House
Legislative
Analysis
Section

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GENETICS TESTING: INFORMED CONSENT AND DISPOSAL OF SAMPLES

Senate Bill 593 (Substitute H-2)
Sponsor: Sen. Michael Goschka

Senate Bill 594 as introduced
Sponsor: Sen. Mike Rogers

Senate Bill 595 (Substitute H-1)
Sponsor: Sen. Joel Gougeon

Senate Bill 815 (Substitute H-1)
Sponsor: Sen. Beverly Hammerstrom

House Committee: Health Policy
Senate Committee: Health Policy

First Analysis (2-22-00)

THE APPARENT PROBLEM:

The Governor's Commission on Genetic Privacy and Progress was created September 26, 1997 by Executive Order 1997-14 and charged with, among other things, recommending legislation and administrative policies that would protect the privacy of genetic information and prevent discrimination in employment. The commission held public forums on various issues surrounding genetic privacy, and the commission's final report was released in February of 1999. During the public forums, it became clear that many people were concerned that genetic information could be used by employers to discriminate in hiring or promotion decisions. Others felt that the public needed to be more clearly educated about genetic tests, and in particular, about who would have access to the samples used for the tests and to the test results. Additional concerns centered on the retention and destruction of DNA samples and reports related to paternity testing and forensic tests, especially when a man is found not to be the father of a child in question and when a person is eliminated as a suspect in a criminal investigation. The commission, after studying these and other concerns, adopted recommendations for the protection of privacy. In light of the concerns of the citizens of Michigan, and the recommendations of the commission, legislation has been introduced to prohibit employers from discriminating against employees or applicants based on genetic information, require doctors to obtain written consent before ordering genetic tests, and strengthen existing laws pertaining to the destruction of test samples and written reports for those eliminated as suspects in criminal investigations and for those men found not to be the father in a paternity proceeding.

THE CONTENT OF THE BILLS:

The bills are part of a package that address issues of genetic privacy. Specifically, the bills would do the following:

Senate Bill 593 would amend Part 170 (which regulates doctors of allopathic medicine) and Part 175 (which regulates osteopathic physicians) of the Public Health Code (MCL 333.16221 et al.) to require written, informed consent before a genetic test could be ordered. Except for tests performed under the newborn screening program administered by the Department of Community Health or other tests allowed under current law (e.g., mandatory DNA profiling for convictions of murder, kidnaping, and sex offenses), beginning six months from the bill's effective date, a physician could not order a presymptomatic or predictive genetic test without obtaining the written, informed consent of the test subject. A "presymptomatic genetic test" would

mean a genetic test performed before the onset of clinical symptoms or indications of disease. A "predictive genetic test" would mean a genetic test performed for the purpose of predicting the future probability that the test subject would develop a genetically related disease or disability. "Genetic information" would be defined as information about a gene, gene product, or inherited characteristic that was derived from a genetic test. The definition of a "genetic test" contained in the bill would require the test used 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, and would refer to the test as an analysis of human DNA, RNA, chromosomes, and proteins and metabolites used in detecting disease-related components. A genetic test would not include a routine analysis such as a chemical analysis of body fluids unless such a test was conducted specifically to determine the presence, absence, or mutation of a gene or chromosome. A genetic test would also not include procedures performed as a component of biomedical research conducted under federal regulations.

Under the bill, the patient or a legal representative would have to sign a consent form confirming that the physician or his or her designee explained, and the person signing the form understood, at least all of the following:

• The nature and purpose of the presymptomatic or predictive genetic 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 (e.g., blood or tissue) taken from the test subject.

• The meaning of the test results and the procedure for providing notice of the test results.

• Who would have access to the sample and to the information obtained from the test results, as well as the test subject's right to confidential treatment of the sample and the information.

A model informed consent form would have to be developed and distributed within six months of the bill's effective date by the Department of Community Health (DCH) in consultation with the Michigan Board Medicine, the Michigan Board of Osteopathic Medicine and Surgery, at least one physician with board certification by the American Board of Medical Genetics, and other appropriate professional organizations. The form would have to include all the information previously discussed, and would be distributed at no cost upon request from a physician or other individual. The department would have to review the model form at least annually for the first five years, and revise the form if necessary to reflect the latest developments in medical genetics. The department, in conjunction with the above entities, could also develop and distribute a pamphlet that further explained the information included in the model informed consent form.

A copy of a signed model informed consent form would have to be given to the patient or his or her legal representative, and the original placed in the subject's medical record. A patient who had signed the model informed consent form could not bring an action later against the physician who had ordered the test by claiming that he or she had not been informed on the genetic test ordered. A physician's duty to inform a patient would not require disclosure of information beyond what a reasonably well-qualified physician would know. Further, a physician who failed to get the written, informed consent of a patient before ordering a genetic test could be subject to administrative reprimand or a fine.

