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**HOUSE OF REPRESENTATIVES
COMMITTEE ON
HEALTH CARE SERVICES
BILL RESEARCH & ECONOMIC IMPACT STATEMENT**

BILL #: CS/HBs 37 & 127

RELATING TO: Genetic Testing and Insurance

SPONSOR(S): The Committee on Health Care Services, Reps. Stafford, Diaz de la Portilla, and others

STATUTE(S) AFFECTED: Sections 624.155, 632.638, 636.0201, 641.30, 641.438, 760.40, F.S.

COMPANION BILL(S): SB 138(s)

ORIGINATING COMMITTEE(S)/COMMITTEE(S) OF REFERENCE:

- (1) HEALTH CARE SERVICES YEAS 9 NAYS 0
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I. SUMMARY:

This bill limits the use of genetic information by health insurers and increases the "informed consent" provisions attached to genetic test results. Specifically the bill:

- ▶ Provides definitions for "genetic information," "genetic test", and "health insurer";
- ▶ Prohibits health insurers from requiring or using genetic information or test results for insurance purposes (life, disability, long-term care, accident-only, hospital or fixed indemnity, dental, or vision policies are excluded);
- ▶ Provides that a person injured due to insurers unauthorized use of genetic information has a civil cause of action;
- ▶ Provides that "informed consent" to genetic testing be given in writing and that the person tested be provided with certain information;
- ▶ Provides that each disclosure of the test results requires a separate consent and specifies the provisions of the consent; and
- ▶ Provides civil as well as criminal penalties for breaching genetic testing confidentiality.

No direct fiscal impact is anticipated.

II. SUBSTANTIVE RESEARCH:

A. PRESENT SITUATION:

Genetic testing can include any diagnostic assessment, such as laboratory analysis, physical examination, family history survey, etc, which reveals a person's genetic status. Test results are used primarily by patients and their physicians for diagnosis and to assess health risks. The utility of such information is immeasurable in monitoring, prevention and early intervention. The tests also allow physicians to diagnose certain syndromes and counsel families about the risks of recurrence in the family.

There are several types of gene disorders. There are those which will occur if the person has the genetic trait for it, such as Tay-Sachs, cystic fibrosis, sickle cell, and Huntington's disease, while others simply show a predisposition to a disease such as colon and breast cancer. As genetic exploration advances many common diseases, not previously thought of as genetic, are in fact being found to have a genetic component. Inherited predispositions and a person's way of life can work together to bring about a disease.

The most accepted and widespread type of genetic testing is infant screening. Each year in the United States, 4 million infants have their blood tested for abnormal or missing gene parts. All states either offer or mandate testing for phenylketonuria (PKU) and congenital hypothyroidism, two metabolic disorders that, if untreated, cause mental retardation. In addition, Florida, like many other states, also tests for galactosemia, hemoglobinopathies (which includes sickle cell disease), and hyperplasia - all genetically caused diseases. Almost 200,000 babies will be tested in Florida this year.

In October 1988, the National Institutes of Health and the U.S. Department of Energy outlined plans for cooperation in mapping and sequencing the human genome. The official start of the Human Genome Project was October 1, 1990, with a projected 15 year completion date of 2005. The goal is to pinpoint the location of each of the 50,000 to 100,000 genes and to identify the exact sequence of their chemical bases. Since the advent of this project, new disease genes are being discovered at a rate of several per month, and more than 50 new genetic tests have been developed. These results have accelerated concern over the implications of genetic testing in insurance and employment discrimination.

Insurers & the Use of Genetic Tests: Health insurance companies have commonly sought information on cholesterol, hypertension, coronary heart disease, cancer, diabetes, and other impairments which may have a genetic base from family history. Many applicants are requested to undergo blood and other tests for conditions or diseases. Insurers evaluate and underwrite on the basis of this information to establish risk classifications. Concerns have been raised that genetic tests assessing a predisposition for disease may also be used by insurers to underwrite and rate risk.

The issue is whether insurers should construe the presence of an imperfect gene as a preexisting condition and deny or mitigate coverage on that basis. This could adversely affect persons who have a particular genetic trait even though the condition or disease may never develop or may be prevented through treatment. The mere possibility that insurers may act on such information may serve to discourage testing which may, in turn, mean that the affected individuals do not take advantage of preventive treatment.

