ConnectedHealthInitiative

August 13, 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, *Development of 21st Century Cures Act Section 3060 Required Report; Request for Input* (Docket No. FDA-2018-N-1910)

The Connected Health Initiative (CHI) submits these comments in response to the Food and Drug Administration's (FDA) request for input[1] on the non-device software functions described in section 520(o)(1)(A)-(E) of the Federal Food, Drug, and Cosmetic Act, as added by section 3060 of the 21st Century Cures Act.[2] FDA has asked for input on patient safety, on the benefits and risks to health, and on best practices to promote safety, education, and competency, and it will address all of these in its report updating the December 2024 Report on Risks and Benefits to Health of Non-Device Software Functions.[3] CHI's members build and deploy many of the software functions that Congress placed outside the device definition, and they do so alongside the regulated software as a medical device (SaMD) and artificial intelligence (AI)-enabled functions that these tools support. Our message is a simple one, and it is consistent with what FDA's own reports have found over the years.[4] These non-device software functions deliver substantial and growing benefits to patient health, their risks are limited and can be managed, and the sound course is to preserve the risk-based line that Congress drew while promoting safety through voluntary best practices rather than new premarket obligations.

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,

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[1] Development of 21st Century Cures Act Section 3060 Required Report; Request for Input, Docket No. FDA-2018-N-1910, https://www.regulations.gov/docket/FDA-2018-N-1910.

[2] 21 U.S.C. § 360j(o)(1)(A)-(E); see 21st Century Cures Act, Pub. L. No. 114-255, § 3060, 130 Stat. 1033 (2016); see also FDA, Changes to Existing Medical Software Policies Resulting from Section 3060 of the 21st Century Cures Act (Sept. 27, 2019), https://www.fda.gov/regulatory-information/search-fda-guidance-documents/changes-existing-medical-software-policies-resulting-section-3060-21st-century-cures-act.

[3] FDA, Report on Risks and Benefits to Health of Non-Device Software Functions (2024) [hereinafter 2024 Report], https://www.fda.gov/media/184083/download?attachment.

[4] FDA has issued these reports biennially. See Reports on Non-Device Software Functions, https://www.fda.gov/about-fda/cdrh-reports/reports-non-device-software-functions (collecting the 2018, 2020, 2022, and 2024 reports).

including FDA regulation of digital health and the rising role of AI in care delivery. For more information, see www.connectedhi.com.

Below, CHI offers five recommendations.

1. Reaffirm and preserve the exclusions that Congress established in section 3060, and resolve any remaining questions through guidance and worked examples rather than through reclassification.
2. Give full credit to the substantial and growing benefits of non-device software functions, including the benefits made possible by recent advances in AI.
3. Promote safety, education, and competency through voluntary consensus standards, transparency, and human-centered design rather than new premarket requirements.
4. Address the known risks, including the gap in adverse-event data, through measured and real-world tools rather than new mandates.
5. For limited clinical decision support (CDS), keep the independent-review line that defines the category.

Underlying all five is the least-burdensome principle, which should guide how FDA describes both the benefits and the risks of these technologies and how it frames the best practices in its report.

I. The record, including FDA's own reports, shows that non-device software functions benefit patient health.

Since Congress enacted section 3060, FDA has looked at these categories again and again, and each report has reached the same basic conclusion, which is that the benefits to patient safety and health outweigh the limited risks.[5] That conclusion has grown stronger as the technology has matured. Administrative software, which is category A, reduces errors and delay in scheduling, eligibility, billing, and inventory, and it increasingly uses AI to surface issues such as language barriers that bear directly on fair access to care. Software that maintains or encourages a healthy lifestyle, which is category B, helps people become more active, manage their weight, lower their stress, and stop smoking, and in doing so it extends the reach of prevention beyond the clinic. Electronic patient records, which are category C, put complete and legible information in the hands of clinicians and patients, support adherence to recommended care, and make possible the real-world evidence and public-health surveillance on which the broader system depends. Software that transfers, stores, converts, or displays laboratory and device data, which is category D, streamlines documentation, and in settings such as cardiac care it is associated with measurably better outcomes. Limited CDS, which is category E, gives clinicians curated medical information, guidelines, and peer-reviewed evidence while leaving their independent judgment in place. Many positive uses have emerged, such as when administrative tools that flag mismatched patient records prevent later billing and safety errors, lifestyle apps that support medication and activity routines improve adherence, data-display tools in cardiac care help clinicians act on results sooner, and clinical decision support that shows its sources helps clinicians catch and correct an automated suggestion rather than simply defer to it. Many of these tools also put useful information and simple actions directly in the hands of patients and caregivers, and clear, understandable information supports shared decisions between patients and their clinicians. CHI