Senate Bill 594 would amend the DNA Identification Profiling System Act (MCL 28.176) to provide that if the state police forensic laboratory determined after analysis that a sample had been submitted by an individual who had been eliminated as a suspect in a crime, the laboratory would have to dispose of the sample and the corresponding DNA identification profile record. The sample would have to be disposed of in compliance with the requirements of the Public Health Code regarding disposal of medical wastes. The sample and the profile record would have to be disposed of in the presence of a witness. After disposal, the laboratory would have to make and keep a written record of the disposal, signed by the witness.

Currently, under the act, the Department of State Police is required to retain permanently a DNA identification profile of an individual if he or she is convicted of or found responsible for murder, attempted murder, kidnaping, or criminal sexual conduct. Any other DNA identification profile must be retained only as long as it is needed for a criminal investigation or prosecution.

Senate Bill 595 would amend the Paternity Act (MCL 722.711 et al.) to revise provisions regarding court-ordered blood or tissue tests to determine paternity, specifically in regard to DNA identification profiling.

Currently, in a paternity proceeding before trial, upon application made by either party or on its own motion, the court may order a mother, child, and alleged father to submit to blood or tissue typing determinations, including DNA profiles, to determine whether the alleged father is likely to be, or is not, the father of the child. The bill would refer to DNA identification profiling, rather than DNA profiles.

Under the act, if the result of blood or tissue typing or a DNA profile is inconclusive, a written report including a calculation of the probability of paternity must be filed with the court. The bill provides instead that the result of blood or tissue typing or a DNA identification profile and a summary report would have to be filed with the court. A "summary report" would be a written summary of the DNA identification profile that included only specified information.

Currently, if a man is found not to be the child's father, the court must order his genetic testing material to be destroyed. The bill provides, instead, that the contracting laboratory would have to destroy the material in the presence of a witness and in compliance with the Public Health Code's requirements for the disposal of medical waste. After the man's genetic testing material was destroyed, the contracting laboratory would have to make and keep a written record of the destruction, and have the individual who witnessed it sign the record. The laboratory also would have to expunge its records regarding the genetic paternity testing performed on the material.

Each year, a contracting laboratory would have to conduct an independent audit verifying its compliance with the bill's requirements. The audit could not identify the test subjects required to submit to blood or tissue typing or DNA identification profiling. The laboratory would have to forward the audit to the Department of Consumer and Industry Services.

Senate Bill 815 would amend the Persons with Disabilities Civil Rights Act (MCL 37.1201 and 37.1202) to prohibit an employer from requiring an individual to submit to a genetic test or to provide genetic information as a condition of employment or promotion; and to place in the act a definition of "genetic information" and "genetic test".

Currently, the act prohibits an employer, on the basis of an individual's disability that is unrelated to the individual's ability to perform the job, from failing or refusing to hire, recruit, promote, or discharge the individual; discriminating against the individual with respect to compensation or the terms, conditions, or privileges of employment; or limiting, segregating, or classifying an employee or applicant in a way that deprives or tends to deprive the individual of employment opportunities or otherwise adversely affects the status of an employee. The bill also would prohibit an employer from taking any of those actions based upon the individual's genetic information. Further, the bill provides that an employer could not take any of the actions prohibited in the act, "except as otherwise required by federal law".

The bill would not prohibit an individual from voluntarily providing to an employer genetic information that was related to the employee's health or safety in the workplace; or prohibit an employer from using genetic information received from an employee to protect the employee's health or safety. In addition, no employer could directly or indirectly acquire or have access to any genetic information concerning an employee or applicant for employment, or a member of the employee's or applicant's family.

"Genetic information" would mean information about a gene, gene product, or inherited characteristic of an individual derived from the individual's family history or a genetic test. "Genetic test" would be defined as it is in Senate Bill 593.

BACKGROUND INFORMATION

In early November of last year, the House Health Policy Committee reported Senate Bills 589, 590, 591, and 807 from committee. Senate Bills 589-591 would amend three acts to prohibit Blue Cross and Blue Shield of Michigan (BCBSM), health insurers, and health maintenance organizations from requiring insured persons or applicants to submit to genetic testing, or to disclose genetic information. Senate Bill 807 would amend provisions of the Public Health Code regarding the newborn screening program conducted by the Department of Community Health. For more information, see the House Legislative Analysis Section's analysis on the bills dated 11-10-99.

FISCAL IMPLICATIONS:

The Senate Fiscal Agency reports in a fiscal note dated 10-22-99 that Senate Bill 593 would have an indeterminate fiscal impact on state and local government. Further, the agency reports that the Department of Community Health could experience nominal costs in developing, printing, and distributing the consent forms.

