

CALIFORNIA  
BIRTH DEFECTS  
MONITORING  
PROGRAM

# STATUTORY AUTHORITY

SCIENTIFIC

FOUNDATIONS

SERIES

FEBRUARY 2006

# STATUTORY AUTHORITY

*Recognizing that birth defects are a public health problem about which too little is known, the State Legislature in 1982 created the California Birth Defects Monitoring Program. 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 rates and trends*
- *Evaluate whether environmental hazards are associated with birth defects*
- *Investigate other possible birth defects causes*
- *Develop birth defects prevention strategies*
- *Conduct interview studies about causes*
- *Operate by contract with a qualified entity.*

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

## CHAPTER 1. BIRTH DEFECTS MONITORING PROGRAM

### Section

103825. Legislative findings and declaration.  
 103830. Collection of information; system establishment; medical records.  
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*Chapter 1 was added by Stats.1995, c. 415 (S.B. 1360), § 4.*

**Historical and Statutory Notes** Legislative findings relating to the nonsubstantive effect of Stats.1995, c. 415 (S.B. 1360), and the legislative intent not to create any new rights, see Historical and Statutory Notes under Health and Safety Code § 100100.

### § 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.

(Added by Stats.1995, c. 415 (S.B., 1360), § 4.)

### Historical and Statutory Notes

**Derivation:** Former §10800, added by Stats.1982, c. 204, § 1, amended by Stats.1985, c. 1137, § 1; Stats.1989, c. 8, § 1; Stats.1990, c. 122, § 1.

### § 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.

(Added by Stats 1995, c. 415 (S.B.1360), § 4.)

### Historical and Statutory Notes

**Derivation:** Former §10801, added by Stats.1982, c. 204, § 1, amended by Stats.1989, c. 8, § 2; Stats.1990, c. 122, § 3.

**§ 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.

(Added by Stats.1995, c. 415 (S.B. 1360), § 4.)

**Historical and Statutory Notes**

**Derivation:** Former § 10802, added by Stats.1982, c. 204, § 1, amended by Stats.1990, c. 122, § 4.

**§ 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.

(Added by Stats.1995, c. 415 (S.B.1360), § 4.)

**Historical and Statutory Notes**

**Derivation:** Former § 10803, added by Stats.1982, c. 204, § 1, amended by Stats.1990, c. 122, § 7.

**§ 103845. Advisory committee; membership**

The director shall appoint an advisory committee to advise on 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.

(Added by Stats.1995, c. 415, (S.B.1360), § 4.)

**Historical and Statutory Notes**

**Derivation:** Former § 10804, added by Stats.1982, c. 204, § 1, amended by Stats.1990, c. 122, § 8.

**§ 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 a 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 it be disclosed, discoverable, or compelled to be produced in any 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 restrictions 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.

(Added by Stats.1995, c. 415, (S.B.1360), § 4.)

#### **Historical and Statutory Notes**

**Derivation:** Former § 10805, added by Stats.1982, c. 204, § 1, amended by Stats.1989, c. 8, § 4; Stats.1990, c. 122, § 9.

#### **Library References**

Records key 31. WESTLAW Topic No. 326. C.J.S. Records § § 74 to 92.

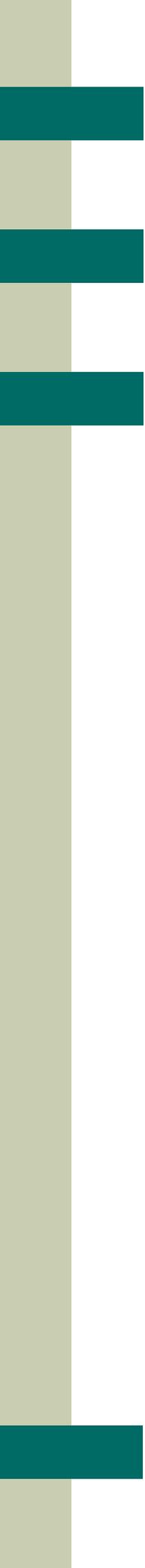
### **§ 103855. Contract for establishment and implementation of program**

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.

(Added by Stats.1995, c. 415, (S.B.1360), § 4.)

#### **Historical and Statutory Notes**

**Derivation:** Former § 10806, added by Stats.1985, c. 1147, § 2, amended by Stats.1989, c. 8, § 5; Stats.1990, c. 122, § 10.



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