

House _____ Amendment NO. _____

Offered By _____

1 AMEND House Committee Substitute for Senate Committee Substitute for Senate Bill No. 716,
2 Page 1, Section A, Line 2, by inserting after all of said section and line the following:

3
4 "191.331. 1. Every infant who is born in this state shall be tested for phenylketonuria and
5 such other metabolic or genetic diseases as are prescribed by the department. The test used by the
6 department shall be dictated by accepted medical practice and such tests shall be of the types
7 approved by the department. All newborn screening tests required by the department shall be
8 performed by the department of health and senior services laboratories. Each birthing hospital or
9 birth center in the state shall designate an employee to be responsible for the newborn screening
10 program in that institution. The attending physician, certified nurse midwife, public health facility,
11 ambulatory surgical center or hospital shall assure that appropriate specimens are collected and all
12 information requested is provided on the newborn screening collection forms purchased from the
13 department and submitted to [the department of health and senior services laboratories] the
14 appropriate courier service pickup location as soon as the specimens are dry, which shall be a
15 minimum of three hours from the time of collection, and no later than within twenty-four hours of
16 collection in order to be transported to the department of health and senior services laboratory by the
17 next scheduled courier pickup. If courier service is not available at the facility or at a location
18 nearby, then first-class mail or other appropriate means can be utilized within the same time
19 constraints for the sending of the specimens.

20 2. Specimens shall be collected in accordance with instructions on the specimen collection
21 form. The timing of specimen collection shall be determined by the conditions specified as follows:

22 (1) A specimen shall be taken from all infants before being discharged from the hospital or
23 birthing facility regardless of age. A specimen collected between twenty-four and forty-eight hours
24 of age is considered optimum for newborn screening. A second or repeat specimen shall be required
25 within fourteen days of age if the initial specimen was collected before twenty-four hours of age;

26 (2) Initial specimens from ill or premature infants shall be collected before a blood
27 transfusion or between twenty-four to forty-eight hours of age. All ill or premature infants shall
28 have a repeat screen collected between seven to fourteen days of age;

29 (3) If an infant has been transferred from one hospital to another, the records shall clearly
30 indicate if a specimen for newborn screening was collected and submitted. If no specimen was
31 collected, the hospital the infant was transferred to shall collect a specimen and submit it within
32 forty-eight hours of the transfer.

33 3. All physicians, certified nurse midwives, certified professional midwives, lay midwives,
34 public health nurses and administrators of ambulatory surgical centers or hospitals shall report to the
35 department all diagnosed cases of phenylketonuria and other metabolic or genetic diseases as
36 designated by the department. The health care provider caring for an infant with an abnormal

Action Taken _____ Date _____

1 high-risk test report from newborn screening shall report a definitive diagnosis within thirty days of
 2 the date of diagnosis for such infant to the appropriate newborn screening follow-up center as
 3 contracted by the department. The department shall prescribe and furnish all necessary reporting
 4 forms.

5 [3.] 4. The department shall develop and institute educational programs concerning
 6 phenylketonuria and other metabolic and genetic diseases and assist parents, physicians, hospitals
 7 and public health nurses in the management and basic treatment of these diseases.

8 [4.] 5. The provisions of this section shall not apply if the parents of such child object to the
 9 tests or examinations provided in this section on the grounds that such tests or examinations conflict
 10 with their religious tenets and practices.

11 [5.] 6. As provided in subsection [4] 5 of this section, the parents of any child who fail to
 12 have such test or examination administered after notice of the requirement for such test or
 13 examination shall be required to document in writing such refusal. All physicians, certified nurse
 14 midwives, certified professional midwives, lay midwives, public health nurses and administrators of
 15 ambulatory surgical centers or hospitals shall provide to the parents or guardians a written packet of
 16 educational information developed and supplied by the department of health and senior services
 17 describing the type of specimen, how it is obtained, the nature of diseases being screened, and the
 18 consequences of treatment and nontreatment. The attending physician, certified nurse midwife,
 19 certified professional midwife, lay midwife, public health facility, ambulatory surgical center or
 20 hospital shall obtain the written refusal [and] , make such refusal part of the medical record of the
 21 infant, and send a copy of the written objection to the department.

