Senate Fiscal Agency
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BILL ANALYSIS

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Senate Bills 1353 and 1354 (as enrolled)
House Bills 6291, 6293, and 6295 (as enrolled)
Sponsor: Senator Laura M. Toy (S.B. 1353)
Senator Gerald Van Woerkom (S.B. 1354)
Representative Glenn Steil (H.B. 6291)
Representative Leslie Mortimer (H.B. 6293)
Representative David Law (H.B. 6295)
Senate Committee: Health Policy
House Committee: Health Policy

PUBLIC ACTS 635 & 636 of 2006
PUBLIC ACTS 637-639 of 2006

Date Completed: 1-16-07

RATIONALE

Blood found in the umbilical cord after childbirth may be used to treat a variety of blood-related illnesses, including leukemia, aplastic anemia, and sickle cell anemia. When the umbilical cord has been separated from the newborn baby, a small amount of blood, usually about three to five ounces, remains in the cord. That blood is rich in hematopoietic stem cells, which are formative cells with the potential to generate other types of blood cells. Although the cord blood often is discarded as medical waste, public and private cord blood banks have emerged as the number of therapies using cord blood has grown.

Both public and private banks store cord blood for later use, but the two types of banks serve different functions. Public banks accept anonymous donations, and attempt to match the donated cord blood to individuals in need of blood-related therapies. Private banks, on the other hand, store blood that is reserved for an individual, in case a child or a family member later needs treatment. Unlike private cord blood banks, public banks do not charge a fee for storing blood. These banks often are associated with hospitals, and pay for the cost of storing and monitoring the cord blood through charitable gifts, and in some cases also through general hospital funds. Because of the high costs of setting up and maintaining a cord blood bank, very few public banks exist in the State, and they are limited in the number of blood units they can accept.

Although cord blood treatments are growing more common, some are concerned that the small number of cord blood banks currently in existence and the lack of public knowledge of cord blood banking options have limited the potential impact of these new treatment options. Consequently, it was suggested that the State should establish a statewide network of cord blood stem cell banks to increase the availability of these stem cells, as well as take steps to raise public awareness of cord blood stem cell therapies.

CONTENT

House Bill 6291 amended the Public Health Code to do the following:

- **Require the Department of Community Health (DCH) to establish a statewide network of cord blood stem cell banks, if funding is made available.**
- **Establish criteria for a donor bank to enter the network, including requiring the bank to establish a system of strict confidentiality and implement donor screening and cord blood collection practices to prevent the transmission of disease.**

-- 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.

House Bill 6293 amended the Public Health Code to require the DCH to do the following:

-- If funding is made available, develop and disseminate information on the uses, benefits, and viability of cord blood cells, along with other related information on cord blood banking and available options.
-- Make that information available on the DCH website in a printable format.
-- Encourage health care professionals and others to disseminate information on cord blood donation and cord blood banking to a pregnant woman before the third trimester of her pregnancy.

House Bill 6295 included within the definition of "life sciences" under the Michigan Strategic Fund Act biotechnology using umbilical cord blood (in addition to biotechnology that uses living organisms, cells, macromolecules, micro-organisms, or substances from living organisms) to make or modify a product for useful purposes.

Senate Bill 1353 amended the Public Health Code to define terms used in House Bills 6291 and 6293, as follows:

-- "Core blood unit" means the blood collected from a single placenta and umbilical cord.
-- "Donor" means a mother who has delivered a baby and consents to donate the newborn's blood remaining in the placenta and umbilical cord.
-- "Donor bank" means a qualified cord blood stem cell bank that enters into a contract with the DCH Director under Section 2682 (which was enacted by House Bill 6291).
-- "Human cord blood stem cells" means hematopoietic stem cells and other stem cells contained in the neonatal blood collected immediately after birth from the separated placenta and umbilical cord.

Senate Bill 1354 amended the Public Health Code to require the DCH to submit a report annually to the Legislature and others detailing the expenditure of funds related to the statewide network of cord blood stem cell banks required under House Bill 6291 and the public awareness efforts described above.

Senate Bill 1353 was tie-barred to House Bill 6291. Senate Bill 1354 was tie-barred to Senate Bill 1353 and House Bill 6291. House Bills 6291 and 6293 were tie-barred to each other and to Senate Bill 1353.

All of the bills took effect on January 4, 2007. Senate Bill 1354 and House Bills 6291 and 6293 are described in detail below.

House Bill 6291

Statewide Network

The bill requires the DCH, if funding is made available, to establish a statewide network of cord blood stem cell banks. The DCH Director must 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

Under the bill, a core blood stem cell bank is eligible to enter the network and be a donor bank if it has 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 are 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 enters the network must 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 complies with applicable Federal regulations, and must make cord blood units collected under the bill or otherwise available to transplant centers for stem cell transplantation.

A donor bank that enters the network also must allocate up to 10% of its cord blood inventory each year for peer-reviewed research, and may meet this quota by using cord blood units that did not meet the cell count standards necessary for transplantation.

