

HOUSE OF REPRESENTATIVES STAFF ANALYSIS

BILL #: CS/HB 879 Genetic Information Used for Insurance Purposes
SPONSOR(S): Health Market Reform Subcommittee; Williamson
TIED BILLS: **IDEN./SIM. BILLS:** SB 258

REFERENCE	ACTION	ANALYST	STAFF DIRECTOR or BUDGET/POLICY CHIEF
1) Health Market Reform Subcommittee	11 Y, 3 N, As CS	Grabowski	Crosier
2) Insurance & Banking Subcommittee	9 Y, 6 N	Fortenberry	Luczynski
3) Health & Human Services Committee			

SUMMARY ANALYSIS

The availability and use of genetic tests has increased dramatically in recent years. The resulting genetic information is generally used by individuals or their physicians to determine whether any action should be taken to improve long-term wellbeing.

Since the advent of genetic testing, there have been concerns about the use of personal genetic information by third parties. In particular, there is a concern that insurers may discriminate against individuals who have genetic markers indicating a heightened risk of developing certain diseases or health conditions.

The federal Health Insurance Portability and Accountability Act of 1996 prohibits health insurers from making coverage decisions solely based on personal genetic information. The federal Genetic Information Nondiscrimination Act of 2008 extended this concept by prohibiting health insurers from using genetic information in the underwriting process, and in the setting of premiums.

Florida law also prohibits health insurers from considering genetic information, both when issuing insurance policies and when setting applicable premium rates. This prohibition, however, does not extend to issuers of life insurance, disability income insurance, and long-term care insurance policies.

The bill expands existing prohibitions on the use of genetic information by insurers to include entities that issue policies for life insurance and long-term care insurance. Specifically, the bill prohibits issuers of life insurance and long-term care insurance from canceling, limiting, or denying coverage, and from setting different premium rates, based on personal genetic information without a specific diagnosis related to the genetic information. The bill also prohibits life insurers and long-term care insurers from requiring or soliciting genetic information, using genetic test results, or considering a person's decisions or actions relating to genetic testing for any insurance purpose.

The bill has no fiscal impact on state or local government. It is unclear whether or life insurers and long-term care insurers are currently using personal genetic information. Therefore, the direct economic impact on the private sector based upon the bill's prohibitions on the use of genetic information is presently unknown.

The bill has an effective date of July 1, 2019.

FULL ANALYSIS

I. SUBSTANTIVE ANALYSIS

A. EFFECT OF PROPOSED CHANGES:

Background

Regulation of Insurance in Florida

The Office of Insurance Regulation (OIR) regulates insurers, including life, health, and long-term care insurers, under the Florida Insurance Code.¹ Parts III and V of ch. 627, F.S., specifically address life insurers. Part VI of ch. 627, F.S. specifically addresses health insurers. The Agency for Healthcare Administration (AHCA) regulates the quality of care provided by health maintenance organizations (HMOs) under part III of ch. 641, F.S., and part I of ch. 641, F.S., focuses on OIR's regulatory role of HMOs. Before receiving a certificate of authority from OIR, an HMO must receive a health care provider certificate from AHCA.² Part XVIII of ch. 627, F.S., specifically addresses long-term care insurance, which is coverage for medical and personal care services provided in a setting other than an acute care unit of a hospital.³

Genetic Testing

The availability and use of genetic tests has increased dramatically in recent years. As of March 2017, there were nearly 70,000 genetic testing products on the market, with an average of 10.6 new testing products entering the market *a day* since 2015.⁴ A 2016 survey indicated that 5.5 percent of adults in the U.S. had had genetic testing. Over half of those tested did so based on a concern about future health problems for them or their children, while 18 percent were tested to learn more about family heritage.⁵ The U.S. Centers for Disease Control and Prevention (CDC) recognizes the development of genomic tests for thousands of diseases and health conditions, while also acknowledging that such tests are not necessarily a conclusive indication that an individual will develop a particular disease or condition.⁶

A wide range of health-related DNA screenings are available. The National Institutes for Health (NIH) categorizes these tests as follows.

