

Appendix 2.1
Sample State Legislation

Appendix 2.1 – Sample State Legislation

| | |
|---|----------|
| Appendix 2.1.1 Arkansas Legislation..... | A2.1.1-1 |
| Appendix 2.1.2 California Legislation | A2.1.2-1 |
| Appendix 2.1.3 New Jersey Legislation | A2.1.3-1 |
| Appendix 2.1.4 New York Legislation..... | A2.1.4-1 |
| Appendix 2.1.5 Oklahoma Legislation..... | A2.1.5-1 |
| Appendix 2.1.6 Texas Legislation..... | A2.1.6-1 |

Appendix 2.1.1
Arkansas Legislation

Arkansas Code of 1987 Annotated
Title 20. Public Health and Welfare
Subtitle 2. Health and Safety
Chapter 16. Reproductive Health
Subchapter 2. Arkansas Reproductive Health Monitoring System

20-16-201 Establishment- Purpose

- a) The Arkansas Reproductive Health Monitoring System is established and is to be administered within the Arkansas Children's Hospital.
- b) The purpose of the system is to collect and analyze data from a number of sources to describe trends in the occurrence of reproductive endpoints such as congenital anomalies, fetal death, developmental disorders, etc., and to correlate those trends and investigate and report on the suspected causes of unexpected deviations in those trends.

History. Acts 1985, No. 214, § 1; A.S.A. 1947, § 82-4608.

20-16-202 Definitions

As used in this subchapter, unless the context otherwise requires:

- 1) "Board" means the technical advisory board established in § 20-16-204;
- 2) "Commission" means the advisory commission established in § 20-16-203; and
- 3) "System" means the Arkansas Reproductive Health Monitoring System.

History. Acts 1985, No. 214, § 3; A.S.A. 1947, § 82-4610.

20-16-203 Advisory Commission- Members- Functions

- a) The Arkansas Reproductive Health Monitoring System shall be administered with the advise of an advisory commission appointed to one-year renewable terms by the Medical Director of the Arkansas Children's Hospital.
- b) The functions of the commission are to:
 - 1) Advise the medical director as to the adequacy of policies, procedures, and performance of the system;
 - 2) Appoint members of the board upon the recommendations of the medical director;
 - 3) Promote the purposes of the system and assist in identification of appropriate funding sources;
 - 4) Promote interagency cooperation toward the goals of this system;
 - 5) Advise the medical director regarding requests for data dissemination; and
 - 6) Review mechanisms ensuring the maintenance of the confidentiality of personal data.
- c) This commission shall be composed of the following state agencies, professional members, and public members:
 - 1) The medical director of the Arkansas Children's Hospital;
 - 2) The chancellor of the University of Arkansas for Medical Science;
 - 3) The director of the Department of Health;
 - 4) The director of the Department of Human Services;
 - 5) The director of the Arkansas Department of Environmental Quality;
 - 6) The director of the National Center for Toxicological Research;
 - 7) One (1) representative of the Arkansas Medical Society;
 - 8) One (1) representative of the Arkansas Academy of Pediatrics;

- 9) One (1) representative of the Arkansas Society of Obstetrics & Gynecology;
 - 10) One (1) representative of the Arkansas Hospital Association;
 - 11) One (1) representative of the State Plant Board;
 - 12) Two (2) consumer representatives;
 - 13) One (1) member from the Senate Public Health, Welfare, and Labor Committee and one (1) member from the House Public Health, Welfare, and Labor Committee; and
 - 14) Up to four (4) additional members at large may be appointed.
- d) Members of the commission who are not employees of the state may receive expense reimbursement in accordance with § 25-16-901 et seq.

History. Acts 1985, No 214, §§ 4, 11; A.S.A. 1947, §§ 82-4611; Acts 1997, No. 250, § 188; 1999, No. 1164, § 173.

Amendments. The 1997 amendment rewrote (d). The 1999 amendment substituted "Environmental Quality" for "Pollution Control and Ecology" in (c) (5).

20-16-204 Technical Advisory Board- Members- Functions

- a) There shall be a technical advisory board whose function shall be to:
- b) (1) This board shall be appointed to one-year renewable terms by the Medical Director of the Arkansas Children's Hospital upon recommendation of the commission and the director.
 - (2) It shall be comprised of a maximum of ten (10) regular members drawn from fields of expertise such as: medicine, industrial hygiene and toxicology, agriculture, environmental sciences, and epidemiology and statistics.
 - (3) At the discretion of the board and the director, ad hoc members of the board may be appointed for specific periods to advise on special needs or problems, which have been identified.
- c) Members of the board who are not employees of the state may receive expense reimbursement in accordance with § 25-16-901 et seq.

History. Acts 1985, No 214, §§ 5, 11; A.S.A. 1947, §§ 82-4612, 82-4618; Acts 1997, No 250, § 189.

Amendments. The 1997 amendment rewrote (c).

20-16-205 Director- Appointment- Power and duties

- a) The Arkansas Reproductive Health Monitoring System shall be administered by a director appointed by the Medical Director of the Arkansas Children's Hospital from among the professional staff of the Arkansas Children's Hospital.
- b) The director shall:
 - 1) Supervise the work of the system and administer the budget;
 - 2) Appoint and remove such other employees as may be necessary to perform the duties and responsibilities of the system; and
 - 3) Select and retain the services of consultants whose advice is considered necessary to carry out the system's mandate.

History. Acts 1985, No 214, § 2; A.S.A. 1947, § 82-4609.

20-16-206 Authority to contract for information

- a) The Arkansas Reproductive Health Monitoring System is expressly authorized to contract for the production of any information, which its technical advisory board determines to be relevant to monitoring reproductive health from any department or agency of the state.
- b) Information shared under this section includes, but is not limited to, information identified by the name or other personal identifier, including information concerning any system by which such data or information is identified or classified if required to decipher the information.

History. Acts 1985, No 214, § 6; A.S.A. 1947, § 82-4613.

20-16-207 Information confidential- Exception

The Arkansas Reproductive Health Monitoring System is expressly exempted and prohibited from supplying any information by individual name or other personal identifier or in a form other than a statistical report or other appropriate form which protects the confidentiality of individuals except to any state agency or department which originally supplied the information to the system unless both the originating agency and the system grant release of this information for a specific purpose.

History. Acts 1985, No 214, § 7; A.S.A. 1947, § 82-4614.

20-16-208 Furnishing of information by hospitals

- a) All hospitals with patient records containing information pertaining to reproduction and development are required to share information in those records with the Arkansas Reproductive Health Monitoring System.
- b) No hospital shall be required to furnish information under this section until appropriate reimbursement in return for the service has been determined by the advisory commission and funds are available to pay the compensation.

History. Acts 1985, No 214, § 8; A.S.A. 1947, § 82-4615.

20-16-209 Furnishing of information by physician, clinic, etc.

- a) Any physician, clinic, person, or organization may provide information relative to reproductive health to the Arkansas Reproductive Health Monitoring System.
- b) No liability of any kind or character for damages or other relief shall arise or be enforced against any person or organization by reason of having provided the information or by reason of having released or published the findings of the system in order to reduce morbidity and mortality or to advance medical research or medical education.

History. Acts 1985, No 214, § 9; A.S.A. 1947, § 82-4616.

20-16-210 Intergovernmental agreements

The Arkansas Reproductive Health Monitoring System shall have the power to enter into agreements with neighboring states and the federal Centers for Disease Control and Prevention consistent with the requirements and restrictions of this subchapter in order to obtain relevant information for the system concerning Arkansas residents who receive health-related services outside the state.