Board of Directors

The bill requires a board of directors to govern and administer the statewide cord blood stem cell bank network. The board must be appointed by the DCH Director and consist of members who represent 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 have 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 must serve a three-year term, except that appointments for the initial members are to be for one, two, and three years, respectively, to provide for the subsequent appointment of an equal number of members each year. Board members may be reappointed for one or more additional terms. The board must elect a chairperson.

The board is required to ensure that the donor banks within the network meet the requirements specified above on a continuing basis, encourage network donor banks to work collaboratively with other donor banks, and encourage network banks to focus their resources in their respective local or regional area. The board also must designate one or more established national or international cord blood registries to serve as a statewide cord blood stem cell registry, and must coordinate the donor banks in the network.

House Bill 6293

The bill requires the DCH, if funding is made available, 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, benefits, and viability 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 must make the materials and information available to the public and to health care facilities and agencies, cord blood banks, and health care professionals on the DCH's website in a printable format. The information must include the following:

-- An explanation of the differences between public and private cord blood banking.
-- Information on the statewide network of cord blood stem cell banks.
-- Available cord blood options.
-- The medical process and risks involved in the collection of cord blood.
-- Medically accepted uses and benefits of cord blood collection and transplantation.
-- A statement that because of ongoing research and development, there may be future uses and benefits of cord blood collection and transplantation.
-- An explanation of any costs to the donor associated with cord blood donation and storage.
-- Information on how to request printed materials and how to access other information available on the DCH's website.
-- Options for ownership and future use of the donated material.
-- An explanation of the storage, maintenance, and viability for transplantation of cord blood stem cells.

The DCH also must encourage health care professionals and health care facilities and agencies, including physicians, nurse midwives, nurses, hospitals, birthing facilities, and local health departments, to disseminate to a pregnant women before her third trimester of pregnancy information about cord blood bank donation and the options for cord blood banking.

Senate Bill 1354

The bill requires the DCH, by April 1, 2007, and each subsequent year, to submit to the House and Senate Appropriations subcommittees on community health, the House and Senate standing committees on community health, the House and Senate Fiscal Agencies, and the State Budget Director, a report detailing the expenditure of funds relating to the statewide network of cord blood stem cell banks, and the required public awareness efforts.

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

BACKGROUND

To be useful, cord blood must be captured immediately after birth in sterile containers and stored in liquid nitrogen-cooled freezers until needed. The frozen units of cord blood later may be used to treat the donating individual, a sibling, or an unrelated individual with matching blood. Cord blood therapies are similar to treatments using bone marrow, which also contain hematopoietic stem cells, but with some advantages. Collecting cord blood is far easier than extracting bone marrow, a complex and painful process. Also, cord blood does not require as precise a match as is needed for bone marrow treatments. Some studies indicate lower rejection rates and higher recovery rates for cord blood therapies, compared with bone marrow treatments. Cord blood treatments have drawbacks as well; the small amount of blood collected is not always large enough to treat an adult, or even some children, and if additional units are needed it may be difficult or impossible to find a second matching donor, whereas identical bone marrow may be collected more than once from the same donor.

Currently, public and private cord blood banks store about 75,000 units of cord blood in the United States. In the case of public banks, all personal identifying information is removed from each unit of blood to protect the privacy of donors, and extensive tests are performed to verify that the donated blood is a close match to the recipient and that no diseases or defects are present in the blood, to minimize the risk of rejection or an immune reaction.

The stored blood units in private cord blood banks, on the other hand, retain all personal identifiers, and the blood is reserved for use by the donor or a family member only. Private banks conduct extensive testing, just as public banks do. In addition, proponents of private banking say that having the family history information enables a better match with less risk of rejection. There also is a higher chance of a good blood match from a related donor than from an unrelated individual. Private banks typically charge a fee of about $2,000 for processing the cord blood initially, and an annual storage fee ranging from about $100 to $150.

ARGUMENTS

(Please note: The arguments contained in this analysis originate from sources outside the Senate Fiscal Agency. The Senate Fiscal Agency neither supports nor opposes legislation.)

Supporting Argument

Because cord blood stem cell therapies are relatively new, many people are unaware of the potential benefits of the blood that can be collected after childbirth, and are unaware of the opportunity to donate that blood or have it stored in a private bank. If provided with information on these options, it is likely that many will be willing to donate their cord blood, since the fluid has no other value and otherwise is considered medical waste. The bills require the DCH to create a statewide network of cord blood banks, if funding is provided, and require the Department and donor banks that join the statewide network to disseminate related information to the public and to health care professionals. These provisions will ensure that individuals have access to the information they need to make informed decisions regarding cord blood banking, and may create an increase in donations of cord blood in the State.

