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SFA BILL ANALYSIS

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Senate Bills 589, 590, and 591 (as enrolled) **PUBLIC ACTS 26-28 of 2000**
Senate Bills 593, 594, and 595 (as enrolled) **PUBLIC ACTS 29-31 of 2000**
Senate Bill 807 (as enrolled) **PUBLIC ACT 33 of 2000**
Senate Bill 815 (as enrolled) **PUBLIC ACT 32 of 2000**

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)

Senate Committee: Health Policy
House Committee: Health Policy

Date Completed: 4-19-00

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) made several specific recommendations and some general recommendations regarding a wide range of issues surrounding genetic technology. It was suggested that many of these issues should be addressed in statute.

CONTENT

The bills amended 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 presymptomatic or predictive 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 has been 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.**

All of the bills took effect on March 15, 2000. The bills are described in more detail below.

Senate Bills 589, 590, and 591

The bills amended 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 amended the Nonprofit Health Care Corporation Reform Act, which governs BCBSM; Senate Bill 590 amended the Insurance Code, which governs private insurers; and Senate Bill 591 amended the Public Health Code in regard to HMOs.

The bills prohibit BCBSM, a health insurer, and an HMO from requiring an insured person, enrollee, or member, 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 has been conducted, or the results of genetic testing or genetic information.

Senate Bill 589 also applies to an applicant for coverage or his or her dependent. Senate Bills 590 and 591 apply to an asymptomatic applicant for insurance or coverage or his or her asymptomatic dependent.

The bills define "genetic test" as 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 must 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 bills. "Genetic test" does 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" means information about a gene, gene product, or inherited characteristic derived from a genetic test. "Clinical purposes" 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 indicates or suggests the presence of heritable mutations in single genes; and other tests if their intended purpose is diagnosis of a presymptomatic genetic condition.

Senate Bills 590 and 591 specify that they do not prohibit an insurer or an HMO from requiring an applicant for coverage to answer questions concerning family history.

Senate Bill 593

The bill amended the Public Health Code to prohibit a presymptomatic or predictive 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" are defined as described above, except that "genetic test" does not include a procedure performed as a component of biomedical research that is conducted pursuant to Federal common rule under the Code of Federal Regulations (21 CFR Parts 50 and 56, and 45 CFR Part 46). The bill defines "predictive genetic test" as a genetic test performed for the purpose of predicting the future probability that the test subject will develop a genetically related disease or disability. "Presymptomatic genetic test" means a genetic test performed before the onset of clinical symptoms or indications of disease.

Beginning six months after the bill's effective date, 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 written, informed consent of the test subject. For purposes of the bill, written, informed consent consists of a signed writing executed by the test subject, or the legally authorized representative of the test subject, that confirms that the physician or the individual acting under delegated authority has explained, and the test subject or the subject's legally authorized representative understands, 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 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 will 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 takes 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, must develop and distribute a model informed consent form that practitioners may adopt. The DCH must include in the model form at least all of the information required to be included in the written informed consent. The DCH must distribute the model form to physicians and other individuals subject to the bill's provisions upon request and at no charge. The DCH must review the model form at least once a year for five years after the first model form is distributed, and revise the form if necessary to make it reflect the latest developments in genetics. In consultation with the boards and professional organizations, the DCH also may develop and distribute a pamphlet that further explains the information included in the model form.

If a test subject, or his or her legally authorized representative, signs a copy of the model informed consent form, the physician, or an individual acting under the delegatory authority of the physician, must 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, signs a copy of the model informed consent form developed by the DCH, the test subject will 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 presymptomatic or predictive genetic test based on failure to obtain informed consent for the test.

A physician's duty to inform a patient under the bill does not require disclosure of information beyond what a reasonably well-qualified licensed physician would know.

A health professional who violates the bill will be subject to a reprimand or fine.

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

Senate Bill 594

Under the DNA Identification Profiling System 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.

The bill amended the Act to provide that if the State Police forensic laboratory determines after analysis that a blood, saliva, or tissue sample has been submitted by an individual who has been eliminated as a suspect in a crime, the laboratory must dispose of the sample and the corresponding DNA identification profile record. The sample must be disposed of in compliance with the requirements of the Public Health Code regarding disposal of medical waste. The sample and the profile record must be disposed of in the presence of a witness. After disposal, the laboratory must make and keep a written record of the disposal, signed by the witness.

Senate Bill 595

The bill amended 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.

Under the bill, 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 identification profiling", to determine whether the alleged father is likely to be, or is not, the father of the child. (Previously, the Act contained this provision but referred to "DNA profiles", rather than "DNA identification profiling".) The bill defines "DNA identification profiling" as 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 is unique to the individual. "Genetic testing material"

means a sample of an individual's blood, saliva, or tissue collected from the individual that is used for genetic paternity testing conducted under the Act. The bill deleted 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.

