FDA Releases Highly Anticipated Discussion Paper on Generative AI-Enabled Medical Devices

ALERT | AUGUST 24, 2026

On August 18, 2026, FDA's Center for Devices and Radiological Health (CDRH) released a discussion paper, **Considerations for the Regulation of Generative AI-Enabled Medical Devices** (the "GenAI Discussion Paper"). The GenAI Discussion Paper seeks public feedback on potential approaches to the evaluation and regulation of genAI-enabled medical devices. Stakeholder feedback is due by **October 19, 2026**.

How We Got Here

Although FDA has issued several discussion papers, frameworks, and guidance documents addressing AI-enabled devices, the Agency has not previously articulated a comprehensive regulatory vision for emerging technologies shaping healthcare such as genAI. The GenAI Discussion Paper follows FDA's November 2024 and November 2025 Digital Health Advisory Committee (DHAC) meetings focused on genAI-enabled devices and reflects the Agency's ongoing effort to evaluate whether existing device regulatory frameworks can be adapted for genAI-enabled devices, or whether new or updated frameworks are needed. FDA seeks feedback on a range of foundational topics spanning risk assessment, premarket evaluation, postmarket monitoring, change management, and the use of third-party foundation models.

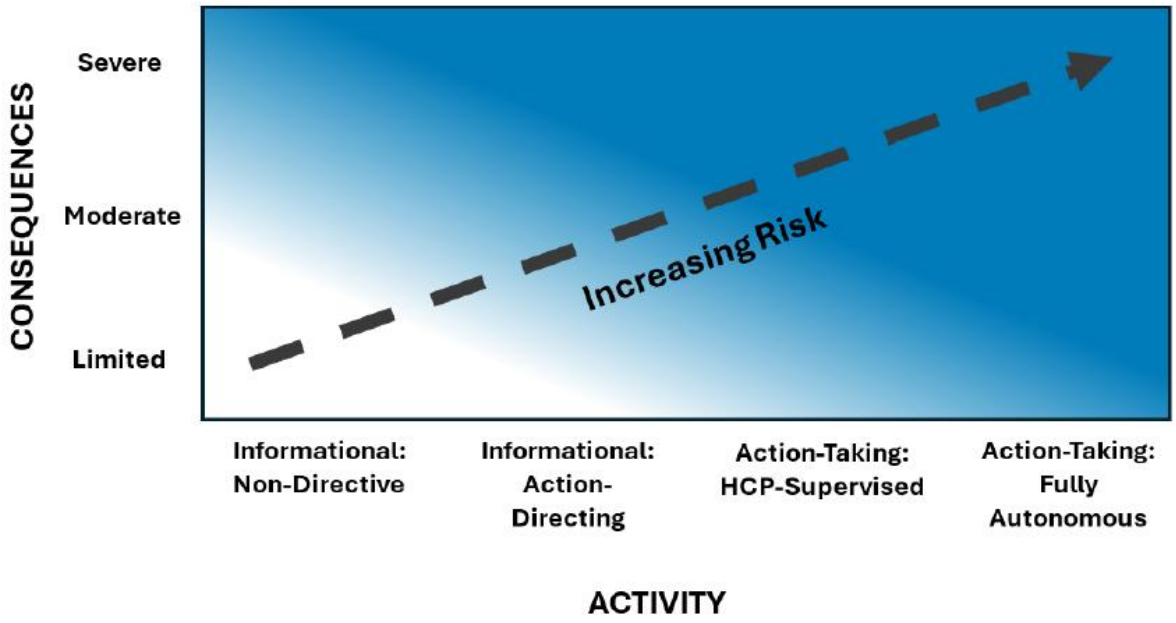
Discussion Paper, Not Guidance

Many stakeholders expected FDA's next step would be draft guidance. Instead, FDA issued the GenAI Discussion Paper and emphasized it is intended solely to facilitate further discussion and does not represent draft guidance, final policy, or proposed regulatory requirements. In practice, this could mean that stakeholders may not see formal FDA policy on genAI for several months or years. As a point of reference, FDA followed a similarly iterative approach for **AI-enabled devices more broadly**, first issuing a discussion paper in 2019, then an AI/ML "action plan" in 2021, with key guidance documents following years later. In the interim, FDA policy emerged by precedent, with the first pre-determined change control plans (PCCPs) emerging as early as 2020, several years before congressional authorization of the authority and guidance documents formalizing the process. If FDA follows a comparable path for genAI, formal guidance could still be several steps away.

A Familiar Risk Framework, Applied to GenAI

The GenAI Discussion Paper confirms that FDA intends to take a risk-based approach to regulating genAI-enabled devices. At the heart of FDA's approach is a framework for assessing the risk of genAI-enabled functions along two dimensions: (1) the activity performed by the software function, ranging from informational outputs to autonomous action-taking functions; and (2) the consequences of relying on an

incorrect output.[1] Risk generally increases as software becomes more directive or autonomous and as the potential consequences of incorrect outputs become more significant.



