

CALIFORNIA
BIRTH DEFECTS
MONITORING
PROGRAM

ENABLING LEGISLATION

SCIENTIFIC

FOUNDATIONS

SERIES

JULY 1993

ENABLING LEGISLATION

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 seven pieces of enabling legislation, and the current Health & Safety Code.

Section 1:

HEALTH & SAFETY CODE,
DIVISION 9.5,
SECTIONS 10800-10805

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Section 2:

SENATE BILL 834

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Section 3:

ASSEMBLY BILL 1950

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DIVISION 9.5. BIRTH DEFECTS MONITORING PROGRAM

Section

- 10800. Legislative findings and declaration.
- 10800.4. Repealed.
- 10801. Collection of information; system establishment; medical records.
- 10802. Scope of program; assessment of resources.
- 10802.1. Repealed.
- 10802.5. Repealed.
- 10803. Investigative studies.
- 10804. Advisory committee; membership.
- 10805. Confidentiality of information; research; review and approval; civil penalty.
- 10806. Contract for establishment and implementation of program.

Division 9.5 was added by Stats.1982, c. 204, p. 677, § 1, eff. May 18, 1982.

The heading of Division 9.5, Birth Defect Monitoring Program, was amended by Stats.1986, c. 1293, § 1.

§ 10800. 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 division 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.1982, c. 204, p. 677, § 1, eff. May 18, 1982. Amended by Stats.1985, c. 1137, § 1, eff. Sept. 28, 1985; Stats.1989, c. 8, § 1, eff. April 7, 1989; Stats.1990, c. 122 (S.B.285), § 1, eff. June 7, 1990.)

§ 10800.4. Repealed by Stats.1990, c. 122 (S.B.285), § 2, eff. June 7, 1990

Historical and Statutory Notes The repealed section, added by Stats. 1986, c. 1293, § 2, related to the expansion of the birth defects monitoring program in specified counties and to funding of the program.

§ 10801. 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 division. 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, which regularly provide services for the diagnosis or treatment of birth defects, genetic counseling, or prenatal diagnostic services.

(Added by stats.1982, c. 204, p. 677, § 1, eff. May 18, 1982. Amended by Stats.1989, c. 8, § 2, eff. April 7, 1989; Stats.1990, c. 122 (S.B.285), § 3, eff. June 7, 1990.)

§ 10802. 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.1982, c. 204, p. 677, § 1, eff. May 18, 1982. Amended by Stats.1990, c. 122 (S.B.285), § 4, eff. June 7, 1990.)

§ 10802.1. Repealed by Stats.1990, c. 122 (S.B.285), § 5, eff. June 7, 1990

Historical and Statutory Notes The repealed section, added by Stats.1987, c. 1197, § 1, amended by Stats.1989, c. 8, § 3, related to further expansion of the birth defects monitoring program in specified counties.

10802.5. Repealed by Stats.1990, c. 122 (S.B.285), § 6, eff. June 7, 1990

Historical and Statutory Notes The repealed section, added by Stats.1987, c. 1197, § 2, related to a report on the feasibility of expanding the birth defects monitoring program into the County of Los Angeles.

§ 10803. Investigative studies

The director shall use the information collected pursuant to Section 10801 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.1982, c. 204, p. 677, § 1, eff. May 18, 1982. Amended by Stats.1990, c. 122 (S.B.285), § 7, eff. June 7, 1990.)

§ 10804. Advisory committee; membership

* * * The director shall appoint an advisory committee to advise on the implementation of this division. 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.1982, c. 204, p. 677, § 1, eff. May 18, 1982. Amended by Stats.1990, c. 122 (S.B.285), § 8, eff. June 7, 1990.)

§ 10805. Confidentiality of information; research; review and approval; civil penalty

(a) All information collected and analyzed pursuant to * * * this division shall be confidential insofar as the identity of the individual patient is concerned and shall be used solely for the purposes provided in this division. Access to the 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 state department shall maintain an accurate record of all persons who are given access to the information in the system. The record shall include: the name of the person authorizing access; name, title, 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 the 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 10801 and to contact case subjects and controls.

(d) 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.

(e) Nothing in this section shall prohibit the publishing by the state department of statistical compilations relating to birth defects, stillbirth, or miscarriage which do not in any way identify individual cases or individual sources of information.

