Clarifying digital health and software regulation: FDA releases three new guidance documents

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On December 7, 2017, the Food and Drug Administration (FDA or the Agency) released three guidance documents that together aim to clarify the framework for the regulation of software and digital health products to bring FDA regulatory policy into line with the 21st Century Cures Act (Cures Act) enacted by Congress in December 2016. These guidance documents included a long-awaited and much anticipated draft guidance on clinical decision support software, *Clinical and Patient Decision Support Software* (*CDS Guidance*), a draft guidance regarding how FDA plans to modify existing guidance documents to implement elements of the Cures Act, *Changes to Existing Medical Software Policies Resulting from Section 3060 of the 21st Century Cures Act* (*Changes Guidance*) as well as a final guidance document, *Software as a Medical Device (SAMD): Clinical Evaluation* (*SaMD Guidance*), adopting principles for regulation of software first proposed by the International Medical Device Regulators Forum (IMDRF). These new releases follow FDA's recent announcement and recruitment for its digital health software precertification pilot program (Pre-Cert).

Read More: Clarifying Digital Health and Software Regulation: FDA Releases Three New Guidance Documents

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