In addition, the establishment of the network will raise the profile of cord blood banks in Michigan and may encourage the creation of additional banks, increasing banking capacity. Currently, only two public banks exist in Michigan, and only a limited number of hospitals in the State are equipped to collect cord blood. Other states, including North Carolina, New York, and California, have created public banks that have spurred increased donations of cord blood. Similarly, some European countries have created large cord blood banks, and international networks of banks have been established to distribute units to recipients as needed. Michigan needs to make similar efforts to expand the pool of available cord blood units, in order to enable donor banks to provide vital cord blood transplants to as many people as possible.

The State's two cord blood banks currently have a limited capacity, and there is high demand for the relatively small number of units available. According to testimony before the Senate Health Policy Committee, the J.P. McCarthy Cord Stem Cell Bank, in Detroit, delivers stem cells from its cord blood bank to recipients around the world. Those in need of treatment are not always able to find a suitable donor, however. Minorities and individuals of mixed ethnic backgrounds, in particular, have trouble finding cord blood that is a close match, because the HLA blood type used to identify a match is determined by the genetic makeup of the cells. Consequently, a donor is more likely to match a recipient if they have similar ethnic backgrounds. By requiring donor banks participating in the statewide network to seek blood units from a diverse group of individuals, House Bill 6291 will help improve minorities' chances of finding a matching donor.

Taken together, these provisions will expand the availability of cord blood in Michigan, and will make more members of the public aware of the options for storing cord blood and receiving treatments using cord blood if the need arises.

Response: Cord blood banking can be extremely expensive, because of the high cost of the necessary equipment and the cost of storing cord blood for extended periods. The units of blood must be kept cooled by liquid nitrogen, and must be monitored continuously to ensure that the storage environment remains stable. In addition, banks must test the units to determine the blood tissue type, screen for diseases, and identify matches. Public banks depend partly on financial donations from supporters to be able to provide this service. Although previous versions of the package offered a tax credit for individuals who donated money to a cord blood bank, the bills as enacted do not do anything to encourage such contributions or address the high cost of operating a cord blood bank. As a result, it is questionable whether the bills will promote the creation of additional banking capacity in the State. In fact, the bills do not provide any funding for the creation of the statewide network or the public awareness efforts specified in the legislation. If the funding is not appropriated, the bills may have very little impact.

Supporting Argument

Cord blood banks sometimes receive donated units of blood that are unsuitable for use in transplants, because the collected sample is too small to contain sufficient stem cells, because of a blood disease or genetic defect in the sample, or for other reasons. House Bill 6291 requires a cord blood bank that enters the network to contribute a portion of its inventory each year for research, and allows a bank to include units that are unsuitable for transplantation. By donating this unusable blood or other blood units for research, the participating bank will provide additional material that will aid in the development of more effective cures, treatments, and therapies, further expanding the benefits and potential uses of cord blood without affecting the bank's ability to supply cord blood to those in need of treatment. Also, by encouraging research on cord blood stem cells in the State, the bills may contribute to Michigan's growing life sciences sector.

Opposing Argument

Although cord blood stem cells can offer great benefits in some situations, they are limited in their potential. Because they are adult stem cells and already differentiated as blood-forming cells, they can be used only to treat blood-related illnesses, while embryonic stem cells have the potential to become any type of cell found in the human body, and may offer cures for a wider variety of ailments. It is inconsistent to encourage cord blood stem cell research while the State has restricted similar research involving embryonic stem cells. In order to advance biotechnology in Michigan and support the development of advanced medical treatments for as many people as possible, the State should not limit its promotion efforts to cord blood stem cells, but should encourage research involving embryonic stem cells as well.

Response: Cord blood stem cells do not pose the same ethical concerns that have been raised regarding embryonic stem cells. Using current technology, the process of extracting stem cells from an embryo in most cases involves destroying the embryo, while cord blood can be collected safely and easily without harming either the baby or the mother. Furthermore, much of the promise of embryonic stem cells is still speculative. Treatments using cord blood are available today, and additional ongoing research eventually may allow the use of cord blood to treat illnesses that are not blood-related such as multiple sclerosis or diabetes. The State should focus on the actual and potential benefits offered by cord blood cures, rather than engage in the uncertain and controversial efforts surrounding embryonic stem cells.

Legislative Analyst: Curtis Walker

FISCAL IMPACT

Senate Bill 1353

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

Senate Bill 1354

The Department of Community Health will see a small increase in administrative cost associated with fulfilling the reporting requirements included in the bill.

House Bill 6291

Establishing a statewide network of cord blood stem cell banks would result in additional cost for the Department of Community Health. The Department would need to devote additional resources to create the network of cord blood banks and oversee and support its board of directors. Language in the bill makes the creation of a statewide network of cord blood stem cell banks contingent upon the appropriation of the financial resources needed to fund its operation, which has not yet occurred.

House Bill 6293

The bill could create a minor, indeterminate increase in administrative cost for the Department of Community Health associated with the creation and distribution of educational materials. Language in the bill makes actions required of the DCH contingent upon the availability of funding to finance these efforts. At this time, funds have not been appropriated for cord blood donation education efforts.

House Bill 6295

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

Fiscal Analyst: David Fosdick

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