(f) 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 state 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 state department or any person.

(Added by Stats.1982, c. 204, p. 677, § 1, eff. May 18, 1982. Amended by Stats. 1989, 8, § 4, eff. April 7, 1989; Stats.1990, c. 122 (S.B.285), § 9, eff. June 7, 1990.)

Historical and Statutory Notes

1989 Legislation

The 1989 amendment substituted references to the state department for references to the State Department of Health Services; and made other nonsubstantive changes.

1990 Legislation

The 1990 amendment substituted "this division" for "Sections 10801 and 10803", in subd. (a); and rewrote subd. (c) which read:

"All research proposed to be conducted using the information in the system shall first be reviewed and approved by the appropriate committee constituted for the protection of human subjects which is approved by the federal Department of Health and Human Services pursuant to Part 46 of Title 45 of the Code of Federal Regulations."

The 1990 amendment also inserted anew subd. (d) relating to protocol when contacting case subjects and controls; in subd. (f), deleted "by the committee for the protection of human subjects" following "approved" and substituted "this section" for "subdivision (c)" preceding "may be denied"; and made nonsubstantive changes throughout.

§ 10806. Contract for establishment and implementation of program

The state 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 division. 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.1985, c. 1147, § 2. Amended by Stats.1989, c. 8, § 5, eff. April 7, 1989; Stats.1990, c. 122 (S.B.285), § 10, eff. June 7, 1990.)

SENATE BILL 834

- *Created the California Birth Defects Monitoring Program in law*
- *Gave access to all hospital medical records on children with birth defects*
- *Described the birth defects to be studied*
- *Required that information collected would be kept confidential*
- *Expanded the original 2 county program to 5 San Francisco Bay Area Counties, to begin in 1983:*
 - *Alameda*
 - *Contra Costa*
 - *San Mateo*
 - *San Francisco*
 - *Santa Clara*

Senate Bill No. 834

CHAPTER 204

An act to add Division 9.5 (commencing with Section 10800) to the Health and Safety Code, relating to health, making an appropriation therefor, and declaring the urgency thereof, to take effect immediately.

[Approved by Governor May 18, 1982. Filed with Secretary of State May 18, 1982.]

LEGISLATIVE COUNSEL'S DIGEST

SB 834, Watson. Health: birth problems, cancer.

(1) Existing law vests in the State Department of Health Services certain powers and duties relating to the health, safety and welfare of the people of this state.

This bill would authorize the department to specify a system for the collection of information concerning birth defects, stillbirths, and miscarriages, as specified. The system would include reporting of birth defects, stillbirths, and miscarriages and authorize the director to require general acute care hospitals to make available to department staff medical records of those patients who have been diagnosed with birth defects, stillbirths, or miscarriages. The bill would provide that the information would be confidential, as prescribed.

The bill would also make various findings and declarations.

(2) The bill would appropriate, without regard to fiscal years, \$725,000 to the department and \$150,000 to the Hazard Evaluation System and Information Services for the purposes of this act, as specified.

(3) The bill would take effect immediately as an urgency statute.

Appropriation: yes.

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

SECTION 1. Division 9.5 (commencing with Section 10800) is added to the Health and Safety Code, to read:

DIVISION 9.5. BIRTH DEFECT MONITORING PROGRAM

10800. 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 such 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 the following:

(a) To provide information on the incidence and trends of birth defects, stillbirths, and miscarriages.

(b) To provide information to determine whether environmental hazards are associated with birth defects, stillbirths, and miscarriages.

(c) To provide information as to other possible causes of birth defects, stillbirths, and miscarriages.

(d) To develop prevention strategies for reducing the incidence of birth defects, stillbirths, and miscarriages.

10801. (a) The director may establish a system for the collection of information concerning birth defects, stillbirths, and miscarriages. In establishing the system, the director may require general acute care hospitals to maintain a list of patients up to age five diagnosed with birth defects incorporated within the ICD-9 diagnostic code categories 740 through 759.9, and all women discharged with a diagnosis of stillbirth or miscarriage. The list shall be made available to departmental staff upon request and shall be used solely for purposes provided for in this division.

(b) The director may require general acute care hospitals to make available to departmental staff the medical records of those patients who have been diagnosed with birth defects, stillbirths, or miscarriages as required in subdivision (a).

