

Midwest Stem Cell Therapy Center; Utilization of Unused Medications Act; SB 199

SB 199 enacts new law requiring the University of Kansas Medical Center (KUMC) to establish the Midwest Stem Cell Therapy Center (Center), provides for the administration and oversight of the Center, and establishes a new fund; and amends 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 will 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 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 will be authorized to appoint the director of the Midwest Stem Cell Therapy Center. The director will report to the Executive Vice Chancellor. Among the requirements for and duties of the director are:

- 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 is required to remit all moneys to the State Treasurer; the Treasurer then will 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 is 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 requires 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 is 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 establishes 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 are 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 requires 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 establishes the Advisory Board, which will 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 is required to meet at least four times each year and will be authorized to meet upon the call of the chairperson. The Board will 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 serves two years);
- A representative of the physician community appointed by the Governor (original member serves three years);
- A representative of the University of Kansas appointed by the Board of Regents (original member serves one year);
- A representative of Kansas State University appointed by the Board of Regents (original member serves one year);
- A representative of KUMC appointed by the Executive Vice Chancellor (original member serves three years);
- A representative of the Institute for Advancing Medical Innovation appointed by the Institute's director (original member serves one year);
- A representative of the University of Kansas Cancer Center appointed by the Cancer Center's director (original member serves two years);
- A representative of the University of Kansas Hospital Authority appointed by the Authority's board of directors (original member serves one year);
- A member of the House of Representatives appointed by the Speaker of the House (original member serves two years);
- A member of the Senate appointed by the Senate President (original member serves for three years);
- A person with a nationally respected reputation representing the physician community appointed by the Speaker of the House (original member serves for three years);
- A person with a nationally respected reputation representing the scientific community appointed by the Senate President (original member serves one year);
- A member of the executive branch of the state agencies appointed by the Governor (original member serves 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 serves three years).

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

The bill states 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 specifically prohibits the use of funds or facilities involving embryonic or fetal tissue cells.

The bill also establishes 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 amends 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 deletes language related to the Cancer Drug Repository Program.

The bill defines 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 requires 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.