

HEALTH AND SAFETY CODE CHAPTER 33. PHENYLKETONURIA, OTHER HERITABLE DISEASES, HYPOTHYROIDISM, AND CERTAIN OTHER DISORDERS

HEALTH AND SAFETY CODE

TITLE 2. HEALTH

SUBTITLE B. TEXAS DEPARTMENT OF HEALTH PROGRAMS

CHAPTER 33. PHENYLKETONURIA, OTHER HERITABLE DISEASES, HYPOTHYROIDISM, AND CERTAIN OTHER DISORDERS

SUBCHAPTER A. GENERAL PROVISIONS

Sec. 33.001. DEFINITIONS. In this chapter:

(1) "Heritable disease" means an inherited disease that may result in mental or physical retardation or death.

(2) "Hypothyroidism" means a condition that may cause severe mental retardation if not treated.

(3) "Other benefit" means a benefit, other than a benefit under this chapter, to which an individual is entitled for the payment of the costs of services. The term includes:

(A) benefits available under:

(i) an insurance policy, group health plan, or prepaid medical care plan;

(ii) Title XVIII of the Social Security Act (42 U.S.C. Section 1395);

(iii) Title XIX of the Social Security Act (42 U.S.C. Section 1396);

(iv) the Veterans' Administration;

(v) the Civilian Health and Medical Program of the Uniformed Services; or

(vi) workers' compensation or any other compulsory employers insurance program;

(B) a public program created by federal or state law or by ordinance or rule of a municipality or political subdivision of the state, except those benefits created by the establishment of a municipal or county hospital, a joint municipal-county hospital, a county hospital authority, a hospital district, or by the facilities of a publicly supported medical school; and

(C) benefits resulting from a cause of action for

health care expenses, or a settlement or judgment based on the cause of action, if the expenses are related to the need for services provided under this chapter.

(4) "Phenylketonuria" means an inherited condition that may cause severe mental retardation if not treated.

(5) "Screening test" means a rapid analytical procedure to determine the need for further diagnostic evaluation. Amended by Acts 1991, 72nd Leg., ch. 14, Sec. 8, eff. Sept. 1, 1991.

Sec. 33.002. DETECTION AND TREATMENT PROGRAM ESTABLISHED.

(a) The department shall carry out a program to combat morbidity, including mental retardation, and mortality in persons who have phenylketonuria, other heritable diseases, or hypothyroidism.

(b) The board shall adopt rules necessary to carry out the program, including a rule specifying other heritable diseases covered by this chapter.

(c) The department shall establish and maintain a laboratory to:

(1) conduct experiments, projects, and other activities necessary to develop screening or diagnostic tests for the early detection of phenylketonuria, other heritable diseases, and hypothyroidism;

(2) develop ways and means or discover methods to be used to prevent or treat phenylketonuria, other heritable diseases, and hypothyroidism; and

(3) serve other purposes considered necessary by the department to carry out the program.

Amended by Acts 1991, 72nd Leg., ch. 14, Sec. 8, eff. Sept. 1, 1991.

Sec. 33.003. COOPERATION OF HEALTH CARE PROVIDERS AND

GOVERNMENTAL ENTITIES. (a) The department may invite all physicians, hospitals, and other health care providers in the state that provide maternity and newborn infant care to cooperate and participate in any program established by the department under this chapter.

(b) Other boards, agencies, departments, and political subdivisions of the state capable of assisting the department in

carrying out the program may cooperate with the department and are encouraged to furnish their services and facilities to the program. Amended by Acts 1991, 72nd Leg., ch. 14, Sec. 8, eff. Sept. 1, 1991.

Sec. 33.004. STUDY ON NEWBORN SCREENING METHODOLOGY AND EQUIPMENT. (a) Not later than March 1, 2006, the department shall:

(1) conduct a study to determine the most cost-effective method of conducting newborn screening, including screening for disorders listed in the core uniform panel of newborn screening conditions recommended in the 2005 report by the American College of Medical Genetics entitled "Newborn Screening: Toward a Uniform Screening Panel and System" or another report determined by the department to provide more appropriate newborn screening guidelines, to protect the health and welfare of this state's newborns and to maximize the number of newborn screenings that may be conducted with the funding available for the screening;

(2) determine the disorders to be studied under Subdivision (1) and ensure the study does not examine screening and services provided under Chapter 47; and

(3) obtain proposals or information regarding the conduct of newborn screening and compare the costs of the department performing newborn screening services to the costs of outsourcing screening to a qualified laboratory with at least two years' experience performing newborn screening tests.