Senate Bill 594 would have no fiscal impact on state or local government, according to a Senate Fiscal Agency fiscal note dated 10-22-99.

According to a Senate Fiscal Agency report dated 10-25-99, Senate Bill 595 would have an indeterminate fiscal impact on state government. The Family Independence Agency, in relation to its child support enforcement activities, contracts with National Legal Laboratories for the testing of individuals to determine probability of paternity. Currently, the department spends per test approximately $51 per person, or approximately $153 for each test of a trio of persons: the alleged father, the mother, and the child. According to the department, an average of 1,400 persons are tested per month. Therefore, the average monthly cost is about $71,400 gross. Testing costs increased over the past year because of 1998 changes in the act concerning expunging the laboratory's records, and contract costs would increase further under the bill with the inclusion of audit provisions.

With regards to Senate Bill 815, according to the Senate Fiscal Agency in a fiscal note dated 10-26-99, the Department of Civil Rights could be required to investigate claims that violated the proposed provisions of this statute. Because it is unknown how many complaints could be filed, the fiscal impact of the bill is indeterminate. There would be no fiscal impact on local government.

ARGUMENTS:

For:

The bill package is a complement to four bills that have previously passed the Senate and are currently waiting action on the House floor. Together, the eight bills represent a comprehensive approach to protecting the privacy rights of individuals in regard to genetic testing. There are many advantages to early screening and detection of diseases, and as tests become more reliable, people should be encouraged to be tested. For many, this would entail being tested to learn what the likelihood of contracting a particular disease could be. For instance, certain genes are now being identified with particular cancers, such as breast cancer. A woman may want to be screened for the genetic marker if she has one or more close relatives with the disease. Though a positive test result would not be a guarantee that she would develop the disease, the knowledge would be useful in making lifestyle changes, such as not smoking, and in medical decisions, such as whether or not to try a prophylactic approach with medications currently on the market or aggressive surgery such as a mastectomy.

The knowledge of potential risk could help a person to make changes that could help her or him to avoid a disease. Therefore, as predictive tests increase in reliability, they could become an important tool enabling doctor and patient to work together to improve the overall health of the patient, catch diseases at their most curable state, and increase both quality and quantity of life. However, if people have a fear that the information gleaned from genetic tests could be used against them in obtaining or retaining health insurance and employment, it could have a chilling effect on people getting needed tests or being willing to participate in research studies. Further, since DNA testing and profiling is commonly used in determining paternity and in criminal investigations, it is important that the samples used for the testing along with the DNA reports be properly destroyed and confidentiality protected for those who are deemed to not be a child's father and for those eliminated as suspects to a crime.

The bills under discussion would establish employment protection and would require proper disposal of samples and genetic information for those cleared of criminal charges or paternity actions, as well as create an informed consent form to ensure that those undergoing genetic testing fully understand the implications of such testing. Along with the bills previously reported from the House Health Policy Committee (Senate Bills 589-592, which would protect consumers from having to disclose the results of genetic tests to health insurers or to submit to genetic tests as prerequisite to obtaining health insurance), Senate Bills 593-595 and Senate Bill 815 would

incorporate many of the recommendations of the Michigan Commission on Genetic Privacy and Progress. Passage of these bills would be an important first step in establishing appropriate privacy protection for the citizens of Michigan.

For:

According to the final report issued by the Michigan Commission on Genetic Privacy and Progress, complex issues and risks arise in the context of presymptomatic and predictive genetic testing that require more involved informed consent. The commission emphasized that informed consent should be a process whereby the doctor and patient have a dialogue about the benefits and risks of the procedure, and about possible implications of taking the test, such as who could have access to the test results. The commission recommended against legislative attempts to tightly control the specifics of what the informed consent should entail, but did recommend that legislation set minimum standards as to what types of information should be included in the informed consent process. To that end, Senate Bill 593 would require that the Department of Community Health develop a model informed consent form that doctors could use in their discussions with patients. Further, a patient's signature on the form would be required before a doctor could proceed with ordering genetic tests. Obtaining a patient's signature would be beneficial to both the patient and the doctor. Since a signed informed consent form would act as a bar from future litigation, it would provide an important impetus for a doctor to take the time necessary to explain the procedure and the implications of having a genetic test done. In short, the form should encourage an informative dialogue between doctor and patient about genetic testing so that the patient can make the proper choice.

