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CHAPTER 44.

 BIRTH DEFECTS

**SECTION 44‑44‑10.** Title of act.

This act may be cited as the “South Carolina Birth Defects Act”.

**SECTION 44‑44‑20.** Definitions.

For purposes of this chapter:

(1) “Birth defect” is defined as structural malformation, deformation, or disruption, present at birth, as determined before or after birth.

(2) “Department” means the South Carolina Department of Health and Environmental Control.

**SECTION 44‑44‑30.** South Carolina Birth Defects Program established; public health monitoring and referral.

(A) There is established the South Carolina Birth Defects Program within the Department of Health and Environmental Control to promote increased understanding of birth defects, prevent and reduce birth defects, and assist families with children who have birth defects.

(B) As part of this program, the department shall conduct public health monitoring, make appropriate referrals and provide other interventions related to birth defects. Information obtained pursuant to this subsection must be used for:

(1) public health and epidemiology purposes in which incidence, distribution, causes, risk factors, and trends may be studied. This data may be published and made accessible for education and research purposes. This information must be released in aggregate form only without identifying information;

(2) referral for service and treatment purposes so that referrals of the individual child and family may be facilitated for optimal care. The department or its employees must not provide referral services or counseling for the purpose of pregnancy termination by induced abortion, nor use any funds under this program for services or counseling for the purpose of pregnancy termination by induced abortion. Referral information is confidential and must be maintained in accordance with Section 44‑44‑140.

**SECTION 44‑44‑40.** Birth Defects Advisory Council established; membership; subject areas for recommendations; compensation.

(A) There is established the Birth Defects Advisory Council composed of at least thirteen members to be appointed by the commissioner of the department, with an odd total number of members. The members shall include at least one representative from each of the following organizations, upon the recommendation of the director of the respective organization:

(1) American Academy of Pediatrics, South Carolina Chapter, a board‑ certified physician in neonatal‑perinatal medicine;

(2) American College of Obstetrics and Gynecology, South Carolina Chapter, a board‑certified physician in maternal fetal medicine;

(3) Greenwood Genetic Center;

(4) University of South Carolina School of Medicine, a board‑certified genetics professional who must be a physician or genetics counselor;

(5) Medical University of South Carolina, a board‑certified physician in pediatric cardiology or a board‑certified genetics professional;

(6) March of Dimes, South Carolina Chapter;

(7) South Carolina Perinatal Association;

(8) South Carolina Department of Disabilities and Special Needs;

(9) South Carolina Department of Health and Human Services;

(10) Parent of a child with a birth defect, recommended by a South Carolina family advocacy or disability organization;

(11) An adult who was born with a birth defect, recommended by a South Carolina family advocacy or disability organization;

(12) South Carolina Hospital;

(13) South Carolina Medical Association, a licensed physician specializing in genetics.

(B) The Birth Defects Advisory Council shall meet periodically, but at least annually, with staff from the department. The commissioner of the department or his designee must be a nonvoting ex officio advisory council member.

(C) The advisory council may make recommendations to the department concerning the following:

(1) the establishment of procedures for the birth defects program;

(2) the transition from the existing South Carolina Neural Tube Defects Prevention Program into an integrated system of comprehensive birth defects monitoring based at the department;

(3) the allocation of funding, cooperative agreements, and grants; and

(4) evaluation of the birth defects program.

(D) The members of the council shall serve in a voluntary capacity and are not entitled to compensation, mileage, per diem, or subsistence.

**SECTION 44‑44‑50.** Monitoring birth defects.

The department shall conduct active monitoring of birth defects, with selection procedures, and internal policy to be established in conjunction with recommendations from the advisory council.

**SECTION 44‑44‑60.** Utilization of data.

The Birth Defects Program shall concentrate on public health surveillance and monitoring birth defects. Data may be made available to persons or institutions outside the program for education, research, provision of services, and other purposes in accordance with program procedures.

**SECTION 44‑44‑70.** Maintenance of central database; case ascertainment.

The department shall maintain a central database for the gathering of data from hospitalizations, specialty clinics, births, pregnancies, stillbirths, and pediatric deaths through age two, throughout the State, including border regions. The department shall establish procedures for active birth defect case ascertainment. The data system must be maintained to be accurate, timely, and dynamic, and the department shall institute procedures to make this system effective. The department may expand the age range for data collection as resources become available and if the department determines the additional data collection would benefit the program.

