

Senate Bill No. 1555

CHAPTER 484

An act to amend Sections 124977 and 125055 of, to add Sections 1604.6 and 125002 to, and to add Article 4 (commencing with Section 123370) to Chapter 1 of Part 2 of Division 106 of, the Health and Safety Code, relating to prenatal testing and umbilical cord blood banking, and making an appropriation therefor.

[Approved by Governor September 26, 2006. Filed with
Secretary of State September 26, 2006.]

LEGISLATIVE COUNSEL'S DIGEST

SB 1555, Speier. Umbilical cord blood banking: education: prenatal screening.

(1) Existing law imposes various responsibilities upon the State Department of Health Services and prenatal care providers with respect to prenatal care, screening, and counseling.

This bill would require the department to conduct the Umbilical Blood Community Awareness Campaign, which would require the department to, among other things, provide awareness, assistance, and information regarding umbilical cord blood banking options, as specified. This bill would authorize a primary prenatal care provider, as defined, to provide to a woman who is known to be pregnant, during the first prenatal visit, information developed by the department pursuant to this bill regarding her options with respect to umbilical cord blood banking.

This bill would require the department to also provide this information, available in Cantonese, English, Spanish, and Vietnamese, about umbilical cord blood donation as specified. The bill would require that the information be made available on the Internet Web sites of the licensing boards or agencies that oversee primary prenatal care providers. The bill would specify that those provisions requiring the department to develop that information only be implemented, upon a determination by the Director of Finance, that sufficient private donations have been collected and deposited into the Umbilical Cord Blood Education Account, which the bill would create. The bill would require that the moneys in the account be available for expenditure, upon appropriation by the Legislature, for that purpose.

(2) Existing law, administered by the State Department of Health Services, contains provisions governing the licensure of blood banks. A violation of these provisions is a misdemeanor.

This bill would, notwithstanding any other provision of law, provide that a blood bank may provide umbilical cord blood banking storage services, only if it is licensed pursuant to these provisions. This bill would

also authorize the department to adopt regulations, as specified, in order to implement any additional standards for blood banks to store umbilical cord blood.

Because a violation of this provision would create a new crime, this bill would impose a state-mandated local program.

(3) Existing law, the Hereditary Disorders Act, declares the intent of the Legislature that the state's hereditary disorders program activities are to be fully supported by fees collected for services provided by the program, unless otherwise provided. Existing law requires the State Department of Health Services to charge a fee to all payers for any tests or activities performed pursuant to provisions relating to genetic disorder prevention services, including the Hereditary Disorders Act. Existing law requires that any fee charged for screening and followup services provided to Medi-Cal eligible persons, health care service plan enrollees, or persons covered by disability insurance policies are to be paid directly to the Genetic Disease Testing Fund, a continuously appropriated fund, to be used for the purposes of the Hereditary Disorders Act.

This bill would authorize the expenditure of funds from the Genetic Disease Testing Fund for the expansion of the Genetic Disease Branch Screening Information System to include the expansion of prenatal screenings through the amendment of the Genetic Branch Screening Information Systems contracts, and would exempt that expansion from specified requirements governing public contracts and contracts for information technology projects. By expanding the purposes for which moneys from the fund may be expended, the bill would make an appropriation.

(4) Existing law 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.

This bill would require the department to expand prenatal screening to include all tests that meet or exceed the current standard of care as recommended by nationally recognized medical or genetic organizations, including, but not limited to, inhibin, would authorize the department to charge a prescribed fee for this testing and would require the department, not later than July 1, 2007, to report to the Legislature on the progress of this expansion, including an estimate of the costs for screening, followup, and treatment as compared to costs and morbidity averted by this testing under the program. Because these fees are deposited in the continuously appropriated Genetic Disease Testing Fund, the bill would constitute an appropriation.

(5) Existing law, the Birth Defects Monitoring Program, requires the Director of Health Services to maintain a system for the collection of prescribed information on birth defects.

