ConnectedHealthInitiative

August 7, 2026

Dockets Management Staff (HFA-305)
Food and Drug Administration
5630 Fishers Lane, Rm. 1061
Rockville, Maryland 20852

RE: Comments of the Connected Health Initiative, *Medical Device User Fee Amendments; Public Meeting; Request for Comments* (Docket No. FDA-2026-N-6655; 91 FR 42198)

The Connected Health Initiative (CHI) submits these comments in response to the request for comments issued by the Food and Drug Administration (FDA) in connection with its public meeting on the proposed recommendations for reauthorization of the Medical Device User Fee Amendments (MDUFA) for fiscal years 2028 through 2032 (MDUFA VI). CHI participated in the August 5, 2026 public meeting and appreciated the opportunity to speak. We write now to submit more detailed recommendations to the docket. CHI's members build products that improve continuously, including software as a medical device (SaMD), remote patient monitoring, and artificial intelligence (AI)-enabled device software functions, and the review system that governs them has to keep pace. We recognize the real progress reflected in the draft commitment letter, and we offer recommendations meant to sharpen the commitments already on the table so that MDUFA VI delivers faster, more predictable patient access to safe and effective connected health technology.

CHI is the leading multistakeholder policy and legal advocacy effort dedicated to improving health outcomes while reducing costs using digital health innovations. A broad coalition of technology companies, care providers, and patient advocates, CHI works to responsibly bring connected health tools, including SaMD, remote patient and therapeutic monitoring, prescription digital therapeutics, and AI-enabled functions, into everyday care. We advocate before Congress, U.S. federal agencies, and state legislatures and agencies on responsible pro-digital health policies, including FDA regulation of digital health and the rising role of AI in care delivery. For more information, see www.connectedhi.com.

Our recommendations build on the priorities CHI raised at the public meeting and reflect broadly shared views across the medical technology and digital health community. CHI offers four recommendations:

1. Dedicate review capacity and specialized expertise to software and AI;
2. Make the Predetermined Change Control Plan work in practice;
3. Measure and publish digital health review performance;
4. Preserve coherence across the ecosystem through harmonized approaches to interoperability, cybersecurity, and real-world evidence, guided throughout by the least-burdensome principle.

Underlying all four is a shared concern that review timelines and FDA's capacity to meet them

remain under real strain, and that adequate, well-directed resources are the foundation for everything else in this letter.

I. The draft commitment letter reflects real progress that FDA should carry through.

CHI begins by recognizing the meaningful steps in the draft commitment letter. The proposed digital health pilots and regulatory sandbox opportunities, the expansion of the Total Product Life Cycle Advisory Program (TAP) to all product areas, the new Focused Follow-Up Pre-Submission with a 45-calendar-day response, and FDA's stated commitment to grow its technical expertise on rapidly evolving digital health technologies, including generative and agentic AI, are all steps in the right direction. We likewise welcome FDA's commitment to hold at least annual engagement with industry on high-priority topics such as Predetermined Change Control Plans, generative AI, adaptive algorithms, and wearables. We support these commitments and encourage the agency to carry them through. The new Focused Follow-Up Pre-Submission and the expansion of TAP to all product areas are especially valuable for software and AI sponsors, who often need rapid, focused feedback as their products iterate between submissions.

At the same time, CHI shares a broadly held concern that review timelines and reviewer capacity remain under strain, and that the value of every enhancement in this letter depends on resources tied to clear performance goals and accountability. We also recognize, as the draft letter acknowledges, that FDA lacks statutory authority to establish legally binding sandboxes with safe harbors and can today proceed only through voluntary pilots and enforcement discretion. CHI encourages FDA to use those tools to the fullest and supports appropriate statutory authority to give innovators durable, predictable pathways to test novel approaches.

