FDA's Holiday Gift: Digital Health Policy Upgrades

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On December 7 and 8, holidays came early for digital health product developers in the form of three new guidance documents from the US FDA.

These include: *Changes to Existing Medical Software Policies Resulting from Section 3060 of the 21st Century Cures Act* (draft guidance); *Clinical and Patient Decision Support Software* (draft guidance); and *Software as a Medical Device: Clinical Evaluation* (final guidance). According to FDA Commissioner Dr. Scott Gottlieb, this trio represents "new, significant policy developments" and is intended to "advance the FDA's approach to the development and proper oversight of innovative digital health tools."

The first draft guidance, when final, will formally update FDA's policy on certain software and mobile apps to be consistent with the provisions of the recently enacted 21st Century Cures Act. For example, mobile apps that provide tools to promote or encourage healthy eating, exercise, weight loss, or other activities generally related to a healthy lifestyle or wellness no longer meet the definition of medical device as amended by the Cures Act. As a result, those developing such mobile apps will no longer have to rely on FDA applying enforcement discretion to legally market these products without prior FDA engagement.

The second draft guidance is also driven by changes made in the Cures Act and clarifies when Clinical and Patient Decision Support Software may or may not be subject to FDA regulation. In general, decision support software that permits the physician to independently review the rationale for its recommendations would not be subject to Agency regulation. In the draft guidance, the Agency extends this thinking to patient decision software to provide a consistent approach.

Additional Resources

Changes to Existing Medical Software Policies Resulting from Section 3060 of 2the 21st Century Cures Act

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Clinical and Patient Decision Support Software

Software as a Medical Device (SAMD): Clinical Evaluation

The last of the three guidance documents establishes a framework upon which FDA's policy on clinical evaluation of software as a medical device (SaMD) will be developed. This final guidance represents the work of the International Medical Device Regulators Forum (IMDRF), demonstrating FDA's continuing support of global alignment in the regulation of medical devices. IMDRF's intent in developing this guidance was "to create common understanding [across regulators and industry] on the application of clinical evaluation and clinical evidence processes and the need for clinical data to support market authorization." Such regulatory convergence affords the possibility to streamline the pathway from approval to market across countries incorporating these basic principles into their regulatory frameworks.

These guidance documents should provide greater reassurance to digital product developers about how and when FDA will classify and regulate their products. FDA itself stands to benefit from a decreased workload and a "focus on the highest-risk products." Whether these policy announcements will translate into more rapid-fire digital innovation in 2018 remains to be seen, but FDA promises to continue to champion digital health innovation throughout the new year.

References available upon request.

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