This bill would make the Birth Defects Monitoring Program part of the department's maternal, child and adolescent health program. This bill would also provide for an increase in prenatal screening fees to support a

variety of Birth Defects Monitoring Program activities and specify the steps for release of pregnancy blood samples for research purposes. Because these fees are deposited in the continuously appropriated Genetic Disease Testing Fund, the bill would constitute an appropriation.

(6) The California Constitution requires the state to reimburse local agencies and school districts for certain costs mandated by the state. Statutory provisions establish procedures for making that reimbursement.

This bill would provide that no reimbursement is required by this act for a specified reason.

Appropriation: yes.

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

SECTION 1. This act shall be known and may be cited as the Maternal and Child Health Advancement Act.

SEC. 1.5. Section 1604.6 is added to the Health and Safety Code, to read:

1604.6. (a) Notwithstanding any other provision of law, in order to provide umbilical cord blood banking storage services, a blood bank shall be licensed pursuant to this chapter. Any additional standards for blood banks to store umbilical cord blood may be implemented by the department through the adoption of regulations.

(b) (1) The department may adopt emergency regulations to implement and make specific subdivision (a) in accordance with Chapter 3.5 (commencing with Section 11340) of Part 1 of Division 3 of Title 2 of the Government Code. For 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.

(2) (A) 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, the department shall submit these regulations directly to the Secretary of State for filing.

(B) Emergency regulations adopted pursuant to this section shall become effective immediately upon filing by the Secretary of State, 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 by the department.

(3) The Office of Administrative Law shall provide for the printing and publication of emergency regulations adopted pursuant to this section in the California Code of Regulations.

(4) Notwithstanding Chapter 3.5 (commencing with Section 11340) of Part 1 of Division 3 of Title 2 of the Government Code, and subject to subparagraph (B) of paragraph (2), the emergency regulations adopted

pursuant to this subdivision shall not be repealed by the Office of Administrative Law and shall remain in effect until revised or repealed by the department.

SEC. 2. Article 4 (commencing with Section 123370) is added to Chapter 1 of Part 2 of Division 106 of the Health and Safety Code, to read:

Article 4. Cord Blood Banking Education

123370. The department shall conduct the Umbilical Cord Blood Community Awareness Campaign to do all of the following:

(a) Provide awareness, assistance, and information regarding umbilical cord blood banking options using brochures, television, print media, radio, Internet Web sites, outdoor advertising, and other media, where appropriate to disseminate information to licensed prenatal care providers, Family PACT providers, and pregnant women.

(b) Establish an Internet Web site to provide information about umbilical cord blood banking options that is accessible to prenatal care providers, pregnant women, and the general public.

(c) Undertake public education activities related to umbilical cord blood donation to targeted populations, as appropriate.

123371. (a) The State Department of Health Services shall develop standardized, objective information about umbilical cord blood donation that is sufficient to allow a pregnant woman to make an informed decision on whether to participate in a private or public umbilical cord blood banking program. This information shall include, but not be limited to, all of the following:

(1) The current and potential future medical uses of stored umbilical cord blood.

(2) The benefits and risks involved in umbilical cord blood banking.

(3) The medical process involved in umbilical cord blood banking.

(4) Medical or family history criteria that can impact a family's consideration of umbilical cord banking.

(5) An explanation of the differences between public and private umbilical cord blood banking.

(6) The availability and costs of public or private umbilical cord blood banks.

(7) Medical or family history criteria that can impact a family's consideration of umbilical cord blood banking.

(8) An explanation that the practices and policies of blood banks may vary with respect to accreditation, cord blood processing and storage methods, costs, and donor privacy.

(b) The information provided by the department pursuant to subdivision (a) shall be made available in Cantonese, English, Spanish, and Vietnamese.

(c) The information provided by the department pursuant to subdivision (a) shall be made available on the Internet Web sites of the licensing boards that have oversight over primary prenatal care providers.

