

# FDA's Evolving Regulation of Artificial Intelligence in Digital Health Products

## IN SHORT

**The Situation:** FDA has been grappling with regulation of rapidly advancing digital products, including artificial intelligence. While Congress and FDA have provided recent clarifications, regulatory questions remain.

**The Result:** Both the 21st Century Cures Act and recent FDA activities provide important, but incomplete, insight regarding regulation of health products utilizing artificial intelligence.

**Looking Ahead:** Digital health product manufacturers should recognize how recent regulatory changes may affect them, and that FDA is engaging industry to further refine its oversight approach.

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Artificial intelligence ("AI") can be broadly defined as a device or product that can imitate intelligent behavior. In the health care space, this includes machine learning algorithms that evolve and improve with new data inputs. While AI-based medical products hold tremendous potential, their regulation has challenged the U.S. Food and Drug Administration ("FDA") because the Medical Device Amendments to the Federal Food, Drug, and Cosmetic Act ("FDCA") were crafted to address medical devices existing in the mid-1970s. These were mostly hardware based, and iterative technology design changes were infrequent. The current device landscape looks quite different; a significant and growing number of products are software based and are developed, validated, and updated differently than is traditional device hardware. This technological shift has caused FDA to reevaluate its regulatory approach for software.



While the draft guidance sheds light on FDA's view of exempt CDS software, companies must still navigate an unclear regulatory path.



### FDA's Digital Health Initiative

In December 2016, Congress enacted the 21st Century Cures Act ("Cures Act"), which contains provisions clarifying FDA's jurisdiction over digital health products. Specifically, Section 3060 of the Cures Act excludes certain categories of "medical software" from the FDCA definition of "device." While most excluded categories are relatively noncontroversial, one category has drawn significant attention: products generally referred to as "clinical decision support" ("CDS") software.

"CDS software" is loosely defined as an application that analyzes data to help health care providers make clinical decisions. Artificial intelligence, like machine learning algorithms, may fall into this category when used for a health purpose. Per the Cures Act, whether a CDS product is excluded from FDA's jurisdiction is dependent on, among other things, the ability of the health care professional to independently review the basis for a clinical recommendation.

FDA issued a [draft guidance on CDS software](#) on December 8, 2017, which discusses each prong of the CDS exclusion and describes how exempted software might allow independent review by a health care professional. FDA says this prong will be met if the software clearly explains: (i) the purpose or intended use of the software function; (ii) the intended user; (iii) the inputs used to generate the recommendation; and (iv) the rationale or support for the recommendation. The user should be able to reach the same recommendation without relying primarily on the software. Further, the sources supporting the recommendation should be identified and easily accessible to the intended user, understandable by the intended user, and publicly available.

While the draft guidance sheds light on FDA's view of exempt CDS software, companies must still navigate an unclear regulatory path. In the context of AI-based software, it's difficult to predict how FDA might interpret the independent review requirement, especially where the recommendation is being produced by a machine learning algorithm that may be proprietary. Considering the above, it seems likely that AI health products will exist on both sides of this newly drawn regulatory line, and uncertainty remains regarding how FDA intends to regulate the AI products remaining under its purview.

The upshot: The recent flurry of FDA activity shows that the regulatory landscape for digital health products is evolving and that FDA seems open to industry input on the regulation of software. To the extent that regulated parties may have insight, thoughts, or advice to impart to FDA, now is a perfect

time to do so. FDA is listening to stakeholders and has shown a willingness to be flexible. This period of transition provides a great opportunity to engage with FDA to help shape the future of digital health.

### THREE KEY TAKEAWAYS

1. The Cures Act recently amended the FDCA to exclude certain types of medical software from the definition of "device."
2. Artificial intelligence-based health products may fall within an excluded category if, among other things, the software enables the health care practitioner to independently review any clinical recommendations it provides.
3. For software remaining under FDA's purview, FDA is actively working with industry and other stakeholders to develop a new, more efficient regulatory paradigm.

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