

The Florida Senate
BILL ANALYSIS AND FISCAL IMPACT STATEMENT

(This document is based on the provisions contained in the legislation as of the latest date listed below.)

Prepared By: The Professional Staff of the Committee on Health Policy

BILL: CS/SB 258

INTRODUCER: Health Policy Committee and Senators Bean and Benacquisto

SUBJECT: Genetic Information Used for Insurance Purposes

DATE: April 9, 2019

REVISED: _____

	ANALYST	STAFF DIRECTOR	REFERENCE	ACTION
1.	<u>Knudson</u>	<u>Knudson</u>	<u>BI</u>	Favorable
2.	<u>Williams</u>	<u>Brown</u>	<u>HP</u>	Fav/CS
3.	_____	_____	<u>RC</u>	_____

Please see Section IX. for Additional Information:

COMMITTEE SUBSTITUTE - Substantial Changes

I. Summary:

CS/SB 258 places certain restrictions on life insurers, long-term care insurers, and disability income insurers relating to the use of the results of genetic testing. For policies entered into or renewed on or after January 1, 2020, the bill prohibits such insurers from requiring an applicant for insurance to take a genetic test, collecting an applicant's genetic information or genetic test results without the applicant's authorization, or canceling, limiting, or denying coverage based on genetic information under certain conditions.

Among other provisions, the bill also prohibits a person, including a company providing direct-to-consumer commercial genetic testing, from selling, releasing, or sharing any personal identifying health information about a consumer with a life or health insurance company without a prior written authorization and a written request from the consumer for release of the information.

The bill has no fiscal impact on state government.

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

II. Present Situation:

Use of Genetic Information for Insurance Purposes – Florida Requirements

Insurance policies for life, disability income, and long-term care¹ are exempt from s. 627.4301, F.S., which provides standards for the use of genetic information by health insurers. Health insurers² may not, in the absence of a diagnosis of a condition related to genetic information, use such information to cancel, limit, or deny coverage, or establish differentials in premium rates. Health insurers are also prohibited from requiring or soliciting genetic information, using genetic test results, or considering a person's decisions or actions relating to genetic testing in any manner for any insurance purpose.

Section 627.4031, F.S., defines “genetic information” to mean information derived from genetic testing to determine the presence or absence of variations or mutations, including carrier status, in an individual's genetic material or genes that are:

- Scientifically or medically believed to cause a disease disorder, or syndrome, or are associated with a statistically increased risk of developing a disease; or
- Associated with a statistically increased risk of developing a disease, disorder, or syndrome, which is producing or showing no symptoms at the time of testing.

Genetic testing, for purposes of s. 627.4031, F.S., does not include routine physical examinations or chemical, blood, or urine analysis, unless specifically conducted to obtain genetic information, or questions regarding family history.

Federal Laws on the Use of Genetic Information for Insurance Purposes

Federal law generally prohibits health insurers from soliciting genetic information and using such information for underwriting purposes. Federal law does not apply these prohibitions to life insurance, disability insurance, or long-term care insurance.

Genetic Information Nondiscrimination Act of 2008

The Genetic Information Nondiscrimination Act of 2008 (GINA) amended a number of existing federal laws to prohibit health insurers from using genetic information for underwriting purposes.³ The act does not apply to life insurance, long-term care insurance, or disability insurance.

¹ Section 627.4301(2)(c), F.S. Other types of insurance that are wholly exempt from the statute are accident-only policies, hospital indemnity or fixed indemnity policies, dental policies, and vision policies.

² Section 627.4301(1)(b), F.S., defines health insurer to mean, “an authorized insurer offering health insurance as defined in s. 624.603, F.S., a self-insured plan as defined in s. 624.031, F.S., a multiple-employer welfare arrangement as defined in s. 624.437, F.S., a prepaid limited health service organization as defined in s. 636.003, F.S., a health maintenance organization as defined in s. 641.19, F.S., a prepaid health clinic as defined in s. 641.402, F.S., a fraternal benefit society as defined in s. 632.601, F.S., or any health care arrangement whereby risk is assumed.”

³ Pub. Law No. 110-233, s. 122 Stat. 881-921 (2008). <https://www.gpo.gov/fdsys/pkg/PLAW-110publ233/pdf/PLAW-110publ233.pdf> (last accessed March 7, 2019).

Title I of GINA provides protections against discrimination by health insurers on the basis of genetic information.⁴ GINA prohibits health insurers and health plan administrators from using genetic information to make rating or coverage decisions.⁵ These decisions include eligibility for coverage and setting premium or contribution amounts.

