ConnectedHealthInitiative

February 2, 2022

Janet Woodcock, MD
Acting Administrator
U.S. Food & Drug Administration
Center for Devices and Radiological Health
10903 New Hampshire Ave.
Silver Spring, Maryland 20993-0002

RE: ***Connected Health Initiative Comments on the Food and Drug Administration's Draft Guidance for Industry and Food and Drug Administration Staff on Content of Premarket Submissions for Device Software Functions [Docket No. FDA-2021-D-0775; 86 FR 60838]***

Dear Acting Director Woodcock:

The Connected Health Initiative (CHI) writes to provide input on the Food and Drug Administration's (FDA) draft guidance on documentation sponsors should include in premarket submissions for FