SESSION OF 2013

SUPPLEMENTAL NOTE ON SENATE BILL NO. 199

As Amended by House Committee of the Whole

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.

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 nonembryonic 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

^{*}Supplemental notes are prepared by the Legislative Research Department and do not express legislative intent. The supplemental note and fiscal note for this bill may be accessed on the Internet at http://www.kslegislature.org

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 only for 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.

Finally, the bill 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."

Background

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 southcentral 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 the original bill 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*.