Previously, the result of blood or tissue typing or a DNA profile determination and, if a determination of exclusion of paternity could not be made, a written report including a calculation of the probability of paternity, had to be filed with the court and served on the mother and alleged father. The bill provides instead that the result of blood or tissue typing or a DNA identification profile and a summary report must be served on the mother and alleged father. The summary report must be filed with the court. The bill defines "summary report" as a written summary of the DNA identification profile that includes 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 can or cannot 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.

Previously, if a man was found not to be the child's father, the court had to order his genetic testing material to be destroyed. The bill provides, instead, that the contracting laboratory must 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 is destroyed, the contracting laboratory must make and keep a written record of the destruction, and have the witness sign the record. The laboratory also must expunge its records regarding the genetic paternity testing performed on the material in accordance with the national standards under which the laboratory is accredited.

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

The bill provides that each year, a contracting laboratory must have conducted an independent audit verifying its compliance with the bill's requirements. The audit may 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 must forward the audit to the Department of Consumer and Industry Services.

Senate Bill 807

The bill amended 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, must develop a schedule for the retention and disposal of the blood specimens used for the screening tests after the tests are completed. The schedule must 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 waste.
-- Require that the disposal be conducted in the presence of a witness (who may 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 bill requires the DCH 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 is conducted in a manner that preserves the anonymity of the test subjects, and is 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 takes place, or both, may offer to draw an additional blood specimen from the infant. If an offer is made, it must be made to the infant's parent, guardian, or person in loco parentis at the time the blood specimens are drawn for the newborn screening tests. If the infant's parent, guardian, or person in loco parentis accepts the offer, the additional blood specimen must be preserved in a manner that does not require special storage conditions or techniques, including lamination. The health professional, or hospital or other facility employee making the offer, must explain to the parent, guardian, or person in loco parentis at the time the offer is made that the additional blood specimen may be used for future identification purposes and should be kept in a safe place. The health professional, or hospital or other facility, may charge a fee that is not more than the actual cost of obtaining and preserving the additional blood specimen.

The bill requires the DCH to rewrite its pamphlet explaining the newborn screening requirements when the supply of pamphlets in existence on the bill's effective date is exhausted. When the DCH rewrites the pamphlet, it must 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 may be used for medical research.

The bill eliminated a provision that required the DCH to promulgate rules defining a good faith effort to report positive newborn screening test results.

Senate Bill 815

The bill amended 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.

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 prohibits an employer from taking any of those actions based upon the individual's genetic information that is unrelated to his or her ability to perform. Further, the bill provides that an employer may not take any of the actions prohibited in the Act, "except as otherwise required by federal law".

The bill specifies that it does not prohibit an individual from voluntarily providing to an employer genetic information that is 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. Otherwise, no employer may 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.

The bill defines "genetic information" as 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" is defined as described above.

MCL 550.1401 (S.B. 589)
500.3407b (S.B. 590)
333.21072a (S.B. 591)
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 congenital and hereditary

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 traits of the human condition perceived to be undesirable, such knowledge may 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 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, 590, and 591 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 prohibits 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 determines that a genetic material sample has been submitted by an individual who was eliminated as a suspect, the lab must dispose of the material and the DNA profile record created on the basis of the sample. This will help to ensure the genetic privacy of innocent persons.

Supporting Argument

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 profiling, to determine paternity. Senate Bill 595 requires that a summary report of a DNA profile be filed with the court, and specifies the contents of the report. This will help to ensure that the genetic information submitted to the court for public record is limited to the question of paternity. The bill also strengthens the Act's requirements regarding the destruction of genetic testing material and the expungement of records.

Opposing Argument

Senate Bills 589, 590, and 591 prohibit health insurers not only from requiring insured individuals and applicants to submit to genetic testing, but also from requiring them to disclose known genetic information. This means that people who have been genetically screened on their own initiative may keep the information from insurers and seek the maximum coverage at standard rates. This will distort the insurance pool by preventing underwriters from adjusting for risks, as they do for smokers and those who engage in dangerous sports. As a result, the legislation may drive up the cost of insurance for everyone else, and place coverage beyond the means of some. It would be preferable to rely on the market to develop insurance products tailored to those with specific identifiable problems. Furthermore, because most health insurance is job-related, genetic screening for employment is basically an insurance precaution. The same set of rules should apply in the context of employment.

Legislative Analyst: G. Towne
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FISCAL IMPACT

Senate Bills 589, 590, and 591

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

Senate Bill 593

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

Senate Bill 594

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

Senate Bill 595

It appears that the bill will 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 will increase further with the inclusion of audit provisions (Sec. 6a(5)).

Senate Bill 807

It appears that additional costs resulting from this bill, if any, will be nominal. Costs to the Department of Community Health will be limited as the required pamphlet will not have to be rewritten until the existing supply of pamphlets has been distributed. Standards already exist for the disposal of biohazardous material and any additional record-keeping will be spread across the 130,000 to 135,000 births each year.

Senate Bill 815

The Department of Civil Rights may be required to investigate claims that employers have violated the new provisions of this statute. Because it is unknown how many complaints may be filed, the fiscal impact of this bill is indeterminate. There will 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)
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