

SENATE THIRD READING  
SB 41 (Umberg)  
As Amended August 30, 2021  
Majority vote

## **SUMMARY**

This bill establishes the Genetic Information Privacy Act, a comprehensive legal framework to regulate the collection, use, maintenance, and disclosure of genetic data collected or derived from a direct-to-consumer (DTC) genetic testing product or service, including enhanced notice and opt-in consent requirements.

### **Major Provisions**

- 1) Requires a DTC genetic testing company to provide clear and complete information regarding the company's policies and procedures for the collection, use, and disclosure of genetic data, including a prominent and easily accessible privacy notice.
- 2) Requires a DTC genetic testing company to obtain the consumer's express consent for the collection, use, and disclosure of the consumer's genetic data and to market to a consumer based on their genetic data, except as specified.
- 3) Requires a company subject to the consent requirements of the bill to provide effective mechanisms, without any unnecessary steps, for a consumer to revoke their consent.
- 4) Requires a DTC genetic testing company to develop procedures that allow a consumer to easily access and delete their genetic data, to delete an account with the company, and to have their biological sample destroyed.
- 5) Prohibits a DTC genetic testing company from disclosing a consumer's genetic data or biological sample to any entity responsible for administering or making decisions regarding health insurance, life insurance, long-term care insurance, disability insurance, or employment, or to any entity providing advice to an entity responsible for those functions, except as specified.
- 6) Imposes civil penalties between \$1,000 and \$10,000 for any violation of the bill and grants authority for enforcement to the Attorney General, district attorneys, and city attorneys.

## **COMMENTS**

As genetic sequencing becomes increasingly inexpensive and accessible, it is also becoming more ubiquitous. In addition to various medical applications, the past several years have seen the rise of a growing industry for direct-to-consumer (DTC) genetic testing products. Businesses such as 23andMe and Ancestry.com market these products as opportunities to better know oneself, based on their capacity to reveal individual traits, medical predispositions, ethnicities and nations of origin, and blood relationships to others. When purchased, DTC genetic testing products provide a kit through which a sample, typically saliva, can be collected and mailed to the company for analysis. The company then provides results to the consumer, generally online, through landing pages where consumers can access their raw genetic data as well as inferences drawn from those analyses. The information that can be extrapolated or inferred from these data

continues to grow each year, as the scientific understanding of genetics and genomics improves, and new uses for databases of such genetic information continue to emerge.

The fact that genetic data is immutable, specific to an individual, revealing of sensitive information about kin and kinship, of ever-increasing informational value, and capable of revealing sensitive health information, renders this data unique even among categories of PI in its sensitivity. Consequently, it is critical that privacy and consumer protection laws treat these data accordingly. Presently, there are very few protections provided by state and federal laws to limit the use and disclosure of genetic information collected by DTC genetic testing companies. Because the businesses offering DTC genetic testing are not health care service plans, insurance providers, or other covered entities, typical protections for health information do not apply to the test results. Though the California Consumer Privacy Act (CCPA) provides baseline protections for personal information generally, and as such, extends such protections to genetic data, it explicitly leaves room for further regulation in circumstances in which more extensive protection is necessary. Genetic data collected by DTC genetic testing companies arguably warrants such protection.

*This bill* would institute several notice and express consent requirements for collection, use, maintenance, and disclosure of genetic data by DTC genetic testing companies, and would require that any DTC genetic testing company provide a consumer with clear and complete information summarizing its privacy practices. Critically, the bill also requires that a DTC genetic testing company obtain a consumer's separate express consent, and provide a simple mechanism by which to revoke consent, for each of the following: 1) the use of the consumer's genetic data; 2) the storage of the consumer's biological sample after the initial testing; 3) each use of genetic data or the biological sample beyond the primary purpose of the genetic testing service; 4) each transfer or disclosure of the consumer's genetic data or biological sample to a third party other than a service provider; 5) each transfer or disclosure of the consumer's genetic data or biological sample to a governmental agency, except as necessary to comply with a court order; and 6) the marketing or facilitation of marketing based on the consumer's genetic data or their status as a consumer of a genetic testing product, except as specified. This bill further requires any DTC genetic testing company to implement and maintain reasonable security procedures and practices to protect against unauthorized access to data, and to develop procedures and practices to enable the consumer to access their genetic data, delete their account and genetic data, and have their biological sample destroyed.

