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HEALTH AND SAFETY CODE - HSC

DIVISION 2. LICENSING PROVISIONS [1200 - 1796.70] (*Division 2 enacted by Stats. 1939, Ch. 60.*)

CHAPTER 4. Human Whole Blood, Human Whole Blood Derivatives, and Other Biologics [1600 - 1630] (*Chapter 4 repealed and added by Stats. 1963, Ch. 1055.*)

ARTICLE 8. Umbilical Cord Blood Program [1627 - 1630] (*Article 8 added by Stats. 2007, Ch. 516, Sec. 2.*)

1627. (a) (1) The University of California is requested to develop a plan to establish and administer the Umbilical Cord Blood Collection Program for the purpose of collecting units of umbilical cord blood for public use in transplantation and providing nonclinical units for research pertaining to biology and new clinical utilization of stem cells derived from the blood and tissue of the placenta and umbilical cord. The program shall conclude no later than January 1, 2027.

(2) For purposes of this article, "public use" means both of the following:

(A) The collection of umbilical cord blood units from genetically diverse donors that will be owned by the University of California. This inventory shall be accessible by the National Registry and by qualified California-based and other United States and international registries and transplant centers to increase the likelihood of providing suitably matched donor cord blood units to patients or research participants who are in need of a transplant.

(B) Cord blood units with a lower number of cells than deemed necessary for clinical transplantation and units that meet clinical requirements, but for other reasons are unsuitable, unlikely to be transplanted, or otherwise unnecessary for clinical use, may be made available for research.

(b) (1) In order to implement the collection goals of this program, the University of California may, commensurate with available funds appropriated to the University of California for this program, contract with one or more selected applicant entities that have demonstrated the competence to collect and ship cord blood units in compliance with federal guidelines and regulations.

(2) It is the intent of the Legislature that, if the University of California contracts with another entity pursuant to this subdivision, the following shall apply:

(A) The University of California may use a competitive process to identify the best proposals submitted by applicant entities to administer the collection and research objectives of the program, to the extent that the University of California chooses not to undertake these activities itself.

(B) In order to qualify for selection under this section to receive, process, cryopreserve, or bank cord blood units, the entity shall, at a minimum, have obtained an investigational new drug (IND) exemption from the FDA or a biologic license from the FDA, as appropriate, to manufacture clinical grade cord blood stem cell units for clinical indications.

(C) In order to qualify to receive appropriate cord blood units and placental tissue to advance the research goals of this program, an entity shall, at a minimum, be a laboratory recognized as having performed peer-reviewed research on stem and progenitor cells, including those derived from placental or umbilical cord blood and postnatal tissue.

(3) A medical provider or research facility shall comply with, and shall be subject to, existing penalties for violations of all applicable state and federal laws with respect to the protection of any medical information, as defined in Section 56.05 of the Civil Code, and any personally identifiable information contained in the umbilical cord blood inventory.

(c) The University of California is encouraged to make every effort to avoid duplication or conflicts with existing and ongoing programs and to leverage existing resources.

(d) (1) All information collected pursuant to the program shall be confidential, and shall be used solely for the purposes of the program, including research. Access to confidential information shall be limited to authorized persons who are bound by appropriate institutional policies or who otherwise agree, in writing, to maintain the confidentiality of that information.

(2) Any person who, in violation of applicable institutional policies or a written agreement to maintain confidentiality, discloses any information provided pursuant to this section, or who uses information provided pursuant to this section in a manner other than as approved pursuant to this section, may be denied further access to any confidential information maintained by the University of California, and shall be subject to a civil penalty not exceeding one thousand dollars (\$1,000). The penalty provided for in this section shall not be construed to limit or otherwise restrict any remedy, provisional or otherwise, provided by law for the benefit of the University of California or any other person covered by this section.

(3) Notwithstanding the restrictions of this section, an individual to whom the confidential information pertains shall have access to their own personal information.

(e) It is the intent of the Legislature that the plan and implementation of the program provide for both of the following:

(1) Limit fees for access to cord blood units to the reasonable and actual costs of storage, handling, and providing units, as well as for related services such as donor matching and testing of cord blood and other programs and services typically provided by cord blood banks and public use programs.