GINA generally prohibits health insurers and health plan administrators from requesting or requiring genetic information of an individual or the individual's family members,⁶ nor may such information be requested, required or purchased for underwriting purposes.⁷ Underwriting purposes include rules for eligibility, determining coverage or benefits, cost-sharing mechanisms, calculating premiums or contribution amounts, rebates, payments in kind, pre-existing condition exclusions, and other activities related to the creation, renewal, or replacement of health insurance or health benefits. Underwriting purposes does not include determining medical appropriateness where an individual seeks a health benefit under a plan, coverage, or policy.⁸ Genetic information may be used by an insurer to make a determination regarding the payment of benefits, for example, as the basis of a diagnosis that then would lead to benefits being provided under the insurance policy.

The protections in GINA apply to the individual and group health markets, including employer sponsored plans under the Employee Retirement Income Security Act of 1974 (ERISA).⁹ GINA generally expanded many of the genetic information protections in the Health Insurance Portability and Accountability Act of 1996¹⁰ (HIPAA) and applied them to the individual, group and Medicare supplemental marketplaces.¹¹ The protections enacted in GINA do not apply to Medicare or Medicaid because both programs bar the use of genetic information as a condition of eligibility.¹² GINA also prohibits employment discrimination on the basis of genetic information.¹³

States may provide stronger protections than GINA, which provides a baseline level of protection against prohibited discrimination on the basis of genetic information.

Health Insurance Portability and Accountability Act of 1996

HIPAA establishes national standards to ensure the privacy and nondisclosure of personal health information. The rule applies to “covered entities” which means a health plan, health care

⁴ 110th Congress, *Summary: H.R.493 Public Law* (May 21, 2008) (last accessed February 1, 2018).

⁵ See 29 USC 1182; 42 USC 300gg-1; and 42 USC 300gg-53.

⁶ Department of Health and Human Services, “GINA” *The Genetic Information Nondiscrimination Act of 2008: Information for Researchers and Health Care Professionals*, (April 6, 2009).

<https://www.genome.gov/pages/policyethics/geneticdiscrimination/ginainfodoc.pdf> (last accessed March 7, 2019).

⁷ See 29 USC 1182(d); 42 USC 300gg-4(d); and 42 USC 300gg-53(e).

⁸ See 45 CFR 164.502(a)(5)(i)(4)(B).

⁹ Perry W. Payne, Jr. et al, *Health Insurance and the Genetic Information Nondiscrimination Act of 2008: Implications for Public Health Policy and Practice*, Public Health Rep., Vol. 124 (March-April 2009), 328, 331.

¹⁰ Codified 42 USC 300gg, 29 USC 1181 et seq., and 42 USC 1320d et seq.

¹¹ See Payne at pg. 329.

¹² National Institutes of Health, *The Genetic Information Nondiscrimination Act (GINA)*.

¹³ See 29 CFR 1635(a), which prohibits the use of genetic information in employment decision making; restricts employers and other entities from requesting, requiring, or purchasing genetic information; requires that genetic information be maintained as a confidential medical record, and places strict limits on disclosure of genetic information; and provides remedies for individuals whose genetic information is acquired, used, or disclosed in violation of GINA.

clearinghouse, other health care providers, and their business associates.¹⁴ HIPAA provides standards for the use and disclosure of protected health information and generally prohibits covered entities and their business associates from disclosing protected health information, except as otherwise permitted or required.¹⁵ Covered entities generally may not sell protected health information.¹⁶ HIPAA, as modified by GINA, also prohibits health plans from using or disclosing protected health information that is genetic information for underwriting purposes.¹⁷

Patient Protection and Affordable Care Act of 2010

The Patient Protection and Affordable Care Act of 2010 (ACA) requires all individual and group health plans to enroll applicants regardless of their health status, age, gender, or other factors that might predict the use of health services.¹⁸ These guaranteed issue and guaranteed renewability requirements apply to genetic testing.

