FIRST REGULAR SESSION

[PERFECTED]

HOUSE COMMITTEE SUBSTITUTE FOR

HOUSE BILL NO. 948

94TH GENERAL ASSEMBLY

Reported from the Committee on Health Care Policy April 4, 2007 with recommendation that House Committee Substitute for House Bill No. 948 Do Pass. Referred to the Committee on Rules pursuant to Rule 25(21)(f).

Reported from the Committee on Rules April 11, 2007 with recommendation that the House Committee Substitute Do Pass.

Taken up for Perfection April 19, 2007. House Committee Substitute ordered Perfected and printed.

D. ADAM CRUMBLISS, Chief Clerk

2393L.05P

AN ACT

To repeal sections 191.300, 191.317, and 191.331, RSMo, and to enact in lieu thereof three new sections relating to genetic and metabolic disease programs.

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

Section A. Sections 191.300, 191.317, and 191.331, RSMo, are repealed and three new sections enacted in lieu thereof, to be known as sections 191.300, 191.317, and 191.331, to read as follows:

191.300. As used in sections 191.300 to 191.380, the following terms mean:

(1) "Committee", the Missouri genetic disease advisory committee;

(2) "Cystic fibrosis", a serious lung problem of children; an inherited disorder which produces chronic involvement of the respiratory and digestive systems;

(3) "Department", the department of health and senior services;

(4) "Director", the director of the state department of health and senior services;

(5) "Genetic counseling", the provision and interpretation of medical information based on expanding knowledge of human genetics;

(6) "Genetic disorders", abnormalities of structure, function, or body metabolism which may be inherited or may result from damage to the fetus;

(7) "Genetic screening", the search through testing for persons with genetic disorders;

(8) **"Health care professional", a physician or other health care practitioner licensed, accredited, or certified by the state of Missouri to perform specified health services;**

(9) "Health care services", services for the diagnosis, treatment, cure, or relief of a health condition, illness, injury, or disease;

(10) "Hemophilia", a bleeding tendency resulting from a genetically determined deficiency factor in the blood;

[(9)**] (11)** "Outreach clinics", medical clinics which provide genetic diagnosis and counseling at sites away from the tertiary genetic centers;

[(10)**] (12)** "Program", the genetic program authorized by the provisions of sections 191.300 to 191.331, 191.340, and 191.365 to 191.380;

[(11)**] (13)** "Sickle cell anemia", a blood disease characterized by the presence of crescent shaped or sickle shaped erythrocytes in peripheral blood, excessive hemolysis, and active hematopoiesis, resulting from a genetic defect;

[(12)**] (14)** "Sickle cell trait", the healthy state wherein one carries the gene for sickle cell and could possibly pass that gene to his offspring;

[(13)**] (15)** "Tertiary genetic centers", permanent genetic divisions that provide comprehensive diagnostic treatment and counseling services.

191.317. **1.** All testing results and personal information obtained from any individual, or from specimens from any individual, shall be held confidential and be considered a confidential medical record, except for such information as the individual, parent or guardian consents to be released; but the individual must first be fully informed of the scope of the information requests to be released, of the risks, benefits and purposes for such release, and of the identity of those to whom the information will be released. Statistical data compiled without reference to the identity of any individual shall not be declared confidential. **Notwithstanding any other provision of law to the contrary, the department may release the results of newborn screening tests to a child's health care professional.**

2. The specimen shall be retained for five years after initial submission to the department. After five years, the specimen shall be destroyed. Unless otherwise directed under this section, a biological specimen may be released for purposes of anonymous scientific study. At the time of collection, the parent or legal guardian of the child from whom a biological specimen was obtained may direct the department to:

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

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

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

3. A biological specimen released for anonymous study under this section shall not 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 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.

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

ambulatory surgical center or hospital shall obtain the written refusal and make such refusal part of the medical record of the infant.

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

7. Subject to appropriations provided for formula for the treatment of inherited diseases of amino acids and organic acids, the department shall provide such formula to persons with inherited diseases of amino acids and organic acids subject to the conditions described in this subsection. State assistance pursuant to this subsection shall be available to an applicant only after the applicant has shown that the applicant has exhausted all benefits from third party payers, including, but not limited to, health insurers, domestic health services corporations, health maintenance organizations, Medicare, Medicaid and other government assistance programs. **[**The department shall establish an income-based means test to be used to determine eligibility for the formula made available pursuant to this section.**]**

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

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

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

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

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

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

✓