

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 Judiciary

BILL: CS/SB 1564

INTRODUCER: Banking and Insurance Committee and Senator Stargel

SUBJECT: Use of Genetic Information

DATE: February 10, 2020

REVISED: _____

	ANALYST	STAFF DIRECTOR	REFERENCE	ACTION
1.	<u>Knudson</u>	<u>Knudson</u>	<u>BI</u>	<u>Fav/CS</u>
2.	<u>Elsesser</u>	<u>Cibula</u>	<u>JU</u>	<u>Pre-meeting</u>
3.	_____	_____	<u>RC</u>	_____

Please see Section IX. for Additional Information:

COMMITTEE SUBSTITUTE - Substantial Changes

I. Summary:

CS/SB 1564 provides that a life insurer, long-term care insurer, or disability income insurer may use genetic information, including the results of direct-to-consumer genetic testing, for underwriting purposes only if the genetic information is:

- In the medical record;
- Relevant to a potential medical condition that impacts mortality or morbidity risk; and
- Related to expected mortality or morbidity based on sound actuarial principles or reasonably expected experience.

The bill prohibits a life insurer, long-term care insurer, or disability income insurer from:

- Cancelling coverage based solely on genetic information;
- Requiring an applicant take a genetic test as a condition of insurability; or
- Obtaining, requesting, or otherwise requiring the complete genome sequence of an applicant's DNA.

The bill applies the existing prohibition against health insurers using genetic information in the absence of a diagnosis to direct-to-consumer genetic testing.

The bill requires companies that provide direct-to-consumer genetic testing to obtain written consent from the consumer prior to sharing genetic information or personally identifiable information about a consumer with a life insurer or health insurer.

The bill has an effective date of July 1, 2020.

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.

Prohibition of Unfair Discrimination Between Individuals

Insurance policy forms for insurance sold in Florida must be filed and approved by the Office of Insurance Regulation (OIR).³ 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 contract, in the dividends or other benefits payable thereon, or in any other term or condition of such contract.”⁴ 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.⁵ Genetic information

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 Section 624.410, F.S.

⁴ Section 626.9541(1)(g)1., F.S.

⁵ Section 626.9541(1)(g)2., F.S.

used in the underwriting and pricing of life insurance, long-term care insurance, and disability income insurance must meet these requirements.

Genetic Testing – Informed Consent and Privacy Requirements

Section 760.40, F.S., provides that the results of DNA analysis are the exclusive property of the person tested. Accordingly, DNA analysis may be performed only with the informed consent of the person to be tested. The results of DNA analysis, whether held by a public or private entity, are confidential, and may not be disclosed without the consent of the person tested. DNA analysis held by a public entity must be held confidential and exempt from public disclosure. Violation of these requirements is a first degree misdemeanor punishable by up to 1 year imprisonment and a fine of up to \$1,000. DNA analysis, for purposes of the statute, is 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 law also requires any person who performs DNA analysis or receives records, results, or findings of DNA analysis to provide the person tested with notice that the analysis was performed or the information was received. The notice must state that, upon the request of the person tested, the information will be made available to his or her physician. Further, the notice must state whether the information was used in any decision to grant or deny any insurance, employment, mortgage, loan, credit, or educational opportunity. If such information was used in a denial of the foregoing, the analysis must be repeated to verify the accuracy of the first analysis, and if the first analysis is found to be inaccurate, the denial must be reviewed.

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.⁶ The act does not apply to life insurance, long-term care insurance, or disability insurance.

Title I of GINA provides protections against discrimination by health insurers on the basis of genetic information.⁷ GINA prohibits health insurers and health plan administrators from using genetic information to make rating or coverage decisions.⁸ These decisions include eligibility for coverage and setting premium or contribution amounts.

⁶ 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 January 24, 2020).

⁷ 110th Congress, *Summary: H.R.493 Public Law* (May 21, 2008) (last accessed January 24, 2020).

⁸ See 29 USC 1182; 42 USC 300gg-1; and 42 USC 300gg-53.