Use of Genetic Information for Insurance Purposes – Requirements in Other States

Federal law under GINA applies to all states and provides a baseline level of protection that states may exceed. The NIH has identified 105 state statutes addressing health insurance nondiscrimination across 48 states and the District of Columbia.¹⁹ Fewer states address genetic testing regarding other lines of insurance such as life insurance, disability insurance, and long-term care insurance.²⁰

Examples of such statutes include Oregon, which requires informed consent to conduct testing, prohibits the use of genetic information for underwriting or ratemaking for any policy for hospital and medical expense, and prohibits using the genetic information of a blood relative for underwriting purposes regarding any insurance policy.²¹ Informed consent when an insurer requests genetic testing for life or disability insurance is required in California, New Jersey, and New York.²² Massachusetts prohibits unfair discrimination based on genetic information or a genetic test and prohibits requiring an applicant or existing policyholder to undergo genetic testing.²³ Arizona prohibits the use of genetic information for underwriting or rating disability insurance in the absence of a diagnosis, and life and disability insurance policies may not use genetic information for underwriting or ratemaking unless supported by the applicant's medical condition, medical history, and either claims experience or actuarial projections.²⁴

¹⁴ See 45 CFR 160.103.

¹⁵ See 45 CFR 164.502(a).

¹⁶ See 45 CFR 164.502(a)(5)(ii)(A).

¹⁷ See 45 CFR 164.502(a)(5)(i).

¹⁸ See 42 USC 300gg-1 and 42 USC 300gg-2.

¹⁹ National Institutes of Health, *Genome Statute and Legislation Database Search*.

<https://www.genome.gov/policyethics/legdatabase/pubsearch.cfm> (database search for “state statute,” “health insurance nondiscrimination” performed by Committee on Banking and Insurance professional staff on March 7, 2019).

²⁰ See *id.* (database search for “state statute,” “other lines of insurance nondiscrimination” performed by Committee on Banking and Insurance professional staff on March 7, 2019).

²¹ Section 746.135, O.R.S.

²² See Cal. Ins. Code s. 10146 et seq.; s. 17B:30-12, N.J.S.; and ISC s. 2615, N.Y.C.L.

²³ Chapter 175 sections 108I and 120E, M.G.L.

²⁴ Section 20-448, A.R.S.

Genetic Testing

Genetic testing includes a number of medical tests that identify and examine chromosomes, genes, or proteins for the purpose of obtaining genetic information.²⁵ Genetic testing is often used for medical or genealogical purposes.

Medical Genetic Testing

Genetic testing can be done to diagnose a genetic disorder, to predict the possibility of future illness, and predict a patient's response to therapy.²⁶ More than 2,000 genetic tests are currently available and more tests are constantly being developed.²⁷ The National Institutes of Health²⁸ (NIH) have identified the following available types of medical genetic testing:²⁹

- *Diagnostic testing* identifies or rules out a specific genetic or chromosomal condition, and is often used to confirm a diagnosis when a particular condition is suspected based on the individual's symptoms. For example, a person experiencing abnormal muscle weakness may undergo diagnostic testing that screens for various muscular dystrophies.
- *Predictive and pre-symptomatic testing* is used to detect gene mutations associated with disorders that appear after birth, often later in life. This testing is often used by people who are asymptomatic, but have a family member with a genetic disorder. Predictive testing can identify mutations that will result in genetic disorder, or that increase a person's risk of developing disorders with a genetic basis, such as cancer.
- *Carrier testing* identifies people who carry one copy of a gene mutation that, when present in two copies, causes a genetic disorder. This test is often used by parents to determine their risk of having a child with a genetic disorder.
- *Preimplantation testing* is used to detect genetic changes in embryos developed by assisted reproductive techniques such as in-vitro fertilization. Small numbers of cells are taken from the embryos and tested for genetic changes prior to implantation of a fertilized egg.
- *Prenatal testing* detects changes in a baby's genes or chromosomes before birth. Such testing is often offered if there is an increased risk the baby will have a genetic or chromosomal disorder.
- *Newborn screening* is performed shortly after birth to identify genetic disorders that can be treated early in life. Florida screens for 31 disorders recommended by the United States Department of Health and Human Services Recommended Uniform Screening Panel and 22 secondary disorders, unless a parent objects in writing.³⁰

²⁵ National Institutes of Health, *Genetic Testing*, pg. 3 (January 30, 2018). Available for download at <https://ghr.nlm.nih.gov/primer/testing/uses> (last accessed March 26, 2019).

²⁶ Francis S. Collins, *A Brief Primer on Genetic Testing* (January 24, 2003). <https://www.genome.gov/10506784/a-brief-primer-on-genetic-testing/> (last accessed March 7, 2019).

²⁷ See Ohio State University Wexner Medical Center, *Facts About Testing*. <https://wexnermedical.osu.edu/genetics/facts-about-testing> (last accessed March 7, 2019).

²⁸ The National Institutes of Health is the medical research agency of the United States federal government. The NIH is part of the United States Department of Health and Human Services. The NIH is made of 27 different Institutes and Centers, each having a specific research agenda.

