

SECOND REGULAR SESSION

HOUSE BILL NO. 2750

103RD GENERAL ASSEMBLY

INTRODUCED BY REPRESENTATIVE DAVIDSON.

4026H.01I

JOSEPH ENGLER, Chief Clerk

AN ACT

To repeal sections 191.317, 191.331, 191.332, and 191.333, RSMo, and to enact in lieu thereof four new sections relating to testing performed by the department of health and senior services laboratories.

Be it enacted by the General Assembly of the state of Missouri, as follows:

Section A. Sections 191.317, 191.331, 191.332, and 191.333, RSMo, are repealed
2 and four new sections enacted in lieu thereof, to be known as sections 191.317, 191.331,
3 191.332, and 191.333, to read as follows:

191.317. 1. All testing results and personal information obtained from any
2 individual, or from specimens from any individual, shall be held confidential and be
3 considered a confidential medical record, except for such information as the individual,
4 parent or guardian consents to be released; but the individual must first be fully informed of
5 the scope of the information ~~[requests]~~ **requested** to be released, of the risks, benefits and
6 purposes for such release, and of the identity of those to whom the information will be
7 released. Statistical data compiled without reference to the identity of any individual shall not
8 be declared confidential. Notwithstanding any other provision of law to the contrary, the
9 department may release the results of newborn screening tests to a child's health care
10 professional. **The department shall destroy the results of newborn screening tests after**
11 **one year from the date the results were finalized.**

12 2. The specimen shall be retained for ~~[five years]~~ **one year** after initial submission to
13 the department. After ~~[five years]~~ **one year**, the specimen shall be destroyed. ~~[Unless~~
14 ~~otherwise directed under this section, a biological specimen may be released for purposes of~~

EXPLANATION — Matter enclosed in bold-faced brackets ~~[thus]~~ in the above bill is not enacted and is intended to be omitted from the law. Matter in **bold-face** type in the above bill is proposed language.

15 ~~anonymous scientific study. At the time of collection, the parent or legal guardian of the child~~
16 ~~from whom a biological specimen was obtained may direct the department to:~~

17 ~~(1) Return a biological specimen that remains after all screening tests have been~~
18 ~~performed;~~

19 ~~(2) Destroy a biological specimen in a scientifically acceptable manner after all~~
20 ~~screening tests required under section 191.331 or rule promulgated thereunder have been~~
21 ~~performed; or~~

22 ~~(3) Store a biological specimen but not release the biological specimen for~~
23 ~~anonymous scientific study.~~

24 ~~3. A biological specimen released for anonymous study under this section shall not~~
25 ~~contain information that may be used to determine the identity of the donor.]~~

191.331. 1. Every infant who is born in this state shall be tested for phenylketonuria
2 and such other metabolic or genetic diseases as are prescribed by the department **if the parent**
3 **or guardian of the infant consented to such testing in the manner provided under**
4 **subsection 4 of this section.** The test used by the department shall be dictated by accepted
5 medical practice and such tests shall be of the types approved by the department. All
6 newborn screening tests ~~[required]~~ **for the diseases prescribed** by the department shall be
7 performed by the department of health and senior services laboratories. The attending
8 physician, certified nurse midwife, public health facility, ambulatory surgical center or
9 hospital shall assure that appropriate specimens are collected and submitted to the department
10 of health and senior services laboratories.

11 2. All physicians, certified nurse midwives, public health nurses and administrators of
12 ambulatory surgical centers or hospitals shall report to the department all diagnosed cases of
13 phenylketonuria and other metabolic or genetic diseases as designated by the department.
14 The department shall prescribe and furnish all necessary reporting forms.

15 3. The department shall develop and institute educational programs concerning
16 phenylketonuria and other metabolic and genetic diseases and assist parents, physicians,
17 hospitals and public health nurses in the management and basic treatment of these diseases.

