

CHAPTER 602

S.B. No. 89

AN ACT

relating to establishing a birth defects registry.

Be it enacted by the Legislature of the State of Texas:

SECTION 1. Subtitle D, Title 2, Health and Safety Code, is amended by adding Chapter 87 to read as follows:

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) "Director" means the executive head of the department.

(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 1, Texas Midwifery Act (Article 4512i, Vernon's Texas Civil Statutes).

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

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

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 the open records law, Chapter 424, Acts of the 63rd Legislature, Regular Session, 1973 (Article 6252-17a, Vernon's Texas Civil Statutes), 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 director, 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.

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.

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.

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.

Sec. 87.006. **SCIENTIFIC ADVISORY COMMITTEE.** (a) The director shall establish a scientific advisory committee to provide practical and scientific advice to the department in implementing an effective birth defects registry and related research, referral, and educational activities.

(b) The committee may be composed of not more than 11 members and must include scientific experts in the fields of birth defects, genetics, epidemiology, and medicine. At least one member must be from the general public.

(c) If the department implements a pilot birth defects registry in selected regions of the state, membership of the scientific advisory committee must include persons who work or live in the areas where the pilot birth defects registry activity is implemented.

(d) The scientific advisory committee shall:

(1) review and advise the department on all proposed projects and programs prior to and during implementation;

(2) monitor the birth defects registry and related programs; and

(3) make recommendations to the department or the legislature, as appropriate.

[Sections 87.007 to 87.020 reserved for expansion]

SUBCHAPTER B. BIRTH DEFECTS MONITORING PROGRAM

Sec. 87.021. **SURVEILLANCE PROGRAM; REGISTRY ESTABLISHED.** (a) The board may 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, not passive, 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.

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.

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.

[Sections 87.024 to 87.040 reserved for expansion]

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.

Sec. 87.042. DEPARTMENTAL INVESTIGATORY POWERS. To conduct an investigation under this chapter, the director or the director'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.

[Sections 87.043 to 87.060 reserved for expansion]

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.

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 the open records law, Chapter 424, Acts of the 63rd Legislature, Regular Session, 1973 (Article 6252-17a, Vernon's

Texas Civil Statutes), and may be inspected during the department's normal hours of operation.

Sec. 87.063. RESEARCH; REVIEW AND APPROVAL. (a) The director 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 director 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 director 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.

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.

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.

SECTION 2. (a) This Act takes effect September 1, 1993.

(b) The Texas Board of Health shall adopt rules as required by Chapter 87, Health and Safety Code, as added by this Act, not later than October 15, 1993.

(c) The Texas Department of Health shall begin to collect information as required by Chapter 87, Health and Safety Code, as added by this Act, not later than January 1, 1994.

SECTION 3. The importance of this legislation and the crowded condition of the calendars in both houses create an emergency and an imperative public necessity that the constitutional rule requiring bills to be read on three several days in each house be suspended, and this rule is hereby suspended.

Passed the Senate on March 11, 1993, by a viva-voce vote; May 22, 1993, Senate refused to concur in House amendments and requested appointment of Conference Committee; May 24, 1993, House granted request of the Senate; May 28, 1993, Senate adopted Conference Committee Report by a viva-voce vote; passed the House, with amendments, on May 21, 1993, by a non-record vote; May 24, 1993, House granted request of the Senate for appointment of Conference Committee; May 28, 1993, House adopted Conference Committee Report by a non-record vote.

Approved June 15, 1993.

Effective Sept. 1, 1993.