I. Summary:

SB 1106 prohibits life insurers, including life insurers providing disability insurance, and long-term care insurers from canceling, limiting, or denying coverage or establishing differentials in premium rates, based on genetic information, if there is no diagnosis of a condition related to the genetic information. The bill also prohibits such insurers 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. Florida currently applies these prohibitions to health insurers. The provisions of the bill will apply to policies issued or renewed by life insurers and long-term care insurers on or after January 1, 2019.

II. Present Situation:

Use of Genetic Information for Insurance Purposes – Florida Requirements

Insurance policies for life, disability income, and long-term care are exempt from s. 627.4301, F.S., which provides standards for the use of genetic information by health insurers. Health insurers 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.

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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.”
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. 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. GINA prohibits health insurers and health plan administrators from using genetic information to make rating or coverage decisions. 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, nor may such information be requested, required or purchased for underwriting purposes. 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.

Genetic information may be used by an insurer to make a determination regarding the

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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.
7 See 29 USC 1182(d); 42 USC 300gg-4(d); and 42 USC 300gg-53(e).
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). GINA generally expanded many of the genetic information protections in the Health Insurance Portability and Accountability Act of 1996 (HIPAA) and applied them to the individual, group and Medicare supplemental marketplaces. 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. GINA also prohibits employment discrimination on the basis of genetic information.

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. 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. Covered entities generally may not sell protected health information. HIPPA, as modified by GINA, also prohibits health plans from using or disclosing protected health information that is genetic information for underwriting purposes.

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

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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.

14 See 45 CFR 160.103.

15 See 45 CFR 164.502(a).


17 See 45 CFR 164.502(a)(5)(i).

18 See 42 USC 300gg-1 and 42 USC 300gg-2.
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.\(^\text{19}\) Fewer states address genetic testing regarding other lines of insurance such as life insurance, disability insurance, and long-term care insurance.\(^\text{20}\)

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.\(^\text{21}\) Informed consent when an insurer requests genetic testing for life or disability insurance is required in California, New Jersey, and New York.\(^\text{22}\) Massachusetts prohibits unfair discrimination because of the basis of genetic information or a genetic test and prohibits requiring an applicant or existing policyholder to undergo genetic testing.\(^\text{23}\) 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.\(^\text{24}\)

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.\(^\text{25}\) 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.\(^\text{26}\) More than 2,000 genetic tests are currently


\(^{20}\) See id. (database search for “state statute,” “other lines of insurance nondiscrimination” performed by Committee on Banking and Insurance professional staff on Feb. 2, 2018).

\(^{21}\) 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.


available and more tests are constantly being developed.\textsuperscript{27} The National Institutes of Health\textsuperscript{28} (NIH) have identified the following available types of medical genetic testing:\textsuperscript{29}

- \textit{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.

- \textit{Predictive and presymptomatic 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.

- \textit{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.

- \textit{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.

- \textit{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.

- \textit{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.\textsuperscript{30}

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.\textsuperscript{31} Testing results as part of a research study are usually not available to patients or healthcare providers.\textsuperscript{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

\textsuperscript{27} See Ohio State University Wexner Medical Center, \textit{Facts About Testing}, https://wexnermedical.osu.edu/genetics/facts-about-testing (last accessed February 1, 2018).

\textsuperscript{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.

\textsuperscript{29} See National Institutes of Health, \textit{Genetic Testing}, at pgs. 5-6.


\textsuperscript{31} See fn. 27, Ohio State University Wexner Medical Center.

\textsuperscript{32} National Institutes of Health, \textit{Genetic Testing}, at pg. 24.
gene account for the lack of a response.\textsuperscript{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.\textsuperscript{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 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.\textsuperscript{35} According to the National Institutes of Health (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:\textsuperscript{36}

- Single nucleotide polymorphism testing 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 identifies genetic variations in mitochondrial DNA, which provides information about the direct female ancestral lines.
- Y chromosome testing, performed exclusively on males, is often used to investigate whether two families with the same surname are related.

\textsuperscript{35} National Institutes of Health, Genetic Testing, at pg. 25.
\textsuperscript{36} National Institutes of Health, Genetic Testing, at pg. 26.
Direct to Consumer Genetic Testing

Traditionally, genetic testing was available only through healthcare providers. Direct-to-consumer genetic testing provides access to genetic testing outside the healthcare context. Generally, the consumer purchases a genetic testing kit from a vendor who 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.

