American Hospital Association™
Advancing Health in America

**Washington, D.C. Office**
800 10th Street, N.W.
Two CityCenter, Suite 400
Washington, DC 20001-4956
(202) 638-1100

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Michelle Tarver
Director
Center for Devices and Radiological Health
Food and Drug Administration
10903 New Hampshire Ave.
Silver Spring, MD 20993

*Submitted Electronically*

***RE: FDA-2018-N-1910 Request for Input: Development of 21st Century Cures Act Section 3060 Required Report***

Dear Director Tarver,

On behalf of our nearly 5,000 member hospitals, health systems and other healthcare organizations, our clinician partners — including more than 270,000 affiliated physicians, 2 million nurses and other caregivers — and the 43,000 healthcare leaders who belong to our professional membership groups, the American Hospital Association (AHA) appreciates the opportunity to provide input on the Food and Drug Administration (FDA) report on the risks and benefits to health and safety that are associated with non-device software as required under Section 3060 of the 21st Century Cures Act.

Advancements in digital health technology, artificial intelligence (AI), wellness applications and wearable devices continue to transform care delivery. These changes pose novel questions on the applicability of medical device regulation. The AHA appreciates that the FDA has been updating its regulations and guidance on what constitutes a medical device and a non-device software function, including updated guidance on Clinical Decision Support (CDS) software and general wellness products released in January 2026.[1,2] However, the FDA can help advance additional innovation by further clarifying its guidance, particularly with respect to appropriate guardrails to ensure patient safety.

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[1] https://www.fda.gov/media/109618/download
[2] https://www.fda.gov/media/90652/download

Specifically, we recommend that the FDA:

- Permanently adopt CDS flexibilities that generate only one clinical recommendation.
- Clarify its General Wellness Guidance, removing references to allowing non-device general wellness applications to make recommendations on escalation to a healthcare provider.
- Continue to update guidance, education and other materials to account for novel AI applications, including generative AI.

Below are our detailed comments.

**Clinical Decision Support Software**

Hospitals and health systems have seen the benefits of CDS tools in supporting quality improvement, improving safety and increasing efficiency. Our members deploy CDS algorithms to analyze large amounts of clinical data to generate patient-specific care recommendations. These recommendations support provider decision-making but ultimately are only one of many inputs, including the healthcare professional's (HCP) own clinical judgment. The AHA has long urged that the FDA adopt policies that do not inadvertently impose barriers to CDS adoption.

Section 3060(a) of the Cures Act sought to deter over-regulation by establishing criteria to exempt this type of low-risk decision support software from FDA regulation while appropriately ensuring FDA's continued authority to regulate software that replaces rather than supports the HCP's decision-making. Section 520(o)(1)(E) outlines four criteria that would exempt manufacturers and developers from FDA oversight as medical devices:

- **Criterion 1:** Not intended to acquire, process or analyze a medical image or signal from an in vitro diagnostic device or a pattern or signal from a signal acquisition system.
- **Criterion 2:** Displaying, analyzing or printing medical information about a patient or other medical information (such as peer-reviewed clinical studies and clinical practice guidelines).
- **Criterion 3:** Supporting or providing recommendations to an HCP about prevention, diagnosis or treatment of a disease or condition.
- **Criterion 4:** Intended for the purpose of enabling an HCP to independently review the basis for the recommendations that such software presents so that it is not the intent that the HCP rely primarily on any of such recommendations to make a clinical diagnosis or treatment decision regarding an individual patient.

The AHA supports the FDA's January 2026 guidance providing enforcement discretion for certain CDS software functions that produce only one clinical recommendation under

Criterion 3. Specifically, the new guidance states: “If only one option is clinically appropriate and the software function otherwise meets all criteria under section 520(o)(1)(E), FDA intends to exercise enforcement discretion (meaning that FDA does not intend to enforce requirements under the FD&C Act) for such functions.” **We respectfully urge the FDA to make this flexibility permanent in its guidance rather than treating it as enforcement discretion.**

**General Wellness Applications**

Wellness, health and lifestyle technologies have expanded rapidly. These types of devices have the potential to support consumer engagement in healthy activities to prevent the onset of conditions, like chronic disease. Many of the FDA’s updates to its general wellness product guidance provide appropriate flexibilities to support innovation. However, the AHA recommends two clarifications to help bolster patient safety.

