h) ~~"Mail service pharmacy"~~
 32 ~~means a licensed Kansas pharmacy that ships, mails or delivers by any~~
 33 ~~lawful means a lawfully dispensed medication in tamper-resistant~~
 34 ~~packaging to residents of this state or another state.~~(i) "Medical care
 35 facility" has the same meaning as such term is defined in K.S.A. 65-425,
 36 and amendments thereto.

37 (j)(f) "Medically indigent person" ~~has means the same meaning as~~
 38 ~~such term is defined in K.S.A. 75-6102, and amendments thereto.~~

39 (k) "Medication" means a prescription drug or drug as defined by this
 40 section.

41 (l) ~~"Mid-level practitioner" has the same meaning as such term is~~
 42 ~~defined in K.S.A. 65-1626, and amendments thereto.~~

43 (m) ~~"Practitioner" has the same meaning as such term is defined in~~

1 K.S.A. 65-1626, and amendments thereto.

2 ~~(n) "Prescription drug" means a drug that may be dispensed only~~
3 ~~upon prescription of a practitioner or mid-level practitioner authorized by~~
4 ~~law and that is approved for safety and effectiveness as a prescription drug~~
5 ~~under section 505 or 507 of the federal food, drug and cosmetic act, 52-~~
6 ~~Stat. 1040 (1938), 21 U.S.C.A. § 301.~~

7 ~~(o)(g) "Qualifying center or clinic" means an indigent healthcare~~
8 ~~clinic, federally qualified health center, pharmacy or community mental~~
9 ~~health center that accepts, administers, supplies or dispenses a drug or~~
10 ~~device under the medication donation program.~~

11 ~~(h) "Qualifying patient" means an individual that is a resident of~~
12 ~~Kansas and a medically indigent person, uninsured or underinsured.~~

13 ~~(p)(i) "Samples of medications or injectables drugs" means a unit of~~
14 ~~drug subject to 21 U.S.C. § 353(b) that is not intended to be sold and is~~
15 ~~intended distributed in accordance with 21 U.S.C. § 353(d) to promote the~~
16 ~~sale of the drug.~~

17 ~~(j) "Underinsured" means either:~~

18 ~~(1) Having healthcare coverage or prescription drug or device~~
19 ~~coverage but having exhausted such coverage benefits or being unable to~~
20 ~~afford any associated deductible, coinsurance, copayments or similar~~
21 ~~charges for the drug or device prescribed; or~~

22 ~~(2) not having healthcare coverage for the drug or device prescribed.~~

23 Sec. 5. K.S.A. 65-1670 is hereby amended to read as follows: 65-
24 1670. (a) ~~The board of pharmacy shall establish and implement a program~~
25 ~~consistent with public health and safety through which unused drugs may~~
26 ~~be transferred from donating entities that elect to participate in the~~
27 ~~program for the purpose of distributing the unused medications to Kansas~~
28 ~~residents who are medically indigent. It shall be unlawful for any person~~
29 ~~to operate a qualifying center within this state without first having~~
30 ~~obtained a registration from the board. Each application for registration~~
31 ~~shall be made on a form furnished by the board. Each registration issued~~
32 ~~by the board shall expire every year on June 30. The board shall not~~
33 ~~impose any fee for the application or registration. Such registration shall~~
34 ~~not be transferable.~~

35 ~~(b) The board may limit, condition, revoke, suspend or place in a~~
36 ~~probationary status a registration or deny an application for issuance of~~
37 ~~any registration on any ground that would authorize the board to take~~
38 ~~action against the registration of a pharmacy under K.S.A. 65-1627, and~~
39 ~~amendments thereto.~~

40 ~~(c) On or before July 15, 2027, and each year thereafter, a qualifying~~
41 ~~center shall provide a report to the board on a form furnished by the board~~
42 ~~that includes the amount and types of drugs and devices received, the~~
43 ~~number of qualifying patients served, the drug or device handling fee, the~~

1 *total drug and device handling fees collected by the qualifying center*
2 *during the registration year and the qualifying center's total restocking,*
3 *dispensing and administration costs for that registration year. The report*
4 *shall include information for the period July 1 to June 30.*

5 *(d) The qualifying center shall make all records generated or*
6 *required as part of a medication donation program readily available at the*
7 *qualifying center by the board for a period of five years.*

8 *(e) A qualifying center or clinic in consultation with a pharmacist or*
9 *practitioner shall establish policies and procedures necessary to*
10 *implement the medication donation program established by the utilization*
11 *of unused medications act consistent with the pharmacy act of the state of*
12 *Kansas and rules and regulations adopted by the board.*

13 ~~*(e) The state board of pharmacy shall provide technical assistance to*~~
14 ~~*entities who may wish to participate in the program.*~~

