

LEGISLATURE OF NEBRASKA
ONE HUNDRED FIFTH LEGISLATURE
FIRST SESSION

LEGISLATIVE BILL 91

FINAL READING

Introduced by Hilkemann, 4; Hansen, 26; Blood, 3; McCollister, 20; Krist, 10; Albrecht, 17; Craighead, 6; Wishart, 27; Linehan, 39; Quick, 35.

Read first time January 05, 2017

Committee: Health and Human Services

- 1 A BILL FOR AN ACT relating to metabolic screening; to amend sections
- 2 71-519, 71-520, 71-522, and 71-523, Reissue Revised Statutes of
- 3 Nebraska; to change provisions relating to infant screening as
- 4 prescribed; to define a term; to change a fee; to harmonize
- 5 provisions; to provide an operative date; and to repeal the original
- 6 sections.
- 7 Be it enacted by the people of the State of Nebraska,

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

3 71-519 (1) All infants born in the State of Nebraska shall be
4 screened for phenylketonuria, congenital primary hypothyroidism,
5 biotinidase deficiency, galactosemia, hemoglobinopathies, medium-chain
6 acyl co-a dehydrogenase (MCAD) deficiency, X-linked adrenoleukodystrophy
7 (X-ALD), mucopolysaccharidoses type 1 (MPS-1), Pompe disease, and such
8 other inherited or congenital infant or childhood-onset metabolic
9 diseases as the Department of Health and Human Services may from time to
10 time specify. Confirmatory tests shall be performed if a presumptive
11 positive result on the screening test is obtained.

12 (2) The attending physician shall collect or cause to be collected
13 the prescribed blood specimen or specimens and shall submit or cause to
14 be submitted the same to the laboratory designated by the department for
15 the performance of such tests within the period and in the manner
16 prescribed by the department. If a birth is not attended by a physician
17 and the infant does not have a physician, the person registering the
18 birth shall cause such tests to be performed within the period and in the
19 manner prescribed by the department. The laboratory shall within the
20 period and in the manner prescribed by the department perform such tests
21 as are prescribed by the department on the specimen or specimens
22 submitted and report the results of these tests to the physician, if any,
23 the hospital or other birthing facility or other submitter, and the
24 department. The laboratory shall report to the department the results of
25 such tests that are presumptive positive or confirmed positive within the
26 period and in the manner prescribed by the department.

27 (3) The hospital or other birthing facility shall record the
28 collection of specimens for tests for metabolic diseases and the report
29 of the results of such tests or the absence of such report. For purposes
30 of tracking, monitoring, and referral, the hospital or other birthing
31 facility shall provide from its records, upon the department's request,

1 information about the infant's and mother's location and contact
2 information, and care and treatment of the infant.

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

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

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

22 (5) The department shall prepare written materials explaining the
23 requirements of this section. The department shall include the following
24 information in the pamphlet:

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

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

31 (c) The department's procedures for retaining and disposing of blood

1 specimens developed under subsection (4) of this section; and

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

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

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

26 (8) Dietary and therapeutic management of the infant with
27 phenylketonuria, primary hypothyroidism, biotinidase deficiency,
28 galactosemia, hemoglobinopathies, MCAD deficiency, X-linked
29 adrenoleukodystrophy (X-ALD), mucopolysaccharidoses type 1 (MPS-1), Pompe
30 disease, or such other inherited or congenital infant or childhood-onset
31 ~~metabolic~~ diseases as the department may from time to time specify shall

1 be the responsibility of the child's parent, guardian, or custodian with
2 the aid of a physician selected by such person.

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

9 Sec. 2. Section 71-520, Reissue Revised Statutes of Nebraska, is
10 amended to read:

11 71-520 The Department of Health and Human Services shall establish a
12 program to provide food supplements and treatment services to individuals
13 suffering from the inherited or congenital infant or childhood-onset
14 ~~metabolic~~ diseases set forth in section 71-519. To defray or help defray
15 the costs of any program which may be established by the department under
16 this section, the department may prescribe and assess a scale of fees for
17 the food supplements. The maximum prescribed fee for food supplements
18 shall be no more than the actual cost of providing such supplements. No
19 fees may be charged for formula, and up to two thousand dollars of
20 pharmaceutically manufactured food supplements shall be available to an
21 individual without fees each year. For purposes of this section,
22 pharmaceutically manufactured foods are chemically synthesized or
23 processed for the treatment of inborn errors in metabolism.

24 Sec. 3. Section 71-522, Reissue Revised Statutes of Nebraska, is
25 amended to read:

26 71-522 The Department of Health and Human Services shall establish
27 and maintain a central data registry for the collection and storage of
28 reported data concerning inherited or congenital infant or childhood-
29 onset ~~metabolic~~ diseases. The department shall use reported data to
30 ensure that all infants born in the State of Nebraska are tested for
31 diseases set forth in section 71-519 or by rule and regulation. The

1 department shall also use reported data to evaluate the quality of the
2 statewide system of newborn screening and develop procedures for quality
3 assurance. Reported data in anonymous or statistical form may be made
4 available by the department for purposes of research.

5 Sec. 4. Section 71-523, Reissue Revised Statutes of Nebraska, is
6 amended to read:

7 71-523 (1) The Department of Health and Human Services shall provide
8 educational and resource services regarding screened ~~metabolic~~ diseases
9 to persons affected by sections 71-519 to 71-524 and to the public
10 generally.

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

16 (3) The Department of Health and Human Services shall adopt and
17 promulgate rules and regulations to implement sections 71-519 to 71-524.

18 (4) The Department of Health and Human Services shall contract,
19 following competitive bidding, with a single laboratory to perform tests,
20 report results, set forth the fee the laboratory will charge for testing,
21 and collect and submit fees pursuant to sections 71-519 to 71-524. The
22 department shall require the contracting laboratory to: (a) Perform
23 testing for all of the diseases pursuant to section 71-519 and in
24 accordance with rules and regulations adopted and promulgated pursuant to
25 this section, (b) maintain certification under the federal Clinical
26 Laboratories Improvement Act of 1967, 42 U.S.C. 263a, as such act and
27 section existed on July 20, 2002, (c) participate in appropriate quality
28 assurance proficiency testing programs offered by the Centers for Disease
29 Control and Prevention of the United States Department of Health and
30 Human Services or other professional laboratory organization, as
31 determined by the Department of Health and Human Services, (d) maintain

1 sufficient contingency arrangements to ensure testing delays of no longer
2 than twenty-four hours in the event of natural disaster or laboratory
3 equipment failure, and (e) charge to the hospital, other birthing
4 facility, or other submitter the fee provided in the contract for
5 laboratory testing costs and the administration fee specified in
6 subsection (5) of this section. The administration fee collected pursuant
7 to such subsection shall be remitted to the Department of Health and
8 Human Services.

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

17 (6) Fees collected for the department pursuant to sections 71-519 to
18 71-523 shall be remitted to the State Treasurer for credit to the Health
19 and Human Services Cash Fund.

20 Sec. 5. This act becomes operative July 1, 2018.

21 Sec. 6. Original sections 71-519, 71-520, 71-522, and 71-523,
22 Reissue Revised Statutes of Nebraska, are repealed.