According to the American Council of Life Insurance (ACLI), no insurer currently requires DNA-based genetic testing as a prerequisite to coverage. However, if a person has such a test done, insurers may use it. Further, much genetic information can be obtained from other than strict DNA testing. As more is known about genetic testing, it is foreseeable that more physicians will be relying upon it as a standard of practice and as the cost of the test declines, more people will be getting such tests for reasons other than a physician's recommendation as part of treatment for a disease. According to the ACLI, it would therefore become increasingly important for insurers to be able to underwrite on the basis of the results of these tests in order to better establish risk classifications. Risk classifications evaluate the probability, not the certainty, of an applicant developing a disease.

In 1995, the Nation Institute of Health in conjunction with the Department of Energy Joint Working Group on Ethical, Legal and Social Implications of Human Genome Research (ELSI Working Group) and the National Action Plan on Breast Cancer developed and published recommendations for state and federal policy makers to protect against genetic discrimination:

- Insurance providers should be prohibited from using genetic information to deny or limit coverage or establish eligibility, continuation, enrollment or contribution requirements.
- Insurance providers should be prohibited from establishing differential rates or premium payments based on genetic information.
- Insurance providers should be prohibited from requesting or requiring collection or disclosure of genetic information.
- Insurance providers and other holders of genetic information should be prohibited from releasing genetic information without prior written authorization of the individual.
- Written authorization should be required for each disclosure and include to whom the disclosure would be made.

The recommendations defined "*genetic information*" to mean "information about genes, gene products, or inherited characteristics that may derive from the individual or a family. "Insurance provider" was defined as "an insurance company, employer, or any entity providing a plan of health insurance or health benefits including group and individual health plans whether fully insured or self-funded."

While life insurance coverage can be of critical importance, public policy regarding the availability and access to life insurance is not as strong as it is for health insurance. For example, life insurers are allowed to risk underwrite their coverage to charge differential premiums, and to deny coverage based on medical conditions. Otherwise a person predisposed to a disease could, in general, purchase as much life insurance as desired knowing that an early death might occur.

Other States & Federal Law: Eleven states (California, Colorado, Georgia, Maryland, Minnesota, New Hampshire, New York, Ohio, Oregon, Virginia, and Wisconsin) and the federal government have passed genetic anti-discrimination legislation which prohibit health insurers from rejecting applicants or raising rates based on genetic data. Most such laws have a common and relatively narrow focus. They address *genetic testing* and forbid health insurers from denying coverage based on genetically increased risk for future illness.

Recently, some states (Colorado, Oregon, and New York) have begun to enact genetic privacy laws that touch on informed consent and the retention of tissue samples for genetic research. Recent legislative attempts (i.e., New Jersey) have begun to focus on the protection of *genetic information* rather than genetic testing and therefore also include risk data inferred from taking a family history.

Of particular significance is the recently enacted Health Insurance Portability Act (1995 Kennedy-Kassebaum Act). Specifically, the Act says that, for the purposes of group health plans, portability between plans, and individual health insurance for persons with prior group coverage - genetic information, in the absence of a diagnosis of the condition related to such information, is not a preexisting condition. Thus, if someone has had a genetic test predicting a high chance of developing a disease in the future but the disease has not yet developed, insurers cannot classify that disease as a "preexisting condition." The law also prohibits discrimination in health care eligibility based on health-related status of which one factor is genetic information. "Genetic information" is not defined.

While Kennedy-Kassebaum applies to all forms of group insurance it does not apply to individual health insurance coverage for persons not previously covered by a group policy, nor does it provide protection against rate classification based on genetic information. The Act also does not address other genetic information concerns such as informed consent and confidentiality.

Section s. 627.6699, Florida Statutes, the Employee Health Care Access Act, requires insurers providing benefit plans to businesses with 1 to 50 employees, to offer a health benefit plan to all such employers. While allowances are made for preexisting conditions for which medical care was recommended or received or that would cause an ordinary person to seek medical advice, carrier premiums can be based only on age, gender, family composition, tobacco usage, and geographic area.

