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Senate Bills 1353 and 1354 (as introduced 6-29-06) House Bill 6291 (Substitute H-2 as passed by the House) House Bill 6292 (Substitute H-2 as passed by the House) House Bill 6293 (Substitute H-1 as passed by the House)

House Bill 6294 (Substitute S-1)

House Bill 6295 (as passed by the House) Sponsor: Senator Laura M. Toy (S.B. 1353)

> Senator Gerald Van Woerkom (S.B. 1354) Representative Glenn Steil (H.B. 6291)

Representative Jacob Hoogendyk, Jr. (H.B. 6292) Representative Leslie Mortimer (H.B. 6293) Representative Tom Casperson (H.B. 6294) Representative David Law (H.B. 6295)

Senate Committee: Health Policy

House Committee: Health Policy (H.B. 6291-6295)

Date Completed: 11-29-06

CONTENT

The bills would amend the Public Health Code and other statutes to do the following:

- Require the Department of Community Health (DCH) to establish a statewide network of cord blood stem cell banks.
- -- Appropriate \$5.0 million in existing funds from the 21st Century Jobs Trust Fund for the creation and maintenance of the statewide network.
- -- Establish criteria for a donor bank to enter the network.
- -- Require a bank entering the network to preserve donated units of cord blood and make them available to transplant centers for stem cell transplantation, and to allocate a portion of its cord blood inventory each year for research.
- Provide for a board of directors to govern and administer the network of cord blood stem cell banks.
- -- Require the DCH to promote public awareness of the uses and benefits of cord blood cells.
- -- Establish a tax credit, up to \$100 for a single return or \$200 for a joint

- return, that was equal to 50% of the sum of cash donations made to the statewide network of cord blood stem cell banks or to a qualified cord blood stem cell bank.
- -- Establish a \$100 tax credit for an individual who donated cord blood to a cord blood stem cell bank or banked cord blood in a private cord blood stem cell bank.
- -- Include in the definition of "life sciences" under the Michigan Strategic Fund Act biotechnology using umbilical cord blood to make or modify a product for useful purposes.

The bills are described in detail below.

House Bill 6291 (H-2)

Statewide Network

The bill would amend the Public Health Code to require the DCH, if funding were made available, to establish a statewide network of cord blood stem cell banks. The DCH Director would have to enter into contracts with qualified cord blood stem cell banks to assist in the establishment, provision, and maintenance of the network.

Requirements to Enter Network

A core blood stem cell bank would be eligible to enter the network and be a donor bank if it had done each of the following:

- Obtained all applicable Federal and State licenses, accreditations, certifications, registrations, and other authorizations required to operate and maintain a cord blood stem cell bank.
- -- Implemented donor screening and cord blood collection practices adequate to protect both donors and transplant recipients and to prevent transmission of potentially harmful infections and other diseases.
- -- Established a system of strict confidentiality to protect the identity and privacy of patients and donors in accordance with existing Federal and State law and consistent with regulations promulgated under the Federal Health Insurance Portability and Accountability Act of 1996 (HIPAA) for the release of the identity of donors, recipients, or identifiable records.
- -- Established a system for encouraging donation by an ethnically and racially diverse group of donors.
- -- Developed adequate systems for communication with other core blood stem cell banks, transplant centers, and physicians with respect to the request, release, and distribution of core blood units nationally, and developed systems to track recipients' clinical outcomes for distributed units that were consistent with the regulations promulgated under HIPAA.
- Developed an objective system for educating the public, including patient advocacy organizations, about the benefits of donating and using core blood stem cells in appropriate circumstances.

A donor bank that entered the network would have to acquire, tissue-type, test, cryo-preserve, and store donated units of human cord blood acquired with the informed consent of the donor, in a manner that complied with applicable Federal regulations, and would have to make cord blood units collected under the bill or otherwise available to transplant centers for stem cell transplantation.

A donor bank that entered the network also would have to allocate up to 10% of the

cord blood inventory each year for peerreviewed research. A donor bank could meet this quota by using cord blood units that did not meet the cell count standards necessary for transplantation.

Board of Directors

The bill would require a board of directors to govern and administer the statewide cold blood stem cell bank network. The board would have to be appointed by the DCH Director and consist of members who represented each of the following:

- -- Cord blood stem cell transplant centers.
- -- Physicians from participating birthing hospitals.
- -- The cord blood stem cell research community.
- -- Recipients of cord blood stem cell transplants.
- -- Family members who had made a donation to a statewide cord blood stem cell bank.
- -- Individuals with expertise in the social sciences.
- -- Members of the general public.
- -- Each network donor bank.

Each member of the board would have to serve a three-year term and could be reappointed for one or more additional terms, except that appointments for the initial members would have to be for one, two, and three years, respectively, to provide for the subsequent appointment of an equal number of members each year.

The board would have to elect a chairperson, ensure that the donor banks within the network met the requirements specified above on a continuing basis, encourage network donor banks to work collaboratively with other donor banks, and encourage them to focus their resources in their respective local or regional area. The board also would have to designate one or more established national or international core blood registries to sere as a statewide cord blood stem cell registry, and would have to coordinate the donor banks in the network.