GINA generally prohibits health insurers and health plan administrators from requesting or requiring genetic information of an individual or the individual's family members,⁹ nor may such information be requested, required or purchased for underwriting purposes.¹⁰ 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.¹¹ 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).¹² GINA generally expanded many of the genetic information protections in the Health Insurance Portability and Accountability Act of 1996¹³ (HIPAA) and applied them to the individual, group and Medicare supplemental marketplaces.¹⁴ 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.¹⁵ GINA also prohibits employment discrimination on the basis of genetic information.¹⁶

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 clearinghouse, other health care providers, and their business associates.¹⁷ 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.¹⁸ Covered entities generally may not sell protected

⁹ 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 January 27, 2020).

¹⁰ See 29 USC 1182(d); 42 USC 300gg-4(d); and 42 USC 300gg-53(e).

¹¹ See 45 CFR 164.502(a)(5)(i)(4)(B).

¹² 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.

¹³ Codified 42 USC 300gg, 29 USC 1181 et seq., and 42 USC 1320d et seq.

¹⁴ See Payne fn. 12 at pg. 329.

¹⁵ See *id.*

¹⁶ 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.

¹⁷ See 45 CFR 160.103.

¹⁸ See 45 CFR 164.502(a).

health information.¹⁹ HIPPA, as modified by GINA, also prohibits health plans from using or disclosing protected health information that is genetic information for underwriting purposes.²⁰

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.²¹ These guaranteed issue and guaranteed renewability requirements apply to genetic testing.

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

Federal law under GINA applies to all states and provides a baseline level of protection that states may exceed. The NIH has identified 106 state statutes addressing health insurance nondiscrimination across 48 states and the District of Columbia.²² Fewer states address genetic testing regarding other lines of insurance such as life insurance, disability insurance, and long-term care insurance.²³

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.²⁴ Informed consent when an insurer requests genetic testing for life or disability insurance is required in California, New Jersey, and New York.²⁵ Massachusetts prohibits unfair discrimination based on genetic information or a genetic test and prohibits requiring an applicant or existing policyholder to undergo genetic testing.²⁶ 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.²⁷

Canadian Genetic Non-Discrimination Act

In 2017, the Canadian Parliament passed a Genetic Non-Discrimination Act²⁸ (Canadian Act). The Canadian Act prohibits requiring an individual to undergo a genetic test, or disclose the

¹⁹ See 45 CFR 164.502(a)(5)(ii)(A).

²⁰ See 45 CFR 164.502(a)(5)(i).

²¹ See 42 USC 300gg-1 and 42 USC 300gg-2.

²² 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 January 24, 2020).

²³ See *id.* (database search for “state statute,” “other lines of insurance nondiscrimination” performed by Committee on Banking and Insurance professional staff on January 24, 2020).

²⁴ Section 746.135, O.R.S.

²⁵ See Cal. Ins. Code s. 10146 et seq.; s. 17B:30-12, N.J.S.; and ISC s. 2615, N.Y.C.L.

²⁶ Chapter 175 sections 108I and 120E, M.G.L.

²⁷ Section 20-448, A.R.S.

²⁸ Statutes of Canada 2017, c. 3. <https://laws-lois.justice.gc.ca/eng/acts/G-2.5/page-1.html#h-1> (last accessed January 27, 2020).

results of a genetic test, as a condition of providing goods or services to that individual, entering into or continuing a contract or agreement with that individual, or offering or continuing specific terms or conditions in a contract or agreement with that individual. Thus, an insurer could not require an applicant provide genetic testing results. The Canadian Act also requires an individual's written consent prior to using or disclosing the results of a genetic test. The Canadian Act exempts physicians and other health care practitioners in respect to an individual to whom they are providing health services and persons conducting medical, pharmaceutical, or scientific research in respect of an individual who is a participant in the research. Violations of the act are punishable under the criminal law. The Canadian Act is currently being challenged before the Supreme Court of Canada.²⁹

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.³⁰ 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.³¹ More than 2,000 genetic tests are currently available and more tests are constantly being developed.³² The National Institutes of Health³³ (NIH) have identified the following available types of medical genetic testing:³⁴

- *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 a genetic disorder, or that increase a person's risk of developing disorders with a genetic basis, such as cancer.

