

LEGISLATIVE BILL 235

Approved by the Governor March 18, 2002

Introduced by Byars, 30

AN ACT relating to public health and welfare; to amend sections 71-521 and 71-524, Reissue Revised Statutes of Nebraska, sections 71-520, 71-522, and 71-523, Revised Statutes Supplement, 2000, and section 71-519, Revised Statutes Supplement, 2001; to change and eliminate provisions relating to newborn screening for metabolic diseases, food supplements and treatment, fees, records, reports, and rules and regulations; to provide immunity from liability; to provide powers and duties; to harmonize provisions; and to repeal the original sections.

Be it enacted by the people of the State of Nebraska,

Section 1. Section 71-519, Revised Statutes Supplement, 2001, is amended to read:

71-519. (1) All infants born in the State of Nebraska shall be screened for phenylketonuria, primary hypothyroidism, biotinidase deficiency, galactosemia, hemoglobinopathies, medium-chain acyl co-a dehydrogenase (MCAD) deficiency, and such other metabolic diseases as the Department of Health and Human Services may from time to time specify. Confirmatory tests shall be performed ~~in the event that~~ if a presumptive positive result on the screening test is obtained.

(2) The attending physician shall collect or cause to be collected the prescribed blood specimen or specimens and shall submit or cause to be submitted the same to ~~a~~ the laboratory designated by the department for the performance of such tests within the period and in the manner prescribed by the department. ~~In the event~~ If a birth is not attended by a physician and the infant does not have a physician, the person registering the birth shall cause such tests to be performed within the period and in the manner prescribed by the department. The laboratory shall within the period and in the manner prescribed by the department perform such tests as are prescribed by the department on the specimen or specimens submitted and report the results of these tests to the physician, if any, ~~and the hospital or other birthing facility or other submitter, and the department.~~ The laboratory shall report to the department the results of such tests that are presumptive positive or confirmed positive within the period and in the manner prescribed by the department.

(3) The hospital or other birthing facility shall record the collection of specimens for tests for metabolic diseases and the reporting report of the results of such tests or the absence of such report. For purposes of tracking, monitoring, and referral, the hospital or other birthing facility shall provide from its records, upon the department's request, information about the infant's and mother's location and contact information, and care and treatment of the infant. The hospital shall report the results of such tests to the department within the period and in the manner prescribed by the department.

(4) The department shall do all of the following in regard to the blood specimens taken for purposes of conducting the tests required under subsection (1) of this section:

(a) Develop a schedule for the retention and disposal of the blood specimens used for the tests after the tests are completed. The schedule shall meet the following requirements:

(i) Be consistent with nationally recognized standards for laboratory accreditation and federal law;

(ii) Require that the disposal be conducted in the presence of a witness. For purposes of this subdivision, the witness may be an individual involved in the disposal or any other individual; and

(iii) Require that a written record of the disposal be made and kept and that the witness sign the record; and

(b) With the written consent of the parent or legal guardian of the infant, allow the blood specimens to be used for medical research during the retention period as long as the medical research is conducted in a manner that preserves the confidentiality of the test subjects and is consistent to protect human subjects from research risks under subpart A of part 46 of 45 C.F.R., as such regulations existed on September 1, 2001.

(5) The department shall prepare written materials explaining the requirements of this section. The department shall include the following

information in the pamphlet:

(a) The nature and purpose of the testing program required under this section, including, but not limited to, a brief description of each condition or disorder listed in subsection (1) of this section;

(b) The purpose and value of the infant's parent, guardian, or person in loco parentis retaining a blood specimen obtained under subsection (6) of this section in a safe place;

(c) The department's schedule for retaining and disposing of blood specimens developed under subdivision (4)(a) of this section; and

(d) That the blood specimens taken for purposes of conducting the tests required under subsection (1) of this section may be used for medical research pursuant to subdivision (4)(b) of this section.

(6) In addition to the requirements of subsection (1) of this section, the attending physician or person registering the birth may offer to draw an additional blood specimen from the infant. If such an offer is made, it shall be made to the infant's parent, guardian, or person in loco parentis at the time the blood specimens are drawn for purposes of subsection (1) of this section. If the infant's parent, guardian, or person in loco parentis accepts the offer of an additional blood specimen, the blood specimen shall be preserved in a manner that does not require special storage conditions or techniques, including, but not limited to, lamination. The attending physician or person making the offer shall explain to the parent, guardian, or person in loco parentis at the time the offer is made that the additional blood specimen can be used for future identification purposes and should be kept in a safe place. The attending physician or person making the offer may charge a fee that is not more than the actual cost of obtaining and preserving the additional blood specimen.

(7) The person responsible for causing the tests to be performed under subsection (2) of this section shall inform the parent or legal guardian of the infant of the tests and of the results of the tests and provide, upon any request for further information, at least a copy of the written materials prepared under subsection (5) of this section.

(8) Dietary and therapeutic management of the infant with phenylketonuria, primary hypothyroidism, biotinidase deficiency, galactosemia, hemoglobinopathies, MCAD deficiency, or such other metabolic diseases as the department may from time to time specify shall be the responsibility of the child's parent, guardian, or custodian with the aid of a physician selected by such person.

(9) Except for acts of gross negligence or willful or wanton conduct, any physician, hospital or other birthing facility, laboratory, or other submitter making reports or notifications under sections 71-519 to 71-524 shall be immune from criminal or civil liability of any kind or character based on any statements contained in such reports or notifications.