To prevent the use of genetic data for potential discrimination in insurance contexts not covered by existing Insurance Code provisions, the bill prohibits a DTC genetic testing company from disclosing a consumer's genetic data to any entity responsible for administering or making decisions regarding health insurance, life insurance, long-term care insurance, disability insurance, or employment, or any entity that provides advice to an entity that is responsible for performing those functions, unless certain criteria are met to ensure that the entity does not primarily operate in the insurance space, and that any component of the entity that does manage insurance cannot access the genetic data.

This bill would subject any person who negligently or willfully violates its provisions to civil penalties, to be paid to the individual whose genetic information was affected. In the event of a negligent violation, a civil penalty of up to \$1,000 would be assessed, and in the event of a willful violation, a civil penalty of not less than \$1,000 and not more than \$10,000 would be assessed. However, the bill lacks a private right of action, and actions for relief can only be

prosecuted by the Attorney General, a district attorney, a county counsel, a city attorney, or a city prosecutor. The language of the bill permits prosecution upon the complaint of a person, or upon complaint of a person who has suffered injury in fact as a result of the violation, making it unclear whether a person must demonstrate injury in fact resulting from the violation in order to bring a complaint. If this is indeed the case, such a standard may be difficult to achieve, as demonstrating injury in fact resulting in the loss of money or property is notoriously difficult in cases in which an individual's privacy has been breached.

Though this provision may benefit from additional clarity, the bill in print nonetheless builds on existing privacy laws to provide extensive, thoughtful protections for this uniquely sensitive data, and would significantly advance the State's interest in protecting the privacy and security of the personal information of its residents.

*Governor's veto of SB 980 (Umberg) of 2020:* In 2020, the author of this bill proposed SB 980, which, through extensive stakeholder input and negotiation, along with considerable input from this Committee, arrived at language nearly identical to the language currently in print as SB 41. SB 980 passed out of this Committee 10-0, off of the Assembly Floor 69-0, and off of the Senate Floor 39-0, but was ultimately vetoed by Governor Newsom.

In his veto message, the Governor stated that "the broad language in this bill risks unintended consequences, as the 'opt-in' provisions of the bill could interfere with laboratories' mandatory requirement to report COVID-19 test outcomes to local public health departments, who report that information to the California Department of Public Health. This reporting requirement is critical to California's public health response to the COVID-19 pandemic, and we cannot afford to unintentionally impede that effort."

In order to address the Governor's stated concerns with SB 980 while still ensuring any test that may fit the limited set of circumstances described would be sufficiently privacy-protective, SB 41 exempts from its provisions "[t]ests conducted exclusively to diagnose whether an individual has a specific disease, to the extent that all persons involved in the conduct of the test maintain, use, and disclose genetic information in the same manner as medical information or protected health information[...]" This language was drafted in consultation with this Committee, CDPH, and stakeholders, and seems to strike an appropriate balance between avoiding unforeseen obstacles to public health objectives on the one hand, and ensuring that resulting genetic information is subject to some privacy protections on the other.

To address industry concerns that this bill may complicate compliance with workplace health and safety laws, the author has amended the bill to exempt "[g]enetic data used or maintained by an employer, or disclosed by an employee to an employer, to the extent that the use, maintenance, or disclosure of that data is necessary to comply with a local, state, or federal workplace health and safety ordinance, law, or regulation." Though this amendment resulted in the removal of industry opposition to the bill, its practical effect is unclear. The exemption described in the previous paragraph should already cover workplace testing for specific diseases, and exclusions for genetic data analyzed by licensed medical professionals or otherwise governed by medical privacy laws should already cover other conceivable workplace health and safety circumstances involving genetic data. Additionally, the capacity for local workplace health and safety ordinances to supersede these proposed statewide protections for genetic privacy may threaten to undermine the bill's overall objective in limited circumstances.

Nonetheless, the exemption is relatively narrow in its construction, and does not preclude the bill from offering robust protections for individual privacy beyond those provided by existing law.

