

FIRST REGULAR SESSION
SENATE COMMITTEE SUBSTITUTE FOR
SENATE BILL NO. 354
98TH GENERAL ASSEMBLY

Reported from the Committee on Small Business, Insurance and Industry, April 9, 2015, with recommendation that the Senate Committee Substitute do pass.

1251S.04C

ADRIANE D. CROUSE, Secretary.

AN ACT

To repeal section 191.331, RSMo, and to enact in lieu thereof one new section relating to amino acid-based elemental formulas.

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

Section A. Section 191.331, RSMo, is repealed and one new section
2 enacted in lieu thereof, to be known as section 191.331, to read as follows:

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

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

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

19 4. The provisions of this section shall not apply if the parents of such
20 child object to the tests or examinations provided in this section on the grounds

21 that such tests or examinations conflict with their religious tenets and practices.

22 5. As provided in subsection 4 of this section, the parents of any child who
23 fail to have such test or examination administered after notice of the requirement
24 for such test or examination shall be required to document in writing such
25 refusal. All physicians, certified nurse midwives, public health nurses and
26 administrators of ambulatory surgical centers or hospitals shall provide to the
27 parents or guardians a written packet of educational information developed and
28 supplied by the department of health and senior services describing the type of
29 specimen, how it is obtained, the nature of diseases being screened, and the
30 consequences of treatment and nontreatment. The attending physician, certified
31 nurse midwife, public health facility, ambulatory surgical center or hospital shall
32 obtain the written refusal and make such refusal part of the medical record of the
33 infant.

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

55 7. Subject to appropriations provided for formula for the treatment of
56 inherited diseases of amino acids and organic acids **including amino acid-**

57 **based elemental formulas**, the department shall provide such formula to
58 persons with inherited diseases of amino acids and organic acids subject to the
59 conditions described in this subsection. State assistance pursuant to this
60 subsection shall be available to an applicant only after the applicant has shown
61 that the applicant has exhausted all benefits from third-party payers, including,
62 but not limited to, health insurers, domestic health services corporations, health
63 maintenance organizations, Medicare, Medicaid and other government assistance
64 programs.

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

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

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

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

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

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

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