ConnectedHealthInitiative

July 18, 2024

Attn: Dockets Management
Food and Drug Administration
5630 Fishers Lane, Rm. 1061
Rockville, Maryland 20852

RE: Comments of the Connected Health Initiative, *Input on Certain Non-Device Software Functions and Impacts to Patient Safety* (Docket No. FDA-2018-N-1910)

CHI appreciates FDA's continued examination of the changing, and increasingly important, role of software in medical devices per Section 3060(b) of the 21st Century Cures Act. The use of non-device software has demonstrated, and continues to demonstrate, immense value across healthcare use cases, including for administrative functions; encouraging a healthy lifestyle; electronic health records (EHRs); the transferring, storing, converting formats, or displaying of patient data; and providing limited clinical decision support (CDS).

CHI is the leading effort by stakeholders across the connected health ecosystem to clarify outdated health regulations, encourage the use of digital health innovations, and support an environment in which patients and consumers can see improvements in their health. We seek essential policy changes that will help all Americans benefit from an information and communications technology-enabled healthcare system. For more information, see www.connectedhi.com.

While non-device software offers a wide range of benefits to American providers and patients, their increased use will give rise to risks. CHI applauds FDA's approach taken to date to address these risks through its evolving guidance, which have appropriately scaled risk mitigation to the harms presented by the particular use case. With proper protections in place, approaches taken to non-device software risks should also promote data access, including open access to appropriate machine-readable public data, development of a culture of securely sharing data with external partners, and explicit communication of allowable use with periodic review of informed consent.

CHI generally urges the FDA to leverage risk-based approaches to ensure that the use of software in healthcare aligns with recognized standards of safety, efficacy, and equity. Providers, technology developers and vendors, health systems, insurers, and other stakeholders all benefit from understanding the distribution of risk and liability in building, testing, and using healthcare AI tools. Policy frameworks addressing liability should ensure the appropriate distribution and mitigation of risk and liability. Specifically, those in the value chain

with the ability to minimize risks based on their knowledge and ability to mitigate should have appropriate incentives to do so.

Further, FDA should encourage the design of software in health care that is informed by real-world workflow, human-centered design and usability principles, and end-user needs. Also, software should help patients, providers, and other care team members overcome the current fragmentation and dysfunctions of the healthcare system. Software solutions should facilitate a transition to changes in care delivery that advance the Quadruple Aim. The design, development, and success of software in healthcare should leverage collaboration and dialogue between caregivers, AI technology developers, and other healthcare stakeholders in order to have all perspectives reflected in AI solutions.

Ultimately, the use of non-device software continues to be underutilized across the healthcare continuum. Without FDA's regulatory clarity around the use of CDS software, mobile devices, and apps generally – and with respect to certain software functions excluded from the definition of device under section 201(h) of the FD&C Act specifically – these solutions are unlikely to meet their full potential. In its next report on non-device software functions under each of the five areas of focus noted in its request for input, we urge FDA's full exploration of the benefits to patient health in light of the advancements in technology since 2022, and, in its discussions addressing risks and best practices to address those risks, to reflect the range of approaches taken, including our recommendations above, which consider non-device software in risk management assessments consistent with FDA guidance addressing cybersecurity risk management, CDS, and other relevant topics.

CHI appreciates the opportunity to provide input to FDA on its 2024 report on the risks and benefits to health of non-device software functions. We welcome the opportunity to further assist FDA moving forward.

Sincerely,

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