



Senate Fiscal Agency
P. O. Box 30036
Lansing, Michigan 48909-7536

BILL ANALYSIS



Telephone: (517) 373-5383
Fax: (517) 373-1986
TDD: (517) 373-0543

Senate Bill 467 (as introduced 5-5-05)
Sponsor: Senator Tom George
Committee: Health Policy

Date Completed: 4-18-06

CONTENT

The bill would amend the Public Health Code to provide for the confidentiality of information regarding genetic testing performed on an individual; restrict the disclosure of such information; and authorize sanctions to be imposed on a person who violated the bill's provisions.

Physicians

Under Sections 17020 and 17520 of the Code, a physician or an individual to whom the physician has delegated authority to perform a selected act, task, or function may not order a presymptomatic or predictive genetic test without first obtaining the test subject's written, informed consent. (The informed consent requirements and definitions are described below, under **BACKGROUND.**)

Under the bill, the fact that a presymptomatic or predictive genetic test had been ordered and conducted under Section 17020 or 17520, and the results of that test would be privileged and confidential. Except as otherwise provided by law, a person could not disclose that a test had been ordered or conducted, or the test results, without first obtaining written authorization from the test subject or his or her legally authorized representative.

The written authorization would have to be on a form that was separate from any other required written, informed consent form, would have to identify to whom the information was to be disclosed, and would have to include the following notice:

"NOTICE OF RIGHTS WITH REGARD TO GENETIC TESTING AND INFORMATION:

Michigan law restricts requests by health insurers, nonprofit health care corporations, health maintenance organizations, and employers for individuals to submit to genetic testing, to disclose genetic information, or to disclose whether genetic testing has been conducted or the results of that genetic testing. Individuals who have questions about their rights may seek legal advice."

The bill specifies that a general consent or authorization given for the release of medical records or other information would not constitute written authorization for disclosure of genetic information. A separate written authorization would have to be obtained for each person to whom the information was to be disclosed. If the test subject or his or her legally authorized representative provided written authorization, the person would have to do each of the following:

- Provide the test subject with a copy of the signed written authorization.
- Maintain the original signed written authorization in the subject's medical record.
- Provide the test subject and the person to whom the information was being disclosed with a notice regarding restrictions on further disclosure of genetic testing and information.

The notice would have to read as follows:

"RESTRICTIONS ON FURTHER DISCLOSURE OF GENETIC TESTING AND INFORMATION

This information is privileged and confidential. This information is being provided to you in accordance with Michigan law and shall not be further disclosed without a separate written authorization from the test subject or his or her legally authorized representative. A general consent or authorization for the release of medical records or other information is not sufficient to authorize the disclosure of genetic testing and information."

If a test subject consented to the performance of a genetic test for the sole purpose of assisting in the recovery or identification of human remains from a disaster or assisting in the identification of living or deceased missing people by matching forensic DNA profiles in the event of an emergency or disaster, those results, as well as the DNA profiles, could be disclosed and used only for those identification purposes. They would not be public records, subject to court subpoena, or discoverable in a legal proceeding. Consent provided for testing and DNA profiling for these purposes would not be consent for secondary research using those results or DNA profiles or any other use except for the identification of living or deceased missing people.

Health Facilities & Agencies

Under the bill, all reports, records, and data pertaining to genetic testing or other genetic information would be privileged and confidential. Except as otherwise provided by law, a health facility or agency could not disclose to anyone, other than the physician or the individual to whom the physician delegated authority under the Code, the test results of a presymptomatic or predictive genetic test, or the fact that such a test was ordered, without first obtaining written authorization from the test subject or his or her legally authorized representative, as required under the bill.

If the test subject or legally authorized representative agreed to the disclosure of information relating to his or her genetics or the presymptomatic or predictive genetic testing, or both, to someone other than the physician or the individual to whom the physician delegated the authority to order the testing, he or she would have to provide the health facility or agency with the requisite written authorization.

If the test subject or representative provided written authorization for disclosure, the health facility or agency would have to give the test subject a copy of the signed written authorization, maintain the original signed written authorization in the subject's medical records, and give the test subject and the person to whom the information was being disclosed the notice regarding restrictions on further disclosure of genetic testing and information (described above).

A health facility or agency also would be subject to the requirements and restrictions described above pertaining to a test subject's consent to the performance of genetic testing to assist in the recovery or identification of human remains or missing people would apply.

Sanctions

Under the Code, the Department of Community Health (DCH) may investigate activities related to the practice of a health profession by a licensee, a registrant, or an applicant for

licensure or registration. The DCH must report its finding to the appropriate disciplinary subcommittee, which must impose administrative sanctions if it finds the existence of certain grounds, such as a personal disqualifications, unethical business practices, prohibited acts, or the violation of specific provisions of the Code (including the requirement for a test subject's written, informed consent to a presymptomatic or predictive genetic test). The sanctions may include a reprimand; probation; the denial, suspension, or revocation of a license or registration; restitution; community service; and/or a fine.

Under the bill, the grounds for administrative sanctions would include a violation of the bill's provisions regarding the disclosure of genetic testing information.

MCL 333.16221 et al.

BACKGROUND

Under Sections 17010 and 17520 of the Public Health Code, for the purposes of ordering a presymptomatic or predictive genetic test, written, informed consent consists of a signed writing executed by the test subject or his or her legally authorized representative confirming that the physician or individual acting under the physician's delegatory authority has explained, and the test subject or representative understands, at a minimum, all of the following:

- The nature and purpose of the test.
- The effectiveness and limitations of the test.
- The implications of taking the test, including the medical risks and benefits.
- The future uses of the sample taken from the test subject in order to conduct the test, and the information obtained from the test.
- The meaning of the test results and the procedure for providing notice to the test subject.
- Who will have access to the sample and the information obtained from the test, as well as the test subject's right to confidential treatment of the sample and information.

If a test subject or his or her legally authorized representative signs a copy of the informed consent form, he or she is barred from bringing a civil action for damages against the physician, or individual to whom the physician delegated authority, based on failure to obtain informed consent for the test.

"Genetic information" means information about a gene, gene product, or inherited characteristic that is derived from a genetic test. "Genetic test" means 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. The term does not include a routine physical examination or a routine analysis, including a chemical analysis, of body fluids, unless conducted specifically to determine the presence, absence, or mutation of a gene or chromosome. A genetic test must be accepted generally 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.

"Presymptomatic genetic test" means a genetic test performed before the onset of clinical symptoms or indications of disease. "Predictive genetic test" means a genetic test performed for the purpose of predicting the future probability that the test subject will develop a genetically related disease or disability.

Legislative Analyst: Julie Koval

FISCAL IMPACT

The bill would have no fiscal impact on State or local government.

Fiscal Analyst: David Fosdick

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This analysis was prepared by nonpartisan Senate staff for use by the Senate in its deliberations and does not constitute an official statement of legislative intent.