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Submitted electronically via www.regulations.gov

Michelle Tarver, M.D., Ph.D.
Director, Center for Devices and Radiological Health
U.S. Food and Drug Administration
10903 New Hampshire Avenue
Silver Spring, MD 20993

RE: ATA Action Comments in Response to Considerations for the Regulation of Generative AI-Enabled Medical Devices: Discussion Paper and Request for Feedback (Docket No. FDA-2026-N-7874)

Dear Dr. Tarver:

On behalf of ATA Action: Advocacy Shaping Virtual Care, the advocacy-focused affiliate of the American Telemedicine Association (ATA), we appreciate the opportunity to respond to the Food and Drug Administration's discussion paper on the regulation of generative AI-enabled medical devices.¹ ATA Action supports the enactment of state and federal telehealth coverage and fair payment policies to secure telehealth access for all Americans, including those in rural and underserved communities.

We commend the administration for their leadership on super intelligence and appreciate the Agency's seeking public input early, before it drafts guidance. Our comments draw on ATA's Policy Principles on Artificial Intelligence, which set out how AI can support safe, effective, and accessible care.² Overall, ATA Action supports the risk-based direction of the discussion paper, including the two-axis risk framework, the competency-based approach to premarket review, and greater reliance on postmarket monitoring. Our comments below follow the structure of ATA's principles.

1. Accountability and Engagement

ATA's principles call for a clear allocation of responsibility among developers, infrastructure providers, and clinical deployers, with accountability that matches a system's function and clinical impact. FDA's approach should follow the same logic. The manufacturer should remain responsible for the safety and performance of the device it sells, including when that device runs on a third-party foundation model. FDA should avoid shifting monitoring duties onto the practices and health systems that use a device, since many virtual care providers, especially small, rural, and safety-net practices, lack the staff to take on that work. Instead, FDA should give clinicians simple ways to report problems. As devices take on more autonomous tasks, oversight should match the function, and FDA should be able to authorize greater autonomy as the evidence supports it, provided there is a reliable, timely means of escalation to, or review by, an appropriately qualified clinical professional.

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¹U.S. Food and Drug Administration, Center for Devices and Radiological Health, Considerations for the Regulation of Generative AI-Enabled Medical Devices: Discussion Paper and Request for Feedback (August 2026), Docket No. FDA-2026-N-7874 (the "Discussion Paper"), <https://www.fda.gov/media/194242/download>.

²American Telemedicine Association, The ATA's Policy Principles on Artificial Intelligence (adopted by the ATA Policy Council November 2025; approved by the ATA Board December 2025), https://info.americantelemed.org/hubfs/Files/Policy%20Docs_letters,%20RFI,%20etc./ATA%20AI%20Policy%20Principles_2025.pdf.

2. Transparency and Explainability

ATA supports clear disclosure when a person is interacting with AI and when AI influences a patient's care, along with clear information from developers about a system's intended purpose. ATA also believes disclosure should be reasonable and proportionate so that patients and clinicians do not tune it out. For FDA, this means labeling that explains in plain language what a device does, who it is for, and its known limitations. Patient-facing devices that are used for clinical purposes should make clear that the user is interacting with AI, should never present themselves as a licensed human clinician, and should offer a clear path to a human clinician or emergency services, as appropriate.

3. Safeguards to Mitigate Bias

ATA's principles call for routine evaluation of clinical AI for bias and for its effect on access to care. We support the discussion paper's attention to performance across patient subgroups. Manufacturers should test devices with people who reflect the intended users, including rural patients, people with limited health literacy, and people who speak languages other than English. Synthetic data can help test rare cases but should supplement real-world data, not replace it. Monitoring after authorization should continue to track performance across groups, since some gaps only appear in real use. These expectations should scale with risk so they do not become a barrier for lower risk tools.