History. Acts 1985, No 214, § 10; A.S.A. 1947, § 82-4617.

20-16-211 Funding and implementation

- a) The Arkansas Reproductive Health Monitoring System shall have the power to receive and expend grants, donations, and funds from public and private sources to carry out its responsibilities under this subchapter.
- b) The Arkansas Children's Hospital is not required to implement this system unless sufficient funds are available as determined by the Medical Director of the Arkansas Children's Hospital.
- c) The system may be implemented in stages or phases.

History. Acts 1985, No 214, § 13; A.S.A. 1947, § 82-4620.

20-16-212 Reports

The Arkansas Reproductive Health Monitoring System shall periodically prepare reports of its findings for dissemination to appropriate agencies and interested persons.

History. Acts 1985, No 214 § 14; A.S.A. 1947, § 82-4621.

20-16-213 Rendering of patient care and regulatory activity prohibited

The Arkansas Reproductive Health Monitoring System is expressly prohibited from rendering patient care, promulgating any rule or regulation, or engaging in any regulatory activity.

History. Acts 1985, No 214, § 13; A.S.A. 1947, § 82-4620.

20-16-214 No actionable right, presumptions, or findings created

- a) Persons other than the state or Arkansas Reproductive Health Monitoring System shall not acquire any actionable right by virtue of this subchapter
- b) A determination by this system that a source is suspected of causing adverse reproductive health outcomes shall not create by reason thereof any presumption of law or finding of a fact which shall inure to, or be for, the benefit of any person other than the state.

History. Acts 1985, No 214, § 12; A.S.A. 1947, § 82-4619.

Arkansas Code of 1987 Annotated
Title 20. Public Health and Welfare
Subtitle 2. Health and Safety
Chapter 16. Reproductive Health
Subchapter 4. Reproductive Health Information

20-16-402 Information from state agencies

- a) (1) Any bona fide appropriately licensed medical facility, including, but not limited to, county hospitals, participating in recognized research in Arkansas and the federal Centers for Disease Control and Prevention are expressly authorized to contract for the production of any information relevant to monitoring reproductive health from any department or agency of the state.
(2) Information acquired under this subsection (a) includes, but is not limited to, information identified by name or other personal identifying information including the methods by which the information was compiled or tabulated.
- b) The University of Arkansas for Medical Sciences, Arkansas Children's Hospital, other participating medical facilities as described in subsection (a) of this section, and the federal Centers for Disease Control and Prevention are expressly prohibited from supplying any information obtained pursuant to subsection (a) of this section by individual name or other personal identifying information or in a form other than a statistical report or other appropriately form which protects the confidentiality of individuals.
- c) Information obtained pursuant to subsection (a) of this section may be returned to any state agency or department from which it was originally obtained.

History. Acts 1983, No 773, §§ 1, 3; A.S.A. 1947, §§ 82-4601, 82-4603.

Appendix 2.1.2
California Legislation

CALIFORNIA
BIRTH DEFECTS
MONITORING
PROGRAM

SCIENTIFIC

FOUNDATIONS

SERIES

STATUTORY AUTHORITY

OCTOBER 1998

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.

HEALTH & SAFETY CODE, DIVISION 102, PART 2, CHAPTER 1

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.

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 and analyzed pursuant to this chapter shall be confidential insofar as the identity of the individual patient is concerned and shall be used solely for the purposes provided in this chapter. 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 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 103830 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 department of statistical compilations relating to birth defects, stillbirth, or miscarriage that 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 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.

(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.



CALIFORNIA
BIRTH DEFECTS
MONITORING
PROGRAM

The California Birth Defects Monitoring Program—
a public health program devoted to finding causes of birth defects—
is funded through the California Department of Health Services
and jointly operated with the March of Dimes Birth Defects Foundation.

For more information about the Program, please call
(559)224-2212.

Appendix 2.1.3
New Jersey Legislation

REGISTRATION - VITAL STATISTICS 26:8-40.22**26:8-40.21. Birth defects registry**

The State Department of Health shall establish and maintain a birth defects registry which shall contain a confidential record of all birth defects that occur in New Jersey and any other information that the department deems necessary and appropriate in order to conduct thorough and complete epidemiologic surveys of birth defects that occur in this State and plan for and provide services to children with birth defects and their families.

L1983, c.291, § 2.

Historical Note

Effective date, see Historical Note under § 26:8-40.20.

Library References

Health and Environmental 34.
C.J.S. Health and Environmental § 41.

26:8-40.2. Confidential reports of abortions of fetus with or infant affected by birth defects

a. The Commissioner of Health, in consultation with the Public Health Council, shall require the confidential reporting to the Department of Health of all cases where a pregnancy results in a naturally aborted fetus or infant affected by a birth defect, and an electively aborted fetus that exhibits or is known to have a birth defect after 15 weeks of gestation. The reporting requirement shall apply to all infants from birth through one year of age.

b. The Commissioner of Health shall determine the health care providers and facilities which shall be required to report all birth defects, the types of conditions or defects that shall be reported, the type of information that shall be contained in the confidential report and the method for making the report. In reports concerning all fetuses with anomalies, the name of the mother shall not be submitted.

Historical Note

Effective date, see Historical Note under § 26:8-40.20.

Library References

Health and Environmental 34.
C.J.S. Health and Environmental § 41.

26:8-40.23 Confidentiality of reports

The confidential reports made pursuant to this act are to be used only by the Department of Health and other agencies that may be designated by the Commissioner of Health and shall not otherwise be divulged or made public so as to disclose the identity of any person to whom they relate; and to that end, such reports shall not be included under materials available to public inspection pursuant to P.L. 1963, c.73 (C.47:1A-1 et seq.).

L.1983, c.291, § 4.

Historical Note

Effective date, see Historical Note under § 26:8-40.20.

Library References

Health and Environment 34.
Records 30 et seq., 50 et seq.
C.J.S. Health and Environment § 41.
C.J.S. Records §§ 34 to 38.

26:8-40.24. Nonliability for divulging confidential information

No individual or organization providing information to the Department of Health in accordance with this act shall be deemed to be or held liable for divulging confidential information.

L.1983, c.291, § 5.

Historical Note

Effective date, see Historical Note under § 26:8-40.20.

Library References

Health and Environmental 34.
Records 30 et seq., 50 et seq.
C.J.S. Health and Environmental § 41.
C.J.S. §§ 34 to 38.

26:8-40.25. Act not to be construed to compel submission to medical examination or to supervision by department of health

Nothing in this act shall be construed to compel any individual to submit to a medical examination or to Department of Health supervision.

L.1983, c.291, §§ 6.

Historical Note

Effective date, see Historical Note under § 26:8-40.20.

Library References

Health and Environmental 34.
C.J.S. Health and Environmental § 41.

26:8-40.26. Rules and regulations

The Commissioner of Health shall promulgate rules and regulations necessary to effectuate the purposes of this act.

L.1983, c.291, § 7.

Historical Note

Effective date, see Historical Note under § 26:8-40.20.

Library References

Administrative Law and Procedure 381 et. Seq.
Health and Environment 7(3), 20, 39.
C.J.S. Health and Environmental §§ 2 to 13, 40 to 51, 62 to 64, 106, 125 to 137, 155, 156.
C.J.S. Public Administrative Law and Procedure §§ 87 to 91.

