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Guidances galore: FDA finalizes multiple digital health guidance documents

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On 27 September 2019 the U.S. Food and Drug Administration (FDA or the agency) released a series of guidance documents addressing the agency's current views on software regulation following the changes implemented in the 21st Century Cures Act (Cures Act) enacted in December 2016. Specifically, FDA released a final guidance document entitled "Changes to Existing Medical Software Policies Resulting from Section 3060 of the 21st Century Cures Act" (changes guidance) along with updated guidance on mobile medical applications (MMA), medical device data systems (MDDS), general wellness products, and Off-the-shelf Software. The final guidances confirm and clarify the exclusions of certain types of software functions from the definition of a medical device as mandated by the Cures Act.

While this set of final digital health guidances primarily confirm existing changes and do not represent major policy shifts, the agency also released a draft guidance entitled "Clinical Decision Support Software" (CDS guidance), which substantially revises the draft guidance that was released in 2017 and is the subject of a companion client alert. Together, these guidances build on FDA's efforts to bring the regulatory framework for software and digital health products into line with the Cures Act.

The changes guidance

The changes guidance, consistent with the draft version of that document, is essentially an "errata" of changes to the other digital health guidances following enactment of the Cures Act and, therefore, serves as a useful summary of all change. With this update, the guidances on MMA, MDDS, general wellness products, and Off-the-shelf Software now reflect FDA's interpretation of the Cures Act.

The final changes guidance and related guidances are not significantly different from the draft versions released in 2017, but there are several points of clarification worthy of note.

The MMA guidance

The MMA guidance has been recast as a Software as Medical Device (SaMD) guidance, emphasizing that the platform does not matter, as regulation is by function and intended use. This dispels any remaining confusion created by the earlier version of this guidance, which had referred to "apps" without elaborating that the term applied to all software applications regardless of platform (e.g., websites).

Similarly, FDA recategorized examples in the MMA guidance to be consistent with the Cures Act's designation of what is and is not a device. Although nothing is fundamentally changed, the clarity and statutory alignment are an improvement and obviate the need to cross-reference between the draft guidance and the changes guidance.

Among examples of regulatory oversight focus for MMAs, FDA highlights that it will continue to actively regulate software that prioritizes patient monitoring displays where immediate clinical action may be needed (e.g., active patient monitoring in-patient). This has been an ongoing area of regulatory concern for the agency.

The MDDS guidance

In the new MDDS guidance, FDA differentiates between software that performs MDDS functions (which is no longer considered a medical device) and hardware that does this. Hardware that performs an MDDS function is under enforcement discretion, but only if the hardware function is limited to assisting the specified nondevice software functions. Thus, FDA clarifies that specialized medical display hardware that is integral for safe and effective use of a medical device hardware product is not considered MDDS.

The MDDS guidance also notes the agency's intent to update the regulation that defines MDDS (21 CFR 880.6310) to bring it in alignment with the Cures Act.

Conclusion

There are no major changes in these final guidances. As a group, they clarify FDA's understanding of its application of the Cures Act, and provide a more precise roadmap for manufacturers operating in this highly dynamic space.

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