Genetic Testing, Informed Consent, & Confidentiality: Section 760.40, F.S., prohibits "DNA analysis" (except for criminal prosecution and determination of paternity purposes) without the informed consent of the person to be tested. Further, the results of such analysis is the exclusive property of the person tested, is confidential, and may not be disclosed without the consent of the person tested. A person violating this section is guilty of a 1st degree misdemeanor. "DNA analysis" is defined to mean "the medical and biological examination and analysis of a person to identify the presence and composition of genes in that person's body" and "includes DNA typing and genetic testing."

The statute also provides that a person who performs DNA analysis, or receives the results of such analysis, must provide the person tested with notice that the test was performed and that, upon the request of the person tested, the test results will be made available to the person's physician. Further, the notice must also state whether the information was used in any decision to grant or deny any insurance, employment, mortgage, loan, credit, or education opportunity. If so used, the test must be repeated and if found to be inaccurate, the denial must be reviewed.

Other Florida Law: Except with respect to sickle-cell disease, Florida law does not prohibit insurers from requiring genetic testing, or from evaluating and underwriting on the basis of genetic information, or from inquiring whether an applicant has ever been subject to genetic testing and if so, requiring the results to be provided as a prerequisite

for coverage. Nor is there any prohibition against using an individual's refusal to disclose the results of such tests to deny, cancel, refuse to renew or limit coverage.

Sections 63.043, 228.201, 448.075, and 448.076, F.S., prohibit any person, firm, corporation, association, state agency, local government, or public or private entity from requiring screening or testing for sickle-cell trait as a condition for employment, for admission into any state educational institution or state-chartered private educational institution, or for becoming eligible for adoption if otherwise eligible for adoption.

Section 624.155, F.S., authorizes a person to bring a civil action if damaged due to an insurer's actions relating to unfair trade practices, favored agents or insurers, decisions to issuance of insurance based on a person's severe disability or sickle-cell disease, or failure to timely return canceled car insurance premiums.

Sections 626.9706 and 626.9707, F.S., prohibit any insurer from refusing to issue and deliver any policy of life or disability insurance solely because such person has the sickle-cell trait, or charge such policyholder a higher premium based on such trait.

Section 627.409, F.S., permits an insurer to deny claims based upon a policyholder's misrepresentation of his or her health on an insurance application if the insurer would have denied coverage initially had they known all of the facts or if the misrepresentation is material. Known genetically based information would be included. Insurers have attempted to identify genetic traits by using insurance applications to ask for a detailed inventory of family illnesses and health problems that may have a genetic base.

Section 742.12, F.S., provides that in a proceeding to establish paternity, a court may order a person to undergo a test to establish paternity.

Section 943.325, F.S., provides that persons convicted of certain crimes may also be required to submit to blood tests which can include genetic analysis.

B. EFFECT OF PROPOSED CHANGES:

Health insurance plans, certain self-insured plans, multiple-employer welfare arrangements, prepaid limited health service organizations, health maintenance organizations, prepaid health clinics, fraternal benefit societies, accountable health partnerships or any health care arrangement where risk is assumed, will be prohibited from using genetic information or requiring genetic testing for insurance purposes.

Except for the purposes of routine laboratory procedures, diagnosis, criminal investigations, infant screening, or testing conducted on anonymous samples, all genetic testing must be accompanied by written informed consent, and the results of the genetic test cannot be released except pursuant to a separate written consent.

Persons who negligently or intentionally violate the confidentiality attached to genetic test results will be subject to civil penalties as well as guilty of a 1st degree misdemeanor.

C. APPLICATION OF PRINCIPLES:

1. Less Government:

a. Does the bill create, increase or reduce, either directly or indirectly:

(1) any authority to make rules or adjudicate disputes?

Yes, the bill gives the Department of Insurance authority to enforce additional standards on health insurers.

(2) any new responsibilities, obligations or work for other governmental or private organizations or individuals?

Health care facilities and providers who perform genetic testing will be required to provide a more elaborate counseling procedure prior to genetic testing and obtain a separate consent for most releases of genetic testing results.