[5] See 2024 Report, supra note 3 (surveying the benefits and limited risks by category and concluding that the benefits to health outweigh the risks).

urges FDA to give full weight to these benefits as it updates its report, and to pay particular attention to the benefits made possible since 2024 by generative and other AI tools.

II. FDA should preserve the statutory line that Congress drew and resolve open questions through guidance, not reclassification.

The exclusions in section 520(o)(1)(A)-(E) reflect a deliberate decision by Congress that certain lower-risk software should sit outside the device framework. Preserving that line is itself a patient-safety measure, because it directs FDA's limited resources toward the higher-risk products that most need premarket review, and it gives innovators the predictability they need to invest and to bring useful tools to patients. Where the boundary between device and non-device software is genuinely unclear, CHI encourages FDA to resolve the question through plain-language guidance, examples, and updated answers to frequently asked questions. Examples would be especially useful for a few recurring gray areas, such as administrative tools that add AI to tasks like scheduling or population health, and limited clinical decision support that uses AI while still letting a clinician review the basis for each recommendation. FDA's January 2026 updates to its Clinical Decision Support Software and General Wellness guidances[6] are a good model, because they clarified the line and confirmed that certain functions are not devices and that many noninvasive wellness tools remain low-risk, all without expanding the reach of device regulation. CHI also encourages FDA to keep this framework in step with international approaches, including the risk-based frameworks developed through the International Medical Device Regulators Forum,[7] so that developers who serve patients around the world face consistent expectations. Keeping the U.S. exclusions in place supports global consistency, because when the United States treats these lower-risk functions the way other regulators do, developers who serve several markets are not forced to meet conflicting requirements for the same software. Any changes should apply going forward and should not be applied to products that are already in use.

III. FDA should promote safety, education, and competency through best practices, not new mandates.

The best practices most likely to improve safety for non-device software are the ones the field already knows well, and they are best advanced through voluntary consensus standards and shared good practice rather than through new premarket requirements that Congress placed outside these categories. CHI recommends that FDA's report describe several such practices. The first is reliance on recognized voluntary consensus standards, including standards for the trustworthy use of AI in health care and for quality management,[8] so that developers can build to a

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[6] FDA, Clinical Decision Support Software: Guidance for Industry and FDA Staff (Jan. 29, 2026) [hereinafter CDS Guidance], https://www.fda.gov/regulatory-information/search-fda-guidance-documents/clinical-decision-support-software; FDA, General Wellness: Policy for Low Risk Devices (Jan. 2026), https://www.fda.gov/regulatory-information/search-fda-guidance-documents/general-wellness-policy-low-risk-devices.

[7] See, e.g., IMDRF, "Software as a Medical Device": Possible Framework for Risk Categorization and Corresponding Considerations, IMDRF/SaMD WG/N12 (2014), https://www.imdrf.org/documents/software-medical-device-possible-framework-risk-categorization-and-corresponding-considerations.

[8] See, e.g., NIST, Artificial Intelligence Risk Management Framework (AI RMF 1.0) (2023), https://www.nist.gov/itl/ai-risk-management-framework; ANSI/AAMI/IEC 62304 on medical device software life cycle processes; ISO 13485 on quality management systems for medical devices.

common baseline. A second is transparency that fits the function, so that users understand what a tool is for, what data it uses, and, for AI-enabled software, how it produces its outputs. A third is human-centered design and human-factors testing that reflect real-world workflow and the diversity of the patients, caregivers, and clinicians who will use the tool. Interoperability matters as well, and it should rest on open standards such as HL7 FHIR,[9] draw on the widely used safety resources for electronic health records,[10] and, for certified records, align with ONC and ASTP certification.[11] Cybersecurity should be risk-based and matched to recognized standards, and it should be scaled so that lower-risk software is not saddled with controls meant for higher-risk products. Because the functions Congress excluded are lower-risk by design, the cybersecurity expectations for them should reflect that lower risk. CHI also encourages FDA to keep working with ONC and ASTP so that the safety resources for certified electronic health records stay current and useful. Finally, developers and FDA should invest in education and competency for clinicians and patients alike, through training, clinical champions, and clear user materials, so that these tools are adopted and used well. Offered as best practices rather than obligations, these steps raise the floor on safety while preserving the innovation and access that Congress intended.