4. Clear Regulatory Guardrails

ATA supports unified, harmonized, and risk-based regulation, with federal leadership to promote national consistency and without general prohibitions or broad pre-authorization schemes. The two-axis framework, based on how much a device does and how much harm an incorrect output could cause, fits this principle well. We urge FDA to base oversight on a tool's function and risk rather than on the fact that it uses generative AI, and to keep today's model designs out of future guidance so the framework holds up as the technology changes. AI systems that serve multiple clinical functions within a single interaction should be evaluated under the two-axis risk framework, with each function assessed according to its own intended use and risk profile, rather than deferred to a separate regulatory process. We also ask FDA to confirm that its January 2026 clinical decision support and general wellness guidance remains in place,³ and that a conversational interface alone does not turn an excluded software function into a device. Worked examples of functions inside and outside device oversight would give developers and health systems needed predictability.

Separately, as states adopt differing approaches to clinical AI, we encourage FDA to clarify how its jurisdiction interacts with state authority, and to provide greater certainty for manufacturers whose generative AI-enabled devices have been authorized, particularly devices performing semi-autonomous or autonomous tasks that states have traditionally reserved for licensed professionals. Without that clarity, developers and providers, especially those serving patients across state lines, face a growing patchwork in which the same authorized device may be permitted in one state and restricted in another. One option is a voluntary federal-state clinical AI sandbox, built on the TEMPO pilot and developed in coordination with HHS and states that choose to participate. It would operate alongside FDA's existing authorization pathways. Participants would generate real-world evidence under common reporting standards and phased clinician oversight, while FDA exercises conditional, time-limited enforcement discretion. Such a sandbox would give HHS and FDA real-world evidence

³U.S. Food and Drug Administration, Clinical Decision Support Software, Guidance for Industry and Food and Drug Administration Staff (January 2026); U.S. Food and Drug Administration, General Wellness: Policy for Low Risk Devices, Guidance for Industry and Food and Drug Administration Staff (January 2026).

and direct insight into how these tools perform once deployed, while building working relationships with states that can inform a durable, nationally consistent framework.

5. Validation and Performance Monitoring

ATA's principles call for evidence of safety, reliability, and clinical relevance for clinical outputs, with developers and deployers leading through strong self-governance. ATA Action supports the competency-based approach, which pairs benchmark testing with clinical confirmation scaled to risk, and agrees that a prospective clinical study should not be required in every case. We also support a voluntary role for qualified independent organizations, including accreditation and certification bodies, as long as FDA recognizes more than one pathway and does not make third-party review mandatory. We strongly support FDA's openness to accepting more uncertainty at authorization when a manufacturer commits to strong postmarket monitoring, along with flexible predetermined change control plans that let validated devices improve over time without a new submission for every update.

6. Privacy and Data Security

ATA supports protecting patient data within established privacy frameworks while allowing responsible use of data to improve care. FDA should rely on existing privacy and cybersecurity requirements rather than create new ones specific to generative AI. Postmarket monitoring and real-world data collection should follow those same protections. FDA should also protect the proprietary and confidential information developers share with the Agency, including through any master file program, so developers have reason to participate.

7. Economic and Workforce Evolution

ATA believes AI should expand clinical capacity, help address workforce shortages, and reduce administrative burden. FDA's review should give weight to those benefits. When FDA weighs a device's risk, it should consider the care a patient would realistically receive without it. In many rural communities and areas with shortages of behavioral health and specialty clinicians, the alternative to an AI-supported service is a long wait or no care at all. We also encourage FDA to keep coordinating with CMS, as it has through the TEMPO pilot, so that safe and effective devices reach the patients who need them.

ATA Action appreciates the Agency's thoughtful approach and looks forward to working with FDA as it moves from discussion to guidance. A framework built on risk, evidence, and clear accountability can protect patients while bringing the benefits of AI-enabled virtual care to more Americans. Please do not hesitate to reach out to me with any questions.

Sincerely,

A handwritten signature in black ink, appearing to read "Joe Nye".

Joe Nye
Head of Federal Government Relations
ATA Action
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