15 *(f) When a qualifying center permanently discontinues operating a*
16 *medication donation program, such qualifying center, within 30 days of*
17 *discontinuation of the program, shall:*

18 *(1) Notify the board of the discontinuation of the medication donation*
19 *program and provide the location, contact information and manner of*
20 *disposition of all records required to be maintained pursuant to the*
21 *pharmacy act of the state of Kansas;*

22 *(2) conduct an inventory and provide the board with the location,*
23 *contact information and manner of disposition of any remaining stock of*
24 *drugs and devices; and*

25 *(3) submit to the board the report required by subsection (c).*

26 *(g) Each qualifying center that is a pharmacy shall comply with all*
27 *requirements for a pharmacy under the pharmacy act of the state of*
28 *Kansas and rules and regulations adopted by the board. Each qualifying*
29 *center that is not a pharmacy shall comply with all requirements for a*
30 *health department under the pharmacy act of the state of Kansas and rules*
31 *and regulations adopted by the board.*

32 *Sec. 6. K.S.A. 65-1671 is hereby amended to read as follows: 65-*
33 *1671. (a) The following criteria shall be used by a qualifying center in*
34 *accepting unused medications, administering, supplying or dispensing a*
35 *drug or device for use under the utilization of unused medications act*
36 *medication donation program:*

37 ~~*(a) The medications shall have come from a controlled storage unit of*~~
38 ~~*a donating entity;*~~

39 ~~*(b)(1) only medications.*~~
40 ~~*A drug shall be in their the original or*~~
41 ~~*pharmacist sealed unit dose and tamper-evident packaging or in tamper*~~
42 ~~*evident packaging, unit of use or sealed, unused injectables, including*~~
43 ~~*samples of medications or injectables, shall be accepted and dispensed*~~
~~*pursuant to the utilization of unused medications act drugs;*~~

1 ~~(e)(2) the drug or device shall not be expired medications shall not be~~
2 ~~accepted;~~

3 (3) *packaging shall be unopened, except that a drug packaged in*
4 *single unit doses may be accepted when the outside packaging is opened if*
5 *the single unit dose packaging is undisturbed;*

6 ~~(d)(4) a medication drug or device shall not be accepted,~~
7 ~~administered, supplied or dispensed by a qualifying center if the person~~
8 ~~individual accepting, administering, supplying or dispensing the~~
9 ~~medication drug or device has reason to believe that the medication drug~~
10 ~~or device is adulterated or misbranded;~~

11 ~~(e) no controlled substances shall be accepted, unless the state board~~
12 ~~of pharmacy designates certain controlled substances as accepted~~
13 ~~medications in the adoption of rules and regulations pursuant to K.S.A. 65-~~
14 ~~1674, and amendments thereto; and~~

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

19 (5) *if the drug or device was packaged by a pharmacy other than the*
20 *qualifying center, the name of the pharmacy and any other pharmacy*
21 *identifiers shall be removed or obscured from the packaging prior to*
22 *administration, supplying or dispensing;*

23 (6) *the donating patient's name and information shall be removed or*
24 *obscured from the packaging prior to administration, supplying or*
25 *dispensing;*

26 (7) *the drug or device shall have been stored according to federal*
27 *and state requirements;*

28 (8) *each drug or device shall include a beyond use date on the label*
29 *or packaging. If the prescription container is the manufacturer's original,*
30 *sealed packaging, the beyond use date is the expiration date listed on the*
31 *packaging; and*

32 (9) *the drug or device and its packaging shall not have any physical*
33 *sign of tampering, misbranding or adulteration.*

34 (b) *The following drugs and drug types shall not be accepted by a*
35 *qualifying center:*

36 (1) *Radiopharmaceuticals;*

37 (2) *a drug for which the federal food and drug administration*
38 *requires, as a risk evaluation and mitigation strategy, that the patient be*
39 *registered with the drug's manufacturer;*

40 (3) *controlled substances; and*

41 (4) *compound drugs.*

42 (c) *In the case of recalls, any donated drugs or devices affected by*
43 *the recall shall not be administered, supplied or dispensed unless the lot*

1 *number can be determined.*

2 *(d) Prior to accepting a drug or device, a pharmacist shall inspect*
3 *each drug or device and verify that it complies with the requirements of*
4 *this section. If the qualifying center is not a pharmacy, the inspection and*
5 *verification may be completed by a practitioner.*

6 *(e) Prior to administering, supplying or dispensing a drug or device*
7 *to an individual under the medication donation program, a qualifying*
8 *center shall verify that the individual is a qualifying patient. A qualifying*
9 *center shall establish policies and procedures to determine eligibility of an*
10 *individual as a qualifying patient.*