**First, the AHA recommends the FDA consider developing additional guidance and educational resources on labeling wellness products to help mitigate potential confusion for consumers.** The latest general wellness product guidance document adds a section on potential exemption applicability for devices that provide physiological data. Specifically, the agency states: “FDA may consider 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.”

Products could be treated as exempt from medical device regulations if they are not intended for the diagnosis, cure, mitigation, prevention or treatment of a disease or condition. However, for consumers, there can be confusion about the distinction between medical device and non-medical device applications that transmit similar types of physiological data, which have different validation processes and uses. We encourage the FDA to consider developing guidance addressing this potential issue in coordination with the Federal Trade Commission (FTC). The FTC has a broad mandate to prevent unfair or deceptive acts or practices, and the FTC and FDA share jurisdiction over marketing of certain health-related products (including devices).

**Second, we encourage the FDA to either clarify or remove the guidance regarding allowing non-device general wellness applications to recommend escalation to a healthcare provider.** The January 2026 guidance indicates that general wellness products may provide notifications to users on when follow-up with a clinician may be beneficial. Specifically, it states:

> “For purposes of this guidance, a product may be considered a general wellness product even if it includes a notification informing a user that evaluation by a healthcare professional may be helpful when outputs fall outside ranges appropriate for general wellness use, provided that such notifications:

- do not identify or name a specific disease or medical condition;
- do not characterize the output as abnormal, pathological, or diagnostic;
- do not include clinical thresholds, diagnoses, or treatment recommendations; and
- do not provide ongoing alerts or monitoring intended to manage a disease or condition."

A wellness product that provides feedback on ranges that are "outside ranges appropriate for general wellness use" may inadvertently expand a product's scope beyond its intended use. Additionally, it is unclear how either consumers or healthcare providers can use a recommendation to consult a clinician if the wellness product also cannot state the reading is abnormal, what thresholds for escalation it is using or what potential medical issue is being detected. **We recommend the FDA consider addressing these issues in additional guidance or remove the section altogether.**

**Artificial Intelligence**

While the request for information focuses on non-device software applications, we do want to take the opportunity to reiterate comments we made previously on AI-enabled devices.[3] AI-enabled devices offer tremendous promise for improved patient outcomes and quality of life. At the same time, they also pose novel challenges — including model bias, hallucinations and model drift — that are not yet fully accounted for in existing medical device frameworks. AI tools are inherently designed to be agile and adaptive, taking in new data points, discerning patterns and continually updating to improve model accuracy. This is especially true for generative AI. As this technology continues to evolve, we anticipate there will continue to be questions about which applications constitute medical device versus non-device function.

In general, the AHA supports AI policy frameworks that balance flexibility to drive market-based innovations with appropriate safeguards to protect privacy and patient safety. As the FDA considers future policy approaches to measuring and evaluating AI-enabled medical device performance, we encourage the agency to:

- Continue to develop educational materials, update guidance documents and provide FAQs with examples on medical device versus non-medical device applications.
- Pursue risk-based post-deployment measurement and evaluation standards for AI-enabled medical device vendors and developers.
- Synchronize measurement and evaluation activities with existing frameworks.
- Align incentives and address infrastructure barriers to measurement and evaluation.

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[3] https://www.aha.org/lettercomment/2025-12-01-aha-letter-fda-ai-enabled-medical-devices

We look forward to working with the FDA to ensure the agency's regulatory approach to implementing Section 3060(a) prioritizes patient safety while allowing hospitals and health systems to continue to implement innovative tools. Please contact me if you have questions, or feel free to have a member of your team contact Jennifer Holloman, AHA director of health IT policy, at jholloman@aha.org.

Sincerely,

/s/

Ashley Thompson
Senior Vice President
Public Policy Analysis and Development