LEGISLATIVE BILL 119

Approved by the Governor March 20, 2003

Introduced by Brown, 6

AN ACT relating to medical tests; to amend sections 71-1,104.01 and 71-519, Revised Statutes Supplement, 2002; to change provisions relating to genetic testing and metabolic disease testing; and to repeal the original sections.

Be it enacted by the people of the State of Nebraska,

Section 1. Section 71-1,104.01, Revised Statutes Supplement, 2002, is amended to read:

71-1,104.01. (1) Except as provided in section 71-519, a ~~A~~ physician or an individual to whom the physician has delegated authority to perform a selected act, task, or function shall not order a ~~presymptomatic or~~ predictive genetic test without first obtaining the written informed consent of the patient to be tested. Written informed consent consists of a signed writing executed by the patient or the ~~legally authorized~~ representative of ~~the~~ a patient lacking decisional capacity that confirms that the physician or individual acting under the delegated authority of the physician has explained, and the patient or his or her ~~legally authorized~~ representative understands:

(a) The nature and purpose of the ~~presymptomatic or~~ predictive genetic test;

(b) The effectiveness and limitations of the ~~presymptomatic or~~ predictive genetic test;

(c) The implications of taking the ~~presymptomatic or~~ predictive genetic test, including the medical risks and benefits;

(d) The future uses of the sample taken to conduct the ~~presymptomatic or~~ predictive genetic test and the genetic information obtained from the ~~presymptomatic or~~ predictive genetic test;

(e) The meaning of the ~~presymptomatic or~~ predictive genetic test results and the procedure for providing notice of the results to the patient; and

(f) Who will have access to the sample taken to conduct the ~~presymptomatic or~~ predictive genetic test and the genetic information obtained from the ~~presymptomatic or~~ predictive genetic test, and the patient's right to confidential treatment of the sample and the genetic information.

(2) The Department of Health and Human Services shall develop and distribute a model informed consent form for purposes of this section. The department shall include in the model form all of the information required under subsection (1) of this section. The department shall distribute the model form and all revisions to the form to physicians and other individuals subject to this section upon request and at no charge. The department shall review the model form at least annually for five years after the first model form is distributed and shall revise the model form if necessary to make the form reflect the latest developments in medical genetics. The department may also develop and distribute a pamphlet that provides further explanation of the information included in the model form.

(3) If a patient or his or her ~~legally authorized~~ representative signs a copy of the model informed consent form developed and distributed under subsection (2) of this section, the physician or individual acting under the delegated authority of the physician shall give the patient a copy of the signed informed consent form and shall include the original signed informed consent form in the patient's medical record.

(4) If a patient or his or her ~~legally authorized~~ representative signs a copy of the model informed consent form developed and distributed under subsection (2) of this section, the patient is barred from subsequently bringing a civil action for damages against the physician, or an individual to whom the physician delegated authority to perform a selected act, task, or function, who ordered the ~~presymptomatic or~~ predictive genetic test, based upon failure to obtain informed consent for the ~~presymptomatic or~~ predictive genetic test.

(5) A physician's duty to inform a patient under this section does not require disclosure of information beyond what a physician reasonably well-qualified ~~physician licensed in Nebraska~~ to order and interpret the predictive genetic test would know. A person acting under the delegated authority of a physician shall understand and be qualified to provide the information required by subsection (1) of this section.

(6) For purposes of this section:

(a) Genetic information means information about a gene, gene product, or inherited characteristic derived from a genetic test;

(b) Genetic test means the analysis of human DNA, RNA, ~~and~~ chromosomes, epigenetic status, and those tissues, proteins, and metabolites used to detect heritable or somatic disease-related genotypes or karyotypes for clinical purposes. ~~A genetic test must be~~ Tests of tissues, proteins, and metabolites are included only when generally accepted in the scientific and medical communities as being specifically determinative ~~for the presence, absence, or mutation of a gene or chromosome in order to qualify under this definition~~ of a heritable or somatic disease-related genetic condition. Genetic test does not include ~~a routine physical examination or~~ a routine analysis, including a chemical analysis, of body fluids or tissues unless conducted specifically to determine ~~the presence, absence, or mutation of a gene or chromosome~~ a heritable or somatic disease-related genetic condition. Genetic test does not include a physical examination or imaging study. Genetic test does not include a procedure performed as a component of biomedical research that is conducted pursuant to federal common rule under 21 C.F.R. parts 50 and 56 and 45 C.F.R. part 46, as such regulations existed on ~~September 1, 2001,~~ January 1, 2003; and

(c) Predictive genetic test means a genetic test for an otherwise undetectable genotype or karyotype relating to the risk for developing a genetically related disease or disability, the results of which can be used to substitute a patient's prior risk based on population data or family history with a risk based on genotype or karyotype. Predictive genetic test does not include diagnostic testing conducted on a person exhibiting clinical signs or symptoms of a possible genetic condition. Predictive genetic testing does not include prenatal genetic diagnosis, unless the prenatal testing is conducted for an adult-onset condition not expected to cause clinical signs or symptoms before the age of majority. ~~performed for the purpose of predicting the future probability that the patient will develop a genetically related disease or disability, and~~

~~(d) Presymptomatic genetic test means a genetic test performed before the onset of clinical symptoms or indications of disease.~~

Sec. 2. Section 71-519, Revised Statutes Supplement, 2002, is amended to read:

71-519. (1) All infants born in the State of Nebraska shall be screened for phenylketonuria, primary hypothyroidism, biotinidase deficiency, galactosemia, hemoglobinopathies, medium-chain acyl co-a dehydrogenase (MCAD) deficiency, and such other metabolic diseases as the Department of Health and Human Services may from time to time specify. Confirmatory tests shall be performed if a presumptive positive result on the screening test is obtained.