²⁹ *Supra* note 25, at pgs. 5-6.

³⁰ Florida Department of Health, *Newborn Screening*. <http://www.floridahealth.gov/programs-and-services/childrens-health/newborn-screening/index.html> (last accessed March 7, 2019).

Genetic testing is often used for research purposes. For example, genetic testing may be used to discover genes or increase understanding of genes that are newly discovered or not well understood.³¹ Testing results as part of a research study are usually not available to patients or health care providers.³²

The Human Genome Project, which in April 2003 successfully sequenced and mapped all of the genes of humans, and a variety of other genetic testing, has led to multiple medical advances. For example, genetic testing identified that the reason the drug Plavix, which is commonly used to prevent blood clots in patients at risk for heart attacks and strokes, does not work for approximately 30 percent of the United States population because variations in the CYP2C19 gene account for the lack of a response.³³ Thus, genetic testing can identify persons for whom the drug will not be effective.

The American Medical Association supports broad protections against genetic discrimination because it believes genetic testing and genetic information is essential to advancements in medical knowledge and care.³⁴ Accordingly, the organization supports comprehensive federal protection against genetic discrimination because “patients remain at-risk of discrimination in a broad array of areas such as life, long-term care, and disability insurance as well as housing, education, public accommodations, mortgage lending, and elections.”

Methods of genetic testing used for medical purposes include:

- Molecular genetic tests (Gene tests) that study single genes or short lengths of DNA to identify variations or mutations that lead to a genetic disorder.
- Chromosomal genetic tests that analyze whole chromosomes or long lengths of DNA to see if there are large genetic changes, such as an extra copy of a chromosome, that cause a genetic condition.
- Biochemical genetic tests that study the amount or activity level of proteins; abnormalities in either can indicate changes to the DNA that result in a genetic disorder.

Genetic Ancestry Testing

Genetic ancestry testing, also called genetic genealogy, is used to identify relationships between families and identify patterns of genetic variation that are often shared among people of particular backgrounds.³⁵ According to the NIH, genetic ancestry testing results may differ between providers because they compare genetic information to different databases. The tests can yield unexpected results because human populations migrate and mix with other nearby groups. Scientists can use large numbers of genetic ancestry test results to explore the history of populations. Three common types of genetic ancestry testing include:³⁶

³¹ *Supra* note 27.

³² National Institutes of Health, *Genetic Testing*, at pg. 24.

³³ Francis S. Collins, Perspectives on the Human Genome Project, pg. 50 (June 7, 2010).

https://www.genome.gov/pages/newsroom/webcasts/2010sciencereportersworkshop/collins_nhgrisciencewriters060710.pdf (last accessed March 7, 2019).

³⁴ American Medical Association, *Genetic Discrimination – Appendix II. AMA Legislative Principles on Genetic Discrimination and Surreptitious Testing*, (March 2013) <https://www.ama-assn.org/sites/default/files/media-browser/public/genetic-discrimination-policy-paper.pdf> (last accessed March 7, 2019).

³⁵ National Institutes of Health, *Genetic Testing*, at pg. 25.

³⁶ National Institutes of Health, *Genetic Testing*, at pg. 26.

- Single nucleotide polymorphism testing to evaluate large numbers of variations across a person's entire genome. The results are compared with those of others who have taken the tests to provide an estimate of a person's ethnic background.
- Mitochondrial DNA testing to identify genetic variations in mitochondrial DNA, which provides information about the direct female ancestral lines.
- Y chromosome testing, performed exclusively on males, often used to investigate whether two families with the same surname are related.

Direct to Consumer Genetic Testing

Traditionally, genetic testing was available only through health care providers.³⁷ Direct-to-consumer genetic testing provides access to genetic testing outside the health care context. Generally, the consumer purchases a genetic testing kit from a vendor that mails the kit to the consumer. The consumer collects a DNA sample and mails it back to the vendor. The vendor uses a laboratory to conduct the test. The consumer is then notified of the test results.

