Food and Drug Administration Starts Treating Mobile Medical Apps as Medical Devices

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Mobile medical apps on cell phones and tablets have risen in popularity in recent years. They enable physicians to diagnose, manage, and monitor medical conditions outside the traditional healthcare environment. At the same time, such apps enable patients and consumers to self-monitor, and they allow for access to useful health-related information. On September 23, 2013, the Food and Drug Administration (FDA) issued a statement providing guidance to mobile medical app developers (1, 2). The FDA guidance classifies medical mobile apps into two categories, minimal or greater risk to the consumer. Although no enforcement is imposed on the vast majority of apps, a small percentage of medical apps might impose a significant health risk in the event of a malfunction. The FDA clearly states that it does not regulate the usage of smart phones or tablets or the medical mobile app distributors (marketplaces). However, the FDA focuses its issued guidance on apps that are used (a) as an accessory to a regulated medical device, (b) to transform a mobile platform in a regulated medical device, or (c) to handle patient-specific medical device data. Examples include, but are not limited to, apps that (i) control the operation and function of an implantable or carried medical device (e.g., infusion pump, x-ray machine, cochlear implant, blood pressure cuff), (ii) use an attached sensor to the mobile platform or tools within the platform itself, such as the light, camera, display, accelerometer, or microphone (e.g., electrocardiograph, electronic stethoscope, audiometer), and (iii) display, transfer, store, or convert medical data (e.g., medical device data system, connections to bedside or cardiac monitors, and perinatal monitoring systems).

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