<u>Tie-Bar</u>

The bill is tie-barred to Senate Bill 1353 and House Bill 6293.

Senate Bill 1354

The bill would amend the Public Health Code to require the DCH to promote public awareness and increase knowledge about the statewide network of cord blood stem cell banks and the benefits of cord blood stem cells by developing and disseminating educational materials on the uses and benefits of cord blood cells, information on research results using cord blood stem cells, and any other related materials and information to enable the public to make informed decisions about the use of cord blood stem cells.

The DCH would have to make the materials and information available to the public through its website and would have to provide copies at no charge to each health facility or agency and health care professional upon request.

The bill is tie-barred to Senate Bill 1353 and House Bill 6291.

Senate Bill 1353

The bill would amend the Public Health Code to define terms used in Senate Bill 1354 and House Bill 6291 (H-2).

"Core blood unit" would mean the blood collected from a single placenta and umbilical cord. "Donor" would mean a mother who had delivered a baby and consented to donate the newborn's blood remaining in the placenta and umbilical cord. "Donor bank" would mean a qualified cord blood stem cell bank that entered into a contract with the DCH Director under Section 2682 (which House Bill 6291 (H-2) would create).

"Human cord blood stem cells" would mean hematopoietic stem cells and any other stem cells contained in the neonatal blood collected immediately after the birth from the separated placenta and umbilical cord. "Network" would mean the statewide network of qualified cord blood stem cell banks established under Section 2682.

The bill is tie-barred to Senate Bill 1354 and House Bill 6291.

House Bill 6292 (H-2)

The bill would amend the Income Tax Act to permit a taxpayer to claim a credit against his or her income tax, for tax years beginning after December 31, 2006, that was equal to 50% of the sum of the following, not to exceed \$100 for a single return or \$200 for a joint return:

- Cash donations made to the statewide network of cord blood stem cell banks established under Section 2682 of the Public Health Code.
- -- Cash donations made to a qualified cord blood stem cell bank in the network.

In addition, for tax years beginning after December 31, 2006, a taxpayer who made a donation of cord blood to a cord blood stem cell bank pursuant to Section 2682 could claim a credit equal to \$100 in the year of the donation. Also, a taxpayer who banked cord blood in a private cord blood stem cell bank could claim a credit equal to \$100 in the year of the donation, if the blood were used exclusively for the taxpayer or a member of his or her family. This credit would not apply if the taxpayer banked cord blood as part of a designated free blood collection and storage program.

If the amount of the credit permitted under the bill exceeded the taxpayer's tax liability for the tax year, the excess portion of the credit would have to be refunded.

Under the bill, "cord blood" would mean blood collected from the separated placenta and umbilical cord immediately after birth. "Family member" would mean a donor child or relative within the second degree of consanguinity (by blood) to the donor.

"Private cord blood stem cell bank" would mean a nongovernmental nonpublic cord stem cell bank that was both registered with the Federal Drug Administration and accredited by the American Association of Blood Banks.

The bill is tie-barred to House Bill 6291.

House Bill 6293 (H-1)

The bill would amend the Public Health Code to require the DCH to promote public awareness and increase knowledge about the statewide network of cord blood stem

cell banks, cord blood banking options, and the benefits of cord blood stem cells by developing and disseminating educational materials on the uses and benefits of cord blood stem cells, information on research results using cord blood stem cells, and any other related materials and information to enable the public to make informed decisions about the use of cord blood stem cells.

The DCH would have to make the materials and information available to the public through its website and would have to provide copies at no charge to each health facility or agency, cord blood bank, and health care professional upon request.

The DCH also would have to encourage health care professionals and health care facilities or agencies, including hospitals, birthing facilities, local health departments, physicians, nurse midwives, and nurses, to disseminate information to pregnant women about cord blood bank donation and the options for cord blood banking.

The bill is tie-barred to Senate Bill 1353 and House Bill 6291.

House Bill 6294 (S-1)

The bill would appropriate \$5.0 million from the 21st Century Jobs Trust Fund and require the Department of Treasury - Michigan Strategic Fund to distribute the funds to the DCH to establish a statewide network of cord blood stem cell banks and award grants to qualified stem cell banks. The bill would reduce previously appropriated nonallocated funds, from the 21st Century Investment and County Work Project, within the 21st Century Jobs Trust Fund. funds appropriated would be to allocate funds already appropriated and would not increase the amount appropriated in Section 88j of the Michigan Strategic Fund Act (which created the 21st Century Jobs Trust Fund).

The unspent funds appropriated for the statewide network would be considered work project appropriations, and any unencumbered or unallotted funds would be carried forward into the next fiscal year. The DCH would be responsible for spending any funds that were carried forward.

From the appropriated funds, the DCH would have to establish a statewide network of cord blood stem cell banks and award grants to qualified stem cell banks. The funds also would have to be used to promote the statewide network of cord blood stem cell banks and to increase awareness and knowledge about the benefits of cord blood and stem cell research.

