

December 10, 2018

XCERTIA, INC.

330 N. Wabash Ave., Ste. 39300

Chicago IL 60611

Submitted electronically at: <https://xcertia.org/the-guidelines/>

Dear Xcertia:

The Alliance for Nursing Informatics (ANI) advances nursing informatics leadership, practice, education, policy and research through a unified voice of nursing informatics organizations. We have reviewed the mHealth Guideline issued by Xcertia with the request for input. In that spirit, ANI offers our comments as nursing stakeholders.

ANI fully endorses the objective of the mHealth Guideline for privacy as a means to assess protection of user information in full compliance with all applicable laws, rules and regulations and to clarify the responsibility of developers to understand the scope and full requirements of the Privacy Rules and potential notification requirements of the region(s) for which they intend to operate.

Specifically, our comments will address the following areas of the guideline:

- **Guideline P1 – Notice of Use and Disclosure**
- **Guideline P2 – Retention**
- **Guideline P4 – Health Insurance Portability and Accountability Act (HIPAA) Entity or Business Associate**
- **Guideline P5 – Children's Online Privacy Protection Act (COPPA)**
- **Guideline P6 – General Data Protection Regulation (GDPR)**

Guideline P1 – Notice of Use and Disclosure

We concur with the requirement that the privacy notice should be unbundled from other information notices regarding the application and that the type(s) of data that the app obtains, and how and by whom that information is used, is disclosed to the user in a Privacy Notice. We endorse the transparency to the user of data points collected and/or accessed by the app and the affirmative express consent required. We applaud the inclusion of the “online Do Not Track”, “opt out” option, and “do not contact” mechanisms, and the ability to delete all

information and cancel accounts, as critical tools to provide consumers with the power to choose how their data is used. We encourage Xcertia to assess alignment with the recent work done by the ONC HIT Policy and HIT Standards combined Consumer Health workgroup, [Model Privacy Notice](#) (MPN).

Guideline P2 – Retention

We strongly endorse the inclusion of data retention considerations in the guidelines. We encourage that these be accompanied by strong guidelines for data governance, data safety and monitoring.

Guideline P4 – Health Insurance Portability and Accountability Act (HIPAA) Entity or Business Associate

We encourage Xcertia to continue to follow HHS Office of Civil rights guidance on Non-Covered Entities (NCE), and expected efforts for HIPAA modernization. We also note edits for point 05 and recommend it reads as follows:

- “05 The publisher must demonstrate that procedures are in place so that in the event of a breach the app publisher shall notify affected individuals, HHS, and in some cases, the media (news agencies, print, radio, etc.) of a breach of unsecured PHI. Notifications must be provided no later than 60 days following the discovery of a breach.”

Guideline P5 – Children's Online Privacy Protection Act (COPPA)

We strongly endorse the inclusion of the set of comprehensive considerations (P5, 01-09) for COPPA, which imposes certain requirements on operators of websites or online services directed to children under 13 years of age, and on operators of other websites or online services that have actual knowledge that they are collecting personal information online from a child under 13 years of age. We encourage Xcertia to continue to follow adoption of these guidelines and encourage local communities with children’s health services to educate children and their families. We recognize that states, and even healthcare facilities within states, have interpreted coming of age requirements in current patient portals differently, including proxy needs for parental access to child’s health information.

Guideline P6 – General Data Protection Regulation (GDPR)

We endorse that the Privacy Notice must be concise and use plain language and highlight the importance of aligning privacy policy language with accepted standards for consumer health literacy levels.

ANI commends the Xcertia mission and development of mHealth guidelines to protect user privacy and increase transparency and accountability by mHealth developers. We recognize the fast paced change of technologies and encourage regular review and opportunity for comments.

We thank you for the opportunity to provide comments.

Sincerely,



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