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LEGISLATURE OF NEBRASKA

ONE HUNDRED FIFTH LEGISLATURE

FIRST SESSION

LEGISLATIVE BILL 91

Introduced by Hilkemann, 4.

Read first time January 05, 2017

Committee: Health and Human Services

A BILL FOR AN ACT relating to metabolic screening; to amend sections 71-519, 71-520, and 71-523, Reissue Revised Statutes of Nebraska; to change provisions relating to infant screening as prescribed; to change a fee; to harmonize provisions; and to repeal the original sections.

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

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Section 1. Section 71-519, Reissue Revised Statutes of Nebraska, is amended to read:

71-519 (1) All infants born in the State of Nebraska shall be screened for phenylketonuria, congenital primary hypothyroidism, biotinidase deficiency, galactosemia, hemoglobinopathies, medium-chain acyl co-a dehydrogenase (MCAD) deficiency, and such other inherited or congenital infant or childhood-onset ~~metabolic~~ diseases as the Department of Health and Human Services may from time to time specify. Confirmatory tests shall be performed 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 the laboratory designated by the department for the performance of such tests within the period and in the manner prescribed by the department. 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, 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 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

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information, and care and treatment of the infant.

(4)(a) The department shall have authority over the use, retention, and disposal of blood specimens and all related information collected in connection with ~~metabolic~~ disease testing conducted under subsection (1) of this section.

(b) The department shall adopt and promulgate rules and regulations relating to the retention and disposal of such specimens. The rules and regulations shall: (i) Be consistent with nationally recognized standards for laboratory accreditation and shall comply with all applicable provisions of federal law; (ii) require that the disposal be conducted in the presence of a witness who may be an individual involved in the disposal or any other individual; and (iii) provide for maintenance of a written or electronic record of the disposal, verified by such witness.

(c) The department shall adopt and promulgate rules and regulations relating to the use of such specimens and related information. Such use shall only be made for public health purposes and shall comply with all applicable provisions of federal law. The department may charge a reasonable fee for evaluating proposals relating to the use of such specimens for public health research and for preparing and supplying specimens for research proposals approved by the department.

(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 procedures for retaining and disposing of blood specimens developed under subsection (4) of this section; and

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(d) That the blood specimens taken for purposes of conducting the tests required under subsection (1) of this section may be used for research pursuant to subsection (4) 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 inherited or congenital infant or childhood-onset ~~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.

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(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, Reissue Revised Statutes of Nebraska, 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 inherited or congenital infant or childhood-onset ~~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 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. For purposes of this section, pharmaceutically manufactured foods are chemically synthesized or processed for the treatment of inborn errors in metabolism.

Sec. 3. Section 71-523, Reissue Revised Statutes of Nebraska, is amended to read:

71-523 (1) The Department of Health and Human Services shall provide educational and resource services regarding screened ~~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 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

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such sections.

(3) 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 July 20, 2002, (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.

(5) The Department of Health and Human Services shall set an administration fee of not more than twenty ~~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

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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 Health and Human Services Cash Fund.

Sec. 4. Original sections 71-519, 71-520, and 71-523, Reissue Revised Statutes of Nebraska, are repealed.