SENATE COMMITTEE ON APPROPRIATIONS
Senator Anthony Portantino, Chair
2021 - 2022 Regular Session

SB 41 (Umberg) - Privacy: genetic testing companies

Version: March 11, 2021
Urgency: Yes
Hearing Date: March 22, 2021
Policy Vote: JUD. 11 - 0
Mandate: Yes
Consultant: Shaun Naidu

Bill Summary: SB 41, an urgency measure, would impose specified requirements and restrictions on direct-to-consumer genetic testing companies related to the sharing and use of people's genetic information and would impose a civil penalty for the violation of any provision of the bill.

Fiscal Impact:
- The Department of Justice (DOJ) reports ongoing annual costs of $357,000 for 1.0 Deputy Attorney General and 1.0 Legal Secretary for enforcement workload associated with this measure. (General Fund)

- Unknown, potentially-significant workload cost pressures to the courts to adjudicate alleged violations of this measure. While the superior courts are not funded on a workload basis, an increase in workload could result in delayed court services and would put pressure on the General Fund to provide for additional staff and resources. For example, the Governor's proposed 2021-2022 budget would appropriate $118.3 million from the General Fund to backfill continued reduction in fine and fee revenue for trial court operations. (General Fund*)

*Trial Court Trust Fund

Background: The California Constitution provides that all people have inalienable rights, including the right to pursue and obtain privacy. (Cal. Const., art. I, § 1.) Regarding personal health privacy, the Confidentiality of Medical Information Act prohibits health care providers, health care service plans, or contractors, as defined, from sharing medical information without the patient's written authorization, subject to certain exceptions. (Civ. Code, § 56 et seq.) "Medical information" is defined as individually-identifiable information, in electronic or physical form, in possession of or derived from a health care provider, health care service plan, pharmaceutical company, or contractor regarding a patient's medical history, mental or physical condition, or treatment. (Civ. Code, § 56.05, subd. (g).) Any health care provider, health care service plan, pharmaceutical company, or contractor who negligently creates, maintains, preserves, stores, abandons, destroys, or disposes of written or electronic medical records is liable for damages in a civil action or an administrative fine, as specified. (Civ. Code, § 56.36.)

With respect to genetic information specifically, the Unruh Civil Rights Act and the Fair Employment and Housing Act (FEHA) prohibit discrimination on the basis of this information (Civ. Code, § 51 & Gov. Code, § 12920 et seq.), and those who improperly disclose genetic tests are subject to civil and criminal penalties. (Civ. Code, § 56.17; Ins. Code, § 10149.1.) More broadly, the California Consumer Privacy Act of 2018

grants consumers certain rights with regard to their personal information, including enhanced notice, access, and disclosure when their personal information is collected; the right to deletion; the right to restrict the sale of information; and protection from discrimination for exercising these rights. It places attendant obligations on businesses to respect those rights. (Civ. Code, § 1798.100 et seq.)

On the federal level, the Health Insurance Portability and Accountability Act (commonly known by its acronym HIPAA) prescribes privacy protections for patients' protected health information and generally prohibits a covered entity, which includes a health plan, health care provider, and health care clearing house, from using or disclosing protected health information except as specified or as authorized by the patient in writing. (45 C.F.R. § 164.500 et seq.) Also, the Genetic Information and Nondiscrimination Act prohibits discrimination in group health plan coverage and employment based on genetic information. (Pub.L. No. 110-233.)

Proposed Law: This bill would establish the Genetic Information Privacy Act. Specifically, it would:

- Require a direct-to-consumer genetic testing 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.
- Require a direct-to-consumer genetic testing company to 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. It would require the company to secure separate and express consent for specified actions.
- Provide that the requirement for separate and express consent for marketing does not require a company to obtain a consumer's express consent to market to the consumer on the company's own website or mobile application, as specified.
- Require a direct-to-consumer genetic testing 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 provided directly by a consumer, to implement and maintain reasonable security procedures and practices. It would require such companies to 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.
- Prohibit a direct-to-consumer genetic testing company 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 specified.
- Prohibit discrimination by a person or public entity against a consumer based on the consumer's exercise of rights provided by this measure, as specified.
- Exempt application of the provisions of SB 41 to certain medical information, health care providers, other covered entities, and their business associates.

- Allow actions for relief from violations of this measure to be prosecuted only by the Attorney General, a district attorney, a county counsel authorized by agreement with the district attorney, or by a city attorney, as specified.
- Impose a civil penalty upon a person who negligently or willfully violates any provision of this measure. Each violation would be separate and actionable.
- Define a "direct-to-consumer genetic testing company" as an entity that does either of the following:
  - Sell, market, interpret, or otherwise offer consumer-initiated genetic testing products or services directly to consumers; or
  - 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.
- Define "genetic data" 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 specified.
- Make specified legislative findings and declarations.

Related Legislation: SB 980 (Umberg, 2019-2020 Reg. Session) was substantially similar to this bill. SB 980 was vetoed by the Governor who stated that he "share[d] the perspective that the sensitive nature of human genetic data warrants strong privacy rights and protections," but "the broad language in [SB 980] 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."

AB 1130 (Levine, Ch. 750, Stats. 2019) revised the definition of "personal information" in specified consumer protection statutes to include certain government identification numbers and biometric data.

AB 2301 (Levine, 2019-2020 Reg. Sess.) would have added "genetic information" to the definition of personal information for purposes of the law requiring certain businesses to implement and maintain reasonable security procedures and practices to protect personal information they own, license, or maintain. It also would require businesses to disclose a breach of genetic information. AB 2301 was never heard by the Assembly Committee on Privacy and Consumer Protection.

SB 180 (Chang, Ch. 140, Stats. 2019) required a person selling a gene therapy kit in California to include a notice on their website that is displayed to the consumer prior to the point of sale and to place the notice on a label on the package containing the gene therapy kit stating that the kit is not for self-administration.

SB 559 (Padilla, Ch. 261, Stats. 2011) expanded anti-discrimination protections under the Unruh Civil Rights Act and the California Fair Employment and Housing Act to include genetic information.

Staff Comments: The Department of Justice anticipates an increased workload resulting from this measure. Committee staff queries if the additional personnel and costs reported by DOJ accurately reflects the enforcement workload that this measure would produce. Without specific information or an estimate as to the likely workload involved, the need for these positions appears to be speculative.

Similarly, the fiscal impact of SB 41 to the courts is unknown and will depend on many factors, including the numbers of violations alleged to have occurred, if parties settle the matter before the filing of an action, and the factors unique to each case. While it is not known how many actions for alleged violations ultimately would be filed, it generally costs about $8,032 (in FY 2020-2021) to operate a courtroom for one eight-hour day. Consequently, if alleged violations of SB 41 lead to the filing of cases that, combined, take 50 or more hours of court involvement, the cost pressures of this measure to the courts would surpass the Suspense File threshold. As indicated above, while courts are not funded on a workload basis, an increase in workload could result in delayed services and would put pressure on the General Fund to provide for additional staff and resources.

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