10802. The system may cover all or any part of the state depending on funding and other appropriate consideration, including an assessment of the need to obtain the information and the ability of the department to utilize the information for the purposes of this division.

10803. The director shall use the information collected pursuant to Section 10801 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 exposure, including diethylstilbesterol (DES), herbicide, or extensive radiation exposure.

10804. (a) The director shall appoint an advisory committee to advise on the implementation of this division. 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.

(b) If the department finds it is necessary to collect information from sources other than general acute care hospitals, the department shall first consult with the advisory committee.

10805. (a) All information collected and analyzed pursuant to Sections 10801 and 10803 shall be confidential insofar as the identity of the individual

patient is concerned and shall be used solely for the purposes provided in this division. Access to such information shall be limited to State Department of Health Services staff, and persons with a valid scientific interest, and qualifications as determined by the Director of the Department of Health Services, who are engaged in demographic, epidemiological or other similar studies related to health, and who agree, in writing, to maintain confidentiality as prescribed herein.

(b) The State Department of Health Services shall maintain an accurate record of all persons who are given access to the information in the system. The record shall include: the name of the person authorizing access; name, title 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 of Health Services.

(c) All research proposed to be conducted using the information in the system shall first be reviewed and approved by the appropriate committee constituted for the protection of human subjects which is approved by the federal Department of Health and Human Services pursuant to Part 46 of Title 45 of the Code of Federal Regulations.

(d) Nothing in this section shall prohibit the publishing by the state department of statistical compilations relating to birth defects, stillbirth, or miscarriage which do not in any way identify individual cases or individual sources of information.

(e) 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 that approved by the committee for the protection of human subjects pursuant to subdivision (c), 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.

SEC. 2. The sum of eight hundred seventy-five thousand dollars (\$875,000) is hereby appropriated from the General Fund without regard to fiscal years, as follows:

(a) Four hundred fifty thousand dollars (\$450,000) to the State Department of Health Services to expand the birth defect monitoring programs to the Counties of San Francisco, Santa Clara and San Mateo.

(b) Two hundred seventy-five thousand dollars (275,000) to the State Department of Health Services for a two-year study to track pregnant women exposed to

malathion in the Santa Clara Valley to determine whether their birth outcomes are significantly different than in pregnant women not exposed to malathion.

(c) One hundred fifty thousand dollars (\$150,000) to the Hazard Evaluation System and Information Services located in the State Department of Health Services to administer a study of the effect of exposure to Ethylene di Bromide (EDB) on the reproductive system of persons exposed.

SEC. 3. It is the intent of the Legislature that funding for the birth defects monitoring program in future years be through the normal budgetary process.

SEC. 4. This act is an urgency statute necessary for the immediate preservation of the public peace, health, or safety within the meaning of Article IV of the Constitution and shall go into immediate effect. The facts constituting the necessity are:

In order for the State of California to be able immediately to respond to expressions of concern about grave health problems, including the possible environmental origins of birth defects, particularly in, but not limited to, the Santa Clara Valley, it is necessary that this act take effect immediately.

ASSEMBLY BILL 1950

■ *Expanded and funded the Program in 10 mostly Central Valley Counties, to start in 1986:*

- *Fresno*
- *Merced*
- *Monterey*
- *Napa*
- *Sacramento*
- *San Joaquin*
- *Santa Cruz*
- *Stanislaus*
- *Tulare*
- *Yolo*

Assembly Bill No. 1950

CHAPTER 1137

An act to amend Section 10800 of the Health and Safety Code, relating to health, making an appropriation therefor, and declaring the urgency thereof, to take effect immediately.

[Approved by Governor September 28, 1985. Filed with Secretary of State September 28, 1985.]

LEGISLATIVE COUNSEL'S DIGEST

AB 1950, Vasconcellos. Birth defect monitoring: appropriation.

Under existing law, there is a birth defect monitoring program, administered by the State Department of Health Services.

This bill would make certain findings of legislative intent concerning this program, including the intent to expand the statewide birth defect monitoring program. It would appropriate \$1,000,000 to the State Department of Health Services for the last 8 months of the 1985-86 fiscal year to expand the program, to specified counties.

This bill would take effect immediately as an urgency statute.

Appropriation: yes.

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

SECTION 1. Section 10800 of the Health and Safety Code is amended to read:

10800. 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 such 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 expand the program of birth defects monitoring.
- (b) To provide information on the incidence 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.

