SENATE RULES COMMITTEE SB 41
Office of Senate Floor Analyses
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UNFINISHED BUSINESS

Bill No: SB 41
Author: Umberg (D), et al.
Amended: 8/30/21
Vote: 21

SENATE JUDICIARY COMMITTEE: 11-0, 3/9/21
AYES: Umberg, Borgeas, Caballero, Durazo, Gonzalez, Hertzberg, Jones, Laird, Stern, Wieckowski, Wiener

SENATE APPROPRIATIONS COMMITTEE: 7-0, 5/20/21
AYES: Portantino, Bates, Bradford, Jones, Kamlager, Laird, Wieckowski

SENATE FLOOR: 38-0, 5/28/21
AYES: 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
NO VOTE RECORDED: Atkins, Limón

ASSEMBLY FLOOR: 80-0, 9/8/21 - See last page for vote

SUBJECT: Privacy: genetic testing companies

SOURCE: Author

DIGEST: This bill establishes the Genetic Information Privacy Act, providing additional protections for genetic data by regulating the collection, use, maintenance, and disclosure of such data.

Assembly Amendments amend definitions, expand exemptions, clarify enforcement, and make other minor changes.

ANALYSIS:

Existing law:

1) Provides, pursuant to the California Constitution, that all people have inalienable rights, including the right to pursue and obtain privacy. (Cal. Const., art. I, Sec. 1.)

2) Specifies, through the federal Health Insurance Portability and Accountability Act (HIPAA), privacy protections for patients' protected health information and generally prohibits a covered entity, from using or disclosing protected health information except as specified or as authorized by the patient in writing. (45 C.F.R. Sec. 164.500 et seq.)

3) Prohibits, under California's Confidentiality of Medical Information Act (CMIA), providers of health care, health care service plans, or contractors, as defined, from sharing medical information without the patient's written authorization, subject to certain exceptions. (Civ. Code Sec. 56 et seq.)

4) Prohibits discrimination under the Unruh Civil Rights Act and the Fair Employment and Housing Act (FEHA) on the basis of genetic information. (Civ. Code Sec. 51 and Gov. Code Sec. 12920 et seq.)

5) Prohibits, pursuant to federal law under the Genetic Information and Nondiscrimination Act (GINA), discrimination in group health plan coverage and employment based on genetic information. (Pub. Law 110-233.)

6) Subjects those improperly disclosing genetic test results to civil and criminal penalties. (Civ. Code § 56.17; Ins. Code § 10149.1.)

7) Establishes the California Consumer Privacy Act of 2018 (CCPA), which grants consumers certain rights with regard to their personal information. (Civ. Code § 1798.100 et seq.)

8) Provides, pursuant to the CCPA, consumers the right to request that a business that sells the consumer's personal information, or that discloses it for a business purpose, provide certain disclosures to the consumer. (Civ. Code § 1798.115.) It further enables a consumer, at any time, to restrict a business from selling that personal information to third parties. (Civ. Code § 1798.120.)

This bill:

1) Creates the Genetic Information Privacy Act to protect consumers' "genetic data," which is defined as any data, regardless of its format, that results from the analysis of a biological sample from a consumer, or from another element enabling equivalent information to be obtained, and concerns genetic material, except deidentified data, as provided.

2) Regulates direct-to-consumer genetic testing companies ("DTC company"), which are defined as entities that do any of the following:

   a) Sell, market, interpret, or otherwise offer consumer-initiated genetic testing products or services directly to consumers;

   b) Analyze genetic data obtained from a consumer, except to the extent that the analysis is performed by a person licensed in the healing arts for diagnosis or treatment of a medical condition; or

   c) Collect, use, maintain, or disclose genetic data collected or derived from a direct-to-consumer genetic testing product or service, or is directly provided by a consumer.

3) Requires a DTC company, or any other company that collects, uses, maintains, or discloses genetic data collected or derived from a direct-to-consumer genetic testing product or service or directly provided by a consumer to provide clear and complete information regarding the company's policies and procedures for the collection, use, maintenance, and disclosure, as applicable, of genetic data by making certain disclosures available to a consumer.

4) Requires the above companies to also obtain a consumer's express consent for collection, use, and disclosure of the consumer's genetic data and methods to revoke such consent, as specified. DTC companies must secure separate and express consent for specified actions.

5) Provides that the requirement for separate and express consent for marketing does not require a DTC company to obtain a consumer's express consent to market to the consumer on the company's own website or mobile application, as specified.

6) Requires a DTC company to implement and maintain reasonable security procedures and practices. Such companies must also develop procedures and practices to enable a consumer to easily access their genetic data, delete the

consumer's account and genetic data, except as specified, and have the consumer's biological sample destroyed.