BIRTH DEFECTS REGISTRY

8:20-1.2

**CHAPTER 20
BIRTH DEFECTS REGISTRY**

Authority

N.J.S.A. 26:8-40 et seq., specifically 26:8-40.26.

Source and Effective Date

R.2000 d.99, effective February 10, 2000.
See: 31 N.J.R. 2863(a), 32 N.J.R. 802(a).

Executive Order No. 66(1978) Expiration Date

Chapter 20, Birth Defects Registry, expires on February 10, 2005.

Chapter Historical Note

Chapter 20, Birth Defects Registry, was adopted as R.1985 d.92, effective March 4, 1985. See: 16 N.J.R. 3118(a), 17 N.J.R. 591(a).

Pursuant to Executive Order No. 66(1978), Chapter 20, Birth Defects Registry, was readopted as R.1990 d.187, effective March 2, 1990. See: 21 N.J.R. 3636(a), 22 N.J.R. 1134(c).

Pursuant to Executive Order No. 66(1978), Chapter 20, Birth Defects Registry, was readopted as R.1995 d.182, effective March 2, 1995. See: 27 N.J.R. 269(a), 27 N.J.R. 1410(b).

Pursuant to Executive Order No. 66(1978), Chapter 20, Birth Defects Registry, was readopted as R.2000 d.99, effective February 10, 2000. See: Source and Effective Date. See, also, section annotations.

CHAPTER TABLE OF CONTENTS

SUBCHAPTER 1. LIVE BIRTHS

- 8:20-1.1 Definitions
- 8:20-1.2 Reporting requirements

SUBCHAPTER 1. LIVE BIRTHS

8:20-1.1 Definitions

The following words and terms when used in this document shall have the following meanings unless the context clearly indicates otherwise.

“Birth defect” means an abnormality of the body’s structure or inherent function which is present at birth, whether such abnormality is manifest at the time of delivery or becomes apparent later in life.

“Infant” means a child from birth to one year of age.

8:20-1.2 Reporting requirements

(a) Any infant who is born to a resident of the State of New Jersey, or who becomes a resident of the State before one year of age, and who is diagnosed as having a birth defect either at birth or any time during the first year of life shall be reported to the State Department of Health and

Senior Services, Special Child, Adult and Early Intervention Services Program as follows:

1. The conditions listed as Congenital Anomalies (Diagnostic Codes 740.00 through 759.90) in the most recent revision of the International Classification of Diseases, Clinical Modification, shall, except as specified in (a)1ii below, be reported to Special Child, Adult and Early Intervention Services. In addition, there are several other conditions considered to be defects that are not listed under Diagnostic Codes 740.00 through 759.90 which describe Congenital Anomalies. The birth defects listed in (a)1i below shall also, in every case, be reported to Special Child, Adult and Early Intervention Services. The minor conditions listed in (a)1ii below shall not be reported to Special Child, Adult and Early Intervention Services in every case, but only as required in (a)1iii, iv and v below.

i. Congenital anomalies, including, but not limited to, the following:

(1) Anencephalus and similar anomalies, such as craniorachischis and inencephaly.

(2) Spina bifida with and without mention of hydrocephalus.

(3) Other congenital anomalies of the nervous system, such as: encephalocele; microcephalus; reduction deformities of the brain; congenital hydrocephalus; congenital cerebral palsies, congenital muscular dystrophies; and other anomalies, congenital diseases, lesions and any other deformities of the brain, nervous system or spinal cord.

(4) Congenital anomalies of the eye, such as: anophthalmos; microphthalmos; buphthalmos; congenital cataract and lens anomalies; coloboma and other anomalies of the anterior or posterior segment; congenital anomalies of eyelids, lacrimal system and orbit; and any other anomalies of the eye.

(5) Congenital anomalies of the ear, face and neck, such as: anomalies of the ear causing impairment of hearing; accessory auricle and any other anomalies of the ear; branchial cleft cyst or fistula; preauricular sinus; webbing of the neck; and any other anomalies of face and neck.

(6) Bulbus cordis anomalies and anomalies of cardiac septal closure such as: common truncus; transposition of great vessels; Tetralogy of Fallot; common ventricle; ventricular septal defect; ostium secundum type atrial septal defect; endocardial cushion defects; cor biloculare; and any other defects of septal closure.

(7) Other congenital anomalies of the heart, such as: anomalies of pulmonary valve; congenital tricus-

pid atresia and stenosis; Ebstein's anomaly; congenital stenosis of aortic valve; congenital mitral stenosis of aortic valve; congenital mitral stenosis or insufficiency; hypoplastic left heart syndrome; and any other structural anomalies of the heart.

(8) Other congenital anomalies of circulatory system, such as: patent ductus arteriosus (only in infants larger than 2,500 grams); coarctation of aorta and other anomalies of the aorta, aortic arch or atresia and stenosis of the aorta; anomalies of pulmonary artery; anomalies of great veins, absence or hypoplasia of umbilical artery; other anomalies of peripheral vascular system; or other unspecified anomalies of circulatory system.

(9) Congenital anomalies of respiratory system, such as: choanal atresia; other anomalies of nose; webbing of larynx; other anomalies of larynx, trachea and bronchus; congenital cystic lung; agenesis, hypoplasia and dysplasia of lung; other anomalies of the lung; and other unspecified anomalies of respiratory system.

(10) Cleft palate and cleft lip.

(11) Other congenital anomalies of upper alimentary tract, such as: anomalies of the tongue; anomalies of mouth and pharynx; tracheoesophageal fistula, esophageal atresia, and stenosis and other anomalies of esophagus; congenital hypertrophic pyloric stenosis, congenital hiatal hernia; other anomalies of stomach; and other unspecified anomalies of upper alimentary tract.

(12) Other congenital anomalies of digestive system, such as: Meckel's diverticulum; atresia and stenosis of small intestine, large intestine, rectum and anal canal; Hirschsprung's disease and other congenital functional disorders of colon; anomalies of intestinal fixation; other anomalies of intestine, gall bladder, bile ducts, liver and pancreas; disorders of tooth formation, development and eruption, dentofacial anomalies, and other unspecified anomalies of the digestive system.

(13) Congenital anomalies of genital organs, such as: anomalies of ovaries, fallopian tubes and broad ligaments; doubling of uterus and other anomalies of uterus; anomalies of cervix, vagina and external female genitalia; undescended testicle; hypospadias and congenital chordee; indeterminate sex and pseudohermaphroditism; and other unspecified anomalies of the genital system.

(14) Congenital anomalies of urinary system, such as: renal agenesis and dysgenesis; cystic kidney disease; obstructive defects of renal pelvis and ureter; other anomalies of kidney and ureter; exstrophy of urinary bladder; atresia and stenosis of urethra and bladder neck; anomalies of urachus; other anomalies of bladder and urethra; and other unspecified anomalies of the urinary system.

(15) Certain congenital musculoskeletal deformities, such as: of skull, face and jaw; of sternocleidomastoid muscle; of spine; congenital dislocation of hip; congenital genu recurvatum and bowing of long bones of leg; varus and valgus deformities of feet; other congenital deformities of feet such as talipes cavus, calcaneus or equinus; and other specified nonteratogenic anomalies such as pectus excavatum, pectus carinatum; club hand; congenital deformity of chest wall; dislocation of elbow; generalized flexion contractures of lower limbs; spade-like hand.