(b) In accordance with rules adopted by the executive commissioner of the Health and Human Services Commission, the department may implement a newborn screening program.

(c) If the department determines under Subsection (a) that the department's performance of newborn screening services is more cost-effective than outsourcing newborn screening, the department shall obtain the use of screening methodologies, including tandem mass spectrometers, and hire the employees necessary to administer newborn screening under this chapter.

(d) If the department determines under Subsection (a) that outsourcing of newborn screening is more cost-effective, the department shall contract for the resources and services necessary

to conduct newborn screening using a competitive procurement process.

(e) The department shall periodically review the newborn screening program as revised under this section to determine the efficacy and cost-effectiveness of the program and determine whether adjustments to the program are necessary to protect the health and welfare of this state's newborns and to maximize the number of newborn screenings that may be conducted with the funding available for the screening.

(f) The department may adjust the amounts charged for newborn screening fees, including fees assessed for follow-up services, tracking confirmatory testing, and diagnosis.

Added by Acts 2005, 79th Leg., Ch. 940, Sec. 2, eff. September 1, 2005.

SUBCHAPTER B. NEWBORN SCREENING

Sec. 33.011. TEST REQUIREMENT. (a) The physician attending a newborn child or the person attending the delivery of a newborn child that is not attended by a physician shall subject the child to screening tests approved by the department for phenylketonuria, other heritable diseases, hypothyroidism, and other disorders for which screening is required by the department.

(a-1) To the extent funding is available for the screening, the department shall require newborn screening tests to screen for disorders listed in the core uniform panel of newborn screening conditions recommended in the 2005 report by the American College of Medical Genetics entitled "Newborn Screening: Toward a Uniform Screening Panel and System" or another report determined by the department to provide more appropriate newborn screening guidelines to protect the health and welfare of this state's newborns.

(b) The department may prescribe the screening test procedures to be used and the standards of accuracy and precision required for each test.

(c) The screening tests required by this section must be performed by the laboratory established by the department or by a laboratory approved by the department under Section 33.016.

Amended by Acts 1991, 72nd Leg., ch. 14, Sec. 8, eff. Sept. 1, 1991.

Amended by:

Acts 2005, 79th Leg., Ch. 940, Sec. 3, eff. September 1, 2005.

Sec. 33.012. EXEMPTION. (a) Screening tests may not be administered to a newborn child whose parents, managing conservator, or guardian objects on the ground that the tests conflict with the religious tenets or practices of an organized church of which they are adherents.

(b) If a parent, managing conservator, or guardian objects to the screening tests, the physician or the person attending the newborn child that is not attended by a physician shall ensure that the objection of the parent, managing conservator, or guardian is entered into the medical record of the child. The parent, managing conservator, or guardian shall sign the entry.

Amended by Acts 1991, 72nd Leg., ch. 14, Sec. 8, eff. Sept. 1, 1991.

Sec. 33.013. LIMITATION ON LIABILITY. A physician, technician, or other person administering the screening tests required by this chapter is not liable or responsible because of the failure or refusal of a parent, managing conservator, or guardian to consent to the tests for which this chapter provides.

Amended by Acts 1991, 72nd Leg., ch. 14, Sec. 8, eff. Sept. 1, 1991.

Sec. 33.014. DIAGNOSIS; FOLLOW-UP. (a) If, because of an analysis of a specimen submitted under Section 33.011, the department reasonably suspects that a newborn child may have phenylketonuria, another heritable disease, hypothyroidism, or another disorder for which the screening tests are required, the department shall notify the person who submits the specimen that the results are abnormal and provide the test results to that person. The department may notify one or more of the following that the results of the analysis are abnormal and recommend further testing when necessary:

(1) the physician attending the newborn child or the physician's designee;

(2) the person attending the delivery of the newborn

child that was not attended by a physician;

(3) the parents of the newborn child;

(4) the health authority of the jurisdiction in which the newborn child was born or in which the child resides, if known; or

(5) physicians who are cooperating pediatric specialists for the program.

(b) If a screening test indicates that a newborn child is at high risk, the department shall recommend that the child be placed under the medical care of a licensed physician for diagnosis and provide the name of a consultant pediatric specialist in the child's geographic area.

(c) The department, the health authority, and the consulting pediatric specialist may follow up a positive test with the attending physician or with a parent of the newborn child if the child was not attended by a physician at birth.

Amended by Acts 1991, 72nd Leg., ch. 14, Sec. 8, eff. Sept. 1, 1991.