11 Sec. 7. K.S.A. 65-1672 is hereby amended to read as follows: 65-
12 1672. ~~(a) Participation in the utilization of unused medications act by~~
13 ~~residents of adult care homes and donating entities medication donation~~
14 ~~program shall be voluntary. Nothing in the utilization of unused~~
15 ~~medications pharmacy act of the state of Kansas shall require any resident~~
16 ~~of an adult care home or any donating entity person to participate in the~~
17 ~~program.~~

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

20 ~~(1) Dispense medications donated under the utilization of unused~~
21 ~~medications act to persons who are medically indigent residents of~~
22 ~~Kansas. Administer or supply a drug or device to a qualifying patient at the~~
23 ~~qualifying center. If the qualifying center is a pharmacy, the qualifying~~
24 ~~center may also dispense a drug or device to a qualifying patient at the~~
25 ~~qualifying center; and~~

26 ~~(2) charge persons receiving donated medications a qualifying patient~~
27 ~~a handling fee that shall not to exceed 200% of the Medicaid dispensing~~
28 ~~fee \$20 per prescription to cover restocking, administration or dispensing~~
29 ~~costs. A qualifying center shall not charge a handling fee for samples of~~
30 ~~drugs. If a qualifying center chooses to charge a handling fee, the fees~~
31 ~~collected in any registration year shall not exceed the program's total~~
32 ~~restocking, dispensing and administration costs for that registration year.~~

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

36 ~~(1) Comply with all applicable federal and state laws related to the~~
37 ~~storage, administration, supply, dispensing and distribution transfer of~~
38 ~~medications drugs and devices;~~

39 ~~(2) visually inspect all medications each drug or device prior to~~
40 ~~accepting, administering, supplying or dispensing the medications drug or~~
41 ~~device to determine that such medications are not adulterated drug or~~
42 ~~device appears to be unadulterated, safe and suitable for administration,~~
43 ~~supplying or dispensing; and~~

1 (3) ~~administer, supply or dispense prescription drugs~~ a drug or
 2 device only pursuant to a medication order or valid prescription order
 3 issued by a practitioner ~~or~~ mid-level practitioner or pursuant to a
 4 statewide protocol established by K.S.A. 65-16,127 and 65-16,131, and
 5 amendments thereto;

6 (4) quarantine donated drugs and devices separately from all other
 7 drug or device stock until the donated drugs and devices have been
 8 inspected and approved in accordance with the medication donation
 9 program; and

10 (5) store donated drugs and devices separately from or in a manner
 11 that identifies such drugs or devices from all other drug or device stock.

12 (d) ~~Medications~~ Each drug or device donated ~~under the utilization of~~
 13 ~~unused medications act~~ to a qualifying center shall not be resold but are
 14 available for transfer ~~may be transferred~~ to another qualifying center ~~or~~
 15 ~~clinic~~.

16 (e) ~~For purposes of the utilization of unused medications act,~~
 17 ~~medications dispensed~~ The administration, supply or dispensing of a drug
 18 or device by a qualifying ~~centers or clinics~~ center shall not be considered
 19 resale of such ~~medications~~ drug or device.

20 (f) Prior to administration, supplying or dispensing a drug or device,
 21 the qualifying center shall require the qualifying patient to sign an
 22 electronic or physical form established by the board to confirm that the
 23 individual understands the immunity provisions and the medication
 24 donation program. Such form shall be maintained by the qualifying center
 25 for a minimum of five years in a readily available format.

26 (g) Prior to donating any drug or device, the qualifying center shall
 27 require that the donating entity to sign an electronic or physical form
 28 established by the board stating that the donating entity is the owner of the
 29 drug or device and intends to voluntarily donate the drug or device to the
 30 qualifying center. The form shall be maintained by the qualifying center
 31 for a minimum of five years in a readily retrievable format.

32 Sec. 8. K.S.A. 65-1673 is hereby amended to read as follows: 65-
 33 1673. (a) For matters related only to the lawful donation, acceptance,
 34 administration, supplying or dispensing of ~~medications~~ drugs and devices
 35 under the ~~utilization of unused medications act~~ medication donation
 36 program, the following persons and entities, in compliance with the
 37 utilization of unused medications act, in the absence of bad faith or gross
 38 negligence, shall not be subject to criminal or civil liability for injury ~~other~~
 39 ~~than~~, death, or loss to person or property, or professional disciplinary
 40 action:

- 41 (1) The state board of pharmacy;
- 42 (2) the department of health and environment;
- 43 (3) the Kansas department for aging and disability services;

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

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

5 (6) any ~~qualifying center or clinic that employs a practitioner or, mid-~~
6 ~~level practitioner or pharmacist who accepts or can legally dispense~~
7 ~~prescription drugs, administers, supplies or dispenses a drug or device~~
8 ~~under the utilization of unused medications act and the pharmacy act of the~~
9 ~~state of Kansas medication donation program.~~

10 (b) For matters related to the donation, acceptance, *administration,*
11 *supply* or dispensing of a ~~medication drug or device~~ manufactured by the
12 ~~prescription drug or device~~ manufacturer that is donated by any *donating*
13 ~~entity under the utilization of unused medications act medication donation~~
14 *program*, a prescription drug *or device* manufacturer shall not, in the
15 absence of bad faith or gross negligence, be subject to criminal or civil
16 liability for injury ~~other than for~~, death, or loss to person or property
17 including, but not limited to, liability for failure to transfer or
18 communicate product or consumer information or the ~~expiration beyond-~~
19 *use* date of the donated ~~prescription drug or device~~.

