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## GENETIC PRIVACY

**Senate Bill 589 as passed by the Senate**  
**Sponsor: Sen. Dale L. Shugars**

**Senate Bill 590 as passed by the Senate**  
**Sponsor: Sen. Bev Hammerstrom**

**Senate Bill 591 as passed by the Senate**  
**Senate Bill 807 (Substitute H-1)**  
**Sponsor: Sen. John H.H. Schwarz, M.D.**

**House Committee: Health Policy**  
**Senate Committee: Health Policy**

**First Analysis (11-10-99)**

### ***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 access to health insurance. The commission held public forums on various issues surrounding genetic privacy, and the commission's final report was released in February of this year. During the public forums, it became clear that many people were concerned that health insurers would use information obtained from genetic tests to deny or cancel health insurance policies. In addition, it became apparent that the fear of losing health insurance has had a chilling effect on people participating in medical research projects. In light of the concerns of the citizens of Michigan, and the recommendations of the commission, legislation has been introduced to prohibit health insurers from requiring people to undergo genetic testing to obtain or renew health insurance.

A separate but somewhat related matter concerns the newborn screening program conducted by the Department of Community Health. Under the Public Health Code, all newborns must be screened for seven specific metabolic diseases that cause mental or physical impairment, as well as other treatable but otherwise disabling conditions as designated by the department. However, since the code does not specify

how or whether the samples may be disposed of, the department feels it may be responsible to keep the samples forever. It has been suggested that the law pertaining to the newborn screening program be amended to require the department to develop a schedule for the retention and disposal of the blood samples.

### ***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 Bills 589-591. The bills would amend three acts to prohibit Blue Cross and Blue Shield of Michigan (BCBSM), health insurers, and health maintenance organizations (HMOs) from requiring insured persons or applicants to submit to genetic testing, or to disclose genetic information. The bills would prohibit BCBSM, a health insurer, and an HMO from requiring an insured person or his or her dependent, to do either of the following:

- Undergo genetic testing before issuing, renewing, or continuing a policy, contract, or certificate.
- Disclose whether genetic testing had been conducted, or the results of genetic testing or genetic information.

The bills also would prohibit a health insurer and an HMO from requiring an asymptomatic applicant for insurance or his or her asymptomatic dependent from doing either of the above.

The DCH could allow the blood specimens to be used for medical research during the retention period

Both Senate Bill 590 and 591 specify that the bills would not prohibit an insurer or an HMO from requiring an applicant for coverage to answer questions concerning family history.

Senate Bill 589 would amend the Nonprofit Health Care Corporation Reform Act (MCL 550.1401) to apply to BCBSM; Senate Bill 590 would amend the Insurance Code (MCL 500.3407b) to apply to private insurers; and Senate Bill 591 would amend the Public Health Code (MCL 333.21072a ) to apply to HMOs.

Senate Bill 807. The bill would amend the Public Code to provide for the retention and disposal of blood specimens taken from a newborn for the newborn screening tests required under the code; allow the blood specimens to be used for medical research under certain conditions; allow the health professional in charge of a birth, or the hospital, to offer to a newborn's parents a blood sample from the newborn, for future identification purposes; and require the Department of Community Health (DCH) to rewrite its pamphlet explaining the newborn screening requirements.

Currently, the health professional in charge of the care of a newborn infant, or the health professional in charge of the birth, must administer to the infant tests for various conditions as prescribed in the code. The bill provides that the DCH, by April 1, 2000, would have to develop a schedule for the retention and disposal of the blood specimens used for the screening tests after the tests were completed. The schedule would have to meet at least all of the following conditions:

- Be consistent with nationally recognized standards for laboratory accreditation and federal law.
- Require that the disposal be conducted in compliance with the code's requirements regarding the disposal of medical wastes.
- Require that the disposal be conducted in the presence of a witness (who could be an individual involved in the disposal or any other individual).
- Require that a written record of the disposal be made and kept, and signed by the witness.

established under the schedule, as long as the medical research was conducted in a manner that preserved the anonymity of the test subjects, and was consistent to protect human subjects from research risks, pursuant to the Code of Federal Regulations.

MCL 333.5431

***HOUSE COMMITTEE ACTION:***

A substitute bill was adopted for Senate Bill 807 to incorporate changes brought about by the enactment of Public Act 138 of 1999.

***FISCAL IMPLICATIONS:***

According to a fiscal note by the Senate Fiscal Agency on Senate Bills 589-591 dated 10-22-99, the bills would have no fiscal impact on state or local government.