(3) any entitlement to a government service or benefit?

No.

b. If an agency or program is eliminated or reduced:

(1) what responsibilities, costs and powers are passed on to another program, agency, level of government, or private entity?

N/A

(2) what is the cost of such responsibility at the new level/agency?

N/A

(3) how is the new agency accountable to the people governed?

N/A

2. Lower Taxes:

- a. Does the bill increase anyone's taxes?

No.

- b. Does the bill require or authorize an increase in any fees?

No.

- c. Does the bill reduce total taxes, both rates and revenues?

No.

- d. Does the bill reduce total fees, both rates and revenues?

No.

- e. Does the bill authorize any fee or tax increase by any local government?

No.

3. Personal Responsibility:

- a. Does the bill reduce or eliminate an entitlement to government services or subsidy?

No.

- b. Do the beneficiaries of the legislation directly pay any portion of the cost of implementation and operation?

Only if the legislation results in higher premiums.

4. Individual Freedom:

- a. Does the bill increase the allowable options of individuals or private organizations/associations to conduct their own affairs?

Yes, because the bill ensures that seeking genetic testing will not be used against a person, and because a person's control over their genetic test results is enhanced.

- b. Does the bill prohibit, or create new government interference with, any presently lawful activity?

Recently enacted federal law (Kennedy-Kassebaum) already prevents a health insurer from considering genetic information when underwriting most health insurance policies. This bill will broaden that prohibition to include individual health policies.

5. Family Empowerment:

a. If the bill purports to provide services to families or children:

(1) Who evaluates the family's needs?

N/A

(2) Who makes the decisions?

N/A

(3) Are private alternatives permitted?

N/A

(4) Are families required to participate in a program?

N/A

(5) Are families penalized for not participating in a program?

N/A

b. Does the bill directly affect the legal rights and obligations between family members?

No.

c. If the bill creates or changes a program providing services to families or children, in which of the following does the bill vest control of the program, either through direct participation or appointment authority:

(1) parents and guardians?

N/A

(2) service providers?

N/A

(3) government employees/agencies?

N/A

D. SECTION-BY-SECTION RESEARCH:

[This section need be completed only in the discretion of the Committee.]

Section 1. Amends s. 624.155, F.S., relating to civil remedies for persons injured due to violations of certain provisions of the insurance code, to add violation of s. 627.4301, F.S. (see below).

Section 2. Creates s. 627.4301, F.S., relating to use of genetic information for insurance purposes to:

- (a) Provide definitions for “genetic information” and “health insurer”;
- (b) Prohibit health insurers from using genetic information to make decisions relating to the issuance of insurance coverage, or requiring or using genetic test results for insurance purposes; and
- (e) Exempt life, disability, long-term care, accident-only, hospital or fixed indemnity, dental, or vision policy from the provisions of this section.

Section 3. Amends s. 632.638, F.S., relating to statutory provisions which apply to fraternal benefit societies to impose the provisions of s. 627.4301, F.S. (see above) on such societies.

Section 4. Creates s. 636.0201, F.S., to impose the provisions of s. 627.4301, F.S. (see above) on prepaid limited health service organizations.

Section 5. Amends s. 641.30, F.S., relating to the applicability of other laws to health maintenance organizations, to impose the provisions of s. 627.4301, F.S. (see above) on HMOs.

Section 6. Creates s. 641.438, F.S., to impose the provisions of s. 627.4301, F.S. (see above) on prepaid health clinics.

Section 7. Amends s. 760.40, F.S., relating to DNA analysis and informed consent to:

- (a) Substitute the term “genetic testing” for “DNA analysis,” provide a new definition, and provide exceptions;
- (b) Delete a provision that test results are the property of the person tested and substitute that the person tested has exclusive control over test results;
- (c) Provide that “informed consent” for the purposes of underwriting health insurance be given in writing and that the testee be provided with certain information;
- (d) Prohibit the release of test results without a separate written consent to each release, specify the contents of such release, and provide an exception for federally monitored clinical trials;
- (e) Prohibit insurers who possess test results from further releasing the information without the consent of person tested;
- (e) Provide criminal and civil penalties for breaching confidentiality; and

- (g) Provide that the testee be informed if the test results resulted in denial or issuance of a substandard insurance policy.

