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SFA BILL ANALYSIS

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Senate Bill 593 (Substitute S-3)
Sponsor: Senator Mike Goschka
Committee: Health Policy

Date Completed: 10-18-99

CONTENT

The bill would amend the Public Health Code to prohibit a genetic test from being ordered without the written informed consent of the test subject; prescribe the content of the written informed consent; and require the Department of Consumer and Industry Services (DCIS) to develop a model informed consent form. "Genetic test" would mean the analysis of human DNA, RNA, chromosomes, and those proteins and metabolites used to detect heritable or somatic disease-related genotypes or karyotypes for clinical purposes. A genetic test would have to be generally accepted in the scientific and medical communities as being specifically determinative for the presence, absence, or mutation of a gene or chromosome to qualify as a genetic test under the bill. "Genetic test" would not include a routine physical examination or a routine analysis, including but not limited to a chemical analysis of body fluids, unless conducted specifically to determine the presence, absence, or mutation of a gene or chromosome. "Genetic information" would mean information about a gene, gene product, or inherited characteristic derived from a genetic test.

The bill provides that beginning six months after its effective date a physician, or an individual to whom the physician had delegated authority to perform a selected act, task, or function, could not order a genetic test without first obtaining the written, informed consent of the test subject. Written, informed consent would consist of a signed writing executed by the test subject, or the legally authorized representative of the test subject, that included, at a minimum, all of the following:

-- The nature and purpose of the genetic test.
-- The effectiveness and limitations of the genetic test.
-- The implications of taking the genetic test, including, but not limited to, the potential medical risks and benefits.
-- The potential future uses of the sample taken from the test subject in order to conduct the genetic test and the information obtained from the genetic test.
-- The meaning of the genetic test results and the procedure for providing notice of the results to the test subject.
-- Who would have access to the sample taken from the test subject in order to conduct the genetic test and the information obtained from it, and the test subject's right to confidential treatment of the sample and the information.

Within six months after the bill took effect, the DCIS, in consultation with the Michigan Board of Medicine, the Michigan Board of Osteopathic Medicine and Surgery, and appropriate professional organizations, would have to develop and distribute a model informed consent form that practitioners could adopt. The DCIS would have to include in the model form at least all of the information required to be included in the written informed consent. The DCIS would have to distribute the model form to physicians and other individuals subject to the bill's provisions upon request and at no charge. The Department, in consultation with the boards, also could develop and distribute a pamphlet that provided further explanation of the information included in the model form.

If a test subject, or his or her legally authorized representative, signed a copy of the model informed consent form, the physician, or an individual acting under the delegatory authority of the physician, would have to give the test subject a copy of the form, and include the original form in the test subject's medical record. The physician or other individual also would have to have the test subject, or his or her legally authorized

representative, sign a form indicating that he or she had been given a copy of the form, and include that form in the test subject's medical record.

If a test subject, or his or her legally authorized representative, signed the informed consent form developed by the DCIS, the test subject would be barred from subsequently bringing a civil action for damages against the physician (or an individual to whom the physician delegated the authority to perform a selected act, task, or function) who ordered the genetic test based on failure to obtain informed consent for the genetic test.

A health professional who violated the provisions of the bill would be subject to a reprimand or fine.

The bill's requirement that a genetic test not be performed without the informed consent of the test subject would not apply to the required newborn screening tests required under the Code; or as otherwise provided by law.

MCL 333.16221 et al. Legislative Analyst: G. Towne

FISCAL IMPACT

According to the Department of Consumer and Industry Services, this bill could increase the regulatory responsibilities of the Department as additional complaints would be filed and investigations would need to be conducted. Additionally, the administrative responsibilities would increase in order for the DCIS to develop and distribute the standard informed consent form. As it is difficult to predict the number of additional investigations this legislation would prompt, the actual cost is unavailable at this time.

Fiscal Analyst: M. Tyszkiewicz