Response:

Though it is true that Senate Bill 593 incorporates the commission's recommendation for minimum standards of an informed consent form, it does not fully represent the commission's concern that a form could become a cut-and-dried legalistic approach by a physician to avoid possible legal liability. The commission emphasized that what is needed is an informed consent process, the informed consent form being merely a component of that process. The issues surrounding genetic testing are indeed complex, merging psychological, economic, and social concerns with medical concerns. For example, certain genetic tests may reveal that a patient does have a serious disease, but is currently not showing symptoms. Where some patients may want to have that type of information, for others it could be psychologically damaging. Others, upon finding that they have a genetic marker for a particular disease such as breast cancer, may decide to undergo radical surgical procedures such as a mastectomy, which also has the implication for social and psychological changes.

To make a decision as to whether to have a genetic test performed, or not, therefore necessitates involved conversations between a doctor and his or her patient; it means the ability for a physician to translate complex medical information and possible emotional effects in a very understandable format. This takes time. Unfortunately, in the day of capitated medicine, time for extended conversations between doctor and patient is rare. Rather than the burden being placed on doctors to communicate effectively with the patient, the bill instead puts the burden on the patient to understand what may be hurriedly communicated. Signing the informed consent form would prohibit a patient from bringing a lawsuit against the doctor later if he or she suffered harm from the genetic test. Again, this puts an unfair burden on the patient. If genetic tests involve such complex and complicated medical and psychological issues, how is the average patient to decide that the information being presented in the doctor's office really represents the situation? Just because a presentation makes sense to a patient would not necessarily ensure that the patient had received the appropriate information. A patient could sign a form in good faith that what is being presented is the most comprehensive presentation of the benefits and risks, and so forth, only to learn later that the doctor had left out crucial information that would have affected the decision to go ahead with the particular test ordered. Yet, he or she would be unable to seek relief for any damages suffered because the signed form would act as a bar.

It is not enough to hand a patient a form with some basic information on it and then declare that a signature means understanding. In fact, a recent study by researchers at the Institute for Ethics at the American Medical Association in Chicago recently analyzed the content of hundreds of hospital consent forms and concluded that the majority of the forms provided "little substantive content to help patients make decisions" (Reuters Health, Jan. 25, 2000). The researchers concluded that the informed consent forms were "likely to increase patient anxiety and frustration, and give the impression that legal protection for the doctor or hospital is more important than patient understanding." The researchers recommended the use of structured interviews and worksheets to aid in discussions between doctors and patients, along with

better training for doctors about the informed consent process.

The informed consent form may be a beginning on which to build an informative dialogue between doctor and patient, but until the time that doctors are more adequately trained to dispense such information and to judge a patient's understanding, the bar from bringing a lawsuit against a doctor should be removed. It is unfair for an untrained patient to bear the greater weight in determining if she or he has been adequately informed to make such a complex decision.

For:

Senate Bill 815 would strengthen protections already contained in the Persons with Disabilities Civil Rights Act. Under the act, it is currently illegal for an employer to fail or refuse to hire, recruit, or promote an individual because of a disability that is unrelated to the individual's ability to perform the duties of a particular job or position. The bill would also make it unlawful for an employer to use genetic information, which would include information derived from an individual's family history, in making such employment decisions. The bill would also prohibit an employer from accessing or acquiring genetic information about an employee or an applicant, or any member of the person's family. This bill would mirror current federal law pertaining to federal employees and legislation that is currently pending before Congress to make it a federal offense for an employer to use results from genetic testing to discriminate against an employee or an applicant for employment.

For:

Senate Bills 594 and 595 primarily deal with the destruction of samples used for DNA testing in criminal investigations and paternity suits. Under current law, after the state forensic laboratory finishes testing samples of people under investigation, it must return samples of any individuals cleared as being suspects to the local law enforcement agency that collected the sample. The bill would instead allow the forensic laboratory to destroy the samples and the corresponding DNA profile report. For those persons who are innocent, this provides an important privacy protection.

Senate Bill 595 would provide a similar protection for those charged in a paternity action. If the man was ruled out as being a child's father, the laboratory that did the testing would have to destroy the sample according to provisions in the Public Health Code pertaining to medical wastes, and the signature of a witness would be required. In addition, any DNA report would also have to be destroyed. Though the samples must be destroyed under current law if a man was found to not be the father, the bill would ensure that the samples were destroyed appropriately and would ensure greater privacy protection by requiring verification from a witness.

POSITIONS:

The Michigan Osteopathic Association supports the bill package. (2-18-00)

The Michigan State Medical Society (MSMS) supports the committee version of Senate Bill 593. (2-21-00)

Golden Rule Insurance Company supports Senate Bill 593. (2-18-00)

The Department of State Police supports Senate Bill 594. (2-18-00)

The American Civil Liberties Union (ACLU) supports Senate Bill 815. (2-17-00)

The Michigan Jewish Conference supports Senate Bill 815. (2-17-00)

Analyst: S. Stutzky

■This analysis was prepared by nonpartisan House staff for use by House members in their deliberations, and does not constitute an official statement of legislative intent.