Section 8. Provides an effective date of January 1, 1998.

III. FISCAL & ECONOMIC IMPACT STATEMENT:

A. FISCAL IMPACT ON STATE AGENCIES/STATE FUNDS:

1. Non-recurring Effects:

None.

2. Recurring Effects:

None.

3. Long Run Effects Other Than Normal Growth:

None.

4. Total Revenues and Expenditures:

None.

B. FISCAL IMPACT ON LOCAL GOVERNMENTS AS A WHOLE:

1. Non-recurring Effects:

None.

2. Recurring Effects:

None.

3. Long Run Effects Other Than Normal Growth:

None.

C. DIRECT ECONOMIC IMPACT ON PRIVATE SECTOR:

1. Direct Private Sector Costs:

Requiring a separate consent for each release of such records may add additional administrative expenses related to record management for health facilities and providers.

To the extent that individuals who know that they have a genetic predisposition to disease "self-select" to carry individual insurance coverage this may result in higher insurance costs which will result, in turn, in higher premiums.

2. Direct Private Sector Benefits:

Because health insurers will be prohibited from using genetic test results in underwriting decisions and consumers will have increased control over the results of genetic testing, consumers may feel freer to undergo genetic testing and illnesses that would otherwise not be detected at an early stage may be prevented or mitigated.

3. Effects on Competition, Private Enterprise and Employment Markets:

Since genetic testing is not yet a routine consideration in health insurance underwriting and risk classification this bill will maintain rather than change present business practice. Further, since all health insurers will be affected similarly there should not be any differential competitive effect.

D. FISCAL COMMENTS:

None.

IV. CONSEQUENCES OF ARTICLE VII, SECTION 18 OF THE FLORIDA CONSTITUTION:

A. APPLICABILITY OF THE MANDATES PROVISION:

This bill does not require counties or municipalities to expend funds.

B. REDUCTION OF REVENUE RAISING AUTHORITY:

This bill does not reduce the authority of counties or municipalities to raise revenues.

C. REDUCTION OF STATE TAX SHARED WITH COUNTIES AND MUNICIPALITIES:

This bill does not reduce the percentage of a state tax shared with counties or municipalities.

V. COMMENTS:

Recent federal legislation (Kennedy-Kassebaum) prohibits health insurance discrimination based on genetic information. However, while Kennedy-Kassebaum applies to group coverage and individual coverage for persons previously covered by a group plan, this bill applies to all forms of health insurance.

VI. AMENDMENTS OR COMMITTEE SUBSTITUTE CHANGES:

This committee substitute differs from both HB 37 and HB 127 as follows:

- ▶ Prohibits health insurers from using “genetic information” rather than “genetic testing” in determining whether to issue a health insurance policy;
- ▶ Exempts accident-only, hospital indemnity or fixed indemnity, dental, and vision policies as well as life, disability and long-term care policies from “genetic information” restrictions;
- ▶ Provides a civil cause of action against insurers for persons who have been injured due to an insurers unauthorized use of genetic information;
- ▶ Applies informed consent and confidentiality provisions to all insurers not just health insurers, and prohibits all insurers, not just health insurers, from sharing genetic test results with an insurance industry data bank;
- ▶ Removes provision applying genetic discrimination provision to reinsurers;
- ▶ Redefines “genetic testing” to mean testing for only asymptomatic conditions, and excepts out infant screening, testing of deceased persons, and testing conducted on anonymous samples;
- ▶ Repeals existing statutory provision that test results are the property of the person tested and substitutes that the person has the exclusive control over test results;
- ▶ Deletes bill provision that test results are not medical records;
- ▶ Limits restrictions on release of test results to records where the person can be identified with the test results;
- ▶ Permits access to test results conducted pursuant to federally monitored clinical trials;
- ▶ Limits civil actions to negligently or intentionally caused unlawful disclosures of test results; and
- ▶ Repeals existing statutory provision requiring person tested to be provided notice that test was performed.

VII. SIGNATURES:

COMMITTEE ON HEALTH CARE SERVICES:

Prepared by:

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Mike Hansen