In a fiscal note also dated 10-22-99, the Senate Fiscal Agency reported that Senate Bill 807 could result in additional, but nominal, costs. The agency reports that costs to the Department of Community Health would be limited as the required pamphlet would not have to be rewritten until the existing supply of pamphlets had been distributed. Further, standards already exist for the disposal of biohazardous material and any additional record-keeping would be spread across the 130,000 to 135,000 births each year. According to an analysis by the Department of Community Health dated 11-4-99, the department expects that there will be a cost savings as a result of limitations placed on the length of time the Department of Management and Budget may store the records.

***ARGUMENTS:***

***For:***

Medical technology is advancing so rapidly that new issues seem to appear almost daily. Of growing concern is the issue of privacy when an individual undergoes genetic testing to screen for genetic markers or mutations associated with certain diseases, such as Huntington Disease or breast cancer. The concern seems to center around the possibility of insurance companies using such information to refuse to issue coverage for health insurance or to refuse to renew an existing policy.

In Michigan, the majority (97 percent) of people with health insurance are covered under group policies through their employers. Group plans typically do not

require genetic testing or consider various risk factors as the group is generally large enough to spread the risk among the members. Further, the 1996 federal Health Insurance Portability and Accountability Act (HIPAA) prohibits discrimination in issuing or renewing coverage based on genetic test results, but it only applies to those covered under large or small group insurance plans. For a person who must purchase his or her own insurance policy, there is a concern that an insurance company could require genetic testing in order to obtain or retain coverage.

According to insurance industry representatives, genetic testing is not required at this time to either obtain or renew a health insurance policy. However, fears that insurers would cancel or deny health insurance coverage were expressed during public forums held by the Commission on Genetic Privacy and Progress. According to the commission's final report, the commission members also found that the fear of losing health insurance coverage was having a chilling effect on people's participation in medical research projects, and that some were unwilling to undergo genetic tests recommended by their doctors. The bills would address these concerns by extending similar privacy protections to persons covered under individual health insurance policies that are currently afforded to those covered under group policies under HIPAA - namely, that insurers could not require an insured or an applicant for insurance to undergo genetic testing or to disclose the results of tests previously undertaken as a condition of obtaining or retaining insurance coverage.

***Against:***

Senate Bills 589-591 would do little to protect either the privacy of those undergoing genetic testing or to protect persons from being rejected for coverage by insurance companies. The bills merely forbid an insurance company to require an insured or applicant to submit to genetic testing or to reveal the results of genetic tests already performed. The bills do not prohibit an insurance company from using the results of a genetic test to discriminate against an insured or applicant.

Under the bills, insurance companies could still obtain access to the medical records of an insured or applicant. It is reasonable to assume that the results of genetic tests would be included in that record along with all other test results and diagnoses. Unless a person, his or her doctor, and the doctor's staff were diligent to separate or flag genetic test results in the patient's file so that they could be easily identified and

removed from the copy sent to the insurance company, it is reasonable to believe that insurance companies could still have access to many people's genetic test results, and could therefore use those results to exclude the person from coverage. According to information supplied by the American Civil Liberties Union, a 1996 Georgetown University study of 332 families that belonged to a genetic-disease support group reported that 22 percent had been refused health insurance. For these and other reasons, some feel strongly that the bills should be amended to expand the definition of genetic information to include medical records and even family history. The bills should also specify that if genetic testing results were provided to an insurance company, whether voluntarily or inadvertently, that the results could not be used as a determining factor in denying or revoking coverage.

***Response:***

There appear to be many misperceptions about how insurance companies operate. First, premiums for individual policies are not based on an individual's health status, but are set by the cost of care in the geographic area where the applicant resides and then adjusted for age and possibly sex. Secondly, insurance companies are currently allowed access to an applicant's medical records if the applicant gives written consent and, with the exception of Blue Cross and Blue Shield of Michigan (BCBSM), can require the applicant to supply information regarding his or her family medical history. Based on a number of factors, the insurance company will decide to either accept or reject the applicant for coverage.

According to representatives of the insurance industry, the primary factor that determines whether to issue an individual policy is the person's current health status. Typically, family history is only considered in those cases where a person's health status puts him or her on the line between acceptance and rejection. Reportedly, the results of genetic tests are not currently given much weight with a person showing no symptoms because they are not accurate enough to predict whether or not a person would actually get the disease. However, in the case of a person who had positive results for a genetic marker associated with a specific disease, the family history may be given more weight in deciding whether to insure the person or not. To do otherwise would force premiums to rise so high that only the wealthiest individuals could afford private insurance. This is due to several factors.

First, without the ability to reject certain applicants, people could wait until they tested positive to a genetic

test or until the onset of disease before obtaining insurance. The large amount of money paid out in reimbursements for medical care would far outweigh the few months or years of paying premiums. The insurance company would have to raise premiums for everyone or face financial collapse. This would place a tremendous burden on the other people insured under the plan to subsidize the seriously ill. Group plans are not affected as there generally are enough members in the plan to spread the risk and the costs. However, private plans are more susceptible to being overly weighted with seriously ill persons or those who have a higher probability of becoming seriously ill. Therefore, insurance companies offering private policies must retain some ability to protect themselves from financial ruin.