- **Diagnostic testing** - identifies a genetic condition or disease that is making or in the future will make a person ill. The results of diagnostic testing can help in treating and managing the disorder.
- **Predictive and pre-symptomatic genetic testing** - identifies genetic variations that increase a person's chance of developing specific diseases. This type of genetic testing may help provide information about a person's risk of developing a disease, and can help in decisions about lifestyle and health care.

¹ Chapters 624–632, 634–636, 641, 642, 648, and 651, F.S. constitute the Florida Insurance Code.

² Ss. 641.21(1) and 641.48, F.S.

³ S. 627.9404, F.S. Long-term care services may encompass a wide array of medical, social, and personal care services required by an individual with a chronic disability. American Academy of Actuaries, *The Use of Genetic Information in Disability Income and Long-Term Care Insurance*, Issue Brief, Spring 2002, available at https://www.actuary.org/files/publications/genetic_25apr02.pdf (last accessed March 7, 2019).

⁴ *The Current Landscape of Genetic Testing*, Concert Genetics, March 2017, available at https://www.concertgenetics.com/wp-content/uploads/2017/05/10_ConcertGenetics_CurrentLandscapeofGeneticTesting_2017Update.pdf (last accessed March 8, 2019).

⁵ Harvard University T.H. Chan School of Public Health, *The Public and Genetic Editing, Testing, and Therapy*, Jan. 2016, available at <https://cdn1.sph.harvard.edu/wp-content/uploads/sites/94/2016/01/STAT-Harvard-Poll-Jan-2016-Genetic-Technology.pdf> (last accessed March 8, 2019). Genetic testing has also given rise to a novel industry aimed at providing individuals with customized data related to family ancestry, including companies like 23andMe, Ancestry.com, FamilyTree DNA, and Living DNA.

⁶ U.S. Centers for Disease Control and Prevention, *Genomic Testing*, last updated July 19, 2017, available at <https://www.cdc.gov/genomics/gtesting/> (last accessed March 7, 2019).

- **Carrier testing** – identifies whether a person “carries” a genetic change that can cause a disease. Carriers usually show no signs of the disorder; however, they can pass on the genetic variation to their children, who may develop the disorder or become carriers themselves.
- **Prenatal testing** - identifies fetuses that have certain diseases.
- **Pre-implantation genetic testing** – identifies whether embryos for implantation carry genes that could cause disease. This is often done in conjunction with *in vitro* fertilization.
- **Newborn screening** - is used to test babies one or two days after birth to determine if those newborns have certain diseases known to cause problems with health and development.
- **Pharmacogenetic testing** - provides information about how certain medicines are processed in a person’s body. This type of testing can help a healthcare provider choose the medicines that work best with a person’s genetic makeup. For example, genetic testing is now available to guide treatments for certain cancers.
- **Research genetic testing** – helps scientists learn more about how genes contribute to health and disease, as well as develop gene-based treatments. Sometimes the results do not directly help the research participant, but they may benefit others in the future by helping researchers expand their understanding of the human body.⁷

One often-cited use of genetic testing involves screening of female patients for a gene mutation that can be an early predictor of breast cancer. *BRCA 1* and *BRCA 2* gene mutations are relatively rare, but women having these mutations develop breast cancer at much higher rates than those without.⁸ *BRCA* testing has become increasingly prevalent among women in families with histories of breast cancer.⁹

Use of Personal Genetic Information in Insurance Markets

The now-widespread availability of genetic tests has given rise to questions and concerns over the appropriate use of genetic information. While an individual may voluntarily submit to genetic testing in an effort to gain insights into his or her own genetic history, third parties may seek to obtain this same information for other purposes, such as for use in insurance markets.

For example, insurers might use genetic information to exclude high-risk individuals from established risk pools. Insurers might also charge higher premium rates to an individual whose genetic information indicates that the individual is at an increased risk of developing a degenerative health condition.¹⁰ Conversely, exclusion of higher-risk insureds could reduce premium inflation for those left in the risk pool.

Similarly, consumers could use personal genetic information to the detriment of insurers. For example, an individual may discover through genetic testing that he or she is likely to develop a serious health condition, and only then purchase life insurance. An insurer is at a disadvantage and cannot accurately gauge the risk posed by covering an individual in this situation.¹¹ Adverse selection¹² of this nature could destabilize insurance markets if access to personal genetic information leads to widespread changes in consumer behavior.¹³ Specifically, the risk-spreading ability of insurance could be compromised if only those who are likely to become ill purchase insurance.¹⁴

⁷ U.S. Department of Health and Human Services, National Institutes for Health, *Genetic Testing: How it is Used for Healthcare*, available at <https://report.nih.gov/nihfactsheets/ViewFactSheet.aspx?csid=43> (last accessed March 8, 2019).