II. Dedicate review capacity and specialized expertise to software and AI.

The single greatest constraint on connected health innovation is not the standard. It is reviewer bandwidth and specialized expertise. CHI urges FDA to tie a defined share of MDUFA VI resources to hiring, training, and retaining reviewers with genuine software, data science, and machine-learning competency, and to report on that capacity publicly. Tying resources to performance goals and accountability, and staffing the review function to the pace at which software evolves, reflects a widely shared priority across the field. The draft letter's commitment to grow expertise on digital health technologies, including generative and agentic AI, is welcome. CHI asks that it be made concrete, measurable, and durable rather than aspirational. Concretely, FDA could report measurable outputs such as the share of reviewers with demonstrated software, data science, and machine-learning competency, the establishment of dedicated digital health and AI review teams or rotations, reviewer training completed, and a public annual report or dashboard on digital health staffing.

III. Make the Predetermined Change Control Plan work in practice.

The Predetermined Change Control Plan (PCCP) framework is one of the most important tools FDA has built for AI-enabled devices. It lets a product improve over its lifecycle without a new marketing submission for every change. CHI asks FDA to commit, in MDUFA VI, to clear performance metrics

for PCCP review, to broaden the products and modifications eligible to use it, and to report on adoption. This reflects a total product lifecycle approach that is widely supported across the field, and it is consistent with FDA's own guidance on AI-enabled device software functions and PCCPs. Aligning PCCP review to real-world software development lifecycles, and pairing the letter's annual engagement commitment with measurable review commitments, would let manufacturers deliver validated improvements to patients faster while preserving FDA oversight. In practice, broadening eligibility should reach the modifications most common in connected health, including adaptive algorithms, generative components, and combined hardware and software functions, and any post-authorization monitoring or reporting should remain least-burdensome so that continuous improvement is encouraged rather than discouraged.

IV. Measure and publish digital health review performance.

Today's MDUFA metrics report how the overall portfolio is doing, but not how software, SaMD, and AI-enabled submissions specifically are faring. CHI asks FDA to disaggregate and publish review performance for these product types, so that industry, the agency, and the public can see where the process is working and where it is not. The draft commitment letter specifies general review timelines but does not establish performance benchmarks specific to AI-enabled or software submissions. Disaggregated, published metrics would close that gap. This transparency reflects the accountability that is central to the reauthorization and would help direct the specialized resources described above to where they are most needed. Breaking these metrics out further, by review pathway such as 510(k), De Novo, and PMA, by AI-enabled versus other software, and by product area such as SaMD, remote monitoring, and wearables, would let the agency target its capacity investments where the need is greatest.

V. Preserve coherence across the connected health ecosystem.

Predictable patient access also depends on coherence across the ecosystem, meaning sensible, harmonized approaches to interoperability, cybersecurity, and real-world evidence, guided throughout by the least-burdensome principle. CHI supports the draft letter's pilot for simultaneous premarket review with international regulators, which advances international harmonization and reduces duplicative burden on innovators serving global patient populations. On real-world evidence, CHI supports FDA's continued development of standards-based methods and offers its Digital Health Evidence Resource, a curated database of U.S. clinical studies on connected health outcomes, for the agency to draw on. On cybersecurity, CHI supports a consistent, risk-based approach harmonized with recognized consensus standards. That approach should scale with risk, so that lower-risk connected devices are not subject to controls designed for higher-risk products. On interoperability, CHI supports standards-based approaches that enable the secure data flows underlying remote monitoring and AI-enabled care without creating new silos. On evidence generation, CHI also encourages standards-based real-world evidence methods that reduce the burden of demonstrating safety and effectiveness for iterative digital products. Every commitment in this letter should be judged against whether it moves the program toward faster, more predictable access to safe and effective connected health technology.

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CHI recognizes the real constraints the agency operates under and the careful balance a commitment letter must strike. The Connected Health Initiative stands ready to be a constructive partner throughout this reauthorization, and we would welcome the opportunity to discuss any of these recommendations in greater detail. CHI would also welcome the opportunity to work directly with FDA technical staff on the design of digital health review metrics, on making the PCCP framework operational, and on the clinical evidence available through its Digital Health Evidence Resource.

Sincerely,

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