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

SFA BILL ANALYSIS

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

Senate Bill 589 (Substitute S-2 as passed by the Senate)
Senate Bill 590 (Substitute S-1 as passed by the Senate)
Senate Bill 591 (Substitute S-1 as passed by the Senate)
Senate Bill 593 (Substitute S-4 as passed by the Senate)
Senate Bill 594 (as passed by the Senate)
Senate Bill 595 (Substitute S-2 as passed by the Senate)
Senate Bill 807 (Substitute S-1 as passed by the Senate)
Senate Bill 815 (Substitute S-1 as passed by the Senate)
Sponsor: Senator Dale L. Shugars (S.B. 589)
Senator Bev Hammerstrom (S.B. 590 & 815)
Senator John J.H. Schwarz, M.D. (S.B. 591 & 807)
Senator Mike Goschka (S.B. 593)
Senator Mike Rogers (S.B. 594)
Senator Joel D. Gougeon (S.B. 595)
Committee: Health Policy

Date Completed: 1-31-00

RATIONALE

In 1990 the Federal government, through the coordinated efforts of the National Institutes of Health and the U.S. Department of Energy, initiated funding for an ambitious scientific research project that, in all likelihood, will have a significant impact on the lives of the nation's denizens. The goals of the U.S. Human Genome Project are to identify all of the genes in human deoxyribonucleic acid (DNA), and determine the sequences of the 3 billion chemical bases that comprise DNA. Although the goals are supposed to be achieved by 2005, it is now expected that, because of technological advances, the project will be completed two years ahead of schedule. According to information published by the project, a genome is all the DNA in an organism, including its genes. The genes carry information for making all the proteins required by an organism, and the proteins determine, among many things, an organism's appearance, behavioral traits, resistance to infection, and metabolic capacities.

Though not yet finished, the project has resulted in substantial discoveries in the knowledge of how humans are put together, and there is great optimism that this knowledge may lead to rapid advances in medicine and other sciences. While the potential benefits of the genome project show great promise, the availability of detailed genetic information also raises many privacy issues, such as who should have access to it, and how it will or should be used by insurers, schools, employers, courts, adoption agencies, the military, etc.

Potential genetic privacy issues raised by the Human Genome Project have not escaped the notice of policy-makers in this State. In his 1997 State of the State Address, the Governor announced his plans, later fulfilled by Executive Order 1997-14, to create the Michigan Commission on Genetic Privacy and Progress, "to recommend ways to protect genetic privacy, prevent discrimination and maximize the beneficial uses of new medical knowledge". The Governor again addressed the issue in his 1999 State of the State speech. Mentioning that the Commission's report would soon be published and that its recommendations should be given prompt attention, he said, "Specifically, genetic testing must not be a precondition for obtaining health insurance. And genetic testing must not be allowed as a precondition of employment."

The Commission's report (February 1999) makes several specific recommendations and some general recommendations regarding a wide range of issues surrounding genetic technology. It has been suggested that many of these issues should be addressed in statute.

CONTENT

The bills would amend various acts to do the following:

- **-- Prohibit health insurers from requiring people to submit to genetic testing or disclose genetic information.**
- **-- Prohibit physicians from ordering a genetic**

test without the informed consent of the test subject.

- **-- Require the State Police to dispose of an individual's blood, saliva, or tissue sample, and the corresponding DNR identification profile record, if the person were eliminated as a suspect in a crime.**
- **-- Revise provisions concerning court-ordered genetic tests to determine paternity.**
- **-- Provide for the retention and disposal of blood specimens taken from infants for newborn screening tests.**
- **-- Prohibit employers from requiring individuals to submit to a genetic test or provide genetic information as a condition of employment or promotion.**

The bills are described in more detail below.

Senate Bills 589 (S-2), 590 (S-1), and 591 (S-1)

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. Senate Bill 589 (S-1) would amend the Nonprofit Health Care Corporation Reform Act, which governs BCBSM; Senate Bill 590 (S-1) would amend the Insurance Code, which governs private insurers; and Senate Bill 591 (S-1) would amend the Public Health Code in regard to HMOs.

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.

"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 in order 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. "Clinical purposes" would include predicted risk of diseases; identifying carriers for single-gene disorders; establishing prenatal and clinical diagnosis or prognosis; prenatal, newborn, and other carrier screening, as well as testing in high-risk families; tests for metabolites if undertaken with high probability that an excess or deficiency of the metabolite indicated or suggested the presence of heritable mutations in single genes; and other tests if their intended purpose were diagnosis of a presymptomatic genetic condition.

Senate Bills 590 (S-1) and 591 (S-1) each specifies that the bill would not prohibit an insurer or an HMO from requiring an applicant for coverage to answer questions concerning family history.

Senate Bill 593 (S-4)

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 Community Health (DCH) to develop a model informed consent form.

