



FEDERAL TRADE COMMISSION
PROTECTING AMERICA'S CONSUMERS

For Release

FTC Warns Health Apps and Connected Device Companies to Comply With Health Breach Notification Rule

Policy statement affirms that covered companies that hold fertility, heart health, glucose levels and other health data must notify consumers in the event of a breach

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Tags: [Consumer Protection](#) | [Bureau of Consumer Protection](#) | [Health](#) | [Health Care](#) | [Mobile](#) | [Privacy and Security](#) | [Data Security](#)

The Federal Trade Commission today issued a policy statement affirming that health apps and connected devices that collect or use consumers' health information must comply with the Health Breach Notification Rule, which requires that they notify consumers and others when their health data is breached.

In a [policy statement](#) adopted during an open meeting, the Commission noted that health apps, which can track everything from glucose levels for those with diabetes to heart health to fertility to sleep, increasingly collect sensitive and personal data from consumers. These apps have a responsibility to ensure they secure the data they collect, which includes preventing unauthorized access to such information.

As part of the American Recovery and Reinvestment Act of 2009, Congress included specific provisions to strengthen privacy and security protections for web-based businesses. The law directed the FTC to ensure that companies contact customers in the event of a security breach. Shortly after, the FTC issued the [Health Breach Notification Rule](#), which requires vendors of personal health records and related entities to notify consumers, the FTC, and, in some cases, the media when that

data is disclosed or acquired without the consumers' authorization. Over a decade later, health apps and other connected devices that collect personal health data are not only mainstream—and have increased in use during the pandemic—but are targets ripe for scammers and other cyber hacks. Yet, there are still too few privacy protections for these apps.

"While this Rule imposes some measure of accountability on tech firms that abuse our personal information, a more fundamental problem is the commodification of sensitive health information, where companies can use this data to feed behavioral ads or power user analytics," said FTC Chair Lina M. Khan. "Given the growing prevalence of surveillance-based advertising, the Commission should be scrutinizing what data is being collected in the first place and whether particular types of business models create incentives that necessarily place users at risk."

The Rule ensures that entities not covered by the Health Insurance Portability and Accountability Act (HIPAA) face accountability when consumers' sensitive health information is breached.

The Commission policy statement notes that apps and connected devices such as wearable fitness tracking devices that collect consumers' health information are covered by the Health Breach Notification Rule if they can draw data from multiple sources, and are not covered by a similar rule issued by the Department of Health and Human Services. For example, a health app would be covered under the FTC's rule if it collects health information from a consumer and has the technical capacity to draw information through an API that enables syncing with a consumer's fitness tracker. Companies that fail to comply with the rule could be subject to monetary penalties of up to \$43,792 per violation per day.

The Commission voted 3-2 to approve the policy statement during the open virtual meeting. [Chair Khan](#) and Commissioners [Rohit Chopra](#) and [Rebecca Kelly Slaughter](#) issued separate statements. Commissioners [Noah Joshua Phillips](#) and [Christine S. Wilson](#) both voted no and each issued dissenting statements.

The Federal Trade Commission works to promote competition and [protect and educate consumers](#). The FTC will never demand money, make threats, tell you to transfer money, or promise you a prize. Learn more about consumer topics at [consumer.ftc.gov](#), or report fraud, scams, and bad business practices at [ReportFraud.ftc.gov](#). Follow the [FTC on social media](#), read [consumer alerts](#) and the [business blog](#), and [sign up to get the latest FTC news and alerts](#).

Press Release Reference

[FTC Announces Tentative Agenda for September 15 Open Commission Meeting](#)

Contact Information

Media Contact

Staff Contacts

Elisa Jillson
Bureau of Consumer Protection
202-326-3001

Ryan Mehm
Bureau of Consumer Protection
Ryan Mehm