(16) Other congenital anomalies of limbs, such as: syndactyly; reduction deformities of upper limb; reduction deformities of lower limb; other anomalies of upper limb, including shoulder girdle; and other anomalies of lower limb, including pelvic girdle.

(17) Other congenital musculoskeletal anomalies, such as: anomalies of skull and facial bones; anomalies of spine; cervical rib; other anomalies of ribs and sternum; chondrodystrophy; osteodystrophies; anomalies of diaphragm; anomalies of abdominal wall such as prune belly syndrome; other specified anomalies of muscle, tendon, fascia and connective tissue; and other unspecified anomalies of musculoskeletal system.

(18) Congenital anomalies of the integument, significant anomalies of skin, subcutaneous tissue, hair, nails and breast, such as birthmarks or nevi measuring four inches or greater in size, multiple skin tags (more than five in number).

(19) Chromosomal anomalies, such as: Down's syndrome; Patau's syndrome; Edwards' syndrome; autosomal deletion syndromes and other conditions due to autosomal anomalies; gonadal dysgenesis; Klinefelter's syndrome; and other conditions due to sex chromosome anomalies or anomalies of unspecified chromosome.

(20) Other and unspecified congenital anomalies, such as: anomalies of spleen, situs inversus; conjoined twins; tuberous sclerosis; other hamartomas; multiple congenital anomalies; and other congenital anomalies including congenital malformation syndromes affecting multiple organ systems including Laurence-Moon-Biedl syndrome, Marfan's syndrome and Prader-Willi syndrome.

(21) Certain endocrine, nutritional and metabolic diseases and immunity disorders, includes congenital hypothyroidism; congenital hypoparathyroidism; hypopituitarism; diencephalic syndrome; adrenogenital syndrome; testicular feminization syndrome; phenylketonuria; albinism; maple syrup urine disease; argininosuccinic aciduria; glycogen storage diseases; cystic fibrosis; alpha-1 antitrypsin deficiency; DiGeorge's syndrome; congenital deficiencies of humoral immunity; cell-mediated immunity; combined immunity deficiencies; and other specified and unspecified disorders of the immune mechanisms.

BIRTH DEFECTS REGISTRY

8:20-1.2

(22) Certain diseases of the blood and blood forming organs, includes hemolytic diseases of the newborn: G-6PD deficiency; hemophilia (all types); Von Willebrand's disease; and sickle-cell anemia or other hemoglobinopathies.

(23) Certain diseases of the nervous system and sense organs, includes hereditary and degenerative diseases of the central nervous system such as Tay Sachs disease and familial degenerative CNS diseases; Werdnig-Hoffmann disease; cerebral palsy; Moebius syndrome; hereditary retinal dystrophies, and chorioretinitis.

(24) Certain diseases of the circulatory system, includes endocardial fibroelastosis; congenital Wolfe-Parkinson-White syndrome; and Budd-Chiari syndrome.

(25) Certain diseases of the digestive system, includes abnormalities of jaw size, micrognathia and macrognathia; congenital inguinal hernia with gangrene (only in females), congenital, inguinal hernia with obstruction with no mention of gangrene (only in females), congenital, inguinal hernia without obstruction with no mention of gangrene (only in females), umbilical hernia (only if not covered by skin), epigastric hernia.

(26) Certain complications of pregnancy child-birth, and the puerperium, includes amniotic bands, amniotic cyst.

(27) Certain diseases of the skin and subcutaneous tissue, pilonidal sinus.

(28) Certain conditions originating in the perinatal period, includes fetal alcohol syndrome, probable fetal alcohol syndrome (includes facies), fetal alcohol effects, fetal hydantoin (Dilantin) syndrome, bronchopulmonary dysplasia, unspecified TORCH infection and certain congenital infections including congenital syphilis, congenital rubella, cytomegalovirus, toxoplasmosis, hepatitis, herpes simplex.

(29) Neoplasms, includes lipomas of skin and subcutaneous tissue of face and other skin and subcutaneous tissue, intrathoracic and intra-abdominal organs, spermatic cord, other specified sites, lumbar, sacral, paraspinal, and other unspecified sites; benign neoplasms of skin includes blue nevus, pigmented nevus (include if greater than four inches in diameter), papilloma, dermatofibroma, syringoadenoma, dermoid cyst, hydrocystoma, syringoma; other benign neoplasms of lip, eyelid, ear, external auditory canal, skin and other unspecified parts of face, scalp, skin of neck, skin of trunk, skin of upper limb, skin of lower limb, other specified and unspecified sites including hairy nevus; hemangioma (include if: greater than four inches in diameter, multiple, more than five in number or cavernous hemangioma) of skin and subcutaneous tissue, intracranial, intra-abdominal cystic

hygroma; lymphangioma of any site, hemangioma of other and unspecified site; and certain malignant neoplasms including Wilm's tumor, retinoblastoma, other congenital neoplasms including neuroblastoma, medulloblastoma, teratoma, fibrosarcoma, histiocytosis (malignant), neurofibromatosis.

ii. Minor conditions, as follows:

Accessory auricle
 Accessory nipple (supernumerary nipple, or skin tag)
 Anal fissure—never a defect
 Anal tags
 Bat ear
 Bell's Palsy
 Bent nose, deviation of septum
 Big lips
 Blue sclera (babies <2500 grams)
 Brachial palsy
 Breast Hypertrophy—never a defect
 Cafe-au-lait spots (register if five or more)
 Caput succedaneum
 Cardiac murmur¹
 Cauliflower ear
 CNS hemorrhage
 Cephalhematoma—never a defect
 Cervical rib
 Chhalasia (gastroesophageal reflux)—never a defect
 Clinodactyly (incurving of fifth finger)
 Congenital hydrocele
 Conjunctivitis—never a defect
 Cryptorchidism (undescended testicle)²
 Darwin's tubercle
 Diastasis recti—never a defect
 Downward eyeslant (antimongoloid)
 Ear tags, preauricular tags
 Elfin ear
 Epicanthal folds
 Epulis—never a defect
 Erb's palsy
 Erythema toxicum
 Esotropia
 Exotropia
 Facial palsy
 Flammeus nevus or port wine stain (<four inches in diameter)
 Flat bridge or nose
 Fontanel (large or small)
 Fractured clavicle
 Fused eyelids (not a defect if birth weight is <1001 grams)
 Gastroesophageal reflux—never a defect
 Gum cysts—includes epulis, ranula, mucocoele—never a defect
 Hemangioma—<four inches in diameter³
 Hepatomegaly
 Hipclick—without follow-up or therapy—not a defect
 Hydrocele
 Hydrocephaly; acquired
 Hymenal tags
 Hypoglycemia, idiopathic
 Hypoplastic scrotum
 Imperforate hymen
 Incurving finger (clinodactyly)
 Inguinal hernia in male (Note: do not report in females)