Overall, this bill would provide meaningful protections for highly sensitive data that are otherwise under-protected or unprotected. These DTC genetic tests are becoming both more ubiquitous, and more exhaustive, as the techniques for genetic sequencing and related processes become cheaper. As such, the bill would address a significant gap in privacy protections for California consumers, and would do so in a manner appropriate to the unique nature of the data.

### **According to the Author**

The Pentagon recently sent out a memo asking service members to not use DTCs due to, 'the increased concern in the scientific community that outside parties are exploiting the use of genetic materials for questionable purposes...without their [consumers'] authorization or awareness.' Furthermore, a study reported by Business Insider showed that 40 to 60 percent of genetic data is re-identifiable when compared against public databases. The evidence is clear; the laws regulating DTCs are inadequate and need to be strengthened to better protect consumers. Currently, at least [four] other states have enacted similar legislation due to the importance of protecting consumers' most sensitive information. By passing the Genetic Information Privacy Act, California will protect its consumers' most sensitive data.

### **Arguments in Support**

A coalition of privacy and consumer rights groups consisting of ACLU California Action, Consumer Federation of America, Electronic Frontier Foundation, Privacy Rights Clearinghouse, Consumer Action, and Access Humboldt argues:

All results from genetic testing should be private by default, yet DTC companies currently can and do use consumer data for purposes other than providing results to consumers – including company-sponsored research, and selling consumer data to third parties without consumer knowledge or consent. SB 41 would put sensible safeguards around this highly private data to ensure consumers have control over their genetic information.

Neither state nor federal law adequately protect Californians in the rapidly changing market of at-home healthcare solutions, testing, and products. No federal law directly addresses consumer privacy issues resulting from DTC genetic testing. While the California Privacy Rights Act gives consumers a limited opportunity to request to opt out of the future sale of this information, DTC genetic testing companies by default can legally sell this very sensitive information to third parties unless each individual consumer is aware of and takes the unnecessarily cumbersome steps to limit this sharing – assuming the consumer can find out who has received their genetic information from the DTC company. Even these steps do not affect the personal information that has already been sold, and nothing prevents sharing of information that occurs without a formal "sale." SB 41 will ensure that sensitive genetic information remains confidential by default and appropriately limits the ways in which companies can use this information.

### **Arguments in Opposition**

None on file

## FISCAL COMMENTS

According to the Assembly Appropriations Committee, "[c]osts (General Fund) of \$269,000 in fiscal year [...] 2021-22 and \$357,000 annually thereafter to the Department of Justice (DOJ) in additional staff and infrastructure to enforce the [bill...and] cost pressures (Trial Court Trust Fund) in the mid-hundreds of thousands of dollars annually to the courts in additional workload."

## VOTES

### SENATE FLOOR: 38-0-2

**YES:** Allen, Archuleta, Bates, Becker, Borgeas, Bradford, Caballero, Cortese, Dahle, Dodd, Durazo, Eggman, Glazer, Gonzalez, Grove, Hertzberg, Hueso, Hurtado, Jones, Kamlager, Laird, Leyva, McGuire, Melendez, Min, Newman, Nielsen, Ochoa Bogh, Pan, Portantino, Roth, Rubio, Skinner, Stern, Umberg, Wieckowski, Wiener, Wilk

**ABS, ABST OR NV:** Atkins, Limón

### ASM PRIVACY AND CONSUMER PROTECTION: 11-0-0

**YES:** Gabriel, Kiley, Bauer-Kahan, Bennett, Berman, Carrillo, Chau, Cunningham, Gallagher, Irwin, Wicks

### ASM JUDICIARY: 11-0-0

**YES:** Stone, Gallagher, Chau, Chiu, Davies, Lorena Gonzalez, Holden, Kalra, Kiley, Maienschein, Reyes

### ASM APPROPRIATIONS: 12-0-4

**YES:** Lorena Gonzalez, Bryan, Calderon, Carrillo, Chau, Gabriel, Eduardo Garcia, Levine, Quirk, Robert Rivas, Akilah Weber, Kalra

**ABS, ABST OR NV:** Bigelow, Megan Dahle, Davies, Fong

## UPDATED

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