SEC. 2. The sum of one million dollars (\$1,000,000) is hereby appropriated from the General Fund to the

State Department of Health Services for the last eight months of the 1985-86 fiscal year for purposes of implementing Division 9.5 (commencing with Section 10800) of the Health and Safety Code to expand the birth defects monitoring program to the Counties of Fresno, Sacramento, Merced, Monterey, Santa Cruz, Yolo, Stanislaus, Tulare, Napa, and San Joaquin.

SEC. 3. It is the intent of the Legislature that the implementation of the expansion described in Section 2 and plans for future expansion be evaluated by the Task Force on Expansion of the Birth Defects Monitoring Program. It is the intent of the Legislature that funding for the birth defects monitoring program in future years be through the normal budgetary process.

SEC. 5. This act is an urgency statute necessary for the immediate preservation of the public peace, health, or safety within the meaning of Article IV of the Constitution and shall go into immediate effect. The facts constituting the necessity are:

In order for the funding for the California Birth Defects Monitoring Program to be synchronized with the fiscal year and in order for birth defects monitoring to begin in the counties of Fresno, Sacramento, Merced, Monterey, Santa Cruz, Yolo, Stanislaus, Tulare, Napa, and San Joaquin, as soon as possible, it is necessary for this act to take effect immediately.

SENATE BILL 694

- *Expanded and funded the Program in Orange County, to start in 1986*

Senate Bill No. 694

CHAPTER 1147

An act to add Section 10806 to the Health and Safety Code, relating to the Birth Defect Monitoring Program, and making an appropriation therefor.

[Approved by Governor September 28, 1985. Filed with Secretary of State September 28, 1985.]

LEGISLATIVE COUNSEL'S DIGEST

SB 694, Seymour. Birth Defect Monitoring Program.

Under existing law, the Birth Defect Monitoring Program has been established in various counties in northern California.

This bill would authorize the State Department of Health Services to enter into an agreement with a county for the implementation of the Birth Defect Monitoring Program and would appropriate \$275,000 to the department for expenditure without regard to fiscal year to extend the program to the County of Orange.

Appropriation: yes.

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

SECTION 1. (a) In Section 10800 of the Health and Safety Code, the Legislature has previously found and declared all of the following:

(1) That birth defects, stillbirths, and miscarriages represent problems of importance to public health about which too little is known.

(2) That the conditions described in paragraph (1) lead to severe mental anguish on the part of parents and relatives and frequently lead to high costs for medical care.

(3) That a program to obtain more information about the medical problems described in paragraph (1) could result in the development of preventive measures to decrease their incidence in the future.

(b) In Section 10801 of the Health and Safety Code, the Legislature has authorized the State Director of Health Services to establish the California Birth Defects Registry, and has provided financing to maintain a birth defect monitoring program in the following five counties in the San Francisco Bay Area: Alameda, Contra Costa, San Francisco, San Mateo, and Santa Clara.

(c) The Legislature recognizes the value of expanding the Birth Defect Monitoring Program provided for in Division 9.5 (commencing with Section 10800) of the Health and Safety Code to include the County of Orange.

This expansion is due to the highly industrialized nature of the county, its location in the southern half of the state, and in recognition of the model tumor registry program already established in the county.

(d) Therefore, it is the purpose of this act to authorize the State Department of Health Services to contract with the County of Orange, in the manner provided in Section 10806 of the Health and Safety Code, for the implementation of the Birth Defect Monitoring Program in that county.

SEC. 2. Section 10806 is added to the Health and Safety Code, to read:

10806. The State Department of Health Services may enter into an agreement with a county for the establishment and implementation of the Birth Defect Monitoring Program in that county. The agreement shall include provisions requiring full compliance with all the requirements of this division.

SEC. 3. The sum of two hundred seventy-five thousand dollars (\$275,000) is hereby appropriated from the General Fund to the State Department of Health Services for expenditure without regard to fiscal year to expand the Birth Defect Monitoring Program provided for in Division 9.5 (commencing with Section 10800) of the Health and Safety Code to the County of Orange.