8:20-1.2

DEPT. OF HEALTH

Infant of a diabetic mother; asymptomatic
 Intussusception
 Lanugo, excessive or persistent
 Large fontanel
 Laryngomalacia or tracheomalacia—never a defect
 Long fingers and/or toes
 Lop ear
 Low set ears
 Macrocheilia (big lips)
 Meckel's diverticulum
 Meconium peritonitis
 Meconium plug
 Meconium stained skin or nails—never a defect
 Metatars adductus—never a defect
 Metatars varus
 Microcheilia (small lips)
 Mongolian spots
 Mucocele—never a defect
 Nasal lacrimal duct obstruction
 Nail defects
 Natal teeth
 Neonatal acne—never a defect
 Nystagmus
 Orthopedic positional anomalies ⁴
 Overlapping toes
 Overriding (overlapping) sutures—never a defect
 Partial syndactyly second and third toes—web extends
 < one-third length of second toe
 Patent ductus arteriosus (PDA) in infants <2500
 grams or resolved prior to or at discharge
 Patulous lips (wide lips)
 Persistent fetal circulation
 Petechiae—never a defect
 Phimosis—never a defect
 Pilonidal dimple
 Pilonidal cyst
 Pixie-like ear
 Pneumothorax
 Pointed ear
 Polydactyly (postaxial, type B)—skin tags on hands or
 feet
 Posteriorly rotated ears
 Preauricular sinus
 Pylorospasm (intermittent)
 Ranula—never a defect
 Rectal fissure
 Redundant foreskin
 Rockerbottom feet
 Sacral dimple
 Sebaceous cysts
 Simian crease (transverse palmar crease)
 Single umbilical artery
 Skin cysts
 Small fontanel
 Small lips
 Splenomegaly
 Thymic hypertrophy
 Tibial torsion
 Tongue-tie
 Torsion of spermatic cord
 Torsion of testes
 Tracheomalacia—never a defect
 Umbilical cord atrophy
 Umbilical hernias (completely covered by skin)
 Undescended testicle ²
 Upturned nose
 Upward eyeslant (mongoloid)

Vaginal cysts
 Vaginal tags
 Webbing of neck
 Wide nasal bridge
 Widely spaced nipples
 Widely spaced first and second toes

iii. If a condition or defect listed in (a)lii above appears as a single defect, a registration form shall not be completed.

iv. If two or more of the conditions listed in (a)lii above appear, a registration form shall be completed.

v. If a condition or defect listed in (a)lii above accompanies a condition or defect listed in either Diagnostic Codes 740.00 through 759.90 in the most recent revision of the International Classification of Diseases, Clinical Modification, or in (a)li above, a registration form shall be completed.

(b) Any live born infant with a birth defect who has not been previously registered and has expired shall be reported. Such reports shall indicate that the infant has expired.

(c) The administrative officer of every health care facility shall be responsible for establishing the reporting procedures for that facility. The reporting procedures must insure that every infant who is initially diagnosed as having a birth defect shall be reported to the Department. All presumptive, tentative, pending, or rule out diagnoses will be reported at the time of discharge, if the child will be diagnosed at a later time or if test results are pending.

(d) Every physician, dentist, certified nurse midwife, advanced practice nurse, and other health care professionals who diagnose or confirm birth defects shall report to the Department each infant diagnosed as having a birth defect not known to be previously reported.

(e) The director of every clinical laboratory shall report to the Department results of postmortem examination from any infant indicating the existence of a birth defect, not known to be previously reported.

(f) The information to be reported shall be provided upon forms supplied by the State Department of Health and Senior Services:

Special Child, Adult and Early Intervention Services
 PO Box 364
 Trenton, New Jersey 08625-0364

(g) The reports made pursuant to these rules are to be used only by the Department of Health and Senior Services and other agencies that may be designated by the Commissioner of Health and Senior Services and shall not otherwise be divulged or made public so as to disclose the identity of any person; and such reports shall be included under materials available to public inspection pursuant to P.L. 1963, c.73 (N.J.S.A. 47:1A-1 et seq.).

BIRTH DEFECTS REGISTRY**8:20-1.2**

(h) Cytogenetic laboratories shall report the results of all postnatal chromosomal abnormalities.

(i) When a live infant is registered, the Department shall inform the parent or legal guardian of the registration.

(j) Every health care facility and independent clinical laboratory shall allow access to, or provide necessary information on infants with birth defects and other patients specified by characteristics for research studies related to birth defects conducted by the State Department of Health and Senior Services and which have been approved by the State Commissioner of Health and Senior Services after appropriate review for assuring protection of human subjects by the Department's Institutional Review Board. This shall include patients who came under the care of the health facility prior to March 4, 1985.

(k) Any agency designated by the Commissioner to receive reports pursuant to this chapter shall provide to Special Child, Adult and Early Intervention Services any updated diagnostic and/or demographic information.

Amended by R.1987 d.361, effective September 8, 1987.
See: 19 N.J.R. 909(b), 19 N.J.R. 1642(b).

Subsection (a) added a list of congenital anomalies and other conditions which also constituted reportable birth defects.

Amended by R.1990 d.187, effective April 2, 1990.

See: 21 N.J.R. 3636(a), 22 N.J.R. 1134(c).

Reporting requirements for certain conditions specified further; reporting requirements for sickle-cell anemia and other hemoglobinopathies added; all presumptive, tentative, pending and rule out diagnoses to be reported at discharge; cytogenetic laboratories to report postnatal chromosomal abnormality test results to the Department.

Amended by R.1991 d.414, effective August 5, 1991.

See: 23 N.J.R. 820(a), 23 N.J.R. 2335(a).

In (a)1, added ii. through v.

Amended by R.1992 d.184, effective April 20, 1992.

See: 24 N.J.R. 171(a), 24 N.J.R. 1494(b).

Minor conditions added at (a)1ii.

Amended by R.2000 d.99, effective March 6, 2000.

See: 31 N.J.R. 2863(a), 32 N.J.R. 802(a).

In (a) and (f), substituted references to Special Child, Adult and Early Intervention Services for references to Special Child Health Services; rewrote (d); in (j), inserted a reference to the Department's Institutional Review Board at the end of the first sentence, and substituted a reference to March 4, 1985 for a reference to the effective date of the regulations at the end of the last sentence; and added (k).

¹ Do not register innocent or functional murmurs: register only if there is a definitive cardiac anomaly or register as a rule out condition if the cause of murmur is not identified at the time of discharge.

² Register only if there is clinical evidence of congenital absence.

³ Register cavernous hemangiomas and multiples of five or more.

⁴ Do not register if defect can be corrected passively and does not require casting or bracing.

Appendix 2.1.4
New York Legislation

Pertinent Public Health Laws and Regulations

The following laws and regulation establish the legal authority to collect information on birth defects and genetic diseases, to perform studies, and to maintain the confidentiality of the information and limits its use to research and the improvement of quality of care.

Section 206 (1) of the Public Health Law

1. The Commissioner shall:

- (d) investigate the causes of disease, epidemics, the sources of mortality, and the effects of localities, employments and other conditions, upon the public health;
- (e) obtain, collect and preserve such information relating to marriage, birth, mortality, disease and health as may be useful in the discharge of his duties or may contribute to the promotion of health or the security of life in the state,
- (j) cause to be made such scientific studies and research which have for their purpose the reduction of morbidity and mortality and the improvement of the quality of medical care through the conduction of medical audits within the state. In conducting such studies and research, the commissioner is authorized to receive reports on forms prepared by him and the furnishing of such information to the commissioner, or his authorized representatives, shall not subject any person, hospital, sanitarium, rest home, nursing home, or other person or agency furnishing such information to any action for damages or other relief. Such information when received by the commissioner, or his authorized representatives, shall be kept confidential and shall be used solely for the purposes of medical or scientific research or the improvement of the quality of medical care through the conduction of medical audits. Such information shall not be admissible as evidence in any action of any kind in any court or before any other tribunal, board, agency or person.

Section 225(5)(t) of the Public Health Law.

