

Q&A: Apple's CareKit and the implications for eHealth

The potential impact of Apple's CareKit software framework

Apple announced on 21 March the introduction of its CareKit product, a software framework designed to enable developers to create apps to allow individuals to actively manage their own health conditions. CareKit follows the introduction of the medical research-oriented ResearchKit by Apple last year. Simon Fuller of *eHealth Law & Policy* spoke to Jodi Daniel, Partner at Crowell & Moring, about CareKit and its legal implications.

To what extent might CareKit drive interest and innovation in the eHealth sector?

An explosion of innovation is already occurring in the eHealth sector. Apple's introduction of CareKit is a response to this innovation. eHealth innovation is being driven by widespread adoption of smartphones and wearable sensors by consumers, growing adoption of eHealth tools by clinicians, changes in payment for healthcare, and policy changes that are promoting consumer engagement. This innovation would continue to occur whether or not Apple entered this market. That said, I applaud Apple for taking steps to help consumers better manage their health and health conditions. As a dominant technology company, many innovators may be attracted to Apple's platform and many consumers may try new technology because they are comfortable using Apple products for other purposes.

What data protection issues does the CareKit trigger?

The same issues apply to CareKit as to any system involving health information: Who controls and has access to the data, and how is it secured? What is most interesting is that the data collected through CareKit will likely not be covered by federal privacy and security protections under Health Insurance Portability and Accountability Act of 1996 ('HIPAA'). Most consumers will not understand that health information is treated differently for entities covered by HIPAA (most healthcare providers and health plans) and those not covered by HIPAA. So when the information is collected, it will only be protected in accordance with the privacy policies established by Apple and the app developer, which can be changed by those companies. When the same information is shared with a person's doctor, that copy of the information will be covered by federal privacy and security laws, which may be more or less stringent than the privacy policies of Apple and the app developer. There are also state laws and other federal laws that may apply to specific data. This uneven playing field of protections generally leaves consumers unclear about what the data holders can or cannot do with their data and how information will be used or protected.

Could consumer concerns about handing over sensitive health data to Apple through the use of CareKit apps be a barrier to uptake?

Apple's approach with HealthKit, a related offering, has been to

try to address concerns about data use by storing the data on individual devices. While there could be consumer concerns, Apple's past practices have been supportive of privacy protection of individual health data. Furthermore, we have seen that patients are often less concerned about privacy when they are collecting information for their doctor or to share with a caregiver if they believe it will help them with managing and treating their health conditions.

What will determine the success of eHealth tools like CareKit?

The widespread success or failure of eHealth tools will be based on four things: ease of use in capturing data, capturing the right data, the ability of analytics in the background to present actionable information from that data, and the usability and timeliness of the information being presented to doctors and patients. For example, there is a lot of concern by healthcare providers about being inundated with data that is not useful, takes too long to process, or is not valid. Just capturing data and helping a patient move it from one place to another is not going to be the driver that leads to physician use of patient-generated data and patient use of these tools. It is the quality of the data, the analytics, and provider and patient experience that are the keys to success of eHealth tools.

What considerations will app developers need to think about?

Some of the key issues are privacy and security, Food and Drug Administration ('FDA') oversight, marketing and claims, and liability. CareKit app developers will need to design privacy and security policies that reflect legal requirements and build the trust of consumers and healthcare providers. App developers will also need to understand the scope of the FDA's oversight. Since CareKit is focused on healthcare rather than wellness and fitness, there will be apps that fall within the FDA's stated enforcement discretion and other products that will require FDA oversight and approval. There will be issues regarding claims made by app developers, which will require careful review of marketing material. There are also liability risks that need to be managed, particularly when apps using CareKit present only certain data points or aggregate data (which may be more useful) and omit other information.

Jodi G. Daniel Partner
Crowell & Moring, Washington DC
jdaniel@crowell.com