ASSEMBLY BILL 2832

■ *Expanded and funded the Program in 21 counties, to start in 1987:*

- *Amador*
- *Calaveras*
- *Colusa*
- *Del Norte*
- *El Dorado*
- *Humboldt*
- *Imperial*
- *Kern*
- *Kings*
- *Madera*
- *Marin*
- *Mariposa*
- *Nevada*
- *Placer*
- *San Benito*
- *San Diego*
- *Sonoma*
- *Solano*
- *Sutter*
- *Tuolumne*
- *Yuba*

Assembly Bill No. 2832

CHAPTER 1293

An act to amend the heading of Division 9.5 (commencing with Section 10800) of, and to add Section 10800.4 to, the Health and Safety Code, relating to health.

[Approved by Governor September 28, 1986. Filed with Secretary of State September 29, 1986]

LEGISLATIVE COUNSEL'S DIGEST

AB 2832, Killea. Birth defect monitoring.

Pursuant to existing law there is a birth defects monitoring program administered by the State Department of Health Services.

Existing law provides that the program may cover all or any part of the state depending upon funding and other considerations.

Existing law further provides a statement of legislative intent that the program encompass certain specified counties.

The bill would expand the program for the second half of the fiscal year 1986-87 and would specify the counties to be covered by the expansion.

This bill would also state the legislative intent that for the fiscal year 1986-87, the program be funded through the State Budget Act.

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

SECTION 1. The heading of Division 9.5 (commencing with Section 10800) of the Health and Safety Code is amended to read:

DIVISION 9.5. BIRTH DEFECTS MONITORING PROGRAM

SEC. 2. Section 10800.4 is added to the Health and Safety Code, to read:

10800.4. The birth defects monitoring program shall be expanded to the counties of Amador, Calaveras, Colusa, Del Norte, El Dorado, Humboldt, Imperial, Kern, Kings, Madera, Marin, Mariposa, Nevada, Placer, San Benito, San Diego, Sonoma, Solano, Sutter, Tuolumne, and Yuba during the second half of the 1986-87 fiscal year.

It is the intent of the Legislature that funding for the birth defects monitoring program in fiscal year 1986-87 be provided through the State Budget Act.

ASSEMBLY BILL 1397

- *Required a report on the feasibility of a future expansion to Los Angeles County*
- *Expanded and funded the Program in 20 counties, to start in 1988:*
 - *Alpine*
 - *Butte*
 - *Glenn*
 - *Inyo*
 - *Lake*
 - *Lassen*
 - *Mendocino*
 - *Modoc*
 - *Mono*
 - *Plumas*
 - *Riverside*
 - *San Bernardino*
 - *San Luis Obispo*
 - *Santa Barbara*
 - *Shasta*
 - *Sierra*
 - *Siskiyou*
 - *Tehama*
 - *Trinity*
 - *Ventura*

Assembly Bill No. 1397

CHAPTER 1197

An act to add Sections 10802.1 and 10802.5 to the Health and Safety Code, relating to health, and making an appropriation therefor.

[Approved by Governor September 25, 1987. Filed with Secretary of State September 26, 1987.]

I am deleting the \$635,000 appropriation contained in Section 3 of Assembly Bill No. 1397.

This bill would appropriate \$635,000 (General Fund) to the Department of Health Services for an expansion of the Birth Defects Monitoring Program into 20 additional counties. The bill also requires the development of a report on the feasibility of expanding the program to Los Angeles County.

The existing Birth Defects Monitoring covers 37 counties and has a current year appropriation of \$3,286,000. An evaluation of the existing program has been recently completed. There has not been sufficient time, though, to fully review and evaluate the benefits of the program to determine if the proposed expansion is appropriate.

The demands placed on budget resources require all of us to set priorities. The budget enacted in July, 1987 appropriated nearly \$41 billion in state funds. This amount is more than adequate to provide the necessary essential services provided for by State Government. It is not necessary to put additional pressure on taxpayer funds for programs that fall beyond the priorities currently provided.

Thus, after reviewing this legislation, I have concluded that its merits do not sufficiently outweigh the need this year for funding top priority programs and continuing a prudent reserve for economic uncertainties.

I would, however, consider funding the provisions of this bill during the budget process for Fiscal Year 1988-89.

It is appropriate to review the relative merits of this program in comparison to all other funding projects. The budget process enables us to weigh all demands on the state's revenues and direct our resources to programs, either new or existing, that have the most merit.

