

SESSION OF 2013

**CONFERENCE COMMITTEE REPORT BRIEF
SENATE BILL NO. 199**

As Agreed to April 4, 2013

Brief*

SB 199 would enact new law requiring the University of Kansas Medical Center (KUMC) to establish the Midwest Stem Cell Therapy Center (Center), provide for the administration and oversight of the Center, and establish a new fund; and would amend the Utilization of Unused Medications Act to expand certain definitions, modify the role of the State Board of Pharmacy in establishing standards and procedures, and delete language related to the Cancer Drug Repository Program.

Midwest Stem Cell Therapy Center

Activities and Duties

Among the activities and duties that would be assigned to the Center are:

- Focusing on activities that would advance adult, cord blood and related stem cell and non-embryonic stem cell research and therapies for patient treatment;
- Serving 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;
- Partnering and collaborating with the Blood and Marrow Transplant Center of Kansas to foster a

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regional network of physicians trained in adult, cord blood and related stem cell therapy applications;

- Creating and maintaining a database resource for physicians and patients that provides a comprehensive global list of available stem cell clinical trials and therapies;
- Initiating clinical trials with adult, cord blood, and related stem cells; and
- Informing the public on available adult, cord blood, and related stem cell therapeutic options.

Administration; Annual Report

The Executive Vice Chancellor of KUMC would be authorized to appoint the director of the Midwest Stem Cell Therapy Center. The director would report to the Executive Vice Chancellor. Among the requirements for and duties of the director would be:

- Having experience in adult or cord blood stem cell research and experience in clinical applications of adult or cord blood stem cell therapies;
- Being responsible for the coordination of patient treatment and research with adult, cord blood and related stem cells and non-embryonic stem cells;
- Soliciting and receiving grants, gifts, contributions, or bequests made for the purpose of furthering the goals and missions of the Center (authorized by the bill). The director would be required to remit all moneys to the State Treasurer; the Treasurer then would deposit the entire amount to the credit of the Midwest Stem Cell Therapy Center Fund; and
- Providing an annual report to the Senate Ways and Means Committee, Senate Public Health and Welfare Committee, House Appropriations

Committee, and the House Health and Human Services Committee. The report would be required to be submitted at the start of each legislative session, beginning in 2014, and address the fees received; the expenditure of moneys appropriated; the activities of the Center, including the activities of its affiliated organizations; and the activities of the Advisory Board.

The bill also would require fees received for core charges for cell processing and manufacturing, clinical trials, and similar service charges be paid to KUMC Research Institute, Inc., or the University of Kansas Endowment, as determined by the director. The University of Kansas Endowment Association would be permitted to 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.

Midwest Stem Cell Therapy Center Fund

The bill would establish the Midwest Stem Cell Therapy Center Fund (Fund) in the state treasury. Expenditures from the Fund could be made for the purposes of furthering the goals and mission of the Center and for other purposes as may be specified with regard to any grant, gift, contribution, or bequest. The expenditures would be required to be authorized by the director and made upon warrants of the Department of Administration's Director of Accounts and Reports issued pursuant to vouchers approved by the director of the Center. The bill would require the director of Accounts and Reports, on or before the tenth of each month, to transfer from the State General Fund to the Fund, the interest earnings based on the average daily balance of moneys in the Fund for the preceding month and the new earnings rate for the Pooled Money Investment Portfolio for the preceding month.

Advisory Board

The bill would establish the Advisory Board, which would serve in an advisory role to the Center's director. Board members' duties could include fund raising, public speaking, and other public relations activities to advance public awareness of successful adult, cord blood and related stem cell therapeutic options. The Board would be required to meet at least four times each year and would be authorized to meet upon the call of the chairperson. The Board would be composed of the following 14 members (staggered terms of service requirements noted):

