

Assembly Bill No. 2599

CHAPTER 680

An act to amend Sections 124977, 124991, and 125002 of the Health and Safety Code, relating to public health.

[Approved by Governor September 30, 2008. Filed with
Secretary of State September 30, 2008.]

LEGISLATIVE COUNSEL'S DIGEST

AB 2599, De Leon. Birth Defects Monitoring Program.

Existing law establishes the Birth Defects Monitoring Program within the State Department of Public Health, and requires the department to provide any umbilical cord blood samples it receives from hospitals to the program for storage and research.

This bill would also require that the program collect any umbilical cord blood samples it receives from hospitals for storage and research.

Existing law requires the department to charge a fee for prenatal screening to support the pregnancy blood sample storage, testing, and research activities of the program, with the revenues from those fees required to be deposited into the Birth Defects Monitoring Program Fund, and made available, upon appropriation by the Legislature, to support the pregnancy blood sample storage, testing, and research activities of the program.

Under existing law, the initial prenatal screening fee increase for activities of the Birth Defects Monitoring Program is \$10.

This bill would, instead, require the prenatal screening fee for these activities to be \$10.

The bill would also require the department to establish guidelines for invoicing, charging, and collecting from approved researchers an amount necessary to cover certain expenses associated with research application requests made pursuant to the above provisions, data linkage, retrieval, data processing, data entry, reinventory, and shipping of blood samples or their components, and related data management.

Existing law provides that when pregnancy blood samples are stored, analyzed, or otherwise shared for research purposes with nondepartmental staff, no information may be released identifying the person from whom the samples were obtained.

This bill would require the department to adopt regulations specifying the protocols and conditions under which blood samples will be released for research purposes, as provided.

Existing law requires the department to establish fees in an amount that does not exceed the costs of administering the Birth Defects Monitoring Program to be collected from researchers and health care providers, and requires that any fees collected pursuant to those provisions be deposited

into the Birth Defects Monitoring Program Fund, for use by the department, upon appropriation by the Legislature, for specified purposes related to data management, and the collection, storage, retrieval, and processing of blood samples.

This bill would, instead, require that any fees collected from researchers who have been approved by the department pursuant to those provisions be deposited into the Birth Defects Monitoring Program Fund, the Genetic Disease Testing Fund, or the Cord Blood Banking Fund, which the bill would create as a special fund in the State Treasury. The bill would require that the amounts of fees deposited in these funds be based on the program providing those samples, and the purpose for which the sample was obtained. The bill, in addition, would provide that the moneys in those funds obtained in those fees may be used by the department, upon appropriation by the Legislature, for costs related to data management, and the collection, storage, retrieval, and processing of those blood samples.

The people of the State of California do enact as follows:

SECTION 1. Section 124977 of the Health and Safety Code is amended to read:

124977. (a) It is the intent of the Legislature that, unless otherwise specified, the genetic disease testing program carried out pursuant to this chapter be fully supported from fees collected for services provided by the program.

(b) (1) The department shall charge a fee to all payers for any tests or activities performed pursuant to this chapter. The amount of the fee shall be established by regulation and periodically adjusted by the director in order to meet the costs of this chapter. Notwithstanding any other provision of law, any fees charged for prenatal screening and followup services provided to persons enrolled in the Medi-Cal program, health care service plan enrollees, or persons covered by health insurance policies, shall be paid in full and deposited in the Genetic Disease Testing Fund or the Birth Defects Monitoring Fund consistent with this section, subject to all terms and conditions of each enrollee's or insured's health care service plan or insurance coverage, whichever is applicable, including, but not limited to, copayments and deductibles applicable to these services, and only if these copayments, deductibles, or limitations are disclosed to the subscriber or enrollee pursuant to the disclosure provisions of Section 1363.

(2) The department shall expeditiously undertake all steps necessary to implement the fee collection process, including personnel, contracts, and data processing, so as to initiate the fee collection process at the earliest opportunity.

(3) Effective for services provided on and after July 1, 2002, the department shall charge a fee to the hospital of birth, or, for births not occurring in a hospital, to families of the newborn, for newborn screening and followup services. The hospital of birth and families of newborns born

outside the hospital shall make payment in full to the Genetic Disease Testing Fund. The department shall not charge or bill Medi-Cal beneficiaries for services provided under this chapter.

(4) (A) The department shall charge a fee for prenatal screening to support the pregnancy blood sample storage, testing, and research activities of the Birth Defects Monitoring Program.

(B) The prenatal screening fee for activities of the Birth Defects Monitoring Program shall be ten dollars (\$10).