Source: FDA, Considerations for the Regulation of Generative AI-Enabled Medical Devices: Discussion Paper and Request for Feedback, Fig. 1, at p. 6 (2026).

Under this framework, the risk posed by a genAI-enabled function depends on how strongly the tool directs users toward (or autonomously takes) a particular action, as well as the context and severity surrounding the nature of the outputs. While this provides a useful starting point, many important questions remain, including the following:

- *First*, the framework does not shed light on a threshold issue that will be critically important for many developers: whether a particular genAI-enabled software function would be considered a device at all. The GenAI Discussion Paper acknowledges that genAI-enabled software functions are increasingly being deployed in healthcare contexts for a variety of use cases, "some or all of which may not be functions that are the focus of FDA's device regulatory oversight," but the Agency does not further opine on the types of features that are or are not medical devices or subject to FDA enforcement discretion.
- *Second*, the Agency states that the level of evidence required for benchmarking, clinical confirmation, postmarket monitoring, and change management could be scaled based on a device's risk profile. Although the GenAI Discussion Paper describes several methods for testing genAI-enabled software functions, it stops short of describing what level of scrutiny FDA might expect for each region of the matrix or how developers should map specific functions to corresponding testing, monitoring, or regulatory expectations.
- *Third*, it is not clear how the matrix maps onto the existing risk-based classifications for medical devices: Class I (low risk); Class II (moderate risk); and Class III (high risk).

[1] This proposed framework is conceptually similar to the risk evaluation matrix set forth in FDA's draft guidance on Considerations for the Use of AI to Support Regulatory Decision-Making for Drug and Biological Products. Find our blog here: **FDA Seeks Input on Use of Digital Health Technologies in Clinical Investigations of Drugs & Biologics**.

These are concepts FDA may clarify in future guidance, and FDA indeed seeks feedback on the utility of this risk evaluation framework.

Evidentiary Bar Remains for GenAI

The GenAI Discussion Paper suggests that FDA does not intend to create a distinct evidentiary standard for evaluating the safety and effectiveness of genAI-enabled devices. Instead, the Agency outlines a range of methodologies that map onto familiar device regulatory concepts, such as premarket performance testing, clinical validation, and lifecycle monitoring. Applying these traditional regulatory concepts to genAI-enabled software functions, however, may be challenging in practice. That said, the GenAI Discussion Paper does signal that FDA may be open to shifting some assurance activities from the premarket to the postmarket setting, given the unique characteristics of genAI-enabled software functions. In particular, FDA requests feedback on whether greater premarket uncertainty could be acceptable if paired with robust postmarket monitoring activities.

Foundation Model Device Master Files

The GenAI Discussion Paper reflects FDA's recognition that many genAI-enabled devices will rely on third-party foundation models. At the same time, FDA makes clear that the finished device, not the foundation model itself, must be evaluated by the device manufacturer. Nevertheless, FDA requests feedback on the mechanisms that device manufacturers can put into place to detect and respond to third-party foundation model updates, such as contractual arrangements and technical controls.

FDA also introduces the concept of voluntary Foundation Model Device Master Files (MAFs). Under the approach described by FDA, foundation model developers and platform providers could voluntarily submit information about underlying models to FDA, such as through model cards. Sponsors could then reference that information, with authorization from the file holder, in support of individual device submissions.

Agentic AI

FDA separately highlights agentic AI systems that can autonomously plan and execute multi-step tasks or use external tools. FDA notes that some agentic AI systems may not be subject to device regulation, while others could qualify as devices depending on their functionality. The Agency does not propose a distinct regulatory framework for these systems, but it acknowledges that agentic architectures may raise unique risks and seeks feedback on whether additional evaluation and oversight measures are needed for agentic genAI-enabled devices.

Request for Comments

Comments may be submitted to Docket No. FDA-2026-N-7874 through **October 19, 2026**. Covington's Digital Health team is closely following FDA's evolving approach to the regulation of genAI-enabled medical devices. Please feel free to contact our team for guidance as you evaluate how this discussion paper may impact your organization.

If you have any questions concerning the material discussed in this client alert, please contact the following members of our Medical Device and Digital Health practices:

Wade Ackerman	+1 424 332 4763	**ackermanw@cov.com**
Scott Danzis	+1 202 662 5209	**sdanzis@cov.com**
Kristin Davenport	+1 202 662 5286	**kdavenport@cov.com**
Pamela Forrest	+1 617 603 8809	**pforrest@cov.com**
Christina Kuhn	+1 202 662 5653	**ckuhn@cov.com**
Amy Leiser	+1 415 591 7069	**aleiser@cov.com**
Olivia Dworkin	+1 424 332 4817	**odworkin@cov.com**
Natalie Maas	+1 415 591 6022	**nmaas@cov.com**
Jess Zuo	+1 202 662 5538	**jzuo@cov.com**

EXPLORE MORE INSIGHTS