20 (c) Any person who in good faith donates ~~medications a drug or~~
21 ~~device~~ without charge under the ~~utilization of unused medications act~~
22 *medication donation program*, which ~~medications are drug or device is~~ in
23 compliance with such ~~act program~~ at the time donated, shall not be subject
24 to criminal or civil liability arising from any injury or death due to the
25 condition of such ~~medications- drug or device~~ unless such injury or death
26 is a direct result of the willful, wanton, malicious or intentional
27 misconduct of such person.

28 Sec. 9. K.S.A. 65-1674 is hereby amended to read as follows: 65-
29 1674. (a) The state board of pharmacy ~~shall may~~ adopt rules and
30 regulations to implement the ~~utilization of unused medications act. Such~~
31 ~~rules shall medication donation program related to the following:~~

32 (1) ~~include~~ Standards and procedures for transfer, acceptance,
33 *administration, supply, dispensing* and safe storage of ~~donated medications~~
34 *a drug or device;*

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

40 (3) ~~establish~~ standards and procedures for acceptance of unused
41 medications from donating entities;

42 (4) ~~establish~~ standards and procedures for designating certain
43 controlled substances as accepted donated medications;

1 ~~(5) establish standards and procedures for a qualifying center or clinic~~
2 ~~to prepare any donated medications for dispensing, supplying or~~
3 ~~administering to a qualified patient; and~~

4 ~~(6) establish, in consultation with the department of health and~~
5 ~~environment and the Kansas department for aging and disability services,~~
6 ~~any additional rules and regulations, and standards and procedures it~~
7 ~~deems appropriate or necessary to implement the provisions of the~~
8 ~~utilization of unused medications act~~

9 (3) *additional drugs, drug types and devices that are ineligible to be*
10 *donated.*

11 (b) ~~In accordance with the rules and regulations and procedures of the~~
12 ~~program established pursuant to this section, a resident of an adult care~~
13 ~~home, or the representative or guardian of a resident may donate unused~~
14 ~~medications for dispensation to medically indigent persons~~*The board shall*
15 *maintain records of program participation including the number of*
16 *donating entities, qualifying center locations, the amount and types of*
17 *drugs and devices received and the number of qualifying patients served.*

18 (c) *The board shall develop a form that a qualifying patient shall sign*
19 *prior to administration, supplying or dispensing of a drug or device under*
20 *the medication donation program to confirm that the qualifying patient*
21 *understands the immunity provisions and the medication donation*
22 *program.*

23 (d) *The board shall develop a form that a donating entity shall sign*
24 *prior to donating stating that the person is the owner of the drug or device*
25 *and intends to voluntarily donate under the medication donation program.*
26 *The form shall include, at minimum:*

27 (1) *The name of the person that was originally dispensed the drug or*
28 *device or the name of the entity that owns the drug or device;*

29 (2) *the full name, contact information and signature of the donating*
30 *entity;*

31 (3) *the name, contact information and license number of any*
32 *practitioner or pharmacist responsible for oversight of the donating entity,*
33 *drug or device;*

34 (4) *the brand name or generic name of the drug or device donated*
35 *and either the name of the manufacturer or the national drug code*
36 *number;*

37 (5) *the quantity of any donated drug;*

38 (6) *the strength of any donated drug; and*

39 (7) *the date of donation and acceptance by the qualifying center.*

40 (e) *The board may inspect in a lawful manner the drugs or devices*
41 *accepted and any records maintained under the medication donation*
42 *program and for this purpose shall have the right to enter and inspect any*
43 *qualifying center during business hours to ensure compliance with the*

1 *medication donation program and to ensure that, in the professional*
2 *judgment of a pharmacist, each drug or device meets all federal and state*
3 *standards and is unadulterated, safe and suitable for administration,*
4 *supply or dispensing.*

5 Sec. 10. K.S.A. 65-1668, 65-1669, 65-1670, 65-1671, 65-1672, 65-
6 1673, 65-1674 and 65- are hereby repealed.

7 Sec. 11. This act shall take effect and be in force from and after its
8 publication in the statute book.