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Federal Trade Commission Continues Its Focus on Health Privacy

Kathleen Benway, Sarah Beach, Sara Pullen Guercio, and Hyun Jai Oh*

In this article, the authors discuss the Federal Trade Commission's continued focus on consumer privacy in the digital health care space.

Since the Federal Trade Commission (FTC) announced its first action involving the Health Breach Notification Rule (HBNR or Rule) against GoodRx Holdings Inc. earlier this year, it has continued to focus on consumer privacy in the digital health care space, including by announcing its second action alleging violation of the HBNR and by proposing amendments to it.

Like its action against GoodRx, where the FTC alleged that the company violated the HBNR by sharing health data with third-party digital advertising and analytics providers in a manner that was inconsistent with its own privacy policy, in this most recent case, the FTC alleged that fertility tracking app Premom's sharing of health-related information with third-party advertisers amounted to a "breach" under the HBNR.

In its proposal to amend the Rule, the FTC states that the scope of "breach" under the Rule is not limited to cybersecurity breaches but also covers any unauthorized disclosure of personal health record (PHR) identifiable health information. Businesses dealing with health information that is not covered by the Health Insurance Portability and Accountability Act (HIPAA) should pay particular attention to the proposed amendments because the FTC's statement that the Notice of Proposed Rulemaking (NPRM) offers a clarification of the existing HBNR, including its broad definition of PHR, means that the FTC considers these "clarifications" to be in effect now.

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Enforcement Action Against Easy Healthcare

The FTC recently announced[1] an enforcement action against Easy Healthcare Corporation, the developer of Premom, which is marketed as a fertility tracking app. In its complaint,[2] the FTC alleged that Easy Healthcare violated (1) Section 5 of the FTC Act by failing to adhere to promises it made to Premom users in its privacy policy regarding its practices for sharing sensitive health information with third parties, and (2) the HBNR by failing to report such unauthorized disclosures as a security breach.

Specifically, the FTC alleged Easy Healthcare stated in its privacy policy that it would not share Premom users' health information with third parties without users' consent, Easy Healthcare would only share non-identifiable data when it did share data with third parties, and identifiable data was only used by Easy Healthcare for its own analytics and advertising purposes.

The FTC alleged that Easy Healthcare shared hundreds of thousands of Premom users' sensitive and identifiable health information, including information about their sexual and reproductive health, parental and pregnancy status, and pregnancy-related symptoms, with third parties for advertising purposes, including Google and two Chinese analytics providers. Specifically, Easy Healthcare allegedly shared health information by allowing third-party software development kits (SDKs) to capture Premom users' interaction with the app that conveyed information about users' fertility and pregnancy. For instance, when a user recorded information related to her period through Premom, Easy Healthcare logged that information as "Log period-save" and shared it via third-party SDKs.

According to the complaint, the information captured by SDKs could also be used by other advertisers to track users across the internet and other apps. This means third parties could infer sensitive health information from what appears to be non-health information collected across multiple platforms, such as device identifiers, geolocation, and media access control addresses.

Finally, the FTC alleged that Easy Healthcare did not implement reasonable privacy and data security measures, including by failing to properly encrypt the data it collected, including users' health information. The FTC further argued that Easy Healthcare failed to conduct adequate assessment of third-party SDKs before

deployment and to continuously monitor SDK publishers' terms and conditions and privacy policies.

The FTC issued a proposed order[3] that, in addition to requiring a civil monetary penalty of $100,000, permanently bans Easy Healthcare from sharing user health information with third parties for advertising purposes and requires Easy Healthcare to submit annual compliance certifications for the next 20 years. The FTC voted 3-0 to refer the complaint and proposed order to the Department of Justice for filing.

Proposed Changes to the Health Breach Notification Rule

The FTC recently published[4] an NPRM seeking comment on the proposed changes to the HBNR that are drawn from the FTC's September 2021 statement on Breaches by Health Apps and Other Connected Devices.[5] The FTC stated that the amendments would change or expand the HBNR in some cases and clarify the FTC's current interpretation of the Rule in other cases.

