SENATE BILL No. 199

AN ACT concerning health care; relating to stem cell therapy and unused medications; 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.

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

Section 1. (a) The university of Kansas medical center shall establish the midwest stem cell therapy center. The center shall:

(1) Focus on activities that advance adult, cord blood and related stem cell and non-embryonic stem cell research and therapies for patient treatment;

(2) serve as a core facility to produce clinical grade stem cells from adult tissues, cord blood and related materials for use in clinical trials and therapies;

(3) facilitate the delivery of adult, cord blood and related stem cell therapies to Kansas City and midwest region hospitals where appropriate;

(4) partner and collaborate with the blood and marrow transplant center of Kansas to foster a regional network of physicians trained in adult, cord blood and related stem cell therapy applications;

(5) create and maintain a database resource for physicians and patients that provides a comprehensive global list of available stem cell clinical trials and therapies;

(6) initiate clinical trials with adult, cord blood and related stem cells;

(7) create education modules to train and educate physicians and research scientists about peer-reviewed adult, cord blood and related stem cell therapy applications for patients;

(8) distribute information to Kansas physicians about methods for successful treatments with adult, cord blood and related stem cells through basic and clinical research; and

(9) inform the public on available adult, cord blood and related stem cell therapeutic options.

Sec. 2. (a) The executive vice chancellor of the university of Kansas medical center shall appoint the director of the midwest stem cell therapy center.

(b) The director shall report to the executive vice chancellor of the university of Kansas medical center.

(c) The director of the midwest stem cell therapy center shall have experience in adult or cord blood stem cell research and experience in clinical applications of adult or cord blood stem cell therapies.

(d) The director of the midwest stem cell therapy center shall be responsible for administration of the midwest stem cell therapy center, including the overall direction of personnel, equipment and facilities.

(e) The director of the midwest stem cell therapy center shall be responsible for coordination of patient treatment and research with adult, cord blood and related stem cells and non-embryonic stem cells.

(f) The director of the midwest stem cell therapy center is hereby authorized to solicit and receive grants, gifts, contributions or bequests made for the purpose of furthering the goals and missions of the midwest stem cell therapy center. The director of the midwest stem cell therapy center shall remit all moneys so received to the state treasurer in accordance with the provisions of K.S.A. 75-4215, and amendments thereto. Upon receipt of each such remittance, the state treasurer shall deposit the entire amount in the state treasury to the credit of the midwest stem cell therapy center fund.

(g) Fees received for core charges for cell processing and manufacturing, clinical trial fees and similar service charges shall be paid to the university of Kansas medical center research institute, inc. or university of Kansas endowment, as determined by the director.

(h) The university of Kansas endowment association may accept gifts directly designated for the benefit of the midwest stem cell therapy center consistent with its corporate purpose as a nonprofit charitable corporation whose mission seeks the advancement of the university of Kansas.

(i) The director of the midwest stem cell therapy center shall annually submit a report to the senate committee on ways and means, senate committee on public health and welfare, house committee on appropriations and house committee on health and human services at the beginning of the regular session of the legislature beginning in 2014 on the fees received, expenditure of moneys appropriated and activities of the midwest

stem cell therapy center, including the activities of its affiliated organizations, and the activities of the advisory board.

Sec. 3. (a) There is hereby established in the state treasury the midwest stem cell therapy center fund. Expenditures from the fund may be made for the purposes of furthering the goals and missions of the midwest stem cell therapy center and for such other purposes as may be specified with regard to any grant, gift, contribution or bequest. All such expenditures shall be authorized by the director of the midwest stem cell therapy center and made upon warrants of the director of accounts and reports issued pursuant to vouchers approved by the director of midwest stem cell therapy center.

(b) On or before the 10th of each month, the director of accounts and reports shall transfer from the state general fund to the midwest stem cell therapy center fund interest earnings based on:

(1) The average daily balance of moneys in the midwest stem cell therapy center fund for the preceding month; and

(2) the net earnings rate for the pooled money investment portfolio for the preceding month.

Sec. 4. (a) There is hereby established the advisory board to the midwest stem cell therapy center which shall be composed of 14 members and one ex officio member as follows:

(1) One person representing the patient community appointed by the governor and such original member shall serve two years;

(2) one person representing the physician community appointed by the governor and such original member shall serve three years;

(3) one person representing the university of Kansas appointed by the state board of regents and such original member shall serve one year;

(4) one person representing Kansas state university appointed by the state board of regents and such original member shall serve one year;

(5) one person representing the university of Kansas medical center appointed by the executive vice chancellor and such original member shall serve three years;

(6) one person representing the institute for advancing medical innovation appointed by the director of the institute for advancing medical innovation and such original member shall serve one year;

(7) one person representing the university of Kansas cancer center appointed by the director of the university of Kansas cancer center and such original member shall serve two years;

(8) one person representing the university of Kansas hospital authority appointed by the board of directors of the university of Kansas hospital authority and such original member shall serve for one year;

(9) one member of the house of representatives appointed by the speaker of the house and such original member shall serve for two years;

(10) one member of the senate appointed by the president of the senate and such original member shall serve for three years;

(11) one person with a nationally respected reputation representing the physician community appointed by the speaker of the house and such original member shall serve three years;

(12) one person with a nationally respected reputation representing the scientific research community appointed by the president of the senate and such original member shall serve one year;

(13) one member of the executive branch of the state agencies appointed by the governor and such original member shall serve for two years;

(14) one member representing the blood and marrow transplant center of Kansas appointed by the chief executive officer of via christi health and such original member shall serve three years; and

(15) the director of the midwest stem cell therapy center as an ex officio member of the board.

