AMENDED IN SENATE MAY 16, 2007

AMENDED IN SENATE APRIL 9, 2007

SENATE BILL No. 164

Introduced by Senator Migden

January 31, 2007

An act to amend Sections 124977 and 125002 of the Health and Safety Code, relating to maternal and child health, and making an appropriation therefor.

LEGISLATIVE COUNSEL'S DIGEST

SB 164, as amended, Migden. Prenatal screening.

Existing law imposes various responsibilities upon the State Department of Public Health and prenatal care providers with respect to prenatal care, screening, and counseling, and requires the department to administer a statewide program for prenatal testing for genetic disorders and birth defects, including, but not limited to, ultrasound, amniocentesis, chorionic villus sampling, and blood testing for genetic disorders and birth defects. Existing law establishes the Birth Defects Monitoring Program in the department's maternal, child, and adolescent health program, and requires the Deputy Director for Maternal, Child, and Adolescent Health to maintain a system for the collection of prescribed information on birth defects. Existing law also provides for an increase in prenatal screening fees to support the program activities and specifies the steps for release of pregnancy blood samples for research purposes. Existing law requires that those fees be deposited in the continuously appropriated Genetic Testing Fund.

This bill would change the name of the Birth Defects Monitoring Program to the Birth Defects Monitoring and Biomedical Resources Program. The bill would require the department to also charge

investigators, who are approved by the department to use pregnancy blood for research purposes, a fee for costs related to data linkage, storage, retrieval, processing, data entry, reinventory, and shipping of pregnancy blood or its components, and related data management, as provided. The bill would require that the moneys collected from the prenatal fee increase and the usage and retrieval charge be deposited in the Birth Defects Monitoring and Biomedical Resources Program Fund, which the bill would create, and that would be continuously appropriated to support the activities of the program.

The bill would additionally require that the program develop pregnancy blood collection and processing protocols, determine conditions and recommendations for the duration of pregnancy blood storage, establish exclusion criteria for blood specimens, and institute safe and secure methods for the disposal of specimens, as determined by the program. The bill would require the department to store the pregnancy blood for research purposes, as prescribed, and analyze the costs of pregnancy blood storage, and annual data linkage and management, and to adjust the fee accordingly.

Existing law prohibits the release of information identifying the person from whom pregnancy blood samples are stored, analyzed, or otherwise shared for research purposes with nondepartment staff.

This bill would exempt from that prohibition the provision of information identifying the person from whom the samples were obtained to Birth Defects Monitoring and Biomedical Resources Program contractors or other entities approved by the department.

The Committee for the Protection of Human Subjects (CPHS) serves as the institutional review board for the California Health and Human Services Agency for the purpose of assuring that research involving human subjects is conducted ethically and with minimum risk to participants.

This bill would require CPHS to determine if certain criteria are met to ensure the confidentiality of a donor's personal information before pregnancy blood is released for research purposes, as provided.

The bill would also authorize the department to bill investigators who are approved by the department to use pregnancy blood for research purposes for reasonable 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 investigator, removing personal information, encrypting or otherwise securing personal information, or assigning subject codes. The bill

would also require the department, health care providers, and local health departments to maintain the confidentiality of patient information in the same manner as other medical record information with patient identification as required by existing law, and would require this information to be used only for prescribed purposes.

Vote: majority. Appropriation: yes. Fiscal committee: yes. State-mandated local program: no.

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 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 directly to the Genetic Disease Testing Fund, 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) The director shall convene, in the most cost-efficient manner and using existing resources, a working group comprised of health insurance, health care service plan, hospital, consumer, and department representatives to evaluate newborn and prenatal screening fee billing procedures, and recommend to the department

ways to improve these procedures in order to improve efficiencies and enhance revenue collections for the department and hospitals. In performing its duties, the working group may consider models in other states. The working group shall make its recommendations by March 1, 2005.

(4) 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.

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

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

(C) The department shall also charge investigators who are approved by the department a fee for costs related to data linkage, storage, retrieval, processing, data entry, reinventory, and shipping of pregnancy blood or its components and related data management. The funds from fees collected pursuant to this subparagraph may be charged *and collected* by the department or by an entity authorized by the department to meet those costs.

(D) The funds from fees collected pursuant to this paragraph shall be deposited into the Birth Defects Monitoring and Biomedical Resources Program Fund, which is hereby created as a special fund in the State Treasury, to be continuously appropriated, to carry out the purposes of the Birth Defects Monitoring and Biomedical Resources Program. Notwithstanding Section 16305.7 of the Government Code, interest earned on the moneys in the fund shall also be deposited as revenue into the fund to support the 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 and the Birth Defects Monitoring and Biomedical Resources Program Fund for purposes related to prenatal and newborn screening 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 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 and Biomedical Resources 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) The Birth Defects Monitoring and Biomedical Resources Program shall develop blood collection and processing protocols, determine conditions and duration of pregnancy blood storage, establish exclusion criteria for pregnancy blood specimens, and institute safe and secure methods of disposing of specimens, as determined by the program. In addition, the Birth Defects Monitoring and Biomedical Resources Program or another entity authorized by the department shall store the pregnancy blood for research purposes from all or a statistically representative sample population of pregnant women who provided a positive consent.

(c) The department shall analyze the costs of pregnancy blood storage and data linkage and management annually, and the amount of the fee shall be adjusted by the department to meet the costs of the Birth Defects Monitoring and Biomedical Resources Program activities.

(d) It is the intent of the Legislature that pregnancy blood samples, taken for prenatal screening, shall be stored and used 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.

(e) 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 *(CPHS), as described in subdivision (i)*.

(f) When pregnancy blood samples are stored, analyzed or otherwise shared for research purposes with nondepartment staff, no information may be released identifying the person from whom the samples were obtained, except that information may be provided to Birth Defects Monitoring and Biomedical Resources Program contractors or to other entities approved by the department.

(g) Since the pregnancy blood samples described in this section will be stored by the Birth Defects Monitoring and Biomedical Resources Program or another entity authorized by the State Department of Health Services, Section 103850, pertaining to confidentiality of information, is applicable.

(h) The department, health care providers, and local health departments shall maintain the confidentiality of patient information 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.

(i) (1) In conducting the protocol review required by paragraph (3) of subdivision (e), CPHS shall determine if all of the following criteria have been met:

(A) The Birth Defects Monitoring and Biomedical Resources Program contractors or other entities approved by the department has 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 Birth Defects Monitoring and Biomedical Resources Program contractors 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 or other entities approved by the department have demonstrated an ongoing need for the personal information for the research activity and has provided a long-term plan sufficient to protect the confidentiality of that information.

(C) The Birth Defects Monitoring and Biomedical Resources Program contractors 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.

(j) In addition to the fee described in subparagraph (C) of paragraph (5) of subdivision (b), the department may bill an investigator 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 investigator, removing personal information, encrypting or otherwise securing personal information, or assigning subject codes.

(k) 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.

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