²⁹ *Canadian Coalition for Genetic Fairness v. Attorney General of Quebec, et. al*, Docket No. 38478 <https://www.scc-csc.ca/case-dossier/info/sum-som-eng.aspx?cas=38478> (last accessed January 27, 2020); Leslie MacKinnon, *Genetic Non-Discrimination Bill Passed by Parliament, But Challenged by Government at Top Court*, iPolitics, (Oct 10, 2019) <https://ipolitics.ca/2019/10/10/genetic-non-discrimination-bill-passed-by-parliament-but-challenged-by-government-at-top-court/>

³⁰ 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 January 27, 2020).

³¹ 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 January 24, 2020).

³² See Ohio State University Wexner Medical Center, *Facts About Testing*. <https://wexnermedical.osu.edu/genetics/facts-about-testing> (last accessed January 24, 2020).

³³ 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.

³⁴ See National Institutes of Health, fn. 30, at pgs. 5-6.

- *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.³⁵

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.³⁶ Testing results as part of a research study are usually not available to patients or health care providers.³⁷

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.³⁸ 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.³⁹ 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.

³⁵ Florida Department of Health, *Newborn Screening*. <http://www.floridahealth.gov/programs-and-services/childrens-health/newborn-screening/index.html> (last accessed January 24, 2020).

³⁶ See Ohio State University Wexner Medical Center, fn. 32.

³⁷ See National Institutes of Health, fn. 30, at pg. 24.

³⁸ 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 January 27, 2020).

³⁹ 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 January 24, 2020).

- 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.⁴⁰ 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:⁴¹

- 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.⁴² 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.⁴³

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, 2017.⁴⁴ The increased proliferation of such testing is accompanied by increased

⁴⁰ See National Institutes of Health, fn. 30, at pg. 25.

⁴¹ See National Institutes of Health, fn. 30, at pg. 26.

⁴² See National Institutes of Health, fn. 30, at pg. 11.

⁴³ 23andMe, *Find Out What Your DNA Says About Your Health, Traits and Ancestry* <https://www.23andme.com/dna-health-ancestry/> (last accessed January 24, 2020).

⁴⁴ 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 January 24, 2020).

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.⁴⁵

Direct-to-consumer genetic testing is being used by law enforcement agencies to identify suspects in crimes.⁴⁶ To do so, law enforcement agencies test crime scene DNA samples for DNA markers that in many cases are shared with blood relatives. The DNA markers can then be uploaded to a free online database, GEDmatch, which is used by the public to search for relatives. The DNA database identifies relatives that match the DNA markers, information which can then be used to focus on an individual suspect.

Concerns Over Direct-to-Consumer Genetic Testing Privacy and Fraud

The use of genetic information to identify other family members has public policy implications that are not limited to criminal law. A 2018 study estimated that a genetic database would need to cover only 2 percent of the target population to provide a third-cousin match to nearly any person.⁴⁷ The authors of the study noted that genetic information and the use of genetic databases that are publicly available could be used for harmful purposes, such as re-identifying research subjects from their genetic data.

Chief Financial Officer Jimmy Patronis issued a consumer alert on August 15, 2019, warning Floridians of genetic testing scams that purport to offer free genetic testing to Medicare beneficiaries, but are actually attempts to obtain personal information for identity theft or Medicare information for fraudulent billing purposes.⁴⁸ The consumer alert noted that the Better Business Bureau had started receiving reports of the genetic testing scams, which occurred through telemarketing calls, booths at public events, health fairs, and door-to-door visits.⁴⁹

A Department of Defense memorandum issued December 20, 2019, advised military personnel to refrain from the purchase or use of direct-to-consumer genetic testing. The department noted that direct-to-consumer genetic tests “are largely unregulated and could expose personal and genetic information, and potentially create unintended security consequences and increased risk

⁴⁵ 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 January 24, 2020).

⁴⁶ Jocelyn Kaiser, *We Will Find You: DNA Search Used to Nab Golden State Killer Can Home In On About 60% of White Americans*, *Science* (October 11, 2018) <https://www.sciencemag.org/news/2018/10/we-will-find-you-dna-search-used-nab-golden-state-killer-can-home-about-60-white> (last accessed January 27, 2020).

