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The Impact of Regulatory Changes on the Development of Mobile Medical Apps

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Abstract : Mobile applications are being used to perform a wide variety of tasks in day-to-day life, ranging from checking email to controlling your home heating. Application developers have recognized the potential to transform a smart device into a medical device, by using a mobile medical application i.e. a mobile phone or a tablet. When initially conceived these mobile medical applications performed basic functions e.g. BMI calculator, accessing reference material etc.; however, increasing complexity offers clinicians and patients a range of functionality. As this complexity and functionality increases, so too does the potential risk associated with using such an application. Examples include any applications that provide the ability to inflate and deflate blood pressure cuffs, as well as applications that use patient-specific parameters and calculate dosage or create a dosage plan for radiation therapy. If an unapproved mobile medical application is marketed by a medical device organization, then they face significant penalties such as receiving an FDA warning letter to cease the prohibited activity, fines and possibility of facing a criminal conviction. Regulatory bodies have finalized guidance intended for mobile application developers to establish if their applications are subject to regulatory scrutiny. However, regulatory controls appear contradictory with the approaches taken by mobile application developers who generally work with short development cycles and very little documentation and as such, there is the potential to stifle further improvements due to these regulations. The research presented as part of this paper details how by adopting development techniques, such as agile software development, mobile medical application developers can meet regulatory requirements whilst still fostering innovation.

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