(5) The department shall set guidelines for invoicing, charging, and collecting from approved researchers the amount necessary to cover all expenses associated with research application requests made under this section, data linkage, retrieval, data processing, data entry, reinventory, and shipping of blood samples or their components and related data management.

(6) The only funds from the Genetic Disease Testing Fund that may be used for the purpose of supporting the pregnancy blood sample storage, testing, and research activities of the Birth Defects Monitoring Program are those prenatal screening fees assessed and collected prior to the creation of the Birth Defects Monitoring Program Fund specifically to support those Birth Defects Monitoring Program activities.

(7) The Birth Defects Monitoring Program Fund is hereby created as a special fund in the State Treasury. Fee revenues that are collected pursuant to paragraph (4) shall be deposited into the fund and shall be available upon appropriation by the Legislature to support the pregnancy blood sample storage, testing, and research activities of the Birth Defects Monitoring Program. Notwithstanding Section 16305.7 of the Government Code, interest earned on funds in the Birth Defects Monitoring Program Fund shall be deposited as revenue into the fund to support the Birth Defects Monitoring Program.

(c) (1) The Legislature finds that timely implementation of changes in genetic screening programs and continuous maintenance of quality statewide services requires expeditious regulatory and administrative procedures to obtain the most cost-effective electronic data processing, hardware, software services, testing equipment, and testing and followup services.

(2) The expenditure of funds from the Genetic Disease Testing Fund for these purposes shall not be subject to Section 12102 of, and Chapter 2 (commencing with Section 10290) of Part 2 of Division 2 of, the Public Contract Code, or to Division 25.2 (commencing with Section 38070). The department shall provide the Department of Finance with documentation that equipment and services have been obtained at the lowest cost consistent with technical requirements for a comprehensive high-quality program.

(3) The expenditure of funds from the Genetic Disease Testing Fund for implementation of the Tandem Mass Spectrometry screening for fatty acid oxidation, amino acid, and organic acid disorders, and screening for congenital adrenal hyperplasia may be implemented through the amendment of the Genetic Disease Branch Screening Information System contracts and shall not be subject to Chapter 3 (commencing with Section 12100) of Part 2 of Division 2 of the Public Contract Code, Article 4 (commencing with

Section 19130) of Chapter 5 of Part 2 of Division 5 of Title 2 of the Government Code, and any policies, procedures, regulations or manuals authorized by those laws.

(4) The expenditure of funds from the Genetic Disease Testing Fund for the expansion of the Genetic Disease Branch Screening Information System to include cystic fibrosis and biotinidase may be implemented through the amendment of the Genetic Disease Branch Screening Information System contracts, and shall not be subject to Chapter 2 (commencing with Section 10290) or Chapter 3 (commencing with Section 12100) of Part 2 of Division 2 of the Public Contract Code, Article 4 (commencing with Section 19130) of Chapter 5 of Part 2 of Division 5 of Title 2 of the Government Code, or Sections 4800 to 5180, inclusive, of the State Administrative Manual as they relate to approval of information technology projects or approval of increases in the duration or costs of information technology projects. This paragraph shall apply to the design, development, and implementation of the expansion, and to the maintenance and operation of the Genetic Disease Branch Screening Information System, including change requests, once the expansion is implemented.

(d) (1) The department may adopt emergency regulations to implement and make specific this chapter in accordance with Chapter 3.5 (commencing with Section 11340) of Part 1 of Division 3 of Title 2 of the Government Code. For the purposes of the Administrative Procedure Act, the adoption of regulations shall be deemed an emergency and necessary for the immediate preservation of the public peace, health and safety, or general welfare. Notwithstanding Chapter 3.5 (commencing with Section 11340) of Part 1 of Division 3 of Title 2 of the Government Code, these emergency regulations shall not be subject to the review and approval of the Office of Administrative Law. Notwithstanding Sections 11346.1 and 11349.6 of the Government Code, the department shall submit these regulations directly to the Secretary of State for filing. The regulations shall become effective immediately upon filing by the Secretary of State. Regulations shall be subject to public hearing within 120 days of filing with the Secretary of State and shall comply with Sections 11346.8 and 11346.9 of the Government Code or shall be repealed.

(2) The Office of Administrative Law shall provide for the printing and publication of these regulations in the California Code of Regulations. Notwithstanding Chapter 3.5 (commencing with Section 11340) of Part 1 of Division 3 of Title 2 of the Government Code, the regulations adopted pursuant to this chapter shall not be repealed by the Office of Administrative Law and shall remain in effect until revised or repealed by the department.