⁸ McCarthy, Anne Marie and Armstrong, Katrina, “The Role of Testing for *BRCA1* and *BRCA2* Mutations in Cancer Prevention.” *JAMA Intern Med.* 2014;174(7):1023–1024. doi:10.1001/jamainternmed.2014.1322, available at <https://www.ncbi.nlm.nih.gov/pmc/articles/PMC4169670/> (last accessed March 8, 2019).

⁹ Id.

¹⁰ Klitzman, Robert, Appelbaum, Paul S., Chung, Wendy K, “Should Life Insurers Have Access to Genetic Test Results?” *JAMA.* 2014;312(18):1855–1856. doi:10.1001/jama.2014.13301, available at <https://www.ncbi.nlm.nih.gov/pmc/articles/PMC4259574/> (last accessed March 8, 2019).

¹¹ Id.

¹² Adverse selection is defined as an imbalance in an exposure group created when persons who perceive a high probability of loss for themselves seek to buy insurance to a much greater degree than those who perceive a low probability of loss. IRMI, <https://www.irmi.com/term/insurance-definitions/adverse-selection> (last accessed Mar. 20, 2019).

¹³ American Academy of Actuaries, *The Use of Genetic Information in Disability Income and Long-Term Care Insurance*, Issue Brief, Spring 2002, available at https://www.actuary.org/files/publications/genetic_25apr02.pdf (last accessed March 8, 2019).

While the specific information provided by the genetic testing industry regarding medical conditions and their associated risks is limited at present, it is rapidly evolving. In 2013, the United States Food and Drug Administration (FDA) instructed 23andMe to stop giving health information to consumers.¹⁵ However, by 2018, 23andMe received approval from the FDA to provide reports regarding certain health conditions or risks, including the genetic variants in the *BRCA 1 and BRCA 2* genes.¹⁶ Other vendors also provide lists of genetic variants, available to consumers, with information regarding the scientific significance of each variant.¹⁷ In the future, consumers may be able to take the ever-evolving information provided by genetic testing, compare it to the information provided by these vendors, and determine they have a genetic condition or disease, or are likely to develop a health condition. Based upon this determination, they may decide to purchase insurance they otherwise would not, without disclosing the results of their genetic testing, and thereby receive the insurance at a rate that is actuarially unsound for their true risk class.

Federal Laws

The Health Insurance Portability and Accountability Act of 1996 (HIPAA) includes the first federal regulations on the use of personal genetic information.¹⁸ HIPAA prohibits health insurers from using “preexisting condition” exclusions based solely on an individual’s genetic information. Under HIPAA, insurers can make coverage decisions using information reflecting diagnosed health conditions, but not based on genetic indicators alone.¹⁹

The Genetic Information Nondiscrimination Act of 2008 (GINA) extended federal patient protections by preventing health insurers from using genetic information in the underwriting of health insurance products.²⁰ Health insurers may not charge higher premiums or make coverage decisions based solely on an individual’s genetic information. However, the prohibitions outlined in GINA do not extend to other types of insurance, such as life insurance and long-term care insurance. There are currently no federal limitations on the use of genetic information by these insurers.

The federal Patient Protection and Affordable Care Act²¹ (PPACA) prohibits most individual and group health insurers from excluding coverage to or otherwise discriminating against persons with pre-existing or complex health conditions. Moreover, the law prohibits plans from using most forms of medical underwriting, which had previously been used to link personal health status to the cost and availability of health insurance.²²

State Laws

States have adopted various regulations related to the use of genetic information by insurers. In general, states address patient privacy for personal genetic information by:²³

1. Requiring informed consent before performing genetic testing;

¹⁴ *Id.*

¹⁵ Tina Hesman Saey, *What consumer DNA data can and can't tell you about your risk for certain diseases*, ScienceNews (Jun. 3, 2018), <https://www.sciencenews.org/article/health-dna-genetic-testing-disease> (last accessed Mar. 22, 2019).

