Proposed guidelines aim for safe, effective mobile health apps

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A nonprofit founded by the AMA and other major players in health care and technology is seeking comments on an early set of guidelines that aim to assess the quality, safety and effectiveness of mHealth apps in the key areas of operability, privacy, security and content.

The American Heart Association, Healthcare Information and Management Systems Society and digital health nonprofit DHX Group are the other founders of the guideline-writing nonprofit, which is called Xcertia. More than 30 organizations have joined the effort with the shared goal of assuring physicians, clinicians and patients that mHealth apps that meet the Xcertia guidelines will deliver value to users. And in late 2017, several prominent leaders in medicine, connected health and the app industry joined the Xcertia board of directors.

“One year since Xcertia announced its formation, the collaboration is releasing initial mobile health apps guidelines as a starting point to build on,” said Michael Hodgkins, MD, chair of Xcertia’s board of directors. “Cooperative input on the guidelines from consumers, developers, payers, clinicians, academia and other motivated stakeholders will provide Xcertia with guidance on where it needs to focus its efforts in 2018 to positively impact the trajectory of the mobile health app industry.”

The proposed guidelines, available to registered users, call for assessment in four vital areas:

- **Operability**—whether a mobile health app installs, loads and runs in a manner that provides a reasonable user experience.
- **Privacy**—whether the app protects the user’s information, including protected health information, in full compliance with all applicable laws, rules and regulations.
- **Security**—whether the application is protected from external threats.
- **Content**—whether the information provided in the mobile health app is current and accurate.

Xcertia continues to seek public comments about mHealth apps. The deadline to provide feedback on the guidelines is Jan. 31.

URL: https://www.ama-assn.org/practice-management/digital/proposed-guidelines-aim-safe-effective-mobile-health-apps
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Apps aplenty, but quality a question mark

In 2016, the AMA adopted a wide-ranging set of policies designed to help integrate the burgeoning field of mHealth into clinical practice. As of a November 2017 report from the IQVIA Institute for Human Data Science, formerly IMS Institute for Healthcare Informatics, there were an estimated 318,000 mHealth apps available to patients with more than 200 added each day. Amid that cornucopia have arisen concerns about quality.

“While some mobile apps and devices are subject to FDA regulation, others are not, and do not undergo rigorous evaluation before deployment for general use, which raises quality and patient safety concerns,” said an AMA Council on Medical Service (CMS) report adopted by the AMA House of Delegates.

“Without ensuring that there is strong and sufficient evidence that provides clinical validation to mHealth apps and associated devices, trackers and sensors,” the CMS report added, “physicians will not fully integrate mHealth apps into their practices. More investment is needed in expanding the evidence base necessary to show the accuracy, effectiveness, safety and security of mHealth apps.”

Among other things, AMA policy says mHealth technologies should “have a high-quality clinical evidence base to support their use in order to ensure mHealth app safety and effectiveness.”

Delegates also voted to encourage the mHealth community to work with the AMA and other physician organizations. Xcertia is an outgrowth of that directive.

As AMA Executive Vice President and CEO James L. Madara, MD, has said, “Physicians recognize the tremendous potential in digital health tools, but without a framework to evaluate them, there could be harmful effects.”

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