Hold the Phone: FDA to Regulate Smart Phone Health Applications

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Abstract : As mobile platforms become more user friendly, computationally powerful, and readily available, innovators have begun to develop mobile apps of increasing complexity to leverage the portability mobile platforms can offer. Some of these new mobile apps are specifically targeted to assisting individuals in their own health and wellness management. Other mobile apps are targeted to healthcare providers as tools to improve and facilitate the delivery of patient care. Although the FDA has not issued an overarching software policy, the Agency has formally classified certain types of software applications that meet the definition of a device and, through classification, identified specific regulatory requirements that apply to these devices and their manufacturers. These software devices include products that feature one or more software components, parts, or accessories (such as electrocardiographic (ECG) systems used to monitor cardiac rhythms), as well as devices that are composed solely of software (such as laboratory information management systems).

Key words : Mobile apps, FDA, regulations, smart phone, medical devices, data systems.

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