7) Prohibits these companies from disclosing a consumer's genetic data to any entity that is responsible for administering or making decisions regarding health insurance, life insurance, long-term care insurance, disability insurance, or employment, or to any entity that provides advice to an entity that is responsible for performing those functions, except as provided.

8) Prohibits discrimination by a person or public entity against a consumer based on the consumer's exercise of rights, as provided.

9) Exempts application of its provision to certain medical information, health care providers, other covered entities and their business associates, and certain tests to diagnose specific diseases, as specified. It also does not apply to scientific research or educational activities conducted by a public or private nonprofit postsecondary educational institution or the California newborn screening program. It also does not extend to certain genetic data in the employment context where use, maintenance, or disclosure of the data is necessary to comply with a local, state, or federal workplace health and safety ordinance, law, or regulation.

10) Provides relevant definitions for the terms included therein, including "affirmative authorization," "express consent," and "service provider."

11) Provides that it does not reduce a direct-to-consumer genetic testing company's duties, obligations, requirements, or standards under any applicable state and federal laws for the protection of privacy and security. It makes clear that in the event of a conflict between its provisions and any other law, the provisions of the law that afford the greatest protection for the right of privacy for consumers shall control.

12) Subjects a company in violation of its provisions to specified civil penalties.

Background

Current law fails to provide adequate guidelines for what can be done with genetic data collected by companies outside of the protective ambit of state and federal health privacy laws. This bill fills the gap by creating the Genetic Information Privacy Act.

This bill safeguards the privacy, confidentiality, security, and integrity of a consumer's genetic data by requiring DTC companies to provide clear disclosures and more consumer control. It also requires these companies to obtain express consent for the collection, use, and disclosure of the consumer's genetic data, including separate and express consent for specified actions. This bill mandates certain security measures and prohibits discrimination against consumers for exercising these rights. This bill subjects negligent and willful violations to varying ranges of civil penalties. For a more thorough analysis of this bill, see the Senate Judiciary Committee analysis of the bill.

Comments

According to the author:

> The Pentagon has asked service members to not use direct-to-consumer genetic testing companies (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.
>
> SB 41 creates strict guidelines for authorization forms in a manner that allows consumers to have control over how their DNA will be used. Due to the fact that genetic data can be reidentified, the act also prohibits DTCs from disclosing genetic data without explicit consumer consent even if it is deidentified. In addition, this bill creates civil penalties for companies that fail to comply with the provisions within it. By passing this bill, California would be joining multiple other states that have made it clear that consumers should control their genetic data without fear of third parties exploiting it.

Establishing Protections at the State Level

SB 980 (Umberg, 2020) was introduced last year attempting to finally establish the Genetic Information Privacy Act. This bill borrowed heavily from SB 980, which passed through both houses of the Legislature. However, SB 980 was vetoed by Governor Newsom. He shared his reasoning in his veto message:

> This bill would establish requirements for direct-to-consumer genetic testing companies, providing opt-in privacy rights and protections for consumers.
>
> I share the perspective that the sensitive nature of human genetic data warrants strong privacy rights and protections.

> However, 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.
>
> Because I agree with the primary goal of this bill, I am directing the California Health and Human Services Agency and the Department of Public Health to work with the Legislature on a solution that achieves the privacy aims of the bill while preventing inadvertent impacts on COVID-19 testing efforts.

This bill again seeks to enact California’s Genetic Information Privacy Act. This bill attempts to protect the sensitive information being collected by DTC companies by attaching a series of requirements to the collection, use, maintenance, and disclosure of genetic data. These companies are required to provide clear and complete information regarding the company’s policies and procedures by making certain information available to consumers. Consumers must be notified that their deidentified genetic or phenotypic information may be shared with or disclosed to third parties for research purposes, as such exemptions are written in to the definition of “genetic data.”

This bill requires DTC companies to obtain a consumer’s *express* consent to the collection, use, and disclosure of the consumer’s genetic data. This bill includes a robust definition for “express consent” that ensures meaningful consumer control.

In order to ensure more meaningful control and informed decision making, this bill requires a consumer’s affirmative authorization in response to a “clear, meaningful, and prominent notice” regarding the relevant actions taken with the genetic data and the specific purpose for it. Securing express consent also requires DTC companies to communicate in “clear and prominent terms” the nature of the data collection, use, maintenance, or disclosure such that “an ordinary consumer would notice and understand it.” Further strengthening this concept are provisions that rule out inferring consent from inaction and specifically call out the use of dark patterns to obtain it. This bill defines the term to mean “a user interface designed or manipulated with the substantial effect of subverting or impairing user autonomy, decisionmaking, or choice.”

