FDA's New Digital Health Guidance Signal Shift for Wellness Devices and CDS

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On January 6, 2026, the Food and Drug Administration (FDA) released updated guidance on Clinical Decision Support Software, as well as General Wellness: Policy for Low Risk Devices, providing clarity to an industry grappling with innovation and regulatory expectations. Both guidance documents contain additional explanation from the FDA on the definitions and applicable regulations which apply to general wellness products and clinical decision support (CDS) software. While FDA notes the guidance is nonbinding and merely represents the FDA's current recommendations and statutory interpretations, it is intended to provide an understanding of what enforcement actions the Administration will undertake. The guidance is part of a larger initiative from the Trump Administration to both deregulate and encourage use of digital health products. Although the guidance limits those products under FDA's regulatory purview, it will be important for providers to be aware of where their devices fall within regulatory definitions as the digital health policy landscape continues to adapt to its current pressures through further policymaking.

General Wellness Products

The FDA's Center for Devices and Radiological Health released updated guidance (last revised in 2019) for low-risk general wellness products. The agency specifically defines general wellness products as those that relate to maintaining a general state of health or the role of a healthy lifestyle to reduce the risk of certain chronic diseases. These products also must present a low risk to the safety of users.

Building off its previous guidance, FDA describes its categories of intended uses in two ways, (1) those claiming to sustain or improve functions associated with a general state of health that *do not make* any reference to diseases or condition, such as weight management, physical fitness, stress management, mental acuity, self-esteem, sleep management or sexual function and (2) those *that make* reference to diseases or conditions and are intended to help reduce the risk of and manage certain chronic conditions. The FDA guidance establishes a standard that products must not be invasive, implanted, or pose a risk to the safety of the user.

The guidance responds to an increased need for clarification that certain non invasive sensing features in wearables—such as optical sensors that estimate

blood pressure, oxygen saturation, blood glucose trends, or heart rate variability—may be treated as general wellness products, rather than medical devices, when the products are intended only for wellness-related use. The FDA provides specific examples of wrist-warn wearables and their applications.

The FDA emphasized that the goal of the guidance is to give companies clear boundaries so that devices that simply provide information—without presenting themselves as medical-grade tools—can operate without FDA oversight. This effort aligns with the Administration's interest in the use of wearables as part of its Make America Health Again initiative, seeking to use innovative means to manage and prevent chronic disease and overall health.

Clinical Decision Support Software

Additionally, FDA released updated guidance (last revised in 2022) outlining a more permissive approach to certain types of clinical decision support (CDS) software, signaling a notable shift from its earlier regulatory stance. The new guidance specifies categories of lower risk CDS tools that will fall outside the scope of medical device regulation, while also clarifying which software functions will continue to be treated as devices.

To qualify as a non device function and therefore not be subject to FDA regulation, CDS software must be:

1. "not intended to acquire, process, or analyze a medical image or a signal from an in vitro diagnostic device or a pattern or signal from a signal acquisition system;
2. intended for the purpose of displaying, analyzing, or printing medical information about a patient or other medical information;
3. intended for the purpose of supporting or providing recommendations to a health care professional about prevention, diagnosis, or treatment of a disease or condition; and
4. intended for the purpose of enabling such health care professional to independently review the basis for such recommendations that such software presents so that it is not the intent that such health care professional rely primarily on any of such recommendations to make a clinical diagnosis or treatment decision regarding an individual patient."

The new guidance clarifies the third criterion for CDS software functions that are excluded from the definition of a medical device under the Food, Drug and Cosmetic Act. The FDA will not enforce regulatory requirements for software that provides a single clinically appropriate recommendation, provided the other criteria are met. Previously, non-device software could only provide a list of treatment recommendations. FDA lists examples that would be subject to enforcement discretion.

Under the FDA guidance, examples of non-device CDS functions include tailored clinician order sets, matching patient medical information, drug formulary guidelines, drug interaction notifications, reminders for preventative care, patient discharge papers, and lists of follow-up options. Examples of items that remain within medical device oversight include software that uses patient images to generate treatment plans, tools that analyze imaging data for surgical planning, and systems that process multiple physiological signals from wearables to detect events such as heart attacks or narcolepsy episodes.

Outlook

The guidance further underscores the Trump Administration's efforts to promote digital health innovation, building on prior announcements, such as the FDA's Technology-Enabled Meaningful Patient Outcomes (TEMPO) for Digital Health Devices Pilot and the Center for Medicare and Medicaid Innovation's (CMMI's) Advancing Chronic Care with Effective, Scalable Solutions (ACCESS) Model which would expand access to new technology-supported care to manage chronic disease. Of note, both updated guidance documents were issued without an opportunity to comment beforehand, limiting input. Stakeholders may submit comments for the FDA to consider at any time, but those comments may not be acted upon by the agency until the document is next revised or updated.

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