- A representative of the patient community appointed by the Governor (original member would serve two years);
- A representative of the physician community appointed by the Governor (original member would serve three years);
- A representative of the University of Kansas appointed by the Board of Regents (original member would serve one year);
- A representative of Kansas State University appointed by the Board of Regents (original member would serve one year);
- A representative of KUMC appointed by the Executive Vice Chancellor (original member would serve three years);
- A representative of the Institute for Advancing Medical Innovation appointed by the Institute's director (original member would serve one year);
- A representative of the University of Kansas Cancer Center appointed by the Cancer Center's director (original member would serve two years);
- A representative of the University of Kansas Hospital Authority appointed by the Authority's

board of directors (original member would serve one year);

- A member of the House of Representatives appointed by the Speaker of the House (original member would serve two years);
- A member of the Senate appointed by the Senate President (original member would serve for three years);
- A person with a nationally respected reputation representing the physician community appointed by the Speaker of the House (original member would serve for three years);
- A person with a nationally respected reputation representing the scientific community appointed by the Senate President (original member would serve one year);
- A member of the executive branch of the state agencies appointed by the Governor (original member would serve for two years); and
- A member representing the Blood and Marrow Transplant Center of Kansas appointed by the Chief Executive Officer of Via Christi Health (original member would serve three years).

The Center's director would serve as an *ex officio* member of the Board. Advisory Board members could serve for only three consecutive terms and its members would serve without compensation. The bill would provide for Board vacancies and appointments of successor members. The Governor would appoint the Board chairperson.

The bill would state that all funds and facilities of the Center must be dedicated to treatments and research with adult, cord blood and related stem cells and non-embryonic stem cells. The bill would specifically prohibit the use of funds or facilities involving embryonic or fetal tissue cells.

The bill also would establish definitions associated with the creation of the Midwest Stem Cell Therapy Center, including the terms “adult, cord blood and related stem cells,” “embryonic stem cells,” “facilities,” “fetal tissue cells,” and “non-embryonic stem cells.”

Utilization of Unused Medications Act—Amendments

The bill would amend the Utilization of Unused Medications Act to expand the definition of “donating entities” to include institutional drug rooms; add definitions for “institutional drug room” and “samples of medications or injectables”; and allow for the donation of samples of medications or injectables and only those controlled substances designated by the State Board of Pharmacy as accepted medications in the adoption of rules and regulations. Further, the bill also would delete language related to the Cancer Drug Repository Program.

The bill would define the following terms:

- “Samples of medications or injectables” means a unit of drug not intended to be sold and intended to promote the sale of the drug; and
- “Institutional drug room” as defined in KSA 65-1626(bb), which means any location where prescription-only drugs are stored and from which prescription-only drugs are administered or dispensed that is maintained or operated for the purpose of providing the drug needs of:
 - Inmates of a jail or correctional institution or facility;
 - Residents of a juvenile detention facility, as defined by the revised Kansas Code for Care of Children and the revised Juvenile Justice Code;
 - Students of a public or private university or college, a community college or any other

institution of higher learning which is located in Kansas;

- Employees of a business or other employer; or
- Persons receiving inpatient hospice services.

The term “institutional drug room” excludes any registered pharmacy, any office of a practitioner, or a location where no prescription-only drugs are dispensed and no prescription-only drugs other than individual prescriptions are stored or administered.

Further, the bill would require the Board to adopt rules and regulations to establish:

- Procedures for acceptance of unused medications from donating entities;
- Standards and procedures for designating certain controlled substances as accepted donated medications; and
- Standards and procedures for a qualifying center or clinic to prepare any donated medications for dispensing or administering.

Conference Committee Action

The second Conference Committee agreed to the House amendments to the bill and further agreed to insert provisions relating to the Utilization of Unused Medications Act (HB 2153, as amended by the Senate Committee on Public Health and Welfare).

Background

SB 199. Proponents present at the Senate Committee hearing included representatives of the KUMC and the Family Research Council; an Assistant Professor of Medicine,

Division of Hematology and Oncology at the KUMC; and a representative of Kansans For Life who presented the testimony for a Rockhurst University professor of philosophy. The KUMC professor stated a center would help attract and recruit subjects to clinical trials offered by the Center, help attract companies and clinical and basic science investigators interested in stem cell therapy to collaborate with this center to conduct their studies, and result in establishing Kansas as a biomedical hub. Testimony submitted by the Executive Vice Chancellor, KUMC, highlighted the 2012 National Cancer Institute designation and research currently conducted with adult stem cells. The testimony also indicated there currently are not funds for this program at KUMC and funding through the appropriations process of the state or development work in the private sector would be needed to implement the initiative and meet the objective of the bill.