⁴⁷ Yaniv Erlich et al., *Identify Inference of Genomic Data Using Long-Range Familial Searches*, *Science* Vol. 362, Issues 6415, Pgs. 690-694 (November 9, 2018) <https://science.sciencemag.org/content/362/6415/690/tab-pdf> (last accessed January 27, 2020).

⁴⁸ Florida Department of Financial Services, *Consumer Alert CFO Jimmy Patronis: Beware of Door to Door Genetic Testing Scams Targeting Seniors*, (August 15, 2019) <https://www.myfloridacfo.com/sitePages/newsroom/pressRelease.aspx?ID=5357> (last accessed January 27, 2020).

⁴⁹ Better Business Bureau, *BBB Warning: Beware of Genetic Testing Scam Hitting Florida*, (August 2, 2019). <https://www.bbb.org/article/news-releases/20457-bbb-warning-beware-of-genetic-testing-scam-hitting-florida> (last accessed January 27, 2020).

to the joint force and mission.”⁵⁰ The memorandum stated that many direct-to-consumer genetic tests that provide health information vary in their validity and are not reviewed by the Food and Drug Administration, and thus are not independently reviewed to verify the claims of the seller.⁵¹ The memorandum also noted that “there is increased concern in the scientific community that outside parties are exploiting the use of genetic data for questionable purposes, including mass surveillance and the ability to track individuals without their authorization or awareness.”⁵²

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

Forms of Life Insurance

Life insurance is the insurance of human lives.⁵³ Life insurance can be purchased in the following forms:⁵⁴

- Term life insurance provides coverage for a set term of years and pays a death benefit if the insured dies during the term.⁵⁵
- 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.⁵⁶

Life Insurance Underwriting and Risk Classification

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.⁵⁷ Mortality risk is the risk of death whereas morbidity risk is the risk of being unhealthy or having a disease. 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

⁵⁰ Department of Defense, *Memorandum on Direct-to-Consumer Genetic Testing Advisory for Military Members*, (Dec 20, 2019) https://www.scribd.com/document/440727436/DOD-memo-on-DNA-testing#download&from_embed (last accessed January 27, 2019).

⁵¹ *See id.*

⁵² *See id.*

⁵³ Section 624.602, F.S.

⁵⁴ National Association of Insurance Commissioners, *Life Insurance – Considerations for All Life Situations*, http://www.insureuonline.org/insureu_type_life.htm (last accessed January 24, 2020).

⁵⁵ National Association of Insurance Commissioners, *Life Insurance FAQs*, http://www.insureuonline.org/consumer_life_faqs.htm (last accessed January 24, 2020).

⁵⁶ *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).

⁵⁷ American Council of Life Insurers, *Life Insurer Issues*. (On file with the Senate Committee on Banking and Insurance).

of return. Accurate risk assessment is important in life insurance because misclassification of risk results in severe consequences because the life insurance contract is often in place for long periods of time, as in the case of long-term and whole life policies.⁵⁸

A 2019 paper in the *Journal of Insurance Regulation* of the National Association of Insurance Commissioners noted that more than 5,000 genes have been identified as relating to a particular disease, many of which have predictive value in estimating the probability in developing a genetic disease that has consequences for mortality.⁵⁹ Examples of genetic tests with informational value for life insurance underwriting include:

- Breast cancer – BRCA1 or BRCA 2;
- Hypertrophic cardiomyopathy;
- Dilated cardiomyopathy;
- Arrhythmogenic right ventricular cardiomyopathy;
- Long QT syndrome;
- Brugada syndrome;
- Huntington’s disease;
- Polycystic kidney disease;
- Myotonic muscular dystrophy – DM1 or DM2;
- Alzheimer’s disease early onset, autosomal dominance;
- Hereditary nonpolyposis colorectal cancer;
- Marfan Syndrome; and
- Catecholaminergic polymorphic ventricular tachycardia.

