May 15, 2019

Xcertia Guidelines
330 N. Wabash Ave., Ste. 39300
Chicago IL 6061

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

cc: Karen Dunn Lopez, PhD, MPH, RN, Xcertia board member, representing The Alliance for Nursing Informatics

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. In that spirit, ANI offers our comments as nursing stakeholders.

We have reviewed the mHealth Guideline issued by Xcertia's with the request for input. ANI previously provided comments on App Privacy and App Security. In this response we will provide comments related to App Operability, App Content, and App Usability.

ANI fully endorses the objective of the mHealth Guideline App Operability, App Content, and App Usability. As a general comment, we emphasize the need to ensure that use of the terms usability, security, privacy and content throughout the guideline should reference and align with those respective sections of the guideline. Our specific comments for each section are found below.

App Operability

We recommend that the issue of an App being retired is added to the guidelines, including how a user may access data leading up to and after an app is retired.

In the overarching statement, the phrase 'reasonable user experience' is used but it is not well defined. We recommend that this statement be defined. We also recommend that this statement refer to the Xcertia App Usability guidelines rather than using the generic phrase 'user experience'.

In *Guideline OP5 Operability with EHR*, the term 'secure' is used. We recommend that any reference to security concepts in this section are cross-referenced (using the same terms) in the security guideline. We recommend that references to data exchange align with principles

delineated in the ONC notice of proposed rule making - "21st Century Cures Act: Interoperability, Information Blocking, and the ONC Health IT Certification Program" - as well as the Interoperability Standards Advisory 2019. We suggest that standard industry definitions for EHR systems, PHR and patient portal are included or referenced for clarity to differentiate the functionality included across these different platforms for the reader.

Requirements for *Guideline OP6 Connectivity with PHR* refer to Microsoft Healthvault, yet service for this product will be shut down as of November 20, 2019. We recommend that this example be removed. In the section, *Requirements for Guideline OP7 Medical Device Status*, we recommend to define the term 'immediately' in reference to user notification by defining the specific parameters for immediate user notification.

App Content

We commend the guideline's thorough discussion of credible information sources, advertising within the app, levels of evidence, and transparency of data.

Pertaining to *Guideline C1 Credible Information Sources,* we emphasize that if an app references a credible source as a foundation for the app, the content in the app should align and not deviate from the reference source.

App Usability

We recommend under *U1 Performance Requirements for Guidelines* that extraneous text, graphics, and animation should not be used unless it serves a purpose and does not distract the user. Under *U3 Performance Requirements for Guidelines* we would suggest that instead of the term 'predictable' an application be logical, consistent, and easy to follow.

We agree with the *Guideline U4 Onboarding* and *U4 Performance Requirements for Guideline*, including that users should be allowed to bypass entry of personal data if it is not critical for app functionality and that apps should be intuitive. We also recommend that all apps have an option for users to select: step by step instructions for initiating use. In addition, under *Performance Requirements for Guideline U6 Notifications, Alerts & Alarms* we agree that an application should allow the user the ability to dismiss alerts and that all notifications, including alerts, and alarms (and the reason for dismissal if captured) should be stored as historical data for ongoing usability improvement.

As a reference we are pointing to existing literature of a user-centered model for designing apps, aligned with our comments and recommendations: Schnall R, Rojas M, Bakken S, Brown W, Carballo-Dieguez A, Carry M, Gelaude D, Mosley JP, Travers J. A user-centered model for designing consumer mobile health (mHealth) applications (apps). J Biomed Inform. 2016 Apr;60:243-51.

In summary, we fully support the Xcertia guidelines and the mission to protect users 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,

Mary Beth Mitchell, MSN, RN, BC, CPHIMS

ANI Co-Chair

marybethmitchell@texashealth.org

Susan C. Hull, MSN, RN-BC, NEA-BC, FAMIA

ANI Co-Chair

Susan.Hull@gartner.com

The Alliance for Nursing Informatics (ANI), cosponsored 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 represents more than 5,000 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 3 million nurses in practice today.