Amended by:

Acts 2005, 79th Leg., Ch. 940, Sec. 4, eff. September 1, 2005.

Sec. 33.015. REPORTS; RECORD KEEPING. (a) Each physician, health authority, or other individual who has the information of a confirmed case of a disorder for which a screening test is required that has been detected by a mechanism other than identification through a screening of a specimen by the department's diagnostic laboratory shall report the confirmed case to the department.

(b) The department may collect data to derive incidence and prevalence rates of disorders covered by this chapter from the information on the specimen form submitted to the department for screening determinations.

(c) The department shall maintain a roster of children born in this state who have been diagnosed as having one of the disorders for which the screening tests are required.

(d) The department may cooperate with other states in the development of a national roster of individuals who have been diagnosed as having one of the disorders for which the screening

tests are required if:

(1) participation in the national roster encourages systematic follow-up in the participating states;

(2) incidence and prevalence information is made available to participating newborn screening programs in other states; and

(3) each participating newborn screening program subscribes to an agreement to protect the identity and diagnosis of the individuals whose names are included in the national roster.

Amended by Acts 1991, 72nd Leg., ch. 14, Sec. 8, eff. Sept. 1, 1991.

Sec. 33.016. APPROVAL OF LABORATORIES. (a) The department may develop a program to approve any laboratory that wishes to perform the tests required to be administered under this chapter. To the extent that they are not otherwise provided in this chapter, the board may adopt rules prescribing procedures and standards for the conduct of the program.

(b) The department may prescribe the form and reasonable requirements for the application and the procedures for processing the application.

(c) The department may prescribe the test procedure to be employed and the standards of accuracy and precision required for each test.

(d) The department may extend or renew any approval in accordance with reasonable procedures prescribed by the board.

(e) The department may for good cause, after notice to the affected laboratory and a hearing if requested, restrict, suspend, or revoke any approval granted under this section.

(f) Hearings under this section shall be conducted in accordance with the hearing rules adopted by the board and the applicable provisions of Chapter 2001, Government Code.

Amended by Acts 1991, 72nd Leg., ch. 14, Sec. 8, eff. Sept. 1, 1991; Acts 1995, 74th Leg., ch. 76, Sec. 5.95(49), eff. Sept. 1, 1995.

SUBCHAPTER C. NEWBORN SCREENING PROGRAM SERVICES

Sec. 33.031. COORDINATION WITH CHILDREN WITH SPECIAL HEALTH CARE NEEDS SERVICES. (a) All newborn children and other

individuals under 21 years of age who have been screened, have been found to be presumptively positive through the newborn screening program for phenylketonuria, other heritable diseases, hypothyroidism, or another disorder for which the screening tests are required, and may be financially eligible may be referred to the department's services program for children with special health care needs.

(b) An individual who is determined to be eligible for services under the services program for children with special health care needs shall be given approved services through that program. An individual who does not meet that eligibility criteria shall be referred to the newborn screening program for a determination of eligibility for newborn screening program services.

Amended by Acts 1991, 72nd Leg., ch. 14, Sec. 8, eff. Sept. 1, 1991; Acts 1999, 76th Leg., ch. 1505, Sec. 3.11, eff. Sept. 1, 1999.

Amended by:

Acts 2005, 79th Leg., Ch. 940, Sec. 5, eff. September 1, 2005.

Sec. 33.032. PROGRAM SERVICES. (a) Within the limits of funds available for this purpose and in cooperation with the individual's physician, the department may provide services directly or through approved providers to individuals of any age who meet the eligibility criteria specified by board rules on the confirmation of a positive test for phenylketonuria, other heritable diseases, hypothyroidism, or another disorder for which the screening tests are required.

(b) The board may adopt:

(1) rules specifying the type, amount, and duration of program services to be offered;

(2) rules establishing the criteria for eligibility for services, including the medical and financial criteria;

(3) rules establishing the procedures necessary to determine the medical, financial, and other eligibility of the individual;

(4) substantive and procedural rules for applying for program services and processing those applications;

(5) rules for providing services according to a sliding scale of financial eligibility;

(6) substantive and procedural rules for the denial, modification, suspension, and revocation of an individual's approval to receive services; and

(7) substantive and procedural rules for the approval of providers to furnish program services.

(c) The department may select providers according to the criteria in the board's rules.

(d) The board may charge fees for the provision of services, except that services may not be denied to an individual because of the individual's inability to pay the fees.