5. The Sanitary code may:

- (t) facilitate epidemiological research into the prevention of environmental diseases, when such research is conducted pursuant

to paragraph (j) of subdivision one of section two hundred six of this chapter, by establishing regulations designating as environmentally related diseases those pathological conditions of the body or mind resulting from contact with toxins, or teratogens in solid, liquid or gaseous form, or in the form of ionizing radiation or nonionizing electromagnetic radiation, and by requiring the reporting of such diseases or suspected cases in such diseases to the department by physicians, medical facilities and clinical laboratories. Any information provided to the department pursuant to such regulations shall be in the form required by the department and shall be kept confidential and used by the commissioner pursuant to the provisions of paragraph (j) of subdivision one of section two hundred six of this chapter, and other applicable laws relating to the confidential treatment of patient and medical data.

Section 2733 of the Public Health Law

1. Birth defects and genetic and allied diseases shall be reported by physicians, hospitals, and persons in attendance at birth in the manner on and such forms as may be prescribed by the commissioner.
2. Such reports and information shall be kept confidential and shall not be admissible as evidence in an action or proceeding in any court or before any other tribunal, board, agency or person. The commissioner may, however, publish analyses of such information from time to time for scientific and public health purposes, in such manner as to assure that the identities of the individuals concerned cannot be ascertained.

State Sanitary Code: Part 22 – Environmental Diseases (Statutory authority: Public Health Law, §§ 225 [5][f], 206 [1][j])

- 22.1 Supplementary reports of spontaneous abortions and fetal deaths for epidemiologic surveillance; filing. Every physician and hospital shall file a supplemental report with the State Commissioner of Health of each spontaneous abortion or other fetal death occurring naturally. Such report shall be filed within 10 days of the occurrence of such event on such forms as may be prescribed by the commissioner to facilitate epidemiologic investigation and surveillance.
- 22.2 Supplementary reports of low birth weights for epidemiologic surveillance; filing. Every physician, hospital, and person in attendance at live births shall file a supplementary report with the State commission of Health of each live birth for which the birth weight is 2,500 grams(5.2 pounds) less.

Such report shall be filed within 10 days of the birth and shall be on such forms as may be prescribed by the commissioner to facilitate epidemiologic investigation and surveillance.

Regulation specifically establishing the CMR

- 22.3 Supplementary reports of certain congenital anomalies for epidemiological surveillance; filing. Every physician and hospital in attendance on an individual diagnosed within two years of birth as having one or more of the congenital anomalies listed in this section shall file a supplementary report with the State Commissioner of Health within 10 days of diagnosis thereof. Such report shall be on such forms as may be prescribed by the commissioner to facilitate epidemiological investigation and surveillance.
- 22.9 Reports: place of filing. All reports required by this part shall be filed with the Director of the Bureau of Environmental Epidemiology and Occupational Health, Division of Epidemiology, New York State Department of Health, Empire State Plaza, Tower Building, Albany, NY 12237.

Appendix 2.1.5
Oklahoma Legislation

PUBLIC HEALTH AND SAFETY**63 § 1-550.2****Historical and Statutory Notes**

The repealed section, derived from Laws 1985, c 60, § 1; Laws 1986, c. 49, § 1, related to the reporting of cases of birth defects.

See, now, §§ 1-550.1, 1-550.2 of this title.

§ 1-550.1 Definitions

As used in this act:¹

1. "Birth defect" means any physical or chemical abnormality present at birth;
2. "Commissioner" means the Commissioner of Health;
3. "Department" means the Oklahoma State Department of Health;
4. "ICD-9-CM diagnostic code categories" means the International Classification of Disease which assigns numbers to each of the congenital anomalies; and
5. "Poor reproductive outcomes" includes but is not limited to stillbirths and miscarriages.

Added by Laws 1987, c. 199, § 1, eff. Nov. 1, 1987.

¹ Section 1-550.1 et seq. of this title.

Historical and Statutory Notes

Section 4 of Laws 1987, c. 199 provides for an effective date.

§ 1-550.2 Birth defects surveillance program

A. It is hereby found that the occurrence of a birth defect is a tragedy for the child, the family and the community, and a matter of vital concern to the public health. A system to obtain more information about these conditions could result in their prevention, treatment and management. Therefore, it is the intent of the Oklahoma State Legislature, in enacting this section, to:

1. Obtain information on the incidence and trends of birth defects and poor reproductive outcomes;
 2. Obtain information to determine whether environmental hazards are associated with birth defects and poor reproductive outcomes;
 3. Obtain information as to other possible causes of birth defects and poor reproductive outcomes;
- and
4. Develop prevention strategies for reducing the incidence of birth defects, and poor reproductive outcomes.

B. The Commissioner of Health may establish a system for the collection and verification of information concerning birth defects and other poor reproductive outcomes. In establishing the system, the Commissioner may require general acute care hospitals to maintain a list of patients up to six (6) years of age who have been diagnosed with birth defects incorporated within the ICD-9-CM diagnostic code categories 740 through 759.9 or such other information as the Commissioner deems appropriate, and all women discharged with a diagnosis of stillbirth or miscarriage. The list shall be made available to the Commissioner upon request and shall be used solely for purposes provided in this section.

C. The Commissioner may require general acute care hospitals, and other sources as deemed necessary, to make available to the State Department of Health the medical records of those patients who have been diagnosed with birth defects or poor reproductive outcomes as required in this section.

D. The system shall be implemented statewide.

E. The Commissioner may use the information collected pursuant to subsection B of this section and information available from other reporting systems and health providers to conduct studies to:

1. Investigate the causes of birth defects and poor reproductive outcomes;

63 § 1-550.2**PUBLIC HEALTH AND SAFETY**

2. Determine and evaluate measures to prevent their occurrences; and

3. Where possible ensure delivery of services for children identified with birth defects. The Department's investigation of poor reproductive outcomes shall include geographic, time-related or occupational associations, as well as investigations of past exposure to potentially harmful substances.

F. Where Commissioner may appoint an advisory committee of health professionals who shall advise on the implementation of this section. Advisory committee members shall serve without compensation.

G. If the Commissioner finds it is necessary to collect information from sources other than general acute care hospitals, the Commissioner shall first submit for approval to the advisory committee a proposal stating the need for such information.

H. All information collected and analyzed pursuant to this section shall be confidential insofar as the identity of the individual patient is concerned and shall be used solely for the purpose provided in this section. Access to such information shall be limited to the State Department of Health, provided that the Commissioner may provide access to those scientists approved by the advisory committee who are engaged in demographic, epidemiological or other similar studies related to health, and who agree, in writing as nonstate employees, to be identified and coded while maintaining confidentiality as described herein.

I. The Department shall maintain an accurate record of all persons who are given access to the information in the system. The record shall include:

1. The name of the persons authorizing access;
2. The name, title and organizational affiliation of persons given access;
3. The dates of access;
4. The specific purpose for which the information is to be used; and
5. The results of the independent research.

J. Nothing in this section shall prohibit the publishing of statistical complications relating to birth defects or poor reproductive outcomes which do not in any way identify individual cases or individual sources of information.

K. Any person who, in violation of a written agreement to maintain confidentiality, willfully discloses any information provided pursuant to this section shall be denied further access to any confidential information maintained by the Department. That person shall also be deemed guilty of a misdemeanor, and upon conviction thereof shall be punished by a fine of Two Hundred Dollars (\$200.00) or imprisonment in the county jail for not more than thirty (30) days, or by both such fine and imprisonment.

