

April Tabor Secretary Federal Trade Commission (FTC) 600 Pennsylvania Avenue, NW Suite CC–5610 (Annex H) Washington, DC 20580

Re: ATA Action Comments on Federal Trade Commission Health Breach Notification Rule, Project No. P205405"

On behalf of ATA Action, the American Telemedicine Association's trade organization focused on advocacy, thank you for the opportunity to comment on this proposed rule that would amend the Health Breach Notification Rule (HBNR). We appreciate your commitment to ensuring consumers' health information is protected and seeking feedback to ensure the appropriate definitions, procedures, and guardrails on this matter are implemented.

ATA Action understands the Federal Trade Commission (FTC) is attempting to modernize the HBNR to encompass health apps and similar technologies, but we believe that the proposed changes go beyond the original intent and could cause unintended consequences for many entities. The FTC notes from the onset the proposed rule would cover an additional 170,000 entities and result in 71 breaches per year. From ATA Action's perspective, this is inaccurate as the proposed changes significantly broaden the scope of the HBNR and would likely cover a far greater number of entities. We recognize the need to update the HBNR to protect the health and wellness of consumers. However, we are deeply concerned that the excessively broad scope of these proposed updates combined with unreasonable obligations on regulated entities will have the unintended consequence of reducing choice and access in the marketplace, and with that eliminating promising opportunities to lower barriers to care and serving the underserved. For example, based on the Statista Global Consumer Survey conducted in the United States 2022, 27% of respondents who used health apps in the preceding 12 months were from low-income households¹.

ATA Action has outlined some recommended proposed changes in the areas of greatest concern.

- The FTC significantly broadens the scope of key definitions in ways that could potentially incorporate not just the purveyors of these health apps, but also any online store offering wellness products such as sneakers or vitamins. For example, the FTC's definition of "health care provider" is particularly broad. "Health care provider" is defined as a provider of services (as defined in 42 U.S.C. 1395x(u) (41)), a provider of medical or other health services (as defined in 42 U.S.C. 1395x(s)), or any other entity furnishing health care services or supplies. ATA Action believes this definition in the notification rule encapsulates more entities than intended by current law. For instance, it would essentially define online retailers as health care providers. We urge FTC to bring into focus its definition of health care provider, such as by simply exclude online retailers and abandon the word "supplies".
- The Commission also proposes to revise the definition of breach of security to clarify that a breach of security includes an unauthorized acquisition of personal health record (PHR) identifiable health

_Stewart, C. (2022, August 23). Distribution of adult health app users in the U.S. as of 2022, by household income level. https://www.statista.com/forecasts/1181575/share-of-us-health-app-users-by-household-income-level#:~:text=According%20to%20the%20results%2C%2043,income%20households%20used%20health%20apps

information in a personal health record that occurs because of a data security breach or an unauthorized disclosure. This proposed definition conflates two distinct concepts—security incidents and ordinary-course disclosures of data—which pose differing levels of concern for and risk to consumers. Ultimately, we believe the definition is too stringent. If the definition were to remain it should contain explicit exceptions that cover: data sharing within a company that includes multiple affiliated businesses, unauthorized but inadvertent good-faith access by an internal employee without a need to know/proper authorization, companies that make good-faith efforts to inform consumers generally of disclosures to third parties and companies that make efforts to contractually limit downward stream uses of the data. The HIPAA Breach Notification Rule is an effective and notable framework that the FTC should utilize as a resource when seeking potential exceptions.

- Relatedly, the FTC suggests that PHR vendors could avoid breaches by de-identifying health
 information before sharing it with a service provider. However, the FTC does not provide a
 definition of, or guidelines related to, what sufficient de-identification would look like. ATA Action
 urges the FTC to provide more guidance around the de-identification process.
- Finally, in its proposed amendments to the HBNR, the Commission weighed whether to change the existing 10 business day notification requirement. However, the Commission failed to propose any modification to its notification timing requirements and did not comment on whether the FTC would consider a risk-based reporting threshold similar to the HIPAA Breach Notification Rule. Given the significant expansion in the nature and scope of the HBNR under the proposed rule, the lack of alignment with existing requirements under the HIPAA Breach Notification Rule will create significant burden for health care providers and, more importantly, result in counterproductive "over-notification" issues and consumer fatigue. Under the HIPAA Breach Notification Rule, covered entities are provided the necessary time to analyze impact and base reporting on risk analyses that determine harm to consumers. FTC has invited comments on notification timelines and expressed interest in stakeholders' views on aligning with the 60-day reporting requirement under HIPAA. We strongly urge the FTC to align the HBNR notification timing requirements to current policy under the HIPAA Breach Notification rule, and additionally adopt a similar risk assessment framework under 45 CFR §§ 164.400-414.

Again, we applaud the FTC for soliciting feedback from stakeholders on this matter and appreciate its work to ensure the security of patients' health data and transparency when data is mishandled. Although, ATA Action believes the FTC's proposed changes are going beyond the intended scope and must be reevaluated. We urge the Commission to consider working alongside Congress to discuss and address these pertinent issues through the legislative process. Thank you for your consideration.

Kind regards,

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