(3) The Legislature finds and declares that the health and safety of California newborns is in part dependent on an effective and adequately staffed genetic disease program, the cost of which shall be supported by the fees generated by the program.

SEC. 2. Section 124991 of the Health and Safety Code is amended to read:

124991. (a) (1) The Birth Defects Monitoring Program, within the State Department of Public Health, shall collect and store any umbilical cord blood samples it receives from hospitals for storage and research. For purposes of ensuring financial stability, the Birth Defects Monitoring Program shall ensure that the following conditions, alone or in combination, are met:

(A) The fees paid by researchers pursuant to subdivision (c) shall be used for, and be sufficient to cover the cost of, collecting and storing blood samples, including umbilical cord blood samples.

(B) The department receives confirmation that a researcher has requested umbilical cord blood samples from the Birth Defects Monitoring Program for research or has requested umbilical cord blood samples to be included within a request for pregnancy or newborn blood samples through the program and has provided satisfactory evidence that adequate funding will be provided to the department from the fees paid by the researcher for the request.

(C) The department receives federal grant moneys to pay for initial startup costs for the collection and storage of umbilical cord blood samples.

(2) The department may limit the number of umbilical cord blood samples the program collects each year.

(b) (1) All information relating to umbilical cord blood samples collected and utilized by the department shall be confidential, and shall be used solely for the purposes of the program, or, if approved by the department, research. Access to confidential information shall be limited to authorized persons who agree, in writing, to maintain the confidentiality of that information. Notwithstanding any other provision of law, when the blood samples specified in subdivision (c), including those samples with any information identifying the person from whom the samples were obtained, are stored, processed, analyzed, or otherwise shared for research purposes with nondepartment staff, those samples may be shared by the program with department-authorized researchers for research purposes, and department representatives approved by the department, subject to the confidentiality and security requirements for confidential information established in this section and in Section 103850.

(2) The department shall maintain an accurate record of all persons who are given confidential information pursuant to this section, and any disclosure of confidential information shall be made only upon written agreement that the information will be kept confidential, used for its approved purpose, and not be further disclosed.

(3) Any person who, in violation of 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 department, and shall be subject to a civil penalty not exceeding one thousand dollars (\$1,000). The penalty provided in this section shall not be construed as to limit or otherwise

restrict any remedy, provisional or otherwise, provided by law for the benefit of the department or any other person covered by this section.

(c) In order to implement this section, the department shall establish fees in an amount that shall not exceed the costs of administering the program and the collection and storage of these samples, which the department shall collect from researchers who have been approved by the department and who seek to use the following types of blood samples for research:

(1) Umbilical cord blood.

(2) Pregnancy blood collected by the Genetic Disease Screening Program, and stored by the Birth Defects Monitoring Program.

(3) Newborn blood collected by the Genetic Disease Screening Program.

(d) Fees collected pursuant to subdivision (c) shall be collected by the department and deposited into the Birth Defects Monitoring Program Fund, the Genetic Disease Testing Fund, created pursuant to Section 124996, or the Cord Blood Banking Fund, which is hereby created as a special fund in the State Treasury. The amount of fees deposited into each of these funds shall be based on the program that is providing those pregnancy blood samples, and the purpose for which the blood sample was obtained. Notwithstanding any other provision of law, the moneys in the Birth Defects Monitoring Program Fund, the Genetic Disease Testing Fund, and the Cord Blood Banking Fund that are collected pursuant to subdivision (c), may be used by the department, upon appropriation by the Legislature, for the purposes specified in subdivision (e).

(e) Moneys in those funds shall be used for the costs related to data management, including data linkage and entry, and blood collection, storage, retrieval, processing, inventory, and shipping.

(f) The department shall comply with the existing requirements in the Birth Defects Monitoring Program, as set forth in Chapter 1 (commencing with Section 103825) of Part 2 of Division 102.

(g) The department, any entities approved by the department, and researchers shall maintain the confidentiality of patient information and blood samples in accordance with existing law and in the same manner as other medical record information with patient identification that they possess, and shall use the information only for the following purposes:

(1) Research to identify risk factors for children's and women's diseases.

(2) Research to develop and evaluate screening tests.

(3) Research to develop and evaluate prevention strategies.

(4) Research to develop and evaluate treatments.

(h) (1) For purposes of ensuring the security of a donor's personal information, before any blood samples are released pursuant to this section for research purposes, the State Committee for the Protection of Human Subjects (CPHS) shall determine if all of the following criteria have been met:

(A) The department, contractors, researchers, or other entities approved by the department have provided a plan sufficient to protect personal information from improper use and disclosures, including sufficient administrative, physical, and technical safeguards to protect personal

information from reasonable anticipated threats to the security or confidentiality of the information.