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. 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 recently warned consumers to consider the privacy implications of genetic testing kits.

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

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

- Term life insurance provides coverage for a set term of years and pays a death benefit if the insured dies during the term.
- Permanent life insurance remains in place if the insured pays premiums and pays a death benefit. Such policies have an actual cash value component that increases over time and from which the policyowner 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.

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37 National Institutes of Health, Genetic Testing, at pg. 11.
41 Section 624.602, F.S.
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.

Life insurance also encompasses annuities and disability policies. 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. 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. 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.

Insurance policy forms must be filed and approved by the OIR. 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.” 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.

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44 Section 624.602, F.S.
45 American Council of Life Insurers, Life Insurer Issues. (On file with the Senate Committee on Banking and Insurance).
47 Section 624.410, F.S.
48 Section 626.9541(1)(g)1., F.S.
49 Section 626.9541(1)(g)2., F.S.
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. Long-term care insurance usually pays fixed-dollar amounts or the actual costs of care, often subject to a maximum daily benefit amount.

The long-term insurance market provides an example of the negative effects of insurers not accurately projecting their underwriting risk. Long-term care insurers made incorrect assumptions when selling the coverage, particularly in the 1980s and 1990s. 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. As a result, long-term care insurance premiums have been rising, often substantially, for the past decade.

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. 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. Many insurers that 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 long-term care insurance obligations.

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50 Section 627.9404(1), F.S.
53 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 February 3, 2018); See Scism at fn. 35
54 See Scism at fn. 35; See Office of Insurance Regulation at fn. 36. https://www.floir.com/Sections/LandH/LongTermCareHearing.aspx (last accessed February 3, 2018).
55 Section 627.9407(7)(c), F.S.
The American Council of Life Insurers has expressed concerns that the proliferation of genetic testing that could increase adverse selection and impact the availability and affordability of products over time.\(^{58}\) Studies addressing whether genetic testing leads to adverse selection have reached different conclusions. Studies of women tested for the BRCA1 gene mutation (linked to breast cancer risk)\(^ {59}\) and adults tested for Alzheimer’s risk\(^ {60}\) 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.\(^ {61}\)

### III. Effect of Proposed Changes:

**Section 1** amends s. 627.4301, F.S., to prohibit life insurers, including life insurers providing disability insurance, and long-term care insurers from canceling, limiting, or denying coverage or establishing differentials in premium rates, based on genetic information, if there is no diagnosis of a condition 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 in any manner for any insurance purpose.

The bill repeals current law that exempts insurance policies for life, disability, or long-term care from s. 627.4301, F.S.

For purposes of s. 627.4301, F.S., the bill defines the following terms:

- “Life insurer” has the same meaning as in s. 624.602, F.S., and includes an insurer issuing life insurance contracts that grant additional benefits if the insured is disabled.  
  
  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.

- “Long-term care insurer” means an insurer that issues long-term care insurance policies as described in s. 627.9404, F.S.

**Section 2** applies the act to policies entered into or renewed after January 1, 2019.

**Section 3** provides an effective date of July 1, 2018.

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\(^{61}\) See Zick fn. 60 at pgs. 487-488.
IV. Constitutional Issues:
   A. Municipality/County Mandates Restrictions:
      None.
   B. Public Records/Open Meetings Issues:
      None.
   C. Trust Funds Restrictions:
      None.

V. Fiscal Impact Statement:
   A. Tax/Fee Issues:
      None.
   B. Private Sector Impact:
      The bill may lead to more individuals undergoing genetic testing, which in the aggregate will lead to advancements in medicine and, regarding the individual, can be useful in identifying and treating disease and disability.
      The bill, to the extent it encourages adverse selection of life, disability, or long-term care insurance, could result in the improper classification of risks for such policies, leading to inadequate rates and, eventually, higher premiums. Such insurers use of genetic information in underwriting, risk classification, and ratemaking could result in individuals either not being able to procure such coverages because the insurer is unwilling to offer the coverage, or offers it at a rate that is unaffordable to the consumer.
   C. Government Sector Impact:
      The bill does not fiscally impact the Office of Insurance Regulation.

VI. Technical Deficiencies:
   None.

VII. Related Issues:
   None.

VIII. Statutes Affected:
   This bill substantially amends section 627.4301 of the Florida Statutes.
IX. Additional Information:

A. Committee Substitute – Statement of Changes:
   (Summarizing differences between the Committee Substitute and the prior version of the bill.)
   None.

B. Amendments:
   None.

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