(2) The attending physician shall collect or cause to be collected the prescribed blood specimen or specimens and shall submit or cause to be submitted the same to the laboratory designated by the department for the performance of such tests within the period and in the manner prescribed by the department. If a birth is not attended by a physician and the infant does not have a physician, the person registering the birth shall cause such tests to be performed within the period and in the manner prescribed by the department. The laboratory shall within the period and in the manner prescribed by the department perform such tests as are prescribed by the department on the specimen or specimens submitted and report the results of these tests to the physician, if any, the hospital or other birthing facility or other submitter, and the department. The laboratory shall report to the department the results of such tests that are presumptive positive or confirmed positive within the period and in the manner prescribed by the department.

(3) The hospital or other birthing facility shall record the collection of specimens for tests for metabolic diseases and the report of the results of such tests or the absence of such report. For purposes of tracking, monitoring, and referral, the hospital or other birthing facility shall provide from its records, upon the department's request, information about the infant's and mother's location and contact information, and care and treatment of the infant.

(4)(a) The department shall have authority over the use, retention, and disposal of blood specimens and all related information collected in connection with metabolic disease testing conducted under subsection (1) of this section.

(b) The department shall adopt and promulgate rules and regulations relating to the retention and disposal of such specimens. The rules and regulations shall: (i) Be consistent with nationally recognized standards for laboratory accreditation and shall comply with all applicable provisions of

federal law; (ii) require that the disposal be conducted in the presence of a witness who may be an individual involved in the disposal or any other individual; and (iii) provide for maintenance of a written or electronic record of the disposal, verified by such witness.

(c) The department shall adopt and promulgate rules and regulations relating to the use of such specimens and related information. Such use 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 evaluating proposals relating to the use of such specimens for public health research and for preparing and supplying specimens for research proposals approved by the department.

~~(4) The department shall do all of the following in regard to the blood specimens taken for purposes of conducting the tests required under subsection (1) of this section:~~

~~(a) Develop a schedule for the retention and disposal of the blood specimens used for the tests after the tests are completed. The schedule shall meet the following requirements:~~

~~(i) Be consistent with nationally recognized standards for laboratory accreditation and federal law;~~

~~(ii) Require that the disposal be conducted in the presence of a witness. For purposes of this subdivision, the witness may be an individual involved in the disposal or any other individual; and~~

~~(iii) Require that a written record of the disposal be made and kept and that the witness sign the record; and~~

~~(b) With the written consent of the parent or legal guardian of the infant, allow the blood specimens to be used for medical research during the retention period as long as the medical research is conducted in a manner that preserves the confidentiality of the test subjects and is consistent to protect human subjects from research risks under subpart A of part 46 of 45 C.F.R., as such regulations existed on September 1, 2001.~~

(5) The department shall prepare written materials explaining the requirements of this section. The department shall include the following information in the pamphlet:

(a) The nature and purpose of the testing program required under this section, including, but not limited to, a brief description of each condition or disorder listed in subsection (1) of this section;

(b) The purpose and value of the infant's parent, guardian, or person in loco parentis retaining a blood specimen obtained under subsection (6) of this section in a safe place;

(c) The department's ~~schedule~~ procedures for retaining and disposing of blood specimens developed under subsection (4) ~~subdivision (4)(a)~~ of this section; and

(d) That the blood specimens taken for purposes of conducting the tests required under subsection (1) of this section may be used for ~~medical~~ research pursuant to subsection (4) ~~subdivision (4)(b)~~ of this section.

(6) In addition to the requirements of subsection (1) of this section, the attending physician or person registering the birth may offer to draw an additional blood specimen from the infant. If such an offer is made, it shall be made to the infant's parent, guardian, or person in loco parentis at the time the blood specimens are drawn for purposes of subsection (1) of this section. If the infant's parent, guardian, or person in loco parentis accepts the offer of an additional blood specimen, the blood specimen shall be preserved in a manner that does not require special storage conditions or techniques, including, but not limited to, lamination. The attending physician or person making the offer shall explain to the parent, guardian, or person in loco parentis at the time the offer is made that the additional blood specimen can be used for future identification purposes and should be kept in a safe place. The attending physician or person making the offer may charge a fee that is not more than the actual cost of obtaining and preserving the additional blood specimen.

(7) The person responsible for causing the tests to be performed under subsection (2) of this section shall inform the parent or legal guardian of the infant of the tests and of the results of the tests and provide, upon any request for further information, at least a copy of the written materials prepared under subsection (5) of this section.

(8) Dietary and therapeutic management of the infant with phenylketonuria, primary hypothyroidism, biotinidase deficiency, galactosemia, hemoglobinopathies, MCAD deficiency, or such other metabolic diseases as the department may from time to time specify shall be the responsibility of the child's parent, guardian, or custodian with the aid of a physician selected by such person.

(9) Except for acts of gross negligence or willful or wanton

conduct, any physician, hospital or other birthing facility, laboratory, or other submitter making reports or notifications under sections 71-519 to 71-524 shall be immune from criminal or civil liability of any kind or character based on any statements contained in such reports or notifications.

Sec. 3. Original sections 71-1,104.01 and 71-519, Revised Statutes Supplement, 2002, are repealed.