¹⁶ *Id.*

¹⁷ *Id.*

¹⁸ Hall, Mark A. and Rich, Stephen S., “Laws Restricting Health Insurers' Use of Genetic Information: Impact on Genetic Discrimination.” *AJHG* 2000: 66(1): 293-307, available at <https://doi.org/10.1086/302714> (last accessed March 8, 2019).

¹⁹ *Id.*

²⁰ U.S. Equal Employment Opportunity Commission, *The Genetic Information Nondiscrimination Act of 2008*, available at <https://www.eeoc.gov/laws/statutes/gina.cfm> (last accessed March 8, 2019).

²¹ Patient Protection and Affordable Care Act (PPACA), Pub. L. No. 111-148. On March 30, 2010, PPACA was amended by the Health Care and Education Reconciliation Act of 2010, Pub. L. No. 111-152.

²² 42 U.S.C. 300gg. The law allows insurers to consider an individual’s age and tobacco use in the development of applicable rates. However, virtually all other underwriting is prohibited.

²³ Miller, Amalia R. and Tucker, Catherine E., “Privacy Protection, Personalized Medicine and Genetic Testing” (July 31, 2014), available at <https://ssrn.com/abstract=2411230> (last accessed March 8, 2019).

2. Restricting the use of genetic data by health insurance, employers or providers of long-term life care or insurance; and,
3. Limiting disclosure of the personal genetic information without the consent of the individual or defining genetic data as the 'property' of the individual.

Most states have enacted laws that prohibit genetic discrimination by health insurers.²⁴ A number of states have taken actions to limit or prohibit the use of genetic information in other lines of insurance as well.²⁵ For example, Arizona, California, Massachusetts and New Jersey restrict use of genetic information by life insurers, and Kansas, Maryland and Massachusetts restrict use by long-term care insurers. Similarly, Arizona, California, Idaho, Kansas, Massachusetts and New Jersey restrict use by disability²⁶ insurers.²⁷

Florida Law

Section 760.40, F.S., makes the results of genetic testing the exclusive personal property of the person tested, and makes it a first degree misdemeanor to sharing test results without the informed consent of the person tested.

Section 627.4301, F.S., prohibits health insurers from considering genetic information, both when issuing insurance policies and when setting applicable premium rates.²⁸ Insurers cannot require or solicit genetic information, or employ underwriting based on the results of any genetic testing that an individual may choose to complete, and cannot use such results for any purpose. This prohibition is currently limited to self-insured health plans, fully-insured health plans, HMOs, prepaid limited health service organizations, prepaid health clinics, fraternal benefit societies, or any other health care arrangement where risk is assumed. This section of law expressly exempts several forms of insurance from the prohibition: life insurance, disability income, long-term care, accident-only, hospital indemnity or fixed indemnity, dental, and vision.

Effect of Proposed Changes

The bill amends s. 627.4301, F.S., existing prohibitions on the use of genetic information by insurers to include entities that issue policies for life insurance and long-term care insurance. Specifically, the bill prohibits issuers of life insurance and long-term care insurance from canceling, limiting, or denying coverage, and from setting different premium rates, based on personal genetic information without a specific diagnosis²⁹ related to the genetic information. The bill also prohibits life insurers and long-term care insurers from requiring or soliciting genetic information, using genetic test results, or considering a person's decisions or actions relating to genetic testing for any insurance purpose.

The bill has an effective date of July 1, 2019, and applies to insurance policies entered into or renewed on or after January 1, 2020.

²⁴ Rothstein, Mark A., "Putting the Genetic Nondiscrimination Act in context." *Genetics in Medicine* 2008: 10: 655-656, available at <https://www.nature.com/articles/gim200899> (last accessed March 8, 2019).

²⁵ The National Human Genome Human Research Institute maintains a searchable database of legislation related to genetic information that has either been enacted or considered by state legislatures. U.S. Department of Health and Human Services, National Institutes of Health – National Human Genome Human Research Institute, *Genome Statute and Legislation Database*, available at <https://www.genome.gov/policyethics/legdatabase/pubsearch.cfm?CFID=22285441&CFTOKEN=7fc536f1b99bbd21-2342A48B-03C6-03BE-03FEEF39A8695C0F> (last accessed March 8, 2019).