L. The State Board of Health is authorized to adopt, amend and repeal rules and regulations for the purpose of carrying out the provisions of this section.

Added by Laws 1987, c. 199, § 2, eff. Nov. 1, 1987. Amended by Laws 1992, c. 123, § 1, emerg. eff. April 23, 1992.

§ 1-551. Repealed by Laws 1987, c. 197, § 2, eff. Nov. 1, 1987

Historical and Statutory Notes

The repealed section, derived from Laws 1985, c. 60, § 2; Laws 1986, c. 49, § 2, related to the reporting cases of cancer.

See, now, § 1-551.1 of this title.

§ 1-551.1 Tumor registry

A. The State Commissioner of Health shall establish and maintain an up-to-date tumor registry to ensure an accurate and continuing source of data concerning such cancerous, precancerous and tumorous diseases as the State Board of Health may by rule specify. Such registry may include data necessary for epidemiological surveys and scientific research, and other data which is necessary and proper to further the recognition, prevention, control, treatment and cure of cancer, precancerous and tumorous diseases.

Appendix 2.1.6
Texas Legislation

Texas legislation

HEALTH & SAFETY CODE

CHAPTER 87. BIRTH DEFECTS

SUBCHAPTER A. GENERAL PROVISIONS

Sec. 87.001. DEFINITIONS. In this chapter:

(1) "Birth defect" means a physical or mental functional deficit or impairment in a human embryo, fetus, or newborn resulting from one or more genetic or environmental causes.

(2) "Communicable disease" has the meaning assigned by Section 81.003.

(3) Repealed by Acts 1995, 74th Leg., ch. 76, Sec. 8.134, eff. Sept. 1, 1995.

(4) "Environmental causes" means the sum total of all the conditions and elements that make up the surroundings and influence the development of an individual.

(5) "Harmful physical agent" has the meaning assigned by Section 503.001.

(6) "Health professional" means an individual whose:

(A) vocation or profession is directly or indirectly related to the maintenance of health in another individual; and

(B) duties require a specified amount of formal education and may require a special examination, certificate, or license or membership in a regional or national association.

(7) "Health facility" includes:

(A) a general or special hospital licensed by the department under Chapter 241;

(B) a physician-owned or physician-operated clinic;

(C) a publicly or privately funded medical school;

(D) a state hospital or state school maintained and managed by the Texas Department of Mental Health and Mental Retardation;

(E) a genetic evaluation and counseling center;

(F) a public health clinic conducted by a local health unit, health department, or public health district organized and recognized under Chapter 121;

(G) a physician peer review organization; and

(H) another facility specified by board rule.

(8) "Midwife" has the meaning assigned by Section 203.002, Occupations Code.

(9) "Local health unit" has the meaning assigned by Section 121.004.

(10) "Toxic substance" has the meaning assigned by Section 503.001.

Added by Acts 1993, 73rd Leg., ch. 602, Sec. 1, eff. Sept. 1, 1993.

Amended by Acts 1995, 74th Leg., ch. 76, Sec. 8.134, eff. Sept. 1, 1995; Acts 2001, 77th Leg., ch. 1420, Sec. 14.774, eff. Sept. 1, 2001.

Sec. 87.002. CONFIDENTIALITY. (a) Except as specifically authorized by this chapter, reports, records, and information furnished to a department employee or to an authorized agent of the department that relate to cases or suspected cases of a health condition are confidential and may be used only for the purposes of this chapter.

(b) Reports, records, and information relating to cases or suspected cases of health conditions are not public information under Chapter 552, Government Code, and may not be released or made public on subpoena or otherwise except as provided by this chapter.

(c) The department may release medical, epidemiological, or toxicological information:

(1) for statistical purposes, if released in a manner that prevents the identification of any person;

(2) with the consent of each person identified in the information or, if the person is a minor, the minor's parents, managing conservator, guardian, or other person who is legally authorized to consent;

(3) to medical personnel, appropriate state agencies, health authorities, regional directors, and public officers of counties and municipalities as necessary to comply with this chapter and board rules relating to the identification, monitoring, and referral of children with birth defects;

(4) to appropriate federal agencies, such as the Centers for Disease Control of the United States Public Health

Service; or

(5) to medical personnel to the extent necessary to protect the health or life of the child identified in the information.

(d) A board member, the commissioner, another employee of the department, or an authorized agent may not be examined in a civil, criminal, special, or other proceeding as to the existence or contents of pertinent records of or reports or information about a child identified or monitored for a birth defect by the department without the consent of the child's parents, managing conservator, guardian, or other person authorized by law of this state or another state or by a court order to give consent.

Added by Acts 1993, 73rd Leg., ch. 602, Sec. 1, eff. Sept. 1, 1993.

Amended by Acts 1995, 74th Leg., ch. 76, Sec. 5.95(88), 8.130, eff. Sept. 1, 1995.

Sec. 87.003. CONTRACTS. The department may enter into contracts or agreements with persons as necessary to implement this chapter. The contracts or agreements may provide for payment by the state for supplies, equipment, data, and data collection and other services.

Added by Acts 1993, 73rd Leg., ch. 602, Sec. 1, eff. Sept. 1, 1993.

Sec. 87.004. LIMITATION OF LIABILITY. A health professional, a health facility, or an administrator, officer, or employee of a health facility subject to this chapter is not civilly or criminally liable for divulging information required to be released under this chapter, except in a case of gross negligence or wilful misconduct.

Added by Acts 1993, 73rd Leg., ch. 602, Sec. 1, eff. Sept. 1, 1993.

Sec. 87.005. COOPERATION OF GOVERNMENTAL ENTITIES. Another state board, commission, agency, or governmental entity capable of assisting the department in carrying out the intent of this chapter shall cooperate with the department and furnish expertise, services, and facilities to the program.

Added by Acts 1993, 73rd Leg., ch. 602, Sec. 1, eff. Sept. 1, 1993.

SUBCHAPTER B. BIRTH DEFECTS MONITORING PROGRAM

Sec. 87.021. SURVEILLANCE PROGRAM; REGISTRY ESTABLISHED. (a) The board shall establish in the department a

program to:

- (1) identify and investigate certain birth defects in children; and
- (2) maintain a central registry of cases of birth defects.

(b) The board may authorize the department to implement a statewide program or to limit the program to a part or all of one or more public health regions, depending on the funding available to the department. In establishing the program, the board shall consider:

- (1) the number and geographic distribution of births in the state;
- (2) the trained personnel and other departmental resources that may be assigned to the program activities; and
- (3) the occurrence or probable occurrence of an urgent situation that requires or will require an unusual commitment of the department's personnel and other resources.

(c) The board and the department shall design the program so that the program will:

- (1) provide information to identify risk factors and causes of birth defects;
- (2) provide information on other possible causes of birth defects;
- (3) provide for the development of strategies to prevent birth defects;
- (4) provide for interview studies about the causes of birth defects;
- (5) together with other departmental programs, contribute birth defects data to a central registry;
- (6) provide for the appointment of authorized agents to collect birth defects information; and
- (7) provide for the active collection of birth defects information.

(d) The board shall adopt rules to govern the operation of the program and carry out the intent of this chapter. At a minimum, the rules shall:

- (1) use a medically recognized system to specify the

birth defects to be identified and investigated;

(2) select a system for classifying the birth defects according to the public health significance of each defect to prioritize the use of resources;

(3) develop a system to select and specify the cases to be investigated;

(4) specify a system for selecting the demographic areas in which the department may undertake investigations; and

(5) prescribe the training and experience a person must have for appointment as an authorized agent of the department.