Written testimony in support of the bill was provided by the Director of the Division of Cardiovascular Diseases and the Cardiovascular Research Institute, KUMC; a physician from the MidAmerica Neuroscience Institute; the Vice President for Research at Kansas State University; and representatives of Concerned Women for America of Kansas and Kansans for Life. There was no opponent testimony.

The Senate Committee on Public Health and Welfare amended a duty assigned to the director for the Center, replacing the term "oversight" with "coordination." A technical amendment also was made.

The Senate Committee of the Whole amendment inserted a reporting requirement for the director of the Midwest Stem Cell Therapy Center. The director would be required to report annually to specified legislative committees.

Proponents present at the House Committee on Health and Human Services hearing included representatives of the KUMC and the Family Research Council; a representative of the Cancer Center of Kansas and Via Christi Health; and a representative of Kansans For Life. The representative of the

Family Research Council testified the Center would be primarily focused on patients and the objectives of the Center would be to expand the access and increase the range of stem cell treatments available to Kansans and others in the region. The representative of the Cancer Center of Kansas and Via Christi Health expressed interest in partnering and collaborating with KUMC in bringing novel transplant procedures for cardiac, neurology, and diabetes to south-central Kansas and proposed amendments to assure active participation.

Written testimony in support of the bill at the House Committee hearing was provided by a Rockhurst University professor of philosophy; the Vice President for Research at Kansas State University; and the Director of the Division of Cardiovascular Diseases and the Cardiovascular Research Institute, KUMC. There was no opponent testimony.

The House Committee on Health and Human Services amended the bill to add partnering and collaborating with the Blood and Marrow Transplant Center of Kansas to the duties assigned to the Center, expand the information to be provided in the Center's annual report, and increase Board membership by one member to include a representative of the Blood and Marrow Transplant Center of Kansas.

The House Committee of the Whole amended the bill to clarify the Chief Executive Officer of Via Christi Health would appoint the representative of the Blood and Marrow Transplant Center of Kansas to the Board and the original term to be served by the member would be three years.

The fiscal note prepared by the Division of the Budget on SB 199 states the University of Kansas indicates the estimated cost for the Midwest Stem Cell Therapy Center would be approximately \$10.7 million over ten years. In FY 2014, for staffing and equipment, the cost would be approximately \$579,500 with an additional \$575,000 for lab renovation, for a total of \$1,154,500. In FY 2015, operation would be approximately \$754,500. Funding for the project

would come from federal grants, private gifts, and other funds. Any fiscal effect associated with the bill is not reflected in *The FY 2014 Governor's Budget Report*.

HB 2153. The bill was introduced by the House Committee on Health and Human Services at the request of Representative Don Hill. A representative of the Kansas Association for the Medically Underserved (KAMU) testified in favor of the bill at the House Health and Human Services Committee hearing. The KAMU representative indicated the bill will potentially assist in diverting additional unused medications for use by federally qualified health centers and indigent health care clinics in assisting medically indigent patients.

No opponents testified at the House Committee hearing. Neutral testimony was provided by a representative of the Kansas Pharmacists Association.

The House Committee on Health and Human Services amended the bill to remove the date for the Board to adopt rules and regulations to implement the Act, as the date has passed.

The House Committee of the Whole made a technical amendment to the bill to correct the omission of part of the definition of an "institutional drug room."

The Senate Committee on Public Health and Welfare amendment is technical in nature. The amendment changes the name of a state agency to conform with enactment of ERO No. 41 in 2012.

The fiscal note prepared by the Division of the Budget on HB 2153 states the Board indicates passage of the bill would have no fiscal effect on state revenues or expenditures.

Midwest Stem Cell Therapy Center; University of Kansas Medical Center; Utilization of Unused Medications Act; health

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