Direct-to-consumer genetic testing has primarily been used for genealogical purposes, but increasing numbers of products now provide medical information. For example, the vendor 23andME offers, with FDA approval, genetic testing that examines the consumer's risks for certain diseases including Parkinson's disease, celiac disease, and late-onset Alzheimer's disease.³⁸

Direct to consumer genetic testing is increasing in popularity, with one company reporting having sold approximately 1.5 million genetic testing kits from November 24, 2017, through November 27, 2017.³⁹ The increased proliferation of such testing is accompanied by increased concerns about the privacy of such information. The privacy protections of HIPAA usually do not apply to direct-to-consumer genetic testing because the vendors selling such tests are often not "covered entities" and thus not subject to HIPAA. The Federal Trade Commission has recently warned consumers to consider the privacy implications of genetic testing kits.⁴⁰

Life Insurance, Disability Insurance, and Long-Term Care Insurance

Life insurance is the insurance of human lives.⁴¹ Life insurance can be purchased in the following forms:⁴²

- Term life insurance provides coverage for a set term of years and pays a death benefit if the insured dies during the term.⁴³

³⁷ National Institutes of Health, *Genetic Testing*, at pg. 11.

³⁸ 23andMe, *Find Out What Your DNA Says About Your Health, Traits and Ancestry* <https://www.23andme.com/dna-health-ancestry/> (last accessed March 7, 2019).

³⁹ Megan Molteni, *Ancestry's Genetic Testing Kits Are Heading For Your Stocking This Year*, Wired, (December 1, 2017) <https://www.wired.com/story/ancestrys-genetic-testing-kits-are-heading-for-your-stocking-this-year/> (last accessed March 7, 2019).

⁴⁰ Federal Trade Commission, *DNA Test Kits: Consider the Privacy Implications*, (December 12, 2017). <https://www.consumer.ftc.gov/blog/2017/12/dna-test-kits-consider-privacy-implications> (last accessed March 7, 2019).

⁴¹ Section 624.602, F.S.

⁴² National Association of Insurance Commissioners, *Life Insurance – Considerations for All Life Situations*, http://www.insureuonline.org/insureu_type_life.htm (last accessed March 7, 2019).

⁴³ National Association of Insurance Commissioners, *Life Insurance FAQs*, http://www.insureuonline.org/consumer_life_faqs.htm (last accessed March 7, 2019).

- Permanent life insurance remains in place if the insured pays premiums, and the coverage pays a death benefit. Such policies have an actual cash value component that increases over time and from which the policy owner may borrow. There are four types of permanent life insurance:
 - Whole life insurance offers a fixed premium, guaranteed annual cash value growth and a guaranteed death benefit. It does not provide investment flexibility and the policy coverage, once established, may not be changed.
 - Universal life insurance allows the policyholder to determine the amount and timing of premium payments within certain limits. The coverage level may be adjusted. It guarantees certain levels of annual cash value growth but not investment flexibility.
 - Variable life insurance allows allocation of investment funds, but does not guarantee minimum cash value because of fluctuations in the value of investments.
 - Variable universal life insurance combines variable and universal life insurance.⁴⁴

Life insurance also encompasses annuities and disability policies.⁴⁵ An annuity is a contract between a customer and an insurer wherein the customer makes a lump-sum payment or a series of payments to an insurer that in return agrees to make periodic payments to the annuitant at a future date, either for the annuitant's life or a specified period. Disability insurance pays a weekly or monthly income for a set period if the insured becomes disabled and cannot continue working or obtain work.

Life insurance underwriters seek to identify and classify the risk represented by a proposed insured and then classify those risks into pools of similar mortality or morbidity risk.⁴⁶ Insureds within the same risk classification pay the same premiums, which must be adequate to ensure solvency, pay claims, and provide the insurer (with investment income) a reasonable rate of return.

Disability insurance compensates the insured for a portion of income lost because of a disabling injury or illness.⁴⁷ There are two types of disability insurance: short-term and long-term. A short-term policy typically replaces a portion of lost income from three to six months following the disability. Long-term policies generally begin six months after the disability and can last a set number of years or until retirement age. Disability insurance is sometimes offered by life insurers.

Insurance policy forms for insurance sold in Florida must be filed and approved by the Office of Insurance Regulation (OIR).⁴⁸ The Unfair Insurance Trade Practices Act prohibits “knowingly making or permitting unfair discrimination between individuals of the same actuarially supportable class and expectation of life, in the rates charged for a life insurance or annuity

⁴⁴ See “What are the different types of permanent life insurance policies?” available at <https://www.iii.org/article/what-are-different-types-permanent-life-insurance-policies> (last accessed March 26, 2019).

⁴⁵ Section 624.602, F.S.

⁴⁶ American Council of Life Insurers, *Life Insurer Issues*. (On file with the Senate Committee on Banking and Insurance).