When a policyholder has access to information about their mortality risk which the life insurer lacks, two problems arise for the life insurer. The first problem is that the policy may be underpriced, which can result in inadequate premium dollars to pay death benefits.⁶⁰ The second problem is that consumers with knowledge of their increased mortality risk will be more likely to keep their policy in-force, which also has an impact on proper pricing of life insurance as premiums are calculated using assumptions that a certain percentage of policyholders will allow the insurance contract to lapse.⁶¹

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.⁶² 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

⁵⁸ Patricia Born, *Genetic Testing in Underwriting: Implications for Life Insurance Markets*, *Journal of Insurance Regulation* Vol. 38, No. 5 (2019), https://www.naic.org/prod_serv/JIR-ZA-38-05-EL.pdf (last accessed January 27, 2020).

⁵⁹ See Born fn. 58 at pg. 5.

⁶⁰ See Born fn. 58 at pg. 10.

⁶¹ See *id.*

⁶² 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 January 24, 2020).

cancer risk)⁶³ and adults tested for Alzheimer's risk⁶⁴ 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 2 percent of those who tested negative and 4 percent of those who did not receive test results.⁶⁵

Annuities

Life insurance also encompasses annuities and disability policies.⁶⁶ 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.

Disability Insurance

Disability insurance compensates the insured for a portion of income lost because of a disabling injury or illness.⁶⁷ There are two types of disability insurance: short-term and long-term. A short-term policy typically replaces a portion of lost income from 3 to 6 months following the disability. Long-term policies generally begin 6 months after the disability and can last a set number of years or until retirement age. Disability insurance is sometimes offered by life insurers.

Long-Term Care Insurance

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.⁶⁸ Long-term care insurance usually pays fixed-dollar amounts or the actual costs of care, often subject to a maximum daily benefit amount.⁶⁹

⁶³ 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 January 24, 2020)).

⁶⁴ 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 January 24, 2020).

⁶⁵ See Zick fn. 64 at pgs. 487-488.

⁶⁶ Section 624.602, F.S.

⁶⁷ 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 January 24, 2020).

⁶⁸ Section 627.9404(1), F.S.

⁶⁹ 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 January 24, 2020).

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.⁷⁰ 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.⁷¹ As a result, long-term care insurance premiums have been rising, often substantially, for the past decade.⁷²

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.⁷³ 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 3 years.⁷⁴ Many insurers that write LTC insurance have taken substantial losses. In January 2018, General Electric announced a \$6.2 billion charge against earnings and a \$15 billion shortfall in insurance reserves related to LTC insurance obligations.⁷⁵

Prohibition of Unfair Discrimination Between Individuals

Insurance policy forms for insurance sold in Florida must be filed and approved by the Office of Insurance Regulation (OIR).⁷⁶ 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 contract, in the dividends or other benefits payable thereon, or in any other term or condition of such contract.”⁷⁷ 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

⁷⁰ 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 January 24, 2020).

⁷¹ 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 January 24, 2020); See Scism at fn. 70.

⁷² See Scism at fn. 70; See Office of Insurance Regulation at fn. 71.

<https://www.floir.com/Sections/LandH/LongTermCareHearing.aspx> (last accessed January 24, 2020).

⁷³ Section 627.9407(7)(c), F.S.

⁷⁴ 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 January 24, 2020); 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 January 24, 2020).

⁷⁵ 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 January 24, 2020); 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 January 24, 2020).

⁷⁶ Section 624.410, F.S.

⁷⁷ Section 626.9541(1)(g)1., F.S.

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.⁷⁸

III. Effect of Proposed Changes:

Section 1 amends s. 627.4301, F.S., to provide criteria that must be met for a life insurer, long-term care insurer, or disability income insurer to use genetic information, including the results of direct-to-consumer genetic testing, for underwriting purposes. The criteria are:

- The genetic information is contained in the medical record;
- The use of genetic testing results is limited to what is in the medical record;
- The genetic information is relevant to a potential medical condition that impacts mortality or morbidity risk; and
- The genetic information is related to expected mortality or morbidity based on sound actuarial principles or reasonably expected experience.

