



August 20, 2020

Honorable April J. Tabor, J.D.  
Acting Secretary  
Federal Trade Commission  
7<sup>th</sup> Street SW  
Washington, D.C. 20024

Submitted electronically via: <https://www.federalregister.gov/documents/2020/05/22/2020-10263/health-breach-notification#open-comment>

Dear Ms. Tabor:

Re: Health Breach Notification Rule, 16 CFR part 318, Project No. P205405

Thank you for the opportunity to provide comments on the Federal Trade Commission (FTC) Health Breach Notification Rule.<sup>[1]</sup> The Alliance for Nursing Informatics appreciates the review process and the opportunity to comment as an alliance of members of the greater clinical and informatics communities.

The Alliance for Nursing Informatics (ANI), co-sponsored by AMIA & HIMSS advances nursing informatics leadership, practice, education, policy and research through a unified voice of nursing informatics organizations. We transform health and healthcare through nursing informatics and innovation. ANI is a collaboration of organizations that represent more than 20,000 nurse informaticists and brings together 25 distinct nursing informatics groups globally. ANI crosses academia, practice, industry, and nursing specialty boundaries and works in collaboration with the more than 4 million nurses in the U. S. in practice today.

As nursing informatics stakeholders who provide patient education and advocacy for health consumers across all care settings, we have reviewed the Health Breach Notification Rule (HBN Rule). As an important supplement to the existing HIPAA Breach Notification Rule<sup>[2]</sup>, we believe the intent of this Rule is to advance the transparency for health consumers to make public breach notifications for non-HIPAA covered entities (NCEs). These needs have increased in significance since the Rule's inception with the proliferation of consumer applications and devices that today collect personal health information. In review of the existing HBN Rule and reporting infrastructure, there are opportunities to align both the terminology with current technologies as well as the standards for FTC disclosures, and proactively support consumer advocacy and education.

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[1] [ Federal Trade Commission, "16 CFR Part 318 - Health Breach Notification Rule; Final Rule," 25 August 2009. [Online]. Available: [https://www.ftc.gov/sites/default/files/documents/federal\\_register\\_notices/health-breach-notification-rule-16-cfr-part-318/090825healthbreachrule.pdf](https://www.ftc.gov/sites/default/files/documents/federal_register_notices/health-breach-notification-rule-16-cfr-part-318/090825healthbreachrule.pdf). [Accessed 15 August 2020].

[2] U.S. Department of Health & Human Service, "Health Information Policy," 26 July 2013. [Online]. [Accessed 18 August 2020].

[3] Y. Kim, B. Lee and E. K. Choe, "Investigating data accessibility of personal health apps," *Journal of the American Medical Informatics Association*, pp. 412-419, 2019.

The current HBN Rule, and definitions within that Rule, reference “Personal Health Record” (PHR) vendors, PHR identifiable information, and PHR related entities.<sup>[1]</sup> Today, consumers are sharing and accessing personal health information via mobile health platforms (mHealth) and devices which may be unrelated to the originally defined concept of a personal health record or PHR system<sup>[3]</sup>. We believe that the Rule as designed to encompass vendors or entities that are otherwise not covered by the HIPAA Breach Notification Rule is important and the language should be updated with terminology that more comprehensively describes the current technology landscape. We believe that protection and security of identifiable health information or protected health information (PHI) should receive protection of law, unrelated to who acquires or accesses the data. Consumers, and many healthcare settings today, lack full understanding of the standards and protections between HIPAA breach notification procedures and disclosures to HHS OCR and non-HIPAA covered entities to FTC.

We offer the following additional considerations to update and improve the HBN Rule, including:

- Increase options for breach notifications to include email rather than via certified mail as the only option
- Provide clarity on timelines for major breach notification to the FTC as well as the end users
- Standardize the format and data elements for reporting of breach notifications between HIPAA and non-HIPAA covered entities
- Include a mechanism for both individuals and entities to report breaches when they have occurred
- Identify sufficiently stringent penalties and monitoring for responsible management of identifiable PHI
- Provide more specificity on post-breach notification requirements
- Align the standards with General Data Protection Regulation (GDPR)<sup>[4]</sup>, the California Consumer Privacy Act (CCPA)<sup>[5]</sup> and other future state legislation to address consumer data privacy
- Provide consumer friendly educational resources regarding the revisions to the HBN Rule.

ANI appreciates the opportunity to offer our comments to inform and enhance the HBN Rule. We are available and willing to support and collaborate on further development of this response, as well as future public responses on these important health and healthcare issues.

Sincerely,



Susan Hull, MSN, RN-BC, NEA-BC, FAMIA  
ANI Co-chair



Mary Beth Mitchell, MSN, RN-BC, CPHIMS  
ANI Co-chair

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[4] European Parliament and Council, "Official Journal of the European Union," 27 April 2016. [Online]. Available: <https://eur-lex.europa.eu/legal-content/EN/TXT/PDF/?uri=CELEX:32016R0679>. [Accessed 15 August 2020].

[5] California Civil Code, "AB-375 Privacy: personal information: businesses.," 8 November 2018. [Online]. Available: [https://leginfo.ca.gov/faces/billCompareClient.xhtml?bill\\_id=201720180AB375&showamends=false](https://leginfo.ca.gov/faces/billCompareClient.xhtml?bill_id=201720180AB375&showamends=false). [Accessed 15 August 2020].