18 4. ~~[The provisions of this section shall not apply if the parents of such child object to~~
19 ~~the tests or examinations provided in this section on the grounds that such tests or~~
20 ~~examinations conflict with their religious tenets and practices.]~~ **An infant shall not be tested**
21 **in accordance with the provisions of this section unless the parent or guardian of the**
22 **infant consented to such testing as described in this subsection. The following criteria**
23 **shall be required for any consent to be deemed valid:**

24 **(1) The consent shall be voluntary and informed and given freely and without**
25 **coercion;**

26 **(2) The consent shall be given in writing;**

27 **(3) The parent or guardian giving consent shall have the capacity to understand**
28 **the risks and benefits of testing; and**

29 **(4) The consent shall be provided before the birth of the infant but not during**
30 **any active labor immediately preceding such birth.**

31 5. ~~[As provided in subsection 4 of this section, the parents of any child who fail to~~
32 ~~have such test or examination administered after notice of the requirement for such test or~~
33 ~~examination shall be required to document in writing such refusal.]~~ All physicians, certified
34 nurse midwives, public health nurses and administrators of ambulatory surgical centers or
35 hospitals **seeking the consent of the parent or guardian under subsection 4 of this section**
36 shall provide to the ~~[parents]~~ **parent** or ~~[guardians]~~ **guardian** a written packet of educational
37 information developed and supplied by the department of health and senior services
38 describing the type of specimen, how it is obtained, the nature of diseases being screened, and
39 the consequences of treatment and nontreatment. ~~[The attending physician, certified nurse~~
40 ~~midwife, public health facility, ambulatory surgical center or hospital shall obtain the written~~
41 ~~refusal and make such refusal part of the medical record of the infant.]~~

42 6. Notwithstanding the provisions of section 192.015 to the contrary, the department
43 may, by rule, annually determine and impose a reasonable fee for each newborn screening test
44 made in any of its laboratories. The department may collect the fee from any entity or
45 individual described in subsection 1 of this section in a form and manner established by the
46 department. Such fee shall be considered as a cost payable to such entity by a health care
47 third-party payer, including, but not limited to, a health insurer operating pursuant to chapter
48 376, a domestic health services corporation or health maintenance organization operating
49 pursuant to chapter 354, and a governmental or entitlement program operating pursuant to
50 state law. Such fee shall not be considered as part of the internal laboratory costs of the
51 persons and entities described in subsection 1 of this section by such health care third-party
52 payers. No individual shall be denied screening because of inability to pay. Such fees shall
53 be deposited in a separate account in the public health services fund created in section
54 192.900, and funds in such account shall be used for the support of the newborn screening
55 program and activities related to the screening, diagnosis, and treatment, including special
56 dietary products, of persons with metabolic and genetic diseases; and follow-up activities that
57 ensure that diagnostic evaluation, treatment and management is available and accessible once
58 an at-risk family is identified through initial screening; and for no other purpose. These
59 programs may include education in these areas and the development of new programs related
60 to these diseases.

61 7. Subject to appropriations provided for formula for the treatment of inherited
62 diseases of amino acids and organic acids, the department shall provide such formula to
63 persons with inherited diseases of amino acids and organic acids subject to the conditions

64 described in this subsection. State assistance pursuant to this subsection shall be available to
65 an applicant only after the applicant has shown that the applicant has exhausted all benefits
66 from third-party payers, including, but not limited to, health insurers, domestic health services
67 corporations, health maintenance organizations, Medicare, Medicaid and other government
68 assistance programs.

69 8. Assistance under subsection 7 of this section shall be provided to the following:

70 (1) Applicants ages birth to five years old meeting the qualifications under subsection
71 7 of this section;

72 (2) Applicants between the ages of six to eighteen meeting the qualifications under
73 subsection 7 of this section and whose family income is below three hundred percent of the
74 federal poverty level;

75 (3) Applicants between the ages of six to eighteen meeting the qualifications under
76 subsection 7 of this section and whose family income is at three hundred percent of the
77 federal poverty level or above. For these applicants, the department shall establish a sliding
78 scale of fees and monthly premiums to be paid in order to receive assistance under subsection
79 7 of this section; and

80 (4) Applicants age nineteen and above meeting the qualifications under subsection 7
81 of this section and who are eligible under an income-based means test established by the
82 department to determine eligibility for the assistance under subsection 7 of this section.