(d) (1) The primary prenatal care provider of a woman who is known to be pregnant may, during the first prenatal visit, provide her with information developed by the department regarding her options with respect to umbilical cord blood banking at the same time the provider provides information regarding the use and availability of prenatal screening for birth defects of the fetus, as required by Section 6527 of Title 17 of the California Code of Regulations.

(2) For purposes of this article, a “prenatal care provider” means a health care provider licensed pursuant to Division 2 (commencing with Section 500) of the Business and Professions Code, or pursuant to an initiative act referred to in that division, who provides prenatal medical care within his or her scope of practice.

(e) The department shall only implement this article upon a determination by the Director of Finance, that sufficient private donations have been collected and deposited into the Umbilical Cord Blood Education Account, which is hereby created in the State Treasury. The moneys in the account shall be available, upon appropriation by the Legislature, for the purposes of this article. No public funds shall be used to implement this article. If sufficient funds are collected and deposited into the account, the Director of Finance shall file a written notice thereof with the Secretary of State.

SEC. 3. 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) 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.

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

(7) 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 specifically to support those Birth Defects Monitoring Program activities.

(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 Section 11346.1 and Section 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. 4. Section 125002 is added to the Health and Safety Code, 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 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.

(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) 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.

(e) 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 State Department of Health Services, Section 103850, pertaining to confidentiality of information, is applicable.

SEC. 5. Section 125055 of the Health and Safety Code is amended to read:

125055. The department shall:

(a) Establish criteria for eligibility for the prenatal testing program. Eligibility shall include definition of conditions and circumstances that result in a high risk of a detectable genetic disorder or birth defect.

(b) Develop an education program designed to educate physicians and surgeons and the public concerning the uses of prenatal testing and the availability of the program.

(c) Ensure that genetic counseling be given in conjunction with prenatal testing at the approved prenatal diagnosis centers.

(d) Designate sufficient prenatal diagnosis centers to meet the need for these services. Prenatal diagnosis centers shall have equipment and staff

trained and capable of providing genetic counseling and performing prenatal diagnostic procedures and tests, including the interpretation of the results of the procedures and tests.

(e) Administer a program of subsidy grants for approved nonprofit prenatal diagnosis centers. The subsidy grants shall be awarded based on the reported number of low-income women referred to the center, the number of prenatal diagnoses performed in the previous year at that center, and the estimated size of unmet need for prenatal diagnostic procedures and tests in its service area. This subsidy shall be in addition to fees collected under other state programs.

(f) Establish any rules, regulations, and standards for prenatal diagnostic testing and the allocation of subsidies as the director deems necessary to promote and protect the public health and safety and to implement the Hereditary Disorders Act (Section 27).

(g) (1) The department shall expand prenatal screening to include all tests that meet or exceed the current standard of care as recommended by nationally recognized medical or genetic organizations, including, but not limited to, inhibin.

(2) The prenatal screening fee increase for expanding prenatal screening to include those tests described in paragraph (1) is forty dollars (\$40).

(3) The department shall report to the Legislature regarding the progress of the program with regard to implementing prenatal screening for those tests described in paragraph (1) on or before July 1, 2007. The report shall include the costs of screening, followup, and treatment as compared to costs and morbidity averted by this testing under the program.

(4) (A) The expenditure of funds from the Genetic Disease Testing Fund for the expansion of the Genetic Disease Branch Screening Information System to include the expansion of prenatal screenings, pursuant to paragraph (1), 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.

(B) (i) The department may adopt emergency regulations to implement and make specific the amendments to this section made during the 2006 portion of the 2005–06 Regular Session 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 Section 11346.1 and Section 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.

(ii) 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.

SEC. 6. No reimbursement is required by this act pursuant to Section 6 of Article XIII B of the California Constitution because the only costs that may be incurred by a local agency or school district will be incurred because this act creates a new crime or infraction, eliminates a crime or infraction, or changes the penalty for a crime or infraction, within the meaning of Section 17556 of the Government Code, or changes the definition of a crime within the meaning of Section 6 of Article XIII B of the California Constitution.