Notably, the FTC referenced the Department of Health and Human Services (HHS) guidance[6] for "securing" electronic health information as the standard for encryption and also disclosed that it "sought informal input from staff at federal agencies . . . including staff at HHS." This NPRM therefore suggests a strong cross-agency coordination in the health care space and sheds further light on what the FTC considers to be unsecured PHR identifiable health information subject to the HBNR.

The NPRM clarifies the HBNR's applicability to health apps and other direct-to-consumer devices and technologies, such as fitness trackers, which, since the Rule's issuance in 2009, "have become commonplace." The FTC makes this clarification through the addition of two new terms, "health care provider" and "health care services or supplies," that include online services that provide health-related services or tools, such as mechanisms to track disease and health conditions, medications, sexual health, diets, and other health-related information.

Other notable changes and clarifications include:

- Revising the definition of "breach of security" to clarify that it includes not just data breaches, but any disclosure

of PHR identifiable health information not authorized by a consumer. A breach of security therefore may include an app provider's voluntary disclosure of PHR identifiable health information that was not authorized by users.

- Clarifying that a "personal health record" is "drawn from multiple sources" when it "has the technical capacity to draw information from multiple sources." This clarification indicates that, when analyzing the scope of PHR, the FTC focuses on a product's technical ability rather than an individual consumer's use of the product.
- Modernizing methods of notice by permitting email notification of consumers, expanding the contents of such notice, and providing examples of permissible notices. The amendments would require applicable notice to include additional content, such as a brief description of the potential harm, description of third-party acquirers of information, description of information involved, and mitigating measures taken.

Businesses should note that the FTC posed some of these changes, such as the expanded definitions of "breach of security" and "personal health record," as "clarifications," meaning the FTC considers them to be currently effective. Other changes, including the modernization of the notice method and expansion of required contents of notice, would become effective 60 days after the publication of the final rule.

The FTC has also requested public comment in several areas, including whether the changes "sufficiently clarify the Rule's application to purveyors of health apps and similar technologies that are not covered by HIPAA," or whether the definition of "electronic mail" may lead to over-notification or may result in collecting more data than necessary.

Conclusion

In summary:

- *Health Privacy Remains a Priority Focus for Regulators*. The FTC continues to take the position that a business's voluntary disclosure of health information to its service providers may constitute a breach under the HBNR. Therefore,

businesses that collect and use health information should assess whether their sharing of health information can trigger liabilities under the HBNR.

- *Use of Tracking Technologies Requires Careful Review and Vendor Due Diligence*. Failure to implement reasonable privacy and data security measures can expose businesses to liabilities under Section 5 of the FTC Act. When implementing third-party tracking technologies, such as cookies, pixels, or SDKs, the FTC expects businesses to conduct ongoing vendor due diligence. Businesses should carefully review the terms and conditions and privacy policies of the vendors of tracking technologies to understand what rights those vendors have over the information exchanged through tracking technologies. Moreover, businesses should ensure there are adequate oversight mechanisms in place; for instance, through contractual rights to conduct periodic privacy and data security audits.
- *The FTC Considers Some of the Proposed Changes to the HBNR to Already Be in Effect*. Notable clarifications include the HBNR's applicability to health apps and other health-related services or tools, expansion of the scope of breach of security, and expansion of the scope of PHR. Therefore, businesses should immediately assess the impact of these amendments, even though the FTC has not published the final rule.

Notes

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1. https://www.ftc.gov/news-events/news/press-releases/2023/05/ovulation-tracking-app-premom-will-be-barred-sharing-health-data-advertising-under-proposed-ftc.

2. https://www.ftc.gov/system/files/ftc_gov/pdf/2023186easyhealthcarecomplaint.pdf.

3. https://www.ftc.gov/system/files/ftc_gov/pdf/2023186easyhealthcarestipulatedorder.pdf.

4. https://www.federalregister.gov/documents/2023/06/09/2023-12148/health-breach-notification-rule.

5. https://www.ftc.gov/system/files/documents/public_statements/1596364/statement_of_the_commission_on_breaches_by_health_apps_and_other_connected_devices.pdf.

6. https://www.hhs.gov/hipaa/for-professionals/breach-notification/guidance/index.html.