22 [6.] 7. Notwithstanding the provisions of section 192.015 to the contrary, the department
 23 may, by rule, annually determine and impose a reasonable fee for each newborn screening test made
 24 in any of its laboratories. The department may collect the fee from any entity or individual described
 25 in subsection 1 of this section in a form and manner established by the department. Such fee shall be
 26 considered as a cost payable to such entity by a health care third-party payer, including, but not
 27 limited to, a health insurer operating pursuant to chapter 376, a domestic health services corporation
 28 or health maintenance organization operating pursuant to chapter 354, and a governmental or
 29 entitlement program operating pursuant to state law. Such fee shall not be considered as part of the
 30 internal laboratory costs of the persons and entities described in subsection 1 of this section by such
 31 health care third-party payers. No individual shall be denied screening because of inability to pay.
 32 Such fees shall be deposited in a separate account in the public health services fund created in section
 33 192.900, and funds in such account shall be used for the support of the newborn screening program
 34 and activities related to the screening, diagnosis, and treatment, including special dietary products, of
 35 persons with metabolic and genetic diseases; and follow-up activities that ensure that diagnostic
 36 evaluation, treatment and management is available and accessible once an at-risk family is identified
 37 through initial screening; and for no other purpose. These programs may include education in these
 38 areas and the development of new programs related to these diseases.

39 [7.] 8. Subject to appropriations provided for formula for the treatment of inherited diseases
 40 of amino acids and organic acids, the department shall provide such formula to persons with
 41 inherited diseases of amino acids and organic acids subject to the conditions described in this
 42 subsection. State assistance pursuant to this subsection shall be available to an applicant only after
 43 the applicant has shown that the applicant has exhausted all benefits from third-party payers,
 44 including, but not limited to, health insurers, domestic health services corporations, health
 45 maintenance organizations, Medicare, Medicaid and other government assistance programs.

46 [8.] 9. Assistance under subsection [7] 8 of this section shall be provided to the following:

47 (1) Applicants ages birth to five years old meeting the qualifications under subsection [7] 8
 48 of this section;

1 (2) Applicants between the ages of six to eighteen meeting the qualifications under
2 subsection [7] 8 of this section and whose family income is below three hundred percent of the
3 federal poverty level;

4 (3) Applicants between the ages of six to eighteen meeting the qualifications under
5 subsection [7] 8 of this section and whose family income is at three hundred percent of the federal
6 poverty level or above. For these applicants, the department shall establish a sliding scale of fees
7 and monthly premiums to be paid in order to receive assistance under subsection [7] 8 of this section;
8 and

9 (4) Applicants age nineteen and above meeting the qualifications under subsection [7] 8 of
10 this section and who are eligible under an income-based means test established by the department to
11 determine eligibility for the assistance under subsection [7] 8 of this section.

12 [9.] 10. The department shall have authority over the use, retention, and disposal of
13 biological specimens and all related information collected in connection with newborn screening
14 tests conducted under subsection 1 of this section. The use of such specimens and related
15 information shall only be made for public health purposes and shall comply with all applicable
16 provisions of federal law. The department may charge a reasonable fee for the use of such specimens
17 for public health research and preparing and supplying specimens for research proposals approved
18 by the department.

19 11. If any person or entity has reason to believe that a physician, certified nurse midwife,
20 certified professional midwife, lay midwife, public health facility, ambulatory surgical center, or
21 hospital has violated a provision of this section, such person or entity shall file a complaint with the
22 department. Upon receipt of such a complaint, the department shall conduct an investigation of the
23 suspected physician, certified nurse midwife, certified professional midwife, lay midwife, public
24 health facility, ambulatory surgical center, or hospital."; and

25
26 Further amend said bill by amending the title, enacting clause, and intersectional references
27 accordingly.