(b) The appointments to the advisory board shall be for terms of three years, except as provided for the original members in subsection (a). No member shall be appointed to the advisory board for more than three consecutive terms. Upon the expiration of the term of office of any member of the advisory board on or after the effective date of this act, and in any case of a vacancy existing on or after the effective date of this act, a successor shall be appointed by the appropriate entity pursuant to this section.

(c) The advisory board shall serve in an advisory role to the director of the midwest stem cell therapy center.

(d) Duties of members may include fundraising, public speaking and other public relation activities to advance public awareness of successful adult, cord blood and related stem cell therapeutic options.

(e) The governor shall appoint the chairperson of the advisory board and the chairperson may serve consecutive terms. The advisory board shall meet at least four times each year and at such other times as it deems appropriate, or upon call of the chairperson.

(f) All members of the advisory board shall serve without compensation.

Sec. 5. All funds and facilities of the midwest stem cell therapy center shall be dedicated to treatments and research with adult, cord blood and related stem cells and non-embryonic stem cells. No funds or facilities of the midwest stem cell therapy center shall involve embryonic stem cells or fetal tissue cells.

Sec. 6. As used in sections 1 through 5, and amendments thereto:

(a) "Adult, cord blood and related stem cells" are stem cells derived from postnatal tissue cells, umbilical cord blood and cord tissue including Wharton's jelly, amniotic fluid and placental tissue.

(b) "Embryonic stem cells" are stem cells derived from early stage human embryos, up to and including the blastocyst stage.

(c) "Facilities" include all equipment used by the midwest stem cell therapy center.

(d) "Fetal tissue cells" are cells harvested from aborted fetal tissue.

(e) "Non-embryonic stem cells" are stem cells such as iPS cells (induced pluripotent stem cells) generated from adult somatic cells or other non-embryonic tissue cells without any embryonic component.

Sec. 7. K.S.A. 2012 Supp. 65-1636 is hereby amended to read as follows: 65-1636. (a) Except as otherwise provided in this act, the sale and distribution of drugs shall be limited to pharmacies operating under registrations as required by this act, and the actual sale or distribution of drugs shall be made by a pharmacist or other persons acting under the 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.~~

~~(c)~~*(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.

Sec. 8. K.S.A. 2012 Supp. 65-1669 is hereby amended to read as follows: 65-1669. 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, *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.

(e) "Federally qualified health center" means a center which meets the requirements for federal funding under 42 U.S.C. § 1396d(1) of the public health service act, and amendments thereto, 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) "Institutional drug room" has the meaning as such term is defined in K.S.A. 65-1626(bb), and amendments thereto.

~~(g)~~*(h)* "Mail service pharmacy" means a licensed Kansas pharmacy 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)~~*(i)* "Medical care facility" has the same meaning as such term is 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.

~~(j)~~*(k)* "Medication" means a prescription drug or drug as defined by this section.

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

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

~~(n)~~*(o)* "Qualifying center or clinic" means an indigent health care 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. 9. 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.

(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.

Sec. 10. K.S.A. 2012 Supp. 65-1671 is hereby amended to read as follows: 65-1671. 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 in tamper evident packaging, unit of use or sealed, unused injectables*, including samples of medications or 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~~*, unless the state board of pharmacy designates certain controlled substances as accepted medications in the adoption of rules and regulations pursuant to K.S.A. 65-1674, and amendments thereto; 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.

Sec. 11. 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 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 *and procedures* for acceptance of unused medications from donating entities;~~ and~~

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

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

(6) establish, in consultation with the department of health and environment and the *Kansas* department ~~on~~ *for* aging *and disability services*, 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.

Sec. 12. K.S.A. 2012 Supp. 65-1636, 65-1664, 65-1665, 65-1666, 65-1667, 65-1669, 65-1670, 65-1671 and 65-1674 are hereby repealed.

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

I hereby certify that the above BILL originated in the SENATE, and passed that body

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SENATE adopted
Conference Committee Report _____

_____
President of the Senate.

_____
Secretary of the Senate.

Passed the HOUSE
as amended _____

HOUSE adopted
Conference Committee Report _____

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Speaker of the House.

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Chief Clerk of the House.

APPROVED _____

_____
Governor.