⁴⁷ See National Association of Insurance Commissioners, *A Worker's Most Valuable Asset: Protecting Your Financial Future with Disability Insurance* http://www.naic.org/documents/consumer_alert_protecting_financial_future_disability_insurance.htm (last accessed March 7, 2019).

⁴⁸ Section 624.410, F.S.

contract, in the dividends or other benefits payable thereon, or in any other term or condition of such contract.”⁴⁹ Similarly, the act prohibits knowingly making or permitting unfair discrimination between individuals of the same actuarially supportable class, as determined at the time of initial issuance of the coverage, and essentially the same hazard, in the amount of premium, policy fees, or rates charged for a policy or contract of disability insurance, in benefits payable, in the terms or conditions of the contract, or in any other manner.⁵⁰

Long-term care (LTC) insurance covers the costs of nursing homes, assisted living, home health care, and other long-term care services. A long-term care insurance policy provides coverage for medically necessary diagnostic, preventive, therapeutic, curing, treating, mitigating, rehabilitative, maintenance or personal care services provided in a setting other than an acute care unit of a hospital.⁵¹ Long-term care insurance usually pays fixed-dollar amounts or the actual costs of care, often subject to a maximum daily benefit amount.⁵²

The LTC insurance market provides an example of the negative effects of insurers not accurately projecting their underwriting risk. LTC insurers made incorrect assumptions when selling the coverage, particularly in the 1980s and 1990s.⁵³ The LTC insurers overestimated the number of people that would cancel their coverage or allow it to lapse, underestimated the life span of insureds and the time span of the treatment they would receive, and overestimated earnings on LTC premiums which were negatively affected by dropping interest rates.⁵⁴ As a result, long-term care insurance premiums have been rising, often substantially, for the past decade.⁵⁵

In response to substantial LTC premium increases, Florida law prohibits LTC rate increases that would result in a premium in excess of that charged on a newly issued policy, except to reflect benefit differences.⁵⁶ If the insurer is not writing new LTC policies, the rate cannot exceed the new business rate of insurers representing 80 percent of the carriers in the marketplace. In January 2017, the OIR issued consent orders allowing two of the state’s largest LTC insurers, Metropolitan Life Insurance Company and Unum Life Insurance Company of America, to substantially raise LTC monthly premiums, phased in over three years.⁵⁷ Many insurers that

⁴⁹ Section 626.9541(1)(g)1., F.S.

⁵⁰ Section 626.9541(1)(g)2., F.S.

⁵¹ Section 627.9404(1), F.S.

⁵² Florida Department of Financial Services, *Long-Term Care: A Guide for Consumers*, pg. 5.

<https://www.myfloridacfo.com/division/consumers/UnderstandingCoverage/Guides/documents/LTCGuide.pdf> (last accessed March 7, 2019).

⁵³ See Leslie Scism, *Millions Bought Insurance to Cover Retirement Health Costs. Now They Face an Awful Choice*, Wall Street Journal (January 17, 2018) <https://www.wsj.com/articles/millions-bought-insurance-to-cover-retirement-health-costs-now-they-face-an-awful-choice-1516206708> (last accessed March 7, 2019).

⁵⁴ See Office of Insurance Regulation, *Long-Term Care Public Rate Hearings*. (The Internet page references a rate filing decision made by the OIR on Jan. 12, 2017, related to LTC products for two insurers).

<https://www.floir.com/Sections/LandH/LongTermCareHearing.aspx> (last accessed March 7, 2019); See Scism at fn. 35

⁵⁵ See Scism at fn. 35; See Office of Insurance Regulation at fn. 36.

<https://www.floir.com/Sections/LandH/LongTermCareHearing.aspx> (last accessed March 7, 2019).

⁵⁶ Section 627.9407(7)(c), F.S.

⁵⁷ See Office of Insurance Regulation, *Consent Order In the Matter of: Metropolitan Life Insurance Company*, Case No. 200646-16-CO (Jan. 12, 2017) <https://www.floir.com/siteDocuments/MetLife200646-16-CO.pdf> (last accessed March 7, 2019); Office of Insurance Regulation, *Consent Order In The Matter of Unum Life Insurance Company of America*, Case No. 200879-16-CO (Jan. 12, 2017) <https://www.floir.com/siteDocuments/Unum200879-16-CO.pdf> (last accessed March 7, 2019).

write LTC insurance have taken substantial losses. Recently, General Electric announced a \$6.2 billion charge against earnings and a \$15 billion shortfall in insurance reserves related to LTC insurance obligations.⁵⁸