With this deletion, I approve Assembly Bill No. 1397.

GEORGE DEUKMEJIAN, Governor

LEGISLATIVE COUNSEL'S DIGEST

AB 1397, Clute. Birth defects.

Existing law permits the Director of Health Services to establish a system for the collection of information concerning birth defects, stillbirths, and miscarriages, in all, or any portion, of the state.

This bill would require that, during the second half of the 1987-88 fiscal year, this program be expanded to include specified counties.

The bill would also require the department, by January 1, 1989, to report to specified committees of the Legislature, on the feasibility of expanding this program to Los Angeles County.

The bill would appropriate \$635,000 from the General Fund to the department, for expenditure during the last 6 months of the 1987-88 fiscal year, for purposes of expanding the birth defects monitoring program into the counties specified in the bill.

Appropriation: yes

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

SECTION 1. Section 10802.1 is added to the Health and Safety Code, to read:

10802.1. During the second half of the 1987-88 fiscal year, the birth defects monitoring program shall be expanded to the Counties of Alpine, Butte, Glenn, Inyo, Lake, Lassen, Mendocino, Modoc, Mono, Plumas, Riverside, San Bernardino, San Luis Obispo, Santa Barbara, Shasta, Sierra, Siskiyou, Tehama, Trinity, and Ventura.

SEC. 2. Section 10802.5 is added to the Health and Safety Code, to read:

10802.5. By January 1, 1989, the department shall submit, to the health policy and fiscal committees of the Legislature, a report on the feasibility of expanding the birth defects monitoring program into the County of Los Angeles. If the expansion is feasible, this report shall include plans for phasing this population into the system, and a listing of the funds needed for this expansion.

SEC. 3. (a) There is hereby appropriated from the General Fund to the State Department of Health Services, the sum of six hundred thirty-five thousand dollars (\$635,000), for expenditure during the last six months of the 1987-88 fiscal year for purposes of implementing Section 10802.1 of the Health and Safety Code, as contained in Section 1 of this act.

(b) It is the intent of the Legislature that funding for the birth defects monitoring program in future years be through the normal budgetary process.

ASSEMBLY BILL 52

- *Clarified access of Program staff to medical records*
- *Consolidated legislative authority*
- *Clarified authority of the Department of Health Services to contract for Program operation*

Assembly Bill No. 52

CHAPTER 8

An act to amend Sections 10800, 10801, 10802.1, 10805, and 10806 of the Health and Safety Code, and to amend Section 14083 of the Welfare and Institutions Code, relating to health, and declaring the urgency thereof, to take effect immediately.

[Approved by Governor April 7, 1989. Filed with Secretary of State April 7, 1989.]

LEGISLATIVE COUNSEL'S DIGEST

AB 52, Killea. Health services.

(1) Under existing law, the State Department of Health Services is authorized to administer a birth defects monitoring program by agreement with specified counties. In addition, the department is authorized to establish a system for the collection of information from general acute care hospitals concerning birth defects, stillbirths, and miscarriages and to require those hospitals to maintain a list of specified classes of patients and make this information available to department staff, among others.

This bill would expand that authority to allow the program to operate in all counties except the County of Los Angeles during the 1989-90 fiscal year, and would authorize the department to contract with a qualified entity to operate the program. It would provide for the department to establish a system for the collection of information from general acute care hospitals and to mandate that the records of specified individuals and other records be made available to authorized program staff, among others.

(2) Existing law provides for the coverage under Medi-Cal of comprehensive perinatal services by certified comprehensive perinatal providers. Existing law requires the California Medical Assistance Commission to negotiate contracts for the provision of inpatient hospital services under the Medi-Cal program, and to consider various factors when so negotiating.

This bill would, in addition, require the commission to take into consideration, when negotiating these contracts, that a hospital provides additional obstetrical beds,

contracts with one or more comprehensive perinatal providers, permits certified nurse midwives to admit patients, or expands overall obstetrical services in the hospital.

The bill would also specify that the Legislature recognizes that the State Department of Health Services is conducting a study to determine whether certain factors are being adequately considered by the department when setting per capita rates for perinatal services in prepaid health plans and whether the per capita rates are sufficient for prepaid health plans to provide those perinatal services.

The bill would require the department to notify the Legislature upon the completion of the study, and to provide copies of the results of the study upon request of the Members of the Legislature and their staff.