The obligation for securing consent in this bill includes the requirement that these companies, at a minimum, secure *separate* and express consent for various purposes. Regarding consent for marketing, this bill does not require such separate express consent when the marketing is contained to the DTC's own platform so long as the content of the marketing does not utilize information specific to that consumer, except for that information related to the relevant products or services of the DTC. However, this bill still restricts placement of advertisements based on specified characteristics. In addition, this bill exempts certain third parties and specified data from these requirements, including academic institutions for research or educational activities and genetic data collected by employers in order to comply with health and safety laws. These exemptions alternatively use the term "genetic information" rather than "genetic data," the latter of which is defined in the bill. The author indicates there is not an intent for the terms to be interpreted differently from one another.

To protect consumers' genetic data from being compromised or used against the consumer's interests, DTC companies are also required to implement and maintain reasonable security procedures and practices and are prohibited from disclosing a consumer's genetic data to various entities, except as provided.

Negligent and willful violations of this provision are subject to varying ranges of civil penalties, up to $10,000 for willful violations as follows:

> Actions for relief pursuant to this chapter shall be prosecuted exclusively in a court of competent jurisdiction by the Attorney General or a district attorney or by a county counsel authorized by agreement with the district attorney in actions involving violation of a county ordinance, or by a city attorney of a city having a population in excess of 750,000, or by a city attorney in a city and county or, with the consent of the district attorney, by a city prosecutor in a city having a full-time city prosecutor in the name of the people of the State of California upon their own complaint or upon the complaint of a board, officer, person, corporation, or association, or upon a complaint by a person who has suffered injury in fact and has lost money or property as a result of the violation of this chapter.

In order to make the injured party whole, penalties recovered, regardless of the party bringing suit, are to be paid to the individual to whom the genetic data at issue pertains, with recovered court costs going to the party prosecuting the action.

FISCAL EFFECT: Appropriation: No Fiscal Com.: Yes Local: Yes

According to the Assembly Appropriations Committee:

- Costs (General Fund) of $269,000 in fiscal year (FY) $371,000 in 2021-22 and $357,000 annually thereafter to the Department of Justice (DOJ) in additional staff and infrastructure to enforce the requirements of the GIPA.

- Cost pressures (Trial Court Trust Fund) in the mid-hundreds of thousands of dollars annually to the courts in additional workload. This bill authorizes the DOJ, a district attorney or a city attorney to file civil actions against GTCs for violations of the requirements specified in this bill. If 20 cases are filed statewide resulting in 20 hours of court time for each case, costs would be approximately $382,400. Although courts are not funded on the basis of workload, increased pressure on the courts and staff may create a need for increased funding for staff and infrastructure.

SUPPORT: (Verified 9/8/21)

23andMe
Access Humboldt
ACLU California Action
Ancestry
Coalition for Genetic Data Protection
Consumer Action
Consumer Federation of America
Consumer Reports
Electronic Frontier Foundation
Media Alliance
Oakland Privacy
Privacy Rights Clearinghouse
University of California

OPPOSITION: (Verified 9/8/21)

None received

ARGUMENTS IN SUPPORT: Oakland Privacy outlines the importance of taking action in this context: “Senate Bill 41 recognizes the inter-related nature of DNA data and elevates its use threshold to an explicit consent standard that includes revocation rights, data destruction and addresses the provision of genetic data to insurance, employer, health and other bodies that potentially could base significant life outcomes on genetic information. This protects not only the source of the DNA from unintended consequences, but also their known and sometimes unknown relatives whose gene patterns are tied to their own."

ASSEMBLY FLOOR: 80-0, 9/8/21
AYES: Aguiar-Curry, Arambula, Bauer-Kahan, Bennett, Berman, Bigelow, Bloom, Boerner Horvath, Mia Bonta, Bryan, Burke, Calderon, Carrillo, Cervantes, Chau, Chen, Chiu, Choi, Cooley, Cooper, Cunningham, Megan Dahle, Daly, Davies, Flora, Fong, Frazier, Friedman, Gabriel, Gallagher, Cristina Garcia, Eduardo Garcia, Gipson, Lorena Gonzalez, Gray, Grayson, Holden, Irwin, Jones-Sawyer, Kalra, Kiley, Lackey, Lee, Levine, Low, Maienschein, Mathis, Mayes, McCarty, Medina, Mullin, Muratsuchi, Nazarian, Nguyen, O'Donnell, Patterson, Petrie-Norris, Quirk, Quirk-Silva, Ramos, Reyes, Luz Rivas, Robert Rivas, Rodriguez, Blanca Rubio, Salas, Santiago, Seyarto, Smith, Stone, Ting, Valladares, Villapudua, Voepel, Waldron, Ward, Akilah Weber, Wicks, Wood, Rendon

Prepared by: Christian Kurpiewski / JUD. / (916) 651-4113
9/8/21 21:52:14

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