The project would have to be accomplished by contract or State employees, and the tentative completion date would be September 30, 2010.

The funds could be spent for the DCH's administrative costs related to programs or activities authorized under the bill, but could not exceed 5% of the gross appropriation. The funds could not be used for any fixed capital costs, including new buildings or building additions.

By April 1, 2007, and annually thereafter, the DCH would have to report to the House and Senate Appropriations Subcommittees on Community Health, the House and Senate Fiscal Agencies, the House and Senate policy committees on public health, and the State Budget Director, accounting for the expenditure of the funds distributed under the bill.

House Bill 6295

The bill would amend the Michigan Strategic Fund Act to include the definition of "life sciences" biotechnology using umbilical cord blood to make or modify a product for useful purposes.

Currently, the definition includes biotechnology, including any technology that uses living organisms, cells, macromolecules, micro-organisms, or substances from living organisms to make or modify a product for useful purposes.

Proposed MCL 333.2681 (S.B. 1353) Proposed MCL 333.2683 (S.B. 1354) Proposed MCL 333.2682 (H.B. 6291) Proposed MCL 206.276 (H.B. 6292) Proposed MCL 333.2683 (H.B. 6293) MCL 125.2088a (H.B. 6295)

Legislative Analyst: Curtis Walker

FISCAL IMPACT

Senate Bill 1353

The bill would have no fiscal impact on State or local government.

<u>Senate Bill 1354 &</u> <u>House Bill 6293 (H-1)</u>

The bills would create a minor, indeterminate increase in administrative cost for the Department of Community Health associated with the creation and distribution of education materials.

House Bill 6291 (H-2)

This legislation would create additional cost in the Department of Community Health. The Department would need to devote administrative resources to establish the network of cord blood banks and oversee and support the board of directors created in the bill. The extent of the cost is largely dependent upon the number of facilities that would participate in the cord blood network. As noted below, House Bill 6294 (S-1) would appropriate \$5.0 million in State restricted funds for the creation and operation of the cord blood stem cell network.

House Bill 6294 (S-1) would limit expenditure for these administrative costs from the \$5.0 million appropriation to \$250,000.

House Bill 6292 (H-2)

Estimating the potential fiscal impact of this bill is very difficult because there is not much information available on how many taxpayers would make contributions to stem cell blood banks. The proposed credit for cash contributions to a statewide network of cord blood stem cell banks or a qualified cord blood stem cell bank would be structured the same way as three existing income tax credits are structured. These existing tax credits are for contributions to public institutions (colleges and universities, public television and radio stations, community foundations, libraries), homeless shelters/food banks. The average credit claimed under each of these tax credits is in the range of \$75 to \$87 and the total cost of these credits ranges from a low of \$3.0 million to a high of \$25.0 million per year. If it is assumed that this proposed

credit for contributions to cord blood stem cell banks and/or a network would not be markedly different from the participation in these existing credits, then the cost of this new credit would fall in the range of \$3.0 million to \$25.0 million and probably closer to the lower end of this range initially. Also, not enough information is available at this time to make a reasonable estimate of the cost of the proposed tax credit for contributions of cord blood made to a qualified blood bank; however, to help put the potential cost in perspective, if donations were made from 5.0% of the births in Michigan, the cost of this credit would be about \$0.6 million annually.

House Bill 6294 (S-1)

The bill would provide \$5.0 million in FY 2005-06 for operation of a statewide network of cord blood stem cell banks by reallocating appropriations from the 21st Century Jobs Trust Fund.

Of the \$400.0 million appropriated from the 21st Century Jobs Trust Fund, there is a balance of \$34.1 million that has not been allocated to specific projects. (This balance assumes that the Michigan Strategic Fund board exercises its authority to spend 4% or \$16.0 million of the \$400.0 million appropriated from the 21st Century Jobs Trust Fund for administration, and 5% or \$20.0 million for business development and marketing.)

Pursuant to Public Act 225 of 2005, the unspent funds are carried forward in work project accounts. This bill would reduce the work project account that includes the unallocated balance by \$5.0 million and direct the Michigan Strategic Fund to distribute \$5.0 million in FY 2005-06 to the Department of Community Health to create a statewide network of cord blood stem cell banks.

The bill would reduce the unallocated balance of the 21st Century Jobs Trust Fund from \$34.1 million to \$29.1 million. Under Public Act 225 of 2005, the Michigan Strategic Fund Board was directed to commit funds to several specific projects and given the authority to allocate remaining funds within statutory guidelines among 21st century investment programs, competitive edge technology grants and loans, and loan enhancement programs.

The bill would have no fiscal impact on local government.

House Bill 6295

The bill would have no fiscal impact on State or local government.

> Fiscal Analyst: Steve Angelotti David Fosdick Elizabeth Pratt Maria Tyszkiewicz Jay Wortley

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This analysis was prepared by nonpartisan Senate staff for use by the Senate in its deliberations and does not constitute an official statement of legislative intent.