This bill would declare that it is to take effect immediately as an urgency statute.

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

SECTION 1. Section 10800 of the Health and Safety Code is amended to read:

10800. 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 expand the program of birth defects monitoring.

(b) To provide information on the incidence 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.

SEC. 2. Section 10801 of the Health and Safety Code is amended to read:

10801. The director may establish a system for the collection of information concerning birth defects, stillbirths, and miscarriages. If such a system is established, the director shall require general acute care hospitals, 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, hospitals 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.

SEC. 3. Section 10802.1 of the Health and Safety Code is amended to read:

10802.1. (a) During the second half of the 1987-88 fiscal year, the birth defects monitoring program shall be expanded to the Counties of Alpine, Butte, Glenn, Inyo, Lake, Lassen, Mendocino, Modoc, Mono, Plumas, Riverside, San Bernardino, San Luis Obispo, Santa Barbara, Shasta, Sierra, Siskiyou, Tehama, Trinity, and Ventura.

(b) During the 1989-90 fiscal year, the birth defects monitoring program shall operate in all counties except the County of Los Angeles.

SEC. 4. Section 10805 of the Health and Safety Code is amended to read:

10805. (a) All information collected and analyzed pursuant to Sections 10801 and 10803 shall be confidential insofar as the identity of the individual

patient is concerned and shall be used solely for the purposes provided in this division. Access to the information shall be limited to authorized program staff, and persons with a valid scientific interest, who meet qualifications as determined by the director, and who are engaged in demographic, epidemiological or other similar studies related to health, and who agree, in writing, to maintain confidentiality as prescribed herein.

(b) The state department shall maintain an accurate record of all persons who are given access to the information in the system. The record shall include: the name of the person authorizing access; name, title, 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 using the information in the system shall first be reviewed and approved by the appropriate committee constituted for the protection of human subjects which is approved by the federal Department of Health and Human Services pursuant to Part 46 of Title 45 of the Code of Federal Regulations.

(d) Nothing in this section shall prohibit the publishing by the state department of statistical compilations relating to birth defects, stillbirths, or miscarriage which do not in any way identify individual cases or individual sources of information.

(e) 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 that approved by the committee for the protection of human subjects pursuant to subdivision (c), may be denied further access to any confidential information maintained by the state 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 state department or any person.

SEC. 5. Section 10806 of the Health and Safety Code is amended to read:

10806. The state department may enter into an agreement for the establishment and implementation of the birth defects monitoring program. The agreement shall include provisions requiring full compliance with all the requirements of this division.

SEC. 6. Section 14083 of the Welfare and Institutions Code is amended to read:

14083. The factors to be considered by the negotiator in negotiating contracts under this article, or in drawing specifications for competitive bidding, include, but are not limited to, all of the following:

- (a) Beneficiary access.
- (b) Utilization controls.
- (c) Ability to render quality services efficiently and economically.
- (d) Demonstrated ability to provide or arrange needed specialized services.
- (e) Protection against fraud and abuse.
- (f) Any other factor which would reduce costs, promote access, or enhance the quality of care.
- (g) The capacity to provide a given tertiary service, such as specialized children's services, on a regional basis.
- (h) Recognition of the variations in severity of illness and complexity of care.
- (i) Existing labor-management collective bargaining agreements.
- (j) The situation of county hospitals and university medical centers contracting with counties for provisions of health care to indigent persons entitled to care under Section 17000, which are burdened to a greater extent than private hospitals with bad debts, indirect costs, medical education programs, and capital needs.
- (k) The special circumstances of hospitals serving a disproportionate number of Medi-Cal beneficiaries and patients who are not covered by other third-party payers.

(l) The costs of providing complex emergency services, including the costs of meeting and maintaining state and local requirements for trauma center designation.

(m) The hospital does any of the following:

- (1) Provides additional obstetrical beds.
- (2) Contracts with one or more comprehensive perinatal providers.
- (3) Permits certified nurse midwives, subject to hospital rules, and consistent with existing laws and regulations, to admit patients to the health facility.
- (4) Expands overall obstetrical services in the hospital.

SEC. 7. (a) The Legislature finds and declares that approximately 6,000 babies were delivered in 1987 to women enrolled in prepaid health plans.