The American Council of Life Insurers has expressed concerns that the proliferation of genetic testing could increase adverse selection and impact the availability and affordability of products over time.⁵⁹ Studies addressing whether genetic testing leads to adverse selection have reached varying conclusions. Studies of women tested for the BRCA1 gene mutation (linked to breast cancer risk)⁶⁰ and adults tested for Alzheimer's risk⁶¹ found little evidence of adverse selection in the life insurance market. However, the study regarding Alzheimer's risk found evidence of adverse selection for long-term care insurance, as 17 percent of those who tested positive subsequently changed their LTC policy in the year after testing positive of Alzheimer's risk, in comparison with two percent of those who tested negative and four percent of those who did not receive test results.⁶²

III. Effect of Proposed Changes:

Section 1 amends s. 627.4301, F.S., to provide the following definitions:

- “Genetic test results” is defined to include, but not be limited to, results of direct-to-consumer commercial genetic testing;
- “Life insurer” is defined to have the same meaning as provided in s. 624.602, F.S.; and to include an insurer issuing life insurance contracts that grant additional benefits in the event of an insured's disability;
- “Long-term care insurer” is defined as an insurer issuing long-term care insurance policies as described in s. 627.9404, F.S.

The bill's definition of “genetic test results” has the effect of modifying the current-law use of that term in s. 627.4301(2), F.S., which provides that health insurers may not require or solicit genetic information, use *genetic test results*, or consider a person's decisions or actions relating to genetic testing in any manner for insurance purposes.

Subsection (3) of s. 627.4301, F.S., is created to provide restrictions on the use of genetic information by life insurers, long-term care insurers, and disability income insurers.

⁵⁸ Sonali Basak, Katherine Chiglinsky, et al, *GE's Surprise \$15 Billion Shortfall Was 14 Years in the Making*, Chicago Tribune, (January 25, 2018) <http://www.chicagotribune.com/business/ct-biz-ge-general-electric-accounting-20180125-story.html> (last accessed March 7, 2019); Steve Lohr and Chad Bray, *At G.E., \$6.2 Billion Charge for Finance Unit Hurts C.E.O.'s Turnaround Push*, New York Times, (January 16, 2018). <https://www.nytimes.com/2018/01/16/business/dealbook/general-electric-ge-capital.html> (last accessed March 7, 2019).

⁵⁹ Gina Kolata, *New Gene Tests Pose a Threat to Insurers*, New York Times (May 12, 2017) <https://www.nytimes.com/2017/05/12/health/new-gene-tests-pose-a-threat-to-insurers.html> (last accessed March 7, 2019).

⁶⁰ Cathleen D. Zick, et. al., *Genetic Testing, Adverse Selection, and the Demand for Life Insurance*, pgs. 29-39 American Journal of Medical Genetics (July 2000) (Abstract provided by NIH at <https://www.ncbi.nlm.nih.gov/pubmed/10861679> (last accessed March 7, 2019)).

⁶¹ Cathleen D. Zick, *Genetic Testing For Alzheimer's Disease And Its Impact on Insurance Purchasing Behavior*, pgs. 483-490, Health Affairs vol. 23, no. 2 (March/April 2005) <https://www.healthaffairs.org/doi/pdf/10.1377/hlthaff.24.2.483> (last accessed March 7, 2019).

⁶² See Zick fn. 60 at pgs. 487-488.

Such insurers are prohibited from:

- Requiring an applicant to take a genetic test;
- Collecting an individual's genetic information or genetic test results without the applicant's authorization; and
- Considering the results of genetic tests that are not related to the individual's medical condition or future health risk and that are designed to share information with an individual concerning the applicant's race, ethnicity, or national origin.

The bill provides that a life insurer, long-term care insurer, or disability income insurer may only consider genetic test results included in an individual's medical record if the tests have been reviewed and confirmed by the individual's physician and the insurer complies with the following:

- The insurer may not cancel, limit, or deny coverage, or establish differentials in premiums, based on genetic information unless such action is based on objective, statistical evidence related to actual or anticipated loss experience that is relevant to an individual's life expectancy or health; and
- The insurer must document the rationale for such action and provide the documentation to the OIR upon request.

The prohibition and requirement denoted in the bullets above serve two functions. They are stand-alone provisions of the bill, and they are conditions insurers must meet in order to lawfully consider the results of genetic testing included in an individual's medical record as described above.

