LEGISLATURE OF NEBRASKA

ONE HUNDRED FIRST LEGISLATURE

SECOND SESSION

LEGISLATIVE BILL 1038

Introduced by Fulton, 29.

Read first time January 21, 2010

Committee: Health and Human Services

A BILL

FOR AN ACT relating to genetic testing; to amend section 71-551, Reissue Revised Statutes of Nebraska; to change provisions relating to written informed consent for genetic tests as prescribed; to harmonize provisions; and to repeal the original section.

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

Section 1. Section 71-551, Reissue Revised Statutes of Nebraska, is amended to read:

71-551 (1) Except as provided in section 71-519 and except for newborn screening tests ordered by physicians to comply with the law of the state in which the infant was born, a physician or an individual to whom the physician has delegated authority to perform a selected act, task, or function shall not order a genetic test 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 representative of 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 representative understands:

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

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

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

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

(e) The meaning of the genetic test 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 genetic test or predictive genetic test and the genetic information obtained from the genetic test or predictive genetic test, and the patient's right to confidential treatment of the sample and the genetic information; and~~.~~

(g) The financial cost of the genetic test or predictive genetic test, including the portion of the financial cost of the genetic test or predictive genetic test which will be paid for by the patient's insurance provider.

(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 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 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 genetic test or predictive genetic test, based upon failure to obtain informed consent for the genetic test 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 to order and interpret the genetic test or 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, chromosomes, epigenetic status, and those tissues, proteins, and metabolites used to detect heritable or somatic disease-related genotypes or karyotypes for clinical purposes. Tests of tissues, proteins, and metabolites are included only when generally accepted in the scientific and medical communities as being specifically determinative of a heritable or somatic disease-related genetic condition. Genetic test does not include a routine analysis, including a chemical analysis, of body fluids or tissues unless conducted specifically to determine 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 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.

Sec. 2. Original section 71-551, Reissue Revised Statutes of Nebraska, is repealed.