(b) The Legislature recognizes that the State Department of Health Services is conducting a study to determine whether the short periods of enrollment of Medi-Cal recipients in prepaid health plans during times of high cost, the lack of access to fee-for-service perinatal care for these recipients, and the frequency of high-risk births in this patient population are being adequately considered by the department when setting per capita rates for perinatal services in prepaid health plans and whether the per capita rates are sufficient for prepaid health plans to provide these perinatal services.

(c) The State Department of Health Services shall notify the Legislature when the study is completed and shall provide copies of the results of the study to the members of the Legislature and their staff upon request.

SEC. 8. This act is an urgency statute necessary for the immediate preservation of the public peace, health, or safety within the meaning of Article IV of the Constitution and shall go into immediate effect. The facts constituting the necessity are:

In order that the birth defects monitoring program may be expanded as soon as possible to provide valuable information concerning birth defects, stillbirths, and miscarriages, it is necessary for this act to take effect immediately.

SENATE BILL 285

- *Expanded the Program statewide with the addition of Los Angeles County*
- *Clarified the definition of “health facilities” at which data are collected*
- *Created a process for review of data by non-Program scientists.*

Senate Bill No. 285

CHAPTER 122

An act to amend Sections 10800, 10801, 10802, 10803, 10804, 10805, and 10806 of, and to repeal Sections 10800.4, 10802.1, and 10802.5 of, the Health and Safety Code, relating to health, and declaring the urgency thereof, to take effect immediately.

[Approved by Governor June 7, 1990. Filed with Secretary of State June 7, 1990.]

LEGISLATIVE COUNSEL’S DIGEST

SB 285, Watson. Birth defects.

Under existing law, the State Department of Health Services is authorized to administer a birth defects monitoring program and to establish a system for the collection of information from general acute care hospitals. Existing law requires that the records derived from this system be made available only to authorized program staff and others determined, as specified, to have a valid scientific interest and to be engaged in certain health studies.

This bill would require the department to maintain an ongoing program of monitoring birth defects, as defined, statewide.

The bill would require the department to maintain a system for the collection of specified information from the health facilities, as defined, which is necessary to accomplish the purposes of the program.

The bill would declare that it is to take effect immediately as an urgency statute.

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

SECTION 1. Section 10800 of the Health and Safety Code is amended to read:

10800. 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 division 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.

SEC. 2. Section 10800.4 of the Health and Safety Code is repealed.

SEC. 3. Section 10801 of the Health and Safety Code is amended to read:

10801. The director shall maintain a system for the collection of information, necessary to accomplish the purposes of this division. 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, which regularly provide services for the diagnosis or treatment of birth defects, genetic counseling, or prenatal diagnostic services.

SEC. 4. Sec 10802 of the Health and Safety Code is amended to read:

10802. 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.

SEC. 5. Section 10802.1 of the Health and Safety Code is repealed.

SEC. 6. Section 10802.5 of the Health and Safety Code is repealed.

SEC. 7. Section 10803 of the Health and Safety Code is amended to read:

10803. The director shall use the information collected pursuant to Section 10801 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.

SEC. 8. Section 10804 of the Health and Safety Code is amended to read:

10804. The director shall appoint an advisory committee to advise on the implementation of this division. 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.

SEC. 9. Section 10805 of the Health and Safety Code is amended to read:

10805. (a) All information collected and analyzed pursuant to this division shall be confidential insofar as the identity of the individual patient is concerned and shall be used solely for the purposes provided in this division. Access to the 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 state department shall maintain an accurate record of all persons who are given access to the information in the system. The record shall include: the name of the person authorizing access; name, title, 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 the 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 10801 and to contact case subjects and controls.

(d) 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.

(e) Nothing in this section shall prohibit the publishing by the state department of statistical compilations relating to birth defects, stillbirth, or miscarriage which do not in any way identify individual cases or individual sources of information.

(f) 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 state 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 state department or any person.

SEC. 10. Section 10806 of the Health and Safety Code is amended to read:

10806. The state 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 division. 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.

SEC. 11. This act is an urgency statute necessary for the immediate preservation of the public peace, health, or safety within the meaning of Article IV of the Constitution and shall go into immediate effect. The facts constituting the necessity are:

In order that this birth defects monitoring program may be expanded into Los Angeles County during the 1989-90 fiscal year, it is necessary that this act take effect immediately.