The bill provides that genetic information, including genetic test results, is non-public, private health information and is subject to the privacy protections under ss. 626.9651⁶³ and 760.40, F.S.⁶⁴

The bill provides that s. 627.4301(3), F.S., as created under the bill:

- Does not relieve the obligation of a life insurer, long-term care insurer, or disability income insurer to comply with ss. 626.9706 and 626.9707, F.S.;⁶⁵
- Does not apply to health insurers; and
- Applies to life insurance, long-term care insurance, and disability income insurance policies entered into or renewed on or after January 1, 2020.

Section 2 amends s. 760.40, F.S., relating to genetic testing, informed consent, confidentiality, penalties, and notice of the use of test results. Existing provisions of law applicable to genetic testing or DNA testing and results are made applicable to direct-to-consumer commercial genetic testing. The bill prohibits a person, including a company providing direct-to-consumer

⁶³ Section 626.9651, F.S., pertains to an insurer's allowable use of a consumer's non-public personal financial and health information.

⁶⁴ Section 760.40(2), F.S., provides that, except for purposes of criminal prosecution and other specified purposes, DNA analysis may be performed only with the informed consent of the person to be tested, and the results of such DNA analysis, whether held by a public or private entity, are the exclusive property of the person tested, are confidential, and may not be disclosed without the consent of the person tested. Such information held by a public entity is exempt from public records.

⁶⁵ Sections 626.9706 and 626.9707, F.S., provide that life insurers and disability insurers may not refuse to cover and may not modify the premiums for coverage solely because the person to be insured has the sickle-cell trait.

commercial genetic testing, from selling, releasing, or sharing any personal identifying health information about a consumer with a life or health insurance company without a prior written authorization and a written request from the consumer for release of the information.

Section 3 provides an effective date of July 1, 2019.

IV. Constitutional Issues:

A. Municipality/County Mandates Restrictions:

None.

B. Public Records/Open Meetings Issues:

None.

C. Trust Funds Restrictions:

None.

D. State Tax or Fee Increases:

None.

E. Other Constitutional Issues:

None.

V. Fiscal Impact Statement:

A. Tax/Fee Issues:

None.

B. Private Sector Impact:

CS/SB 258 will restrict the use of genetic information in underwriting, risk classification, and rate setting by life, long-term care, and disability income insurers and could result in changes in premiums for such products.

C. Government Sector Impact:

None.

VI. Technical Deficiencies:

None.

VII. Related Issues:

None.

VIII. Statutes Affected:

This bill substantially amends sections 627.4301 and 760.40 of the Florida Statutes.

IX. Additional Information:**A. Committee Substitute – Statement of Substantial Changes:**

(Summarizing differences between the Committee Substitute and the prior version of the bill.)

CS by Health Policy on April 8, 2019:

The CS:

- Amends s. 627.4301, F.S., relating to genetic information for insurance purposes, to provide that a life insurer, long-term care insurer, or disability income insurer may not:
 - Require an applicant to take a genetic test;
 - Collect an applicant's genetic information or genetic test results without the applicant's authorization; or
 - Consider the results of a genetic test that is designed to share information with an individual concerning the applicant's race, ethnicity, or national origin and that is not related to an applicant's medical condition or future health risk;
- Creates s. 627.4301(3), F.S., to provide that:
 - A life insurer, long-term care insurer, or disability income insurer may only consider genetic test results included in an individual's medical record if the tests have been reviewed and confirmed by the individual's physician and the insurer complies with the following two requirements, which are also stand-alone requirements:
 - A life insurer, long-term care insurer, or disability income insurer may not cancel, limit, or deny coverage, or establish differentials in premium rates, based on genetic information unless such action is based on objective statistical evidence related to actual or anticipated loss experience that is relevant to an individual's life expectancy or health;
 - A life insurer, long-term care insurer, or disability income insurer must document the rationale for such action and provide the documentation to the OIR upon request;
 - Genetic information, including genetic test results, is non-public, private health information and is subject to specified privacy protections granted under existing Florida law;
- Provides that s. 627.4301(3), F.S., does not relieve insurers of the duty to comply with specified anti-discrimination protections under current law, applies to policies entered into or renewed on or after January 1, 2020, and does not apply to health insurers;
- Provides that specified, current-law requirements on genetic testing also apply to direct-to-consumer commercial genetic testing; and

- Provides that a person, including a company providing direct-to-consumer commercial genetic testing, may not sell, release, or share any personal identifying health information about a consumer with a life or health insurance company without a prior written authorization and a written request from the consumer for release of the information.

B. Amendments:

None.

This Senate Bill Analysis does not reflect the intent or official position of the bill's introducer or the Florida Senate.
