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2012 Issue 12

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FDA Safety and Innovation Act Includes Important Provision Regarding Mobile Health Care Technology

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On July 9, 2012 President Obama signed into law the Food and Drug Administration Safety and Innovation Act (FDASIA) [PDF]. [At press-time, a public law version of the bill was not available. The link provided here leads to the "enrolled bill" version of the law which was approved by both the House and Senate and submitted for the President's signature.] The law provides for a host of changes to the existing FDA regulatory framework, including much-debated provisions relating to user fees, altered regulatory processes, and some incentive programs. One section, however, has drawn little attention but may have an outsized impact on the large-and-rapidly-growing mobile health care technology (mHealth) industry.

Section 618 of FDASIA provides that the FDA, within 18 months, must produce (and make publicly available) "a report that contains a proposed strategy and recommendations on an appropriate, risk-based regulatory framework pertaining to health information technology, including mobile medical applications, that promotes innovation, protects patient safety, and avoids regulatory duplication." The law requires that the FDA develop this report in consultation with the Office of the National Coordinator for Health Information Technology (the "ONC," which is also tasked with setting technical standards for the EHR Incentive program) and the Federal Communications Commission (FCC). The report will be published jointly on all three agencies' web pages.

The statute directs that the report be prepared through a "workgroup" process which will include private stakeholders. All three named agencies are instructed to work together to create a "working group of external stakeholders and experts to

provide appropriate input on the strategy and recommendations required for the report." This group, according to the law, must be assembled in a matter ensuring "that the working group is geographically diverse and includes representatives of patients, consumers, health care providers, startup companies, health plans or other third-party payers, venture capital investors, information technology vendors, health information technology vendors, small businesses, purchasers, employers, and other stakeholders with relevant expertise."

Ober|Kaler's Comments

It is impossible, at this stage, to know for certain how important such a jointly crafted report will be. Interested stakeholders, however, should make an effort to get a seat at the workgroup table or, at a minimum, to closely follow the workgroup's proceedings. This provision of the FDASIA appears to add legitimacy to the FDA's claim that it has the (sole) authority to regulate mobile health care technology – a position that has been debated in the recent past. The FDA's Mobile Medical Applications web page includes links to the agency's "Draft Guidance" (for comment purposes only) on mobile technology, issued last year. Providers and others who work in the mobile health industry would do well to familiarize themselves with the existing FDA missives on mHealth technology and follow developments in this area. If FDASIA is any indication, it seems more detailed guidance, perhaps in the form of formal regulations, should be expected from the FDA in the not-too-distant future.