Amended by Acts 1991, 72nd Leg., ch. 14, Sec. 8, eff. Sept. 1, 1991.

Amended by:

Acts 2005, 79th Leg., Ch. 940, Sec. 6, eff. September 1, 2005.

Sec. 33.033. CONSENT. The department may not provide services without the consent of the individual or, if the individual is a minor, the minor's parent, managing conservator, or guardian.

Amended by Acts 1991, 72nd Leg., ch. 14, Sec. 8, eff. Sept. 1, 1991.

Sec. 33.034. DENIAL, MODIFICATION, SUSPENSION, AND REVOCATION OF APPROVAL TO PROVIDE SERVICES. (a) After notice and an opportunity for a fair hearing, the department may deny the approval or modify, suspend, or revoke the approval of a person to provide services under this chapter.

(b) Notice shall be given and the hearing shall be conducted in accordance with the department's informal hearing procedures.

(c) Chapter 2001, Government Code, does not apply to the notice and hearing required by this section.

Amended by Acts 1991, 72nd Leg., ch. 14, Sec. 8, eff. Sept. 1, 1991;

Acts 1995, 74th Leg., ch. 76, Sec. 5.95(66), eff. Sept. 1, 1995.

Amended by:

Acts 2005, 79th Leg., Ch. 728, Sec. 9.001, eff. September 1, 2005.

Sec. 33.035. INDIVIDUALS ELIGIBLE FOR SERVICES. (a) An individual is not eligible to receive the services authorized by this chapter at no cost or reduced cost to the extent that the individual or the parent, managing conservator, guardian, or other person with a legal obligation to support the individual is eligible for some other benefit that would pay for all or part of the services.

(b) The department may waive ineligibility under Subsection (a) if the department finds that:

(1) good cause for the waiver is shown; and

(2) enforcement of the requirement would tend to defeat the purpose of this chapter or disrupt the administration or prevent the provision of services to an otherwise eligible recipient.

(c) When an application for services is filed or at any time that an individual is eligible for or receiving services, the applicant or recipient shall inform the department of any other benefit to which the applicant, recipient, or person with a legal obligation to support the applicant or recipient may be entitled.

(d) The board by rule shall provide criteria for actions taken under this section.

Amended by Acts 1991, 72nd Leg., ch. 14, Sec. 8, eff. Sept. 1, 1991.

Sec. 33.036. DENIAL, MODIFICATION, SUSPENSION, AND REVOCATION OF ELIGIBILITY TO RECEIVE SERVICES. (a) After notice to the individual or, if the individual is a minor, the individual's parent, managing conservator, or guardian and an opportunity for a fair hearing, the department may deny, modify, suspend, or revoke the determination of a person's eligibility to receive services at no cost or at reduced cost under this chapter.

(b) Notice shall be given and the hearing shall be conducted in accordance with the department's informal hearing procedures.

(c) Chapter 2001, Government Code, do not apply to the notice and hearing required by this section.

Amended by Acts 1991, 72nd Leg., ch. 14, Sec. 8, eff. Sept. 1, 1991; Acts 1995, 74th Leg., ch. 76, Sec. 5.95(66), eff. Sept. 1, 1995.

Sec. 33.037. REIMBURSEMENT. (a) The board may require an individual or, if the individual is a minor, the minor's parent, managing conservator, or guardian, or other person with a legal obligation to support the individual to pay or reimburse the department for all or part of the cost of the services provided.

(b) The recipient or the parent, managing conservator, guardian, or other person with a legal obligation to support an individual who has received services from the department that are covered by some other benefit shall, when the other benefit is received, reimburse the department for the cost of services provided.

Amended by Acts 1991, 72nd Leg., ch. 14, Sec. 8, eff. Sept. 1, 1991.

Sec. 33.038. RECOVERY OF COSTS. (a) The department is entitled to recover an expenditure for services provided under this chapter from:

(1) a person who does not reimburse the department as required by this chapter; or

(2) a third party with a legal obligation to pay other benefits and who has received prior written notice of the department's interests in the other benefits.

(b) This section creates a separate and distinct cause of action, and the commissioner may request the attorney general to bring suit in the appropriate court of Travis County on behalf of the department.

(c) In a judgment in favor of the department, the court may award attorney fees, court costs, and interest accruing from the date on which the department provides the service to the date on which the department is reimbursed.

(d) The board by rule shall provide criteria for actions taken under this section.

Amended by Acts 1991, 72nd Leg., ch. 14, Sec. 8, eff. Sept. 1, 1991.