The terms "genetic test" and "genetic information" would be defined as described above.

Beginning six months after the bill's 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 the medical risks and benefits.
-- The future uses of the sample taken from the test subject in order to conduct the genetic test and the information obtained from the 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 DCH, in consultation with the Michigan Board of Medicine, the Michigan Board of Osteopathic Medicine and Surgery, at least one physician certified by the American Board of Medical Genetics, and appropriate professional organizations, would have to develop and distribute a model informed consent form that practitioners could adopt. The DCH would have to include in the model form at least all of the information required to be included in the written informed consent. The DCH 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 DCH would have to review the model form at least once a year for five years after the first model form was distributed, and revise the form if necessary to make it reflect the latest developments in genetics. In consultation with the boards, the DCH also could develop and distribute a pamphlet that further explained 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.

If a test subject, or his or her legally authorized representative, signed the informed consent form developed by the DCH, 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 physician's duty to inform a patient under the bill would not require disclosure of information beyond what a reasonably well-qualified licensed physician would know.

A health professional who violated 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 newborn screening tests required under the Code; or as otherwise provided by law.

Senate Bill 594

The bill would amend the DNA Identification Profiling System Act to provide that if the State Police forensic laboratory determined after analysis that a blood, saliva, or tissue 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, kidnapping, 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 (S-2)

The bill would amend the Paternity Act to revise provisions regarding court-ordered blood or tissue tests to determine paternity, specifically in regard to DNA identification profiling, the destruction of genetic testing material, and the expungement of records.

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.

"DNA identification profiling" would mean a validated scientific method of analyzing components of DNA molecules in a sample of genetic testing material to identify the pattern of the components' chemical structure that was unique to the individual. "Genetic testing material" would mean a sample of an individual's blood, saliva, or tissue collected from the individual that was used for genetic paternity testing conducted under the Act. The bill would delete the definition of "DNA profile", i.e., the pattern of fragments of DNA used both to identify individuals and to study the relatedness of individuals.

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: the court case number, if applicable, the laboratory case number or identification number, and the Family Independence Agency case number; the mother's name and race; the child's name; the alleged father's name and race; the collection dates and identification numbers of the genetic testing material; the cumulative paternity index; the probability of paternity; the conclusion as to whether the alleged father would or could not be excluded as the biological father; the name, address, and telephone number of the contracting laboratory; and the name of the individual certifying the report.

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 compliance with the Public Health Code's requirements for the disposal of medical waste, and in the presence of a witness. 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 in accordance with the national standards under which the laboratory was accredited.

Currently, if two or more persons are determined to have a probability of paternity of 99% or higher, paternity must be presumed for the person with the highest probability. The bill provides, instead, that if the results of the analysis of genetic testing material from two or more persons indicated a probability of paternity greater than 99%, the contracting laboratory would have to conduct additional genetic paternity testing until all but one of the putative fathers were eliminated, unless the dispute involved two or more putative fathers who had identical DNA.

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

Senate Bill 807 (S-1)

The bill would amend the Public Health Code to provide for the retention and disposal of blood specimens taken from a newborn infant 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 to rewrite its pamphlet explaining the newborn screening requirements.

Under the Code, 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 that the witness sign the record.

Further, the DCH would have to allow the blood specimens to be used for medical research during the retention period 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.

The bill provides that a health professional in charge of the birth of an infant, or the hospital or other facility in which the birth took place, or both, could offer to draw an additional blood specimen from the infant. If an offer were made, it would have to be made to the infant's parent, guardian, or person in loco parentis at the time the blood specimens were drawn for the newborn screening tests. If the infant's parent, guardian, or person in loco parentis accepted the offer, the additional blood specimen would have to be preserved in a manner that did not require special storage conditions or techniques, including lamination. The health professional, or hospital or other facility employee making the offer, would have to explain to the parent, guardian, or person in loco parentis at the time the offer was made that the additional blood specimen could be used for future identification purposes and should be kept in a safe place. The health professional, or hospital or other facility, could charge a fee that was not more than the actual cost of obtaining and preserving the additional blood specimen.

The bill would require the DCH to rewrite its pamphlet explaining the newborn screening requirements when the supply of pamphlets in existence on the bill's effective date was exhausted. When the DCH rewrote the pamphlet, it would have to include at least all of the following information in the pamphlet:

-- The nature and purpose of the testing program required under the Code, including a brief description of each condition or disorder for which a screening test is required.
-- The purpose and value of an infant's parent, guardian, or person in loco parentis retaining a blood specimen in a safe place.
-- The DCH's schedule for retaining and disposing of blood specimens.
-- That the blood specimens taken for purposes of conducting the newborn screening tests could be used for medical research.

The bill would eliminate a current provision that requires the DCH to promulgate rules that define a good faith effort to report positive newborn screening test results.