(B) The department, contractors, researchers, or other entities approved by the department have provided a sufficient plan to destroy or return all personal information as soon as it is no longer needed for the research activity, unless the program contractors, researchers, or other entities approved by the department have demonstrated an ongoing need for the personal information for the research activity and have provided a long-term plan sufficient to protect the confidentiality of that information.

(C) The department, contractors, researchers, or other entities approved by the department have provided sufficient written assurances that the personal information will not be reused or disclosed to any other person or entity, or used in any manner not approved in the research protocol, except as required by law or for authorized oversight of the research activity.

(2) As part of its review and approval of the research activity for the purpose of protecting personal information held in agency databases, CPHS shall accomplish at least all of the following:

(A) Determine whether the requested personal information is needed to conduct the research.

(B) Permit access to personal information only if it is needed for the research activity.

(C) Permit access only to the minimum necessary personal information needed for the research activity.

(D) Require the assignment of unique subject codes that are not derived from personal information in lieu of social security numbers if the research can still be conducted without social security numbers.

(E) If feasible, and if cost, time, and technical expertise permit, require the agency to conduct a portion of the data processing for the researcher to minimize the release of personal information.

(i) In addition to the fees described in subdivision (c), the department may bill a researcher for the costs associated with the department's process of protecting personal information, including, but not limited to, the department's costs for conducting a portion of the data processing for the researcher, removing personal information, encrypting or otherwise securing personal information, or assigning subject codes.

(j) Nothing in this section shall prohibit the department from using its existing authority to enter into written agreements to enable other institutional review boards to approve research activities, projects or classes of projects for the department, provided the data security requirements set forth in this section are satisfied.

SEC. 3. Section 125002 of the Health and Safety Code is amended to read:

125002. (a) In order to align closely related programs and in order to facilitate research into the causes of, and treatment for, birth defects, the Birth Defects Monitoring Program provided for pursuant to Chapter 1 (commencing with Section 103825) of Part 2 of Division 102 shall become part of the Maternal, Child, and Adolescent Health program provided for

in Article 1 (commencing with Section 123225) of Chapter 1 of Part 2 of Division 106.

(b) It is the intent of the Legislature that pregnancy blood samples, taken for prenatal screening, shall be stored and made available to any researcher who is approved by the department for the following purposes:

- (1) Research to identify risk factors for children's and women's diseases.
- (2) Research to develop and evaluate screening tests.
- (3) Research to develop and evaluate prevention strategies.
- (4) Research to develop and evaluate treatments.

(c) Before any pregnancy blood samples are released for research purposes, all of the following conditions must be met:

(1) Individual consent at the time the sample is drawn to allow confidential use of the sample for research purposes by the department or the department's approved researchers.

(2) Protocol review for scientific merit by the department or another entity authorized by the department.

(3) Protocol review by the State Committee for the Protection of Human Subjects.

(d) Since the pregnancy blood samples described in this section will be stored by the California Birth Defects Monitoring Program or another entity authorized by the department, the storage, analysis, and sharing of pregnancy blood samples for research purposes shall be done in compliance with Section 103850, pertaining to confidentiality of information.

(e) The department shall adopt regulations specifying the protocols and conditions under which blood samples will be released for research purposes, in accordance with the procedures set forth in subdivision (d) of Section 124977.

(f) Until such time that regulations are adopted by the department pursuant to subdivision (e), the Genetic Disease Screening Program and the Birth Defects Monitoring Program shall release blood samples to only those researchers who meet the requirements of this section, including all of the following:

(1) The research project was approved by the State Committee for the Protection of Human Subjects.

(2) The research project's protocol was approved by the State Committee for the Protection of Human Subjects, and specifically included a description of the number and type of blood samples requested from the Genetic Disease Screening Program or the Maternal, Child, and Adolescent Health Program, including the Birth Defects Monitoring Program for the project.

(3) There is written documentation that the Genetic Disease Screening Program or the Maternal, Child, and Adolescent Health Program, including the Birth Defects Monitoring Program, approved a request for the blood samples for the research project approved by the State Committee for the Protection of Human Subjects.

(4) The researcher has agreed to pay fees to the department to pay reasonable costs for processing the samples and information, including, but

not limited to, costs of data management, including data linkage and entry, and costs of blood collection, storage, retrieval, inventory, and shipping.

(g) Subdivision (f) shall become inoperative on the date that the department adopts regulations specifying the protocols and conditions for release of the blood samples for research purposes.

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