As Amended by House Committee

Session of 2013

HOUSE BILL No. 2153

By Committee on Health and Human Services

1-30

AN ACT concerning the utilization of unused medications act; relating to
 donating entities, unused medications; authority and rules and
 regulations of the state board of pharmacy; repealing the cancer drug
 repository program; amending K.S.A. 2012 Supp. 65-1636, 65-1669,
 65-1670, 65-1671 and 65-1674 and repealing the existing sections; also
 repealing K.S.A. 2012 Supp. 65-1664, 65-1665, 65-1666 and 65-1667.

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

9 Section 1. K.S.A. 2012 Supp. 65-1636 is hereby amended to read as 10 follows: 65-1636. (a) Except as otherwise provided in this act, the sale and 11 distribution of drugs shall be limited to pharmacies operating under 12 registrations as required by this act, and the actual sale or distribution of 13 drugs shall be made by a pharmacist or other persons acting under the 14 immediate personal direction and supervision of the pharmacist.

(b) The donation, acceptance, transfer, distribution or dispensing of
any drug in compliance with the provisions of the cancer drug repository
program established by K.S.A. 2012 Supp. 65-1664 through 65-1667, and
amendments thereto, and any rules and regulations promulgated
thereunder shall not constitute a violation of this section.

(e) (b) The donation, acceptance, transfer, distribution or dispensing
 of any drug in compliance with the provisions of the utilization of unused
 medications act and any rules and regulations promulgated thereunder
 shall not constitute a violation of this section.

24 Sec. 2. K.S.A. 2012 Supp. 65-1669 is hereby amended to read as 25 follows: 65-1669. As used in the utilization of unused medications act:

(a) "Adult care home" has the same meaning as such term is definedin 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, *institutional drug rooms* 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.

1 (e) "Federally qualified health center" means a center which meets 2 the requirements for federal funding under 42 U.S.C. § 1396d(1) of the 3 public health service act, and amendments thereto, and which has been 4 designated as a "federally qualified health center" by the federal 5 government.

6 (f) "Indigent health care clinic" has the same meaning as such term is 7 defined in K.S.A. 75-6102, and amendments thereto.

8 (g) "Institutional drug room" has the meaning as such term is defined
 9 in K.S.A. 65-1626(bb) {(1)(A)}, and amendments thereto.

10 (g) (h) "Mail service pharmacy" means a licensed Kansas pharmacy 11 that ships, mails or delivers by any lawful means a lawfully dispensed 12 medication in tamper-resistant packaging to residents of this state or 13 another state.

14 (h) (*i*) "Medical care facility" has the same meaning as such term is 15 defined in K.S.A. 65-425, and amendments thereto.

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

18 (i) (k) "Medication" means a prescription drug or drug as defined by 19 this section.

20 (k) (l) "Mid-level practitioner" has the same meaning as such term is 21 defined in K.S.A. 65-1626, and amendments thereto.

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

(m) (n) "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. § 301), and amendments
thereto.

30 (n)(o) "Qualifying center or clinic" means an indigent health care 31 clinic, federally qualified health center or community mental health center.

(p) "Samples of medications or injectables" means a unit of drug that
 is not intended to be sold and is intended to promote the sale of the drug.

Sec. 3. K.S.A. 2012 Supp. 65-1670 is hereby amended to read as follows: 65-1670. (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.

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

(c) The state board of pharmacy shall provide technical assistance to 1 2 entities who may wish to participate in the program.

Sec. 4. K.S.A. 2012 Supp. 65-1671 is hereby amended to read as 3 follows: 65-1671. The following criteria shall be used in accepting unused 4 medications for use under the utilization of unused medications act: 5

6 (a) The medications shall have come from a controlled storage unit of 7 a donating entity;

8 (b) only medications in their original or pharmacist sealed unit dose 9 packaging or in tamper evident packaging, unit of use or sealed, unused injectables, including samples of medications or injectables, shall be 10 accepted and dispensed pursuant to the utilization of unused medications 11 12 act:

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(c) expired medications shall not be accepted;

14 (d) a medication shall not be accepted or dispensed if the person accepting or dispensing the medication has reason to believe that the 15 medication is adulterated: 16

17 (e) no controlled substances shall be accepted; and , unless the state 18 board of pharmacy designates certain controlled substances as accepted 19 medications in the adoption of rules and regulations pursuant to K.S.A. 20 65-1674. and amendments thereto: and

21 (f) subject to the limitation specified in this section, unused medications dispensed for purposes of a medical assistance program or 22 23 drug product donation program may be accepted and dispensed under the utilization of unused medications act. 24

25 Sec. 5. K.S.A. 2012 Supp. 65-1674 is hereby amended to read as follows: 65-1674. (a) The state board of pharmacy shall adopt rules and 26 regulations by December 1, 2008, to implement the utilization of unused 27 28 medications act. Such rules shall:

(1) Include standards and procedures for transfer, acceptance and safe 29 30 storage of donated medications:

31 (2) include standards and procedures for inspecting donated 32 medications to ensure that the medications are in compliance with the utilization of unused medications act and to ensure that, in the professional 33 34 judgment of a pharmacist, the medications meet all federal and state 35 standards for product integrity;

- 36 (3) establish standards and procedures for acceptance of unused 37 medications from donating entities; and
- 38 (4) establish standards and procedures for designating certain controlled substances as accepted donated medications; 39

(5) establish standards and procedures for a qualifying center or 40 clinic to prepare any donated medications for dispensing or 41 administering; and 42

43 (6) 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.

5 (b) In accordance with the rules and regulations and procedures of the 6 program established pursuant to this section, a resident of an adult care 7 home, or the representative or guardian of a resident may donate unused 8 medications, other than prescription drugs defined as controlled 9 substances, for dispensation to medically indigent persons.

10 Sec. 6. K.S.A. 2012 Supp. 65-1636, 65-1664, 65-1665, 65-1666, 65-11 1667, 65-1669, 65-1670, 65-1671 and 65-1674 are hereby repealed.

12 Sec. 7. This act shall take effect and be in force from and after its 13 publication in the statute book.