83 9. The department shall have authority over the use, retention, and disposal of
84 biological specimens and all related information collected in connection with newborn
85 screening tests conducted under subsection 1 of this section. The use of such specimens and
86 related information shall only be made for public health purposes and shall comply with all
87 applicable provisions of federal law. ~~[The department may charge a reasonable fee for the use
88 of such specimens for public health research and preparing and supplying specimens for
89 research proposals approved by the department.]~~

191.332. 1. By January 1, 2002, the department of health and senior services shall,
2 subject to appropriations, expand the newborn screening ~~[requirements]~~ **tests** in section
3 191.331 to include potentially treatable or manageable disorders, which may include but are
4 not limited to cystic fibrosis, galactosemia, biotinidase deficiency, congenital adrenal
5 hyperplasia, maple syrup urine disease (MSUD) and other amino acid disorders, glucose-6-
6 phosphate dehydrogenase deficiency (G-6-PD), MCAD and other fatty acid oxidation
7 disorders, methylmalonic acidemia, propionic acidemia, isovaleric acidemia and glutaric
8 acidemia Type I.

9 2. By January 1, 2017, the department of health and senior services shall, subject to
10 appropriations, expand the newborn screening ~~[requirements]~~ **tests** in section 191.331 to
11 include severe combined immunodeficiency (SCID), also known as bubble boy disease. The

12 department may increase the fee authorized under subsection 6 of section 191.331 to cover
13 any additional costs of the expanded newborn screening ~~[requirements]~~ **tests** under this
14 subsection.

15 3. By January 1, 2019, the department of health and senior services shall, subject to
16 appropriations, expand the newborn screening ~~[requirements]~~ **tests** in section 191.331 to
17 include spinal muscular atrophy (SMA) and Hunter syndrome (MPS II). The department may
18 increase the fee authorized under subsection 6 of section 191.331 to cover any additional
19 costs of the expanded newborn screening ~~[requirements]~~ **tests** under this subsection. To help
20 fund initial costs incurred by the state, the department shall apply for available newborn
21 screening grant funding specific to screening for spinal muscular atrophy and Hunter
22 syndrome. The department shall have discretion in accepting the terms of such grants.

23 4. The department of health and senior services may promulgate rules to implement
24 the provisions of this section. No rule or portion of a rule promulgated pursuant to the
25 authority of this section shall become effective unless it has been promulgated pursuant to
26 chapter 536.

191.333. 1. This section shall be known and may be cited as the "Brady Alan
2 Cunningham Newborn Screening Act".

3 2. By July 1, 2012, the department of health and senior services shall expand the
4 newborn screening ~~[requirements]~~ **tests** in section 191.331 to include the following lysosomal
5 storage diseases: Krabbe disease, Pompe disease, Gaucher disease, Niemann-Pick disease,
6 and Fabry disease. The department may by rule screen for additional lysosomal storage
7 disorders when the following occurs:

8 (1) The registration of the necessary reagents with the federal Food and Drug
9 Administration;

10 (2) The availability of the necessary reagents from the Centers for Disease Control
11 and Prevention;

12 (3) The availability of quality assurance testing methodology for such processes; and

13 (4) The acquisition and installment by the department of equipment necessary to
14 implement the expanded screening tests.

15 3. The department may promulgate rules to implement the provisions of this section.
16 Any rule or portion of a rule, as that term is defined in section 536.010, that is created under
17 the authority delegated in this section shall become effective only if it complies with and is
18 subject to all of the provisions of chapter 536 and, if applicable, section 536.028. This section
19 and chapter 536 are nonseverable and if any of the powers vested with the general assembly
20 pursuant to chapter 536 to review, to delay the effective date, or to disapprove and annul a
21 rule are subsequently held unconstitutional, then the grant of rulemaking authority and any
22 rule proposed or adopted after August 28, 2009, shall be invalid and void.

23 4. The department may increase the fee authorized in subsection 6 of section 191.331
24 to cover the additional cost of the expanded newborn screening ~~[test required in]~~ **tests under**
25 this section.

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