Sec. 2. Section 71-520, Revised Statutes Supplement, 2000, is amended to read:

71-520. The Department of Health and Human Services shall establish a program to provide food supplements and treatment services to individuals suffering from the metabolic diseases set forth in section 71-519. To defray or help defray the costs of any program which may be established by the department under this section, the department may:

(1) ~~Prescribe~~ prescribe and assess a scale of fees for the food supplements. The maximum prescribed fee for food supplements shall be no more than the actual cost of providing such supplements. No fees may be charged for formula, and up to two thousand dollars of pharmaceutically manufactured food supplements shall be available to an individual without fees each year.
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(2) ~~Assess a fee of three dollars for each infant screened pursuant to section 71-519. The laboratory performing the tests pursuant to section 71-519 shall collect the three-dollar fee for infant screening and shall submit the amounts collected to the Department of Health and Human Services Finance and Support on a monthly basis.~~

~~Any fees collected shall be deposited in the state treasury and shall be credited to the Department of Health and Human Services Finance and Support Cash Fund.~~

Sec. 3. Section 71-521, Reissue Revised Statutes of Nebraska, is amended to read:

71-521. ~~The Department of Health and Human Services Regulation and Licensure with the advice of the Department of Health and Human Services shall prescribe the tests, the test methods and techniques, and such reports and reporting procedures as are necessary to implement sections 71-519 to 71-524.~~

~~The Department of Health and Human Services Regulation and Licensure shall set fees for metabolic disease tests performed by the department's~~

laboratory. The fees shall be set at the rate necessary to recover the actual costs of providing such tests. Such fees shall be deposited in the state treasury and credited to the Department of Health and Human Services Regulation and Licensure Cash Fund.

Sec. 4. Section 71-522, Revised Statutes Supplement, 2000, is amended to read:

71-522. The Department of Health and Human Services shall establish and maintain a central data registry for the collection and storage of reported data concerning metabolic diseases. The department shall use reported data to ensure that all infants born in the State of Nebraska are tested for diseases set forth in section 71-519 or by rule and regulation. The department shall also use reported data to evaluate the quality of the statewide system of newborn screening and develop procedures for quality assurance. Reported data in anonymous or statistical form may be made available by the department for purposes of research.

Sec. 5. Section 71-523, Revised Statutes Supplement, 2000, is amended to read:

71-523. (1) The Department of Health and Human Services shall provide educational and resource services regarding metabolic diseases to persons affected by sections 71-519 to 71-524 and to the public generally.

(2) The Department of Health and Human Services, the Department of Health and Human Services Finance and Support, and the Department of Health and Human Services Regulation and Licensure may apply for, receive, and administer assessed fees and federal or other funds which are available for the purpose of implementing sections 71-519 to 71-524 and may contract for or provide services as may be necessary to implement such sections.

(3) ~~The Department of Health and Human Services Regulation and Licensure with the advice of the~~ Department of Health and Human Services shall adopt and promulgate rules and regulations to implement sections 71-519 to 71-524.

(4) The Department of Health and Human Services shall contract, following competitive bidding, with a single laboratory to perform tests, report results, set forth the fee the laboratory will charge for testing, and collect and submit fees pursuant to sections 71-519 to 71-524. The department shall require the contracting laboratory to: (a) Perform testing for all of the diseases pursuant to section 71-519 and in accordance with rules and regulations adopted and promulgated pursuant to this section, (b) maintain certification under the federal Clinical Laboratories Improvement Act of 1967, 42 U.S.C. 263a, as such act and section existed on the effective date of this act, (c) participate in appropriate quality assurance proficiency testing programs offered by the Centers for Disease Control and Prevention of the United States Department of Health and Human Services or other professional laboratory organization, as determined by the Department of Health and Human Services, (d) maintain sufficient contingency arrangements to ensure testing delays of no longer than twenty-four hours in the event of natural disaster or laboratory equipment failure, and (e) charge to the hospital, other birthing facility, or other submitter the fee provided in the contract for laboratory testing costs and the administration fee specified in subsection (5) of this section. The administration fee collected pursuant to such subsection shall be remitted to the Department of Health and Human Services Finance and Support.

(5) The Department of Health and Human Services shall set an administration fee of not more than ten dollars. The department may use the administration fee to pay for the costs of the central data registry, tracking, monitoring, referral, quality assurance, program operation, program development, program evaluation, and treatment services authorized under sections 71-519 to 71-523. The fee shall be collected by the contracting laboratory as provided in subdivision (4)(e) of this section.

(6) Fees collected for the department pursuant to sections 71-519 to 71-523 shall be remitted to the State Treasurer for credit to the Department of Health and Human Services Finance and Support Cash Fund.

Sec. 6. Section 71-524, Reissue Revised Statutes of Nebraska, is amended to read:

71-524. In addition to any other remedies which may be available by law, a civil proceeding to enforce section 71-519 may be brought in the district court of the county where the infant is domiciled or found. The attending physician, the hospital or other birthing facility, the Attorney General, or the county attorney of the county where the infant is domiciled or found may institute such proceedings as are necessary to enforce such section. It shall be the duty of the Attorney General or the county attorney to whom the Director of Regulation and Licensure reports a violation to cause appropriate proceedings to be initiated without delay. A hearing on any

action brought pursuant to this section shall be held within seventy-two hours of the filing of such action, and a decision shall be rendered by the court within twenty-four hours of the close of the hearing.

Sec. 7. Original sections 71-521 and 71-524, Reissue Revised Statutes of Nebraska, sections 71-520, 71-522, and 71-523, Revised Statutes Supplement, 2000, and section 71-519, Revised Statutes Supplement, 2001, are repealed.