IV. FDA should address known risks with measured, real-world tools, including by closing the adverse-event data gap.

CHI does not downplay the risks that FDA has identified,[12] which include data-integrity and patient-identification errors in records and in data-display software, over-reliance on automated outputs, and abandonment or unsupported claims in the wellness space, among others. These risks can be addressed through the best practices described above and through measured, real-world monitoring rather than through new premarket controls. CHI shares FDA's understanding that, because non-device software is not subject to mandatory adverse-event reporting, the available data likely understate both the benefits and the harms.[13] The better response is to strengthen real-world evidence and voluntary reporting rather than to reclassify these functions in order to capture data. CHI welcomes the chance to work with FDA on standards-based methods for generating real-world evidence for software that improves over time. As a starting point, FDA could support voluntary and structured reporting templates that make it easy to share outcomes, align data collection with quality-reporting programs that developers and providers already use, and pilot lightweight approaches for tracking adaptive AI software as it changes over time.

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[9] Health Level Seven International, Fast Healthcare Interoperability Resources (FHIR), https://hl7.org/fhir/.

[10] See ONC/ASTP, SAFER Guides (Safety Assurance Factors for EHR Resilience), https://www.healthit.gov/topic/safety/safer-guides.

[11] See ONC Health IT Certification Program, https://www.healthit.gov/topic/certification-health-it/about-onc-health-it-certification-program; see also 42 U.S.C. § 300jj-11(c)(5) (the certification referenced in 21 U.S.C. § 360j(o)(1)(C)).

[12] See 2024 Report, supra note 3 (cataloguing category-specific risks, including data-integrity and patient-identification errors).

[13] See 2024 Report, supra note 3 (noting that reported adverse events are likely underrepresented because non-device software functions are not subject to mandatory adverse-event reporting).

V. For limited clinical decision support, FDA should keep the independent-review line and use transparency to reduce automation bias.

CHI appreciates that FDA has continued to refine its approach to CDS and the line between device and non-device software. The key point in the statutory exclusion in section 520(o)(1)(E)[14] is that the software lets a health care professional independently review the basis for its recommendations, so that the professional does not have to rely mainly on them. CHI urges FDA to keep that criterion at the center of its analysis and to confirm that the basis for a recommendation can be made open to independent review even when the underlying algorithm is proprietary, because the two are not in conflict. Transparency, meaning clear and accessible information about a tool's inputs and the basis for its outputs, is the most effective safeguard against automation bias, and CHI supports the weight that FDA placed on it in the January 29, 2026, CDS update.[15] Because much innovative CDS now draws on AI and machine learning, CHI also encourages FDA to make sure that low-risk and transparent CDS keeps the regulatory relief that Congress intended,[16] so that these tools remain available to the clinicians and patients who benefit from them.

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[14] 21 U.S.C. § 360j(o)(1)(E); see CDS Guidance, supra note 6 (interpreting the criteria that keep clinical decision support software outside the device definition).

[15] See CDS Guidance, supra note 6 (addressing transparency and the risk of automation bias).

[16] See 21st Century Cures Act, supra note 2, § 3060; 21 U.S.C. § 360j(o)(1)(E).

CHI appreciates the opportunity to inform FDA's report on the risks and benefits to health of non-device software functions, and we commend the agency for seeking input from stakeholders as it updates its analysis. The Connected Health Initiative stands ready to be a constructive partner as this work moves forward, and we welcome the chance to discuss any of these recommendations in more detail. We would be glad to share the clinical evidence available through our Digital Health Evidence Resource[17] and to work with FDA technical staff on best practices for the safe and effective use of these technologies.

Sincerely,

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[17] Connected Health Initiative, Digital Health Evidence Resource, https://connectedhi.com/resources/digital-health-evidence-resource/.