²⁶ Disability income insurance protects earned income against potential loss due to disabling injury or illness. American Academy of Actuaries, *The Use of Genetic Information in Disability Income and Long-Term Care Insurance*, Issue Brief, Spring 2002, available at https://www.actuary.org/files/publications/genetic_25apr02.pdf (last accessed March 8, 2019).

²⁷ *Supra* note 19.

²⁸ See also s. 626.9706, F.S., which prohibits insurers from refusing coverage or charging higher premiums to individuals determined to carry the sickle-cell trait.

²⁹ Florida law does not define "diagnosis." However, "diagnosis" is generally defined as the "art or act of identifying a disease from its signs and symptoms." Merriam-Webster, <https://www.merriam-webster.com/dictionary/diagnosis> (last accessed Mar. 22, 2019).

B. SECTION DIRECTORY:

Section 1: Amends s. 627.4301, F.S., relating to the use of genetic information for insurance purposes.

Section 2: Establishes that the bill's requirements are applicable to insurance policies entered into or renewed on or after January 1, 2020.

Section 3: Provides an effective date of July 1, 2019.

II. FISCAL ANALYSIS & ECONOMIC IMPACT STATEMENT

A. FISCAL IMPACT ON STATE GOVERNMENT:

1. Revenues:

None.

2. Expenditures:

None.

B. FISCAL IMPACT ON LOCAL GOVERNMENTS:

1. Revenues:

None.

2. Expenditures:

None.

C. DIRECT ECONOMIC IMPACT ON PRIVATE SECTOR:

It is unclear whether or how, issuers of life insurance and long-term care insurance are currently using personal genetic information, so the economic impact of the bill's prohibition on its use is unknown. As genetic testing evolves and provides additional information that indicates a consumer has an increased risk of developing a certain health conditions, but that consumer has not yet received a diagnosis, the consumer may be more likely to purchase additional life or long-term care insurance coverage at a rate that is not actuarially sound. Such purchases, if done in significant quantities, could have a negative impact on the financial solvency of insurers.

D. FISCAL COMMENTS:

None.

III. COMMENTS

A. CONSTITUTIONAL ISSUES:

1. Applicability of Municipality/County Mandates Provision:

Not applicable. This bill does not appear to affect county or municipal governments.

2. Other:

None.

B. RULE-MAKING AUTHORITY:

The bill neither authorizes nor requires administrative rulemaking.

C. DRAFTING ISSUES OR OTHER COMMENTS:

Because diagnosis is not defined under Florida law, the use of the word diagnosis on line 46 of the bill may cause some confusion. While diagnosis is traditionally done by a medical practitioner, a Health Information National Trends survey revealed that the numbers of people who use the internet for medical information before going to their physicians for that information is over four-to-one.³⁰ Some in the medical field have recognized that in certain circumstances “self-diagnosis may be in the public interest.”³¹ As genetic testing further evolves, people may be more readily able to self-diagnose certain medical conditions based upon the information provided by these genetic tests. The bill does not specify that the diagnosis which prevents an insurer from using genetic information to cancel, limit, or deny coverage, or modify rates must be made by a medical practitioner. Therefore, insurers may be able to ask consumers whether they have self-diagnosed any medical conditions and circumvent the limitation on using genetic information that the bill aims to implement.

IV. AMENDMENTS/ COMMITTEE SUBSTITUTE CHANGES

On March 13, 2019, the Health Market Reform Subcommittee adopted an amendment to the bill that prohibits all issuers of life insurance and long-term care insurance from soliciting genetic information from potential clients and from using personal genetic information for any insurance purpose.

The bill was reported favorably as a committee substitute. The analysis is drafted to the committee substitute as passed by the Health Market Reform Subcommittee.

³⁰ Annemarie Jutel, *Self-Diagnosis: A Discursive Systematic Review of the Medical Literature*, Society for Participatory Medicine (September 15, 2010), <https://participatorymedicine.org/journal/evidence/research/2010/09/15/self-diagnosis-a-discursive-systematic-review-of-the-medical-literature> (last accessed Mar. 22, 2019).

³¹ *Id.*