(e) In adopting the rules required by Subsection (d), the board shall consider at least:

(1) the known incidence and prevalence rates of a birth defect in the state or portions of the state;

(2) the known incidence and prevalence rates of a particular birth defect in specific population groups who live in the state or portions of the state;

(3) the morbidity and mortality resulting from the birth defect; and

(4) the existence, cost, and availability of a strategy to prevent and treat the birth defect.

(f) In addition to providing for the active collection of birth defects information under Subsection (c)(7), the board and the department may design the program to also provide for the passive collection of that information.

Added by Acts 1993, 73rd Leg., ch. 602, Sec. 1, eff. Sept. 1, 1993.

Amended by Acts 2003, 78th Leg., ch. 1042, Sec. 1, eff. June 20, 2003.

Sec. 87.022. DATA COLLECTION. (a) To ensure an accurate source of data necessary to investigate the incidence, prevalence, and trends of birth defects, the board may require a health facility, health professional, or midwife to make available for review by the department or by an authorized agent medical records or other information that is in the facility's, professional's, or midwife's custody or control and that relates to the occurrence of a birth defect specified by the board.

(b) The board by rule shall prescribe the manner in which

records and other information are made available to the department.

(c) The board shall adopt procedural rules to facilitate cooperation between the health care facility, health professional, or midwife and a department employee or authorized agent, including rules for notice, requests for medical records, times for record reviews, and record management during review.

Added by Acts 1993, 73rd Leg., ch. 602, Sec. 1, eff. Sept. 1, 1993.

Sec. 87.023. REFERRAL FOR SERVICES. A child who meets the medical criteria prescribed by board rule, and the child's family, shall be referred to the department's case management program for guidance in applying for financial or medical assistance available through existing state and federal programs.

Added by Acts 1993, 73rd Leg., ch. 602, Sec. 1, eff. Sept. 1, 1993.

SUBCHAPTER C. INVESTIGATIONS AND INSPECTIONS

Sec. 87.041. INVESTIGATIONS. (a) The department may conduct investigations, including epidemiological or toxicological investigations, of cases of specified birth defects.

(b) The department may conduct these investigations to determine the nature and extent of the disease or the known or suspected cause of the birth defect and to formulate and evaluate control measures to protect the public health. The department's investigation is not limited to geographic, temporal, or occupational associations and may include investigation of past exposures.

(c) A person shall provide medical, demographic, epidemiological, toxicological, and environmental information to the department under this chapter.

(d) A person is not liable in damages or other relief for providing medical or other confidential information to the department during an epidemiological or toxicological investigation.

Added by Acts 1993, 73rd Leg., ch. 602, Sec. 1, eff. Sept. 1, 1993.

Sec. 87.042. DEPARTMENTAL INVESTIGATORY POWERS. To conduct an investigation under this chapter, the commissioner or the commissioner's designee has the same authority to enter, inspect, investigate, and take samples and to do so in the same manner as is provided for communicable diseases under Sections

81.061, 81.063, 81.064, and 81.065.

Added by Acts 1993, 73rd Leg., ch. 602, Sec. 1, eff. Sept. 1, 1993.

Amended by Acts 1995, 74th Leg., ch. 76, Sec. 8.132, eff. Sept. 1, 1995.

SUBCHAPTER D. CENTRAL REGISTRY

Sec. 87.061. REGISTRY; CONFIDENTIALITY. (a) Information collected and analyzed by the department or an authorized agent under this chapter may be placed in a central registry to facilitate research and to maintain security. The department may also store information available from other departmental programs and information from other reporting systems and health care providers.

(b) The department shall use the registry to:

(1) investigate the causes of birth defects and other health conditions as authorized by Texas statutes;

(2) design and evaluate measures to prevent the occurrence of birth defects and other health conditions; and

(3) conduct other investigations and activities necessary for the board and department to fulfill their obligation to protect the health of the public.

(c) The department may store in the central registry information that is obtained from the section of the birth certificate entitled "For Medical and Health Use Only." This information may be used only as provided by Section 191.002(b), relating to the form and contents of the birth certificate.

Added by Acts 1993, 73rd Leg., ch. 602, Sec. 1, eff. Sept. 1, 1993.

Sec. 87.062. ACCESS TO INFORMATION. (a) Access to the central registry information is limited to authorized department employees and other persons with a valid scientific interest who are engaged in demographic, epidemiological, or other studies related to health and who agree in writing to maintain confidentiality.

(b) The department shall maintain a listing of each person who is given access to the information in the central registry. The listing shall include:

(1) the name of the person authorizing access;

(2) the name, title, and organizational affiliation of each person given access;

- (3) the dates of access; and
- (4) the specific purpose for which the information was used.

(c) The listing is public information, is open to the public under Chapter 552, Government Code, and may be inspected during the department's normal hours of operation.

Added by Acts 1993, 73rd Leg., ch. 602, Sec. 1, eff. Sept. 1, 1993.

Amended by Acts 1995, 74th Leg., ch. 76, Sec. 5.95(88), eff. Sept. 1, 1995.

Sec. 87.063. RESEARCH; REVIEW AND APPROVAL. (a) The commissioner and the department's committee for the protection of human subjects shall review each research proposal that requests the use of information in the central registry. The board shall adopt rules establishing criteria to be used in deciding if the research design should be approved. A proposal that meets the approval criteria is considered to establish a valid interest as required by Section 87.062(a), and the commissioner and the committee shall authorize the researcher to review the records relevant to the research proposal and to contact cases and controls.

(b) If an investigator using central registry data under a research design approved under this section believes it is necessary to contact case subjects and controls, the investigator must submit a protocol describing the purpose and method to the commissioner and the department's committee for the protection of human subjects. If the contact protocol is approved, the investigator is considered to have established a bona fide research, development, or planning purpose and is entitled to carry out the contacts without securing additional approvals or waivers from any entity.

Added by Acts 1993, 73rd Leg., ch. 602, Sec. 1, eff. Sept. 1, 1993.

Amended by Acts 1995, 74th Leg., ch. 76, Sec. 8.133, eff. Sept. 1, 1995.

Sec. 87.064. REPORT OF CENTRAL REGISTRY ACTIVITIES AND FINDINGS. (a) The department shall publish an annual report of activities using data contained in the central registry. The report shall include:

(1) a description of research projects in progress since the last report and the sponsors and principal investigators directing each project;

(2) results of the completed research projects either as an abstract or a complete scientific paper that has been reviewed and approved by an appropriate jury;

(3) a summary of the statistical information compiled in the registry, including a specific discussion of any clusters, high or low incidences, or prevalences or trends encountered;

(4) any policy, research, educational, or other recommendations the department considers appropriate; and

(5) such other information the editors of the report find is appropriate.

(b) The department may publish periodic reports in addition to the annual report.

Added by Acts 1993, 73rd Leg., ch. 602, Sec. 1, eff. Sept. 1, 1993.

Sec. 87.065. COORDINATION WITH MEXICO. In developing the central registry and conducting research in areas of this state that border Mexico, the department shall make every effort to coordinate its efforts with similar efforts and research programs in Mexico.

Added by Acts 1993, 73rd Leg., ch. 602, Sec. 1, eff. Sept. 1, 1993.