Further, under Michigan law, BCBSM is mandated to be the state's insurer of last resort, meaning that anyone, regardless of health status, can obtain health insurance coverage. Therefore, insurance coverage is available to any resident in the state.

In a nutshell, forbidding private insurers to consider medical records or family history could inadvertently price more people out of affordable health insurance.

***For:***

Though the Public Health Code provides for newborns to be screened for several debilitating diseases, it does not provide for disposal of the blood samples used for the screening tests. Reportedly, as a result, the Department of Community Health (DCH) feels compelled to keep the samples forever although under federal law, the samples must be retained only as long as is medically appropriate. According to the Michigan Commission on Genetic Privacy and Progress, the newborn screening samples "contain a wealth of information" and "represent a vital resource for the study and treatment of disease". Using the samples for research could yield important data in the fight against many deadly and debilitating diseases. The samples could also help individual families, as a newborn screening sample could be used for DNA testing to identify a missing child.

Senate Bill 807 would address these concerns by requiring the DCH to develop a schedule for the retention and disposal of the screening samples by April 1, 2000. Though the department would have discretion in creating the policy, the policy would have to conform with nationally recognized standards for laboratories and federal law, as well as comply with current state laws regarding disposal of medical wastes. If the samples were used for medical research during the storage period, confidentiality of the test subjects would have to be maintained and the research would have to be conducted

under federal laws designed to protect human test subjects from abuse. In addition, the department would have the discretion to design a facility to house the samples. Currently, they are being stored in a Department of Management and Budget warehouse at room temperatures. Ideally, the samples should be stored at or below -20 degrees Centigrade, though it is reported that DNA tests on the samples performed years after being collected have been successful. As technology evolves, and as DNA analysis becomes more widespread, samples could be stored at or below 4 degrees Centigrade. The bill would provide the department with the flexibility to design storage facilities to match the technology at hand.

Further, the bill would allow an extra sample to be drawn from an infant and be given to the parents or guardian. The sample provided to the parents would be preserved in such a way that no special handling precautions would have to be taken. In addition, the bill would require that the availability of the extra sample be included in the informational pamphlet that the department must rewrite and distribute. On several occasions, the samples stored by the department have been instrumental in identifying the remains of a missing child. Having a copy of the baby's screening sample in the hands of a parent, as opposed to searching through files at the DMB warehouse, could expedite such forensic tests, or could be used to confirm the identity of a child who had been kidnaped but not found until he or she was much older.

The bill would allow for the development of appropriate retention and disposal methods and schedules, yet would retain important confidentiality provisions to protect the privacy of all newborns undergoing the screening tests.

***Response:***

The Michigan Commission on Genetic Privacy and Progress feels so strongly that the newborn screening samples could provide a major benefit to medical research that the commission recommended in its final report that the samples be retained forever. Others in the scientific and medical community agree that too much valuable information could be lost to the detriment of society. Further, some people feel that though it could be presumed that the extra sample of a baby's blood drawn at a parent's request would be given to the parent, the provision is not clear and could therefore inadvertently compromise the bill's attempt to protect the privacy rights of newborns and their families.

***POSITIONS:***

The Office of the Governor supports the Senate-passed versions of Senate Bills 589-591. (11-8-99)

Blue Cross and Blue Shield of Michigan supports Senate Bills 589-591. (11-9-99)

The Michigan State Medical Society (MSMS) supports Senate Bills 589-591. (11-8-99)

The Michigan Association of Health Plans is neutral on Senate Bills 589-591. (11-8-99)

The Health Association of America has no position on Senate Bills 589-591. (11-8-99)

Golden Rule Insurance Company does not oppose Senate Bills 589-591 as passed by the Senate. (11-9-99)

The Michigan Jewish Conference supports the need for anti-discrimination legislation, but would like the definition of genetic information in Senate Bills 589-591 broadened to include family history. (11-8-99)

The American Civil Liberties Union/Michigan (ACLU) believes that, without excluding medical records and family history from genetic information, Senate Bills 589-591 do not provide adequate privacy protection. The ACLU also supports Senate Bill 807, but feels that a specific schedule for retention of the samples should be in the bill. (11-9-99)

The Department of Community Health supports Senate Bill 807. (11-4-99)

The Michigan State Medical Society (MSMS) would support Senate Bill 807 if it were amended to retain the newborn screening samples indefinitely. (11-8-99)

Analyst: S. Stutzky

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■ 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.