

## FDA Issues Key Guidance Updates for Digital Health and Wellness

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On January 6, the Food and Drug Administration (FDA) updated its guidance documents on Clinical Decision Support (CDS) software and general wellness products, and withdrew its guidance on the adoption of international principles for Software as a Medical Device (SaMD): Clinical Evaluation. FDA's policy changes lean toward a more deregulatory approach to digital health, including enforcement discretion for certain prediction software, and exemption of certain wearables with non-invasive monitoring from FDA regulation.

### Clinical Decision Support (CDS) Software

FDA updated its guidance on CDS, last revised in 2022, which clarifies FDA's thinking on the types of CDS functions that are excluded from the definition of device by the criteria specified by the 21st Century Cures Act.

Among other changes, FDA deviates from prior guidance by providing that it will not enforce FDA regulatory requirements for software functions that otherwise meet the exclusion criteria under the 21st Century Cures Act, but which produce only one clinically appropriate treatment option or recommendation. Previously, FDA provided that non-device software may only provide a list of treatment recommendations, not only one clinically appropriate directive. FDA lists several examples of software functions that would be subject to enforcement discretion, such as software that recommends a specific FDA-approved antibiotic agent for a health care professional to consider based on the patient's symptoms, recent hospitalizations and previous antibiotic exposure. However, if the same software function also analyzes spectroscopy data to diagnose bacterial infections, it would be subject to FDA oversight. FDA also struck language from the previous version of the guidance that

interpreted the CDS exemption as not applicable to a software function that produced a risk probability or risk score.

## General Wellness: Policy for Low Risk Devices

The **General Wellness guidance**, last updated in 2019, describes FDA's approach to low risk products that promote a healthy lifestyle (general wellness products). In a notable change, FDA will treat non-invasive monitoring features as general wellness products not subject to FDA device oversight under specific circumstances. FDA may consider that certain products that use "non-invasive sensing (e.g., optical sensing) to estimate, infer, or output physiologic parameters (e.g., blood pressure, oxygen saturation, blood glucose, heart rate variability) to be general wellness products when such outputs are intended solely for wellness uses." The sensing features must meet additional criteria to be considered general wellness products, such as not being implanted.

FDA also added examples of wearables that may or may not be considered general wellness products. A wrist-worn wearable product intended to assess activity and recovery that outputs multiple biomarkers, among which are hours slept, sleep quality, pulse rate and blood pressure, would be a general wellness product, unless the functionality implied the product's use in a medical or clinical context. FDA also considers a wearable product intended to provide blood glucose monitoring for nutritional impacts to be a general wellness product, if it is not for diabetics or pre-diabetics and uses minimally invasive technology.

## Withdrawal of SaMD Guidance

Additionally, FDA withdrew the guidance "**Software as a Medical Device (SaMD): Clinical Evaluation**," which adopted internationally converged principles from the International Medical Device Regulators Forum (IMDRF). While this framework informed FDA's regulatory approaches, it did not modify regulatory expectations or submission requirements. Although FDA did not release information about its rationale for withdrawing this guidance upon taking this action, this development and the updates to the CDS and general wellness guidance collectively suggest that FDA continues to examine its policy framework with the potential for further updates going forward.

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