Senate Bill 815 (S-1)

The bill would amend the Persons with Disabilities Civil Rights Act 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.

"Genetic information" would mean information about a gene, gene product, or inherited characteristic of an individual derived from his or her family history or a genetic test. "Genetic test" would have the definition described above.

MCL 550.1401 (S.B. 589)
Proposed MCL 500.3407b (S.B. 590)
Proposed MCL 333.21072a (S.B. 591)
MCL 333.16221 et al. (S.B. 593)
28.176 (S.B. 594)
722.711 et al. (S.B. 595)
333.5431 (S.B. 807)
37.1201 & 37.1202 (S.B. 815)

ARGUMENTS

(Please note: The arguments contained in this analysis originate from sources outside the Senate Fiscal Agency. The Senate Fiscal Agency neither supports nor opposes legislation.)

Supporting Argument
The Human Genome Project has caused a rapid progression in the science of genetics over the last decade, and promises more in the near future. The genome project has produced detailed DNA maps that have aided researchers seeking genes associated with many genetic conditions. Already, the project has identified numerous genes associated with various ailments and conditions, including Alzheimer's disease, colon cancers, breast cancers, and dystrophy. Though much remains to be done, increased knowledge about the effects of DNA variations among individuals will lead to new ways to diagnose, treat, and perhaps prevent the numerous disorders that affect humans. Obviously, if scientists can identify a gene or sequence of genes that causes or prevents certain maladies, abnormalities, or perceived undesirable traits of the human condition, such knowledge could have a profound impact on individuals and society. While the potential benefits of the genome project show enormous promise, there are also many troubling privacy issues raised by the availability of detailed genetic information. For instance, if a person's genetic test showed that he or she had a high probability of developing a serious medical condition at some future time, an insurance company or an employer could use the information to deny insurance coverage or employment. The bills would attempt to address these and other genetic privacy issues.

Supporting Argument
The Michigan Commission on Genetic Privacy and Progress made several recommendations regarding the uses of genetic technology. The Commission considered the question of whether genetic testing should be part of the application process for health insurance and employment. The Commission pointed out that while there is a lack of conclusive evidence that discrimination based on genetic testing has decreased access to health insurance, there is a perception that the problem exists. Further, while Federal law prohibits discrimination against asymptomatic persons based on genetic testing of applicants or participants in group health plans, the law does not address the availability of insurance for persons who apply for individual health insurance policies. The Commission recommended that health insurers be prohibited from requiring predictive genetic testing or testing for carrier status of individuals. Senate Bills 589 (S-2), 590 (S-1), and 591 (S-1) would codify this recommendation.

Regarding employment issues, through the years people have raised concerns about the potential for discrimination in the workplace based on the status of an individual's health. Although both State and Federal laws prohibit discrimination against persons with disabilities, genetic advances raise questions of employers' using information derived from genetic tests to make hiring and work assignment decisions. The Commission recommended that employers be prohibited from using genetic testing as a condition of employment. Senate Bill 815 (S-1) would 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.

Supporting Argument
Some have expressed concerns regarding the collection, use, and storage of genetic material used in criminal investigations. Senate Bill 594 specifies that if the State Police forensic laboratory determined that a genetic material sample had been submitted by an individual who was eliminated as a suspect, the lab would have to dispose of the material and the DNA profile record created on the basis of the sample. This would help to ensure the genetic privacy of innocent persons.

Supporting Argument
Currently, in a paternity proceeding before trial, the court may order a mother, child, or alleged father to submit to blood or tissue typing determinations, including DNA profiles, to determine paternity. Senate Bill 595 (S-2) would require that a summary

report of a DNA profile be submitted to the court, and specify the contents of the report. This would help to ensure that the genetic information submitted to the court for public record would be limited to the question of paternity.

Legislative Analyst: G. Towne

FISCAL IMPACT

Senate Bills 589 (S-2), 590 (S-1), and 591 (S-1)

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

Senate Bill 593 (S-4)

The bill would have an indeterminate fiscal impact on State and local government. The DCH could experience nominal costs in developing, printing, and distributing the consent forms.

Senate Bill 594

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

Senate Bill 595 (S-2)

It appears that the bill 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 during 1999 because of Act changes in 1998 for expunging the laboratory's records (Sec. 6a(2)), and contract costs would increase further with the inclusion of audit provisions (Sec. 6a(5)).

Senate Bill 807 (S-1)

It would appear that additional costs resulting from this bill, if any, would be nominal. 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. 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.

Senate Bill 815 (S-1)

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 this bill is indeterminate. There would be no fiscal impact on local government.

Fiscal Analyst: J. Walker
(S.B. 589-591, 593, 807)
B. Baker (S.B. 594)
C. Cole (S.B. 595)

A9900\s589a

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.