This bill regulates the use of genetic data by “direct-to-consumer genetic testing companies.” Specifically, the bill requires any such company to (1) provide consumers with information regarding the company’s policies and procedures; (2) obtain specified types of consent from the consumer prior to collecting, using, or disclosing the consumer’s genetic data; and (3) develop and implement policies and procedures to protect genetic data, including policies related to the disclosure of genetic data to law enforcement or other government agencies. Violation of the bill is an unfair, abusive, or deceptive trade practice under the Maryland Consumer Protection Act (MCPA), subject to MCPA’s civil and criminal penalty provisions.

**Fiscal Summary**

**State Effect:** The bill’s imposition of existing penalty provisions does not have a material impact on State finances or operations. The Office of the Attorney General, Consumer Protection Division, can handle the bill’s requirements with existing resources.

**Local Effect:** The bill’s imposition of existing penalty provisions does not have a material impact on local government finances or operations.

**Small Business Effect:** None.
Analysis

Bill Summary:

The bill defines “direct-to-consumer genetic testing company” as an entity that (1) offers genetic testing products or services directly to a consumer or (2) collects, uses, or analyzes genetic data provided to the company by a consumer.

Applicability

The bill does not apply to (1) protected health information that is collected by an entity in accordance with federal regulations or (2) an institution of higher education (including an entity owned or operated by such an institution).

Disclosure

A direct-to-consumer genetic testing company must provide a consumer with clear and complete information regarding the company’s policies and procedures for collecting, using, or disclosing genetic data, including:

- a high-level overview of the company’s privacy policy that includes basic and essential information about how the company collects, uses, and discloses genetic data; and
- a privacy notice that, at a minimum, includes information about the company’s data collection, consent, use, access, disclosure, transfer, security, and retention and deletion practices.

The required information must be (1) made publicly available and (2) placed in a prominent area of the company’s website.

Required Consent

A direct-to-consumer genetic testing company must, at a minimum, obtain specified consents (e.g., initial express consent describing the uses of the genetic data collected, express consent for transferring or disclosing the genetic data or using it beyond the primary purpose of the testing product or service the consumer requested, etc.) from a consumer before collecting, using, or disclosing the consumer’s genetic data.

Policies and Procedures to Protect Genetic Data

A direct-to-consumer genetic testing company must establish legal policies and processes for disclosing genetic data to law enforcement (or another government agency) without a
consumer’s express written consent. Further, any such company must develop, implement, and maintain a comprehensive security program to protect consumers’ genetic data against unauthorized access, use, or disclosure. The company must also establish a process for a consumer to (1) access the consumer’s genetic data; (2) delete the consumer’s account and genetic data; and (3) request the destruction of the consumer’s biological sample.

Regardless of any other provisions of law, a direct-to-consumer genetic testing company may not, without a consumer’s written consent, disclose a consumer’s genetic data to (1) an entity offering health insurance, life insurance, or long-term care insurance or (2) an employer of the consumer.

Miscellaneous Provisions

The bill’s requirements do not prevent an individual from pursuing any other remedy provided by law. Further, the disclosure of genetic data in accordance with the bill’s requirements must comply with all State and federal laws for the protection of privacy and security.

Current Law: Although the Commercial Law Article does not include provisions regulating direct-to-consumer genetic testing companies, other provisions of State law regulate genetic analysis by law enforcement agencies. Chapters 681 and 682 of 2021 (Title 17 of the Criminal Procedure Article) establish requirements and procedures for forensic genetic genealogical DNA analysis and related searches of publicly accessible databases using genetic profiles, including provisions regarding regulation and oversight of testing connected to this analysis and direct-to-consumer genetic genealogy services. For example, Title 17 includes informed consent requirements that must be met before law enforcement can obtain a DNA sample from a third party to assist in certain types of DNA analysis.

Maryland Consumer Protection Act

An unfair, abusive, or deceptive trade practice under MCPA includes, among other acts, any false, falsely disparaging, or misleading oral or written statement, visual description, or other representation of any kind which has the capacity, tendency, or effect of deceiving or misleading consumers. The prohibition against engaging in any unfair, abusive, or deceptive trade practice encompasses the offer for or actual sale, lease, rental, loan, or bailment of any consumer goods, consumer realty, or consumer services; the extension of consumer credit; the collection of consumer debt; or the offer for or actual purchase of consumer goods or consumer realty from a consumer by a merchant whose business includes paying off consumer debt in connection with the purchase of any consumer goods or consumer realty from a consumer.
The Consumer Protection Division is responsible for enforcing MCPA and investigating the complaints of aggrieved consumers. The division may attempt to conciliate the matter, issue a cease and desist order, or file a civil action in court. A merchant who violates MCPA is subject to a fine of up to $10,000 for each violation and up to $25,000 for each repetition of the same violation. In addition to any civil penalties that may be imposed, any person who violates MCPA is guilty of a misdemeanor and, on conviction, is subject to a fine of up to $1,000 and/or imprisonment for up to one year.

Additional Information

**Prior Introductions:** None.

**Designated Cross File:** HB 866 (Delegate Qi) - Economic Matters.

**Information Source(s):** Maryland Department of Health; Department of Legislative Services

**Fiscal Note History:** First Reader - February 24, 2022

js/jkb

Analysis by: Eric F. Pierce

Direct Inquiries to:
(410) 946-5510
(301) 970-5510