**SECTION 44‑44‑80.** Access to health and medical records; confidentiality.

All hospitals, health providers, birth centers, clinics, medical records departments, third party payors, laboratories, universities, and other sources of birth defects information shall provide access to all health or medical records for the purpose of surveillance and identification of birth defects in accordance with procedures promulgated by the department in regulation. This access is protected by state and federal law concerning birth defects monitoring, and confidentiality must be maintained by the department in accordance with Section 44‑44‑140. Individually identifiable data may not be made available to the public.

**SECTION 44‑44‑90.** Reports.

The department shall report annually, beginning within two years of this program becoming operational, to the General Assembly and the Governor and shall make copies of the report available to the public. The report may include data about birth defects in South Carolina including, but not limited to, analysis of incidence and trends and mortality and outcomes. The report must contain only aggregate data and may not identify any individual.

**SECTION 44‑44‑100.** Use and disclosure of birth defects data.

Birth defects data may be used and disclosed for the purposes of scientific research concerning causation, prevention strategies, epidemiological analysis, environmental and geographic study, and other purposes authorized by the department.

**SECTION 44‑44‑110.** Providing data to National Center for Birth Defects and Developmental Disabilities at the Centers for Disease Control and Prevention.

Data may be provided to the National Center for Birth Defects and Developmental Disabilities at the Centers for Disease Control and Prevention to enhance scientific, epidemiological, and investigative efforts and studies.

**SECTION 44‑44‑120.** Agreements with other agencies.

The department may negotiate and enter into cooperative agreements and contracts with federal agencies, other states, universities, genetics centers, and other parties, as appropriate, in order to facilitate operation of the program.

**SECTION 44‑44‑130.** Use of data to make treatment available to affected children and families.

Birth defects data must also be used to ensure that optimal treatment and services are available to any affected child and family. A family whose child is identified with a structural birth defect may be contacted by the department through the child’s health care provider, or directly when necessary, in order to offer services. Family acceptance of referrals is voluntary. Referral procedures must be promulgated by the department in regulation.

**SECTION 44‑44‑140.** Confidentiality; immunity of entities providing information; access records; penalty; parental access.

(A) All birth defects information collected by the department in the birth defects program is confidential and must be used solely for the purposes provided in this chapter.

(B) The department shall maintain confidentiality in regard to:

(1) data ascertainment;

(2) data and record retention;

(3) epidemiological study and reporting;

(4) research uses;

(5) referral for services for children and families;

(6) identifying data obtained from health and medical records; and

(7) data obtained from any source for any other use.

(C) An entity required to provide information to the department pursuant to Section 44‑44‑80 is not subject to liability for providing access and information or use and disclosure of protected health information. This access and reporting may not be considered a waiver, breach, or violation of a confidential relationship.

(D) Any use and disclosure of birth defects information must be governed by applicable confidentiality procedures of the department, using written confidentiality agreements and applicable laws. Information that is disclosed must be used only for purposes approved by the department.

(E) The program shall keep an accurate record of all persons allowed access to birth defects information for research or other authorized purposes. Records are not required to be kept on information shared with providers or families pursuant to the referral for services procedures in Section 44‑44‑130 and on data provided pursuant to Section 44‑44‑110 or Section 44‑44‑120. Records of access must be retained for six years and open to public inspection. Persons allowed access to data must be required to sign and maintain confidentiality agreements.

(F) A person who violates any of the confidentiality provisions of this chapter or an agreement entered into pursuant to this chapter is guilty of a misdemeanor and, upon conviction, must be fined not more than one thousand dollars or imprisoned not more than one hundred eighty days.

(G) Nothing in this section prohibits publication of reports and statistical compilations without identifying information.

(H) A child’s parent or legal guardian who wants to review information concerning their child from the birth defects information system may request access to their child’s information from the department. The department shall disclose and discuss the database information and the nature of all uses of this information with the parent. A parent may request in writing, on a form provided by the department, removal of this information from the system and the child’s data must be deleted. To the extent that an individual child’s information may have been included in aggregate releases, that information must not be deleted.

**SECTION 44‑44‑150.** Promulgation of regulations.

The department shall promulgate regulations necessary to carry out the provisions of this chapter.

**SECTION 44‑44‑160.** Funding contingency.

Implementation of this chapter is contingent upon the appropriation of state general funds or the availability of financial support from other sources and must be operational within one year of adequate funding becoming available.