(2) The submittal of the plan developed pursuant to subdivision (a) to the health and fiscal committees of the Legislature.

(f) It is additionally the intent of the Legislature that the plan and implementation of the program attempt to provide for all of the following:

(1) Development of a strategy to increase voluntary participation by hospitals in the collection and storage of umbilical cord blood and identify funding sources to offset the financial impact on hospitals.

(2) Consideration of a medical contingency response program to prepare for and respond effectively to biological, chemical, or radiological attacks, accidents, and other public health emergencies where victims potentially benefit from treatment.

(3) Exploration of the feasibility of operating the program as a self-funding program, including the potential for charging users a reimbursement fee.

(Amended by Stats. 2022, Ch. 604, Sec. 1. (SB 883) Effective January 1, 2023. Repealed as of January 1, 2027, pursuant to Section 1630.)

1628. (a) The University of California may accept public and private funds for the purpose of implementing this article.

(b) The Umbilical Cord Blood Collection Program Fund is hereby created in the State Treasury. Any fees collected pursuant to Section 103625 shall be deposited into the fund. Moneys in the fund shall be available, upon appropriation by the Legislature, for purposes of this article.

(c) The fund may include additional federal, state, and private funds made available for purposes of the program, including, but not limited to, the fees collected for the fund pursuant to Section 103625, and, notwithstanding Section 16305.7 of the Government Code, any interest earned on moneys in the fund.

(d) (1) Funds shall be appropriated for the purposes of this article to the extent the plan the University of California is requested to develop pursuant to subdivision (a) of Section 1627 and the implementation of the plan are consistent with the goals and intent of this article.

(2) In the event that funds are not appropriated for the program as described in this article, it is the intent of the Legislature that the University of California shall not implement the program.

(Amended by Stats. 2010, Ch. 529, Sec. 3. (AB 52) Effective September 29, 2010. Repealed as of January 1, 2027, pursuant to Section 1630.)

1629. In implementing the program, the department shall make every effort to avoid duplication or conflicts with existing and ongoing programs and to leverage existing resources.

(Added by Stats. 2007, Ch. 516, Sec. 2. Effective January 1, 2008. Repealed as of January 1, 2027, pursuant to Section 1630.)

1629.5. (a) On or before January 1, 2026, if it elects to administer the Umbilical Cord Blood Collection Program, the University of California shall provide a report to the Assembly and Senate Committees on Health that addresses, at a minimum, all of the following:

(1) The number of cord blood units collected and registered under the program, disaggregated by race and ethnicity.

(2) The number of registered units transplanted as a result of the program, disaggregated by race and ethnicity.

(3) The number of California residents receiving a transplant as a result of the program.

(4) The number of units made available for research and a summary of key research findings as a result of the program.

(5) Annual budget information on the program, including revenues, spending, and beginning- and end-of-year balances.

(6) Budget information for each participating cord blood bank, including collection and storage costs and available revenues to cover those costs.

(7) Fees charged by participating cord blood banks for collecting, storing, handling, and providing units, and a summary of how these fees were determined.

(8) Nationwide data on cord blood units collected, registered, and transplanted, disaggregated by race and ethnicity.

(9) A summary of available cell sources for a hematopoietic stem cell transplant and research on the ability of underrepresented groups to find a suitable match for a transplant.

(10) Any other outcomes or data regarding the impact of the program.

(b) The requirement for submitting a report imposed under subdivision (a) is inoperative on December 31, 2026, pursuant to Section 10231.5 of the Government Code.

(Amended by Stats. 2022, Ch. 604, Sec. 2. (SB 883) Effective January 1, 2023. Repealed as of January 1, 2027, pursuant to Section 1630.)

1630. This article shall remain in effect only until January 1, 2027, and as of that date is repealed.

(Repealed and added by Stats. 2022, Ch. 604, Sec. 4. (SB 883) Effective January 1, 2023. Repealed as of January 1, 2027, by its own provisions.

Note: Repeal affects Article 8, commencing with Section 1627.)