The bill prohibits a life insurer, long-term care insurer, or disability income insurer from cancelling coverage based solely on genetic information. Florida law currently provides that life insurance and long-term care insurance policies are incontestable and may not be cancelled except for nonpayment of premium after 2 years in force.⁷⁹ For life insurance and long-term care insurance contracts, the prohibition on cancellations based solely on genetic information would only be relevant during the first 2 years the contract is in force. The prohibition would be relevant throughout the time a disability income policy is in-force because provisions in an insurance policy relating to disability benefits may, at the option of the insurer, be exempt from the 2-year incontestability period.

The bill prohibits a life insurer, long-term care insurer, or disability income insurer from requiring an applicant take a genetic test as a condition of insurability, and prohibits such insurers from obtaining, requesting, or otherwise requiring the complete genome sequence of an applicant's DNA.

The bill defines:

- “Life insurer” to have the same meaning as provided in s. 624.602, F.S.;⁸⁰ 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” as an insurer issuing long-term care insurance policies as described in s. 627.9404, F.S.⁸¹

⁷⁸ Section 626.9541(1)(g)2., F.S.

⁷⁹ See ss. 627.455, F.S., and 627.94076, F.S.

⁸⁰ Section 624.602, F.S., defines a life insurer as an insurer engaged in the business of issuing life insurance contracts, including contracts of combined life and health and accident insurance. Life insurance is defined as the insurance of human lives, transactions of which include annuity contracts, granting endowment benefits, providing additional benefits in the event of death or dismemberment by accident or accidental means, additional benefits in the event of the insured's disability.

⁸¹ Section 627.9404, F.S., defines a long-term care insurance policy to mean any insurance policy or rider advertised, marketed, offered, or designed to provide coverage on an expense-incurred, indemnity, prepaid, or other basis for one or more necessary or medically necessary diagnostic, preventative, therapeutic, curing, treating, mitigating, rehabilitative, maintenance, or personal care services provided in a setting other than an acute care unit of a hospital. The definition specifies various coverages that are not long-term care insurance such as Medicare supplement coverage, disability income coverage, and others.

The bill amends the definition of “genetic information” to include the results of direct-to-consumer genetic testing. This explicitly applies the existing prohibition against health insurers using genetic information in the absence of a diagnosis to direct-to-consumer genetic testing. The inclusion of direct-to-consumer genetic testing results within the definition of genetic information means that under this bill, life insurers, long-term care insurers, and disability income insurers may only use direct-to-consumer genetic testing for underwriting purposes if such testing is contained in the medical record and relevant to a medical condition impacting mortality or morbidity risk based on sound actuarial principles.

Section 2 amends s. 760.40, F.S., to require companies that provide direct-to-consumer genetic testing must obtain written consent from the consumer prior to sharing genetic information or personally identifiable information about a consumer with a life insurer or health insurer.

Section 3 provides an effective date of July 1, 2020.

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 identified.

V. Fiscal Impact Statement:

A. Tax/Fee Issues:

None.

B. Private Sector Impact:

None.

C. Government Sector Impact:

None.

VI. Technical Deficiencies:

The bill provides that a life insurer, long-term care insurer, or disability income insurer may only use genetic information if certain criteria are met. These criteria include, on lines 54-55, that “the genetic information is relevant to a *potential* medical condition that impacts mortality or morbidity risk.” This appears to unintentionally allow use of genetic information when relevant to a potential medical condition, but not when relevant to an actual medical condition.

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 Banking and Insurance on January 28, 2020:

The CS provides conditions under which life insurers, long-term care insurers, and disability income insurers may use genetic information, including direct-to-consumer genetic testing, in underwriting. The CS requires companies that provide direct-to-consumer genetic testing must obtain written consent from the consumer prior to sharing genetic information or personally identifiable information about a consumer with a life insurer or health insurer.

Previously, the bill prohibited such insurers from using genetic information to cancel, limit, or deny coverage, or establish differentials in premium rates, nor could such insurers require or solicit genetic information, use genetic test results, or consider a person’s decisions regarding genetic testing in any manner for any insurance purpose.

B. Amendments:

None.