

FIRST REGULAR SESSION
HOUSE COMMITTEE SUBSTITUTE FOR
HOUSE BILL NO. 665
98TH GENERAL ASSEMBLY

1563H.03C

D. ADAM CRUMBLISS, Chief Clerk

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Section A. Section 191.331, RSMo, is repealed and one new section enacted in lieu thereof, to be known as section 191.331, to read as follows: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 phenylketonuria and such other metabolic or genetic diseases as are prescribed by the department. The test used by the department shall be dictated by accepted medical practice and such tests shall be of the types approved by the department. All newborn screening tests required by the department shall be performed by the department of health and senior services laboratories. The attending physician, certified nurse midwife, public health facility, ambulatory surgical center or hospital shall assure that appropriate specimens are collected and submitted to the department of health and senior services laboratories.

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

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

4. The provisions of this section shall not apply if the parents of such child object to the tests or examinations provided in this section on the grounds that such tests or examinations conflict with their religious tenets and practices.

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.

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

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

47 7. Subject to appropriations provided for formula **including amino acid-based**
48 **elemental formulas** for the treatment of inherited diseases of amino acids and organic acids
49 **including immunoglobulin E and nonimmunoglobulin E mediated allergies to multiple**
50 **food proteins, food protein-induced enterocolitis syndrome, eosinophilic disorders, and**
51 **impaired absorption of nutrients caused by disorders affecting the absorptive surface,**
52 **functional length, and motility of the gastrointestinal tract,** the department shall provide such
53 formula to persons with inherited diseases of amino acids and organic acids subject to the
54 conditions described in this subsection. State assistance pursuant to this subsection shall be

55 available to an applicant only after the applicant has shown that the applicant has exhausted all
56 benefits from third-party payers, including, but not limited to, health insurers, domestic health
57 services corporations, health maintenance organizations, Medicare, Medicaid and other
58 government assistance programs. **For purposes of this section, “amino acid-based elemental
59 formulas” means formulas made from single nonallergenic amino acids.**

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

61 (1) Applicants ages birth to five years old meeting the qualifications under subsection
62 7 of this section;

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

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

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

74 9. The department shall have authority over the use, retention, and disposal of biological
75 specimens and all related information collected in connection with newborn screening tests
76 conducted under subsection 1 of this section. The use of such specimens and related information
77 shall only be made for public health purposes and shall comply with all applicable provisions of
78 federal law. The department may charge a reasonable fee for the use of such specimens for
79 public health research and preparing and supplying specimens for research proposals approved
80 by the department.

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