

**S T A T U T O R Y**

**A U T H O R I T Y**

**California Birth Defects Monitoring Program**

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## Statutory Authority

Recognizing that birth defects are a public health problem about which too little is known, in 1982 the State Legislature created the California Birth Defects Monitoring Program (CBDMP). From 1982-1990, seven pieces of legislation were passed and enacted mandating the Program to:

- Maintain an ongoing birth defects monitoring program statewide
- Track birth defects and trends
- Evaluate whether environmental hazards are associated with birth defects
- Investigate other possible birth defect causes
- Develop birth defect prevention strategies
- Conduct interview studies about causes
- Operate by contract with a qualified entity

The California Birth Defects Monitoring Program was subsequently modified in 2006 and 2007 to provide for

- The Program to become part of the Maternal, Child and Adolescent Health Program (MCAH)
- Provide a funding mechanism to support the pregnancy blood sample storage, testing and research activities of the Program
- Include within the Program umbilical cord blood samples received from hospitals for storage and research.

This document includes the Program's current statutory authority in the Health and Safety Code.

**CALIFORNIA HEALTH AND SAFETY CODE SECTION (103825-103855)**

DIVISION 102. VITAL RECORDS AND HEALTH STATISTICS

PART 2. POPULATION AND PUBLIC HEALTH SURVEILLANCE

CHAPTER 1. BIRTH DEFECTS MONITORING PROGRAM

**Section**

- 103825. Legislative findings and declaration.
- 103830. Collection of information; system establishment; medical records.
- 103835. Scope of program; assessment of resources.
- 103840. Investigative studies.
- 103845. Advisory committee; membership.
- 103850. Confidentiality of information; research; review and approval; civil penalty.
- 103855. Contract for establishment and implementation of program.

### **§ 103825. Legislative findings and declaration**

The Legislature hereby finds and declares that birth defects, stillbirths, and miscarriages represent problems of public health importance about which too little is known; that these conditions lead to severe mental anguish on the part of parents and relatives and frequently to high medical care costs; and that a system to obtain more information about these conditions could result in development of preventive measures to decrease their incidence in the future. Therefore, it is the intent of the Legislature in enacting this section to accomplish all of the following:

- (a) To maintain an ongoing program of birth defects monitoring statewide. "Birth defect" as used in this chapter means any medical problem of organ structure, function, or chemistry of possible genetic or prenatal origin.
- (b) To provide information on the incidence, prevalence, and trends of birth defects, stillbirths, and miscarriages.
- (c) To provide information to determine whether environmental hazards are associated with birth defects, stillbirths, and miscarriages.
- (d) To provide information as to other possible causes of birth defects, stillbirths, and miscarriages.
- (e) To develop prevention strategies for reducing the incidence of birth defects, stillbirths, and miscarriages.
- (f) To conduct interview studies about the causes of birth defects.
- (g) To affirm the authority of the state department to contract with a qualified entity to operate the birth defects monitoring program statewide.

### **§ 103830. Collection of information; system establishment; medical records**

The director shall maintain a system for the collection of information, necessary to accomplish the purposes of this chapter. The director shall require health facilities, with 15 days' notice, to make available to authorized program staff the medical records of children suspected or diagnosed as having birth defects, including the medical records of their mothers. In addition, health facilities shall make available the medical records of mothers suspected or diagnosed with stillbirths or miscarriages and other records of persons who may serve as controls for interview studies about the causes of birth defects. If it is necessary to photocopy records made available under this section, copying expenses shall be paid by the state department.

"Health facilities" as used in this section means general acute care hospitals, and physician-owned or operated clinics, as defined in Section 1200, that regularly provide services for the diagnosis or treatment of birth defects, genetic counseling, or prenatal diagnostic services.

### **§ 103835. Scope of program; assessment of resources**

The birth defects monitoring program shall operate statewide. It is the intent of the Legislature that the adequacy of program resources shall be assessed annually, and that the annual assessment shall include a consideration of at least all the following factors:

- (a) The numbers of births in the state.
- (b) The scope of program activities.
- (c) Any urgent situation requiring extraordinary commitment of present or planned program staff or resources.

### **§ 103840. Investigative studies**

The director shall use the information collected pursuant to Section 103830 and information available from other reporting systems and health providers to conduct studies to investigate the causes of birth defects, stillbirths, and miscarriages and to determine and evaluate measures designed to prevent their occurrence.

The department's investigation of poor reproductive outcomes shall not be limited to geographic, temporal, or occupational associations, but may include investigation of past exposures.

### **§ 103845. Advisory committee; membership**

The director shall appoint an advisory committee to advise the implementation of this chapter. Each of the disciplines of epidemiology, hospital administration, biostatistics, maternal and child health and public health shall be represented on the committee.

At least one of the members shall be a representative of the manufacturing industry.

### **§ 103850. Confidentiality of information; research; review and approval; civil penalty**

- (a) All information collected pursuant to this chapter shall be confidential and shall be used solely for the purposes provided in this chapter. For purposes of this chapter, this information shall be referred to as "confidential information." Access to confidential information shall be limited to authorized program staff, and persons with a valid scientific interest, who meet qualifications as determined by the director, who are engaged in demographic, epidemiological or other similar studies

related to health, and who agree, in writing, to maintain confidentiality.

(b) The department shall maintain an accurate record of all persons who are given access to confidential information. The record shall include: the name of the person authorizing access; name, title, address, and organizational affiliation of persons given access; dates of access; and the specific purpose for which information is to be used. The record of access shall be open to public inspection during normal operating hours of the state department.

(c) All research proposed to be conducted by persons other than program staff, using confidential information in the system, shall first be reviewed and approved by the director and the State Committee for the Protection of Human Subjects. Satisfaction of the terms of the director's rules for data access shall be deemed to establish a valid scientific interest for purposes of subdivision (a), entitling the researcher to review records collected pursuant to Section 103830 and to contact case subjects and controls. Before confidential information is disclosed pursuant to this section to any other person, agency, or organization, the requesting entity shall demonstrate to the department that the entity has established the procedures and ability to maintain the confidentiality of the information.

(d) Notwithstanding any other provision of law, any disclosure authorized by this section shall include only the information necessary for the stated purpose of the requested disclosure, and shall be made only upon written agreement that the information will be kept confidential, used for the approved purpose, and not be further disclosed.

(e) The furnishing of confidential information to the department or its authorized representative in accordance with this section shall not expose any person, agency, or entity furnishing the information to liability, and shall not be considered a waiver of any privilege or violation of a confidential relationship.

(f) Whenever program staff, pursuing program objectives, deems it necessary to contact case subjects and controls, program staff shall submit a protocol describing the research to the director and to the State Committee for the Protection of Human Subjects. Once a protocol is approved by that committee, program staff shall be deemed to have established a bona fide research purpose, and shall be entitled to complete the approved project and contact case subjects and controls without securing any additional approvals or waivers from any entity.

(g) Notwithstanding any other provision of law, no part of the confidential information shall be available for subpoena, nor shall civil, criminal, administrative, or other proceeding, nor shall this information be deemed admissible as evidence in any civil, criminal,

administrative, or other tribunal or court for any reason. Nothing in this section shall prohibit the publishing by the department of reports and statistical compilations relating to birth defects, stillbirth, or miscarriage that do not in any way identify individual cases or individual sources of information.

(h) 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. That person shall also be subject to a civil penalty of five hundred dollars (\$500). The penalty provided in this section shall not be construed as restricting any remedy, provisional or otherwise, provided by law for the benefit of the department or any person.

(i) Notwithstanding the restriction in this section, an individual to whom the information pertains shall have access to his or her own information in accordance with Chapter 1 (commencing with Section 1798) of Title 1.8 of the Civil Code.

#### **§ 103855. Contract for establishment and implementation of program**

The department may enter into a contract for the establishment and implementation of the birth defects monitoring program. The contract shall include provisions requiring full compliance with all the requirements of this chapter. The term of the contract may be in excess of one year, but no longer than three years. Funds shall be allocated in accordance with the state Budget Act. Funds withheld from the contractor at the conclusion of a fiscal year until specified tasks are completed shall be released promptly on proof of substantial completion, and shall not be offset against any funding for the subsequent fiscal year.

**CALIFORNIA HEALTH AND SAFETY CODE SECTION (124975-124996)**

DIVISION 106. PERSONAL HEALTH CARE (INCLUDING MATERNAL, CHILD, AND ADOLESCENT)

PART 5. HEREDITARY DISEASES / CONGENITAL DEFECTS

CHAPTER 1. GENETIC PREVENTION SERVICES

ARTICLE 1. Hereditary Disorders Act

**Section**

124977. Fees; legislative intent; creation of Birth Defects Monitoring Program Fund.

124991. Storage and Use of Umbilical Cord Blood Samples; Fees; Confidentiality.

**§ 124977. Fees; legislative intent; creation of Birth Defects Monitoring Program Fund**

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(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 follow up 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 Defect 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.

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(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.

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**§ 124991. Storage and Use of Umbilical Cord Blood Samples; Fees; Confidentiality**

(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 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 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.

(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.

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

**CALIFORNIA HEALTH AND SAFETY CODE SECTION (125000-125002)**

DIVISION 106. PERSONAL HEALTH CARE (INCLUDING MATERNAL, CHILD, AND ADOLESCENT)

PART 5. HEREDITARY DISEASES / CONGENITAL DEFECTS

CHAPTER 1. GENETIC PREVENTION SERVICES

ARTICLE 2. Newborn Screening

**Section**

125002. Maternal, Child, and Adolescent Health; storage of blood samples; release of blood samples for research; regulations

**§ 125002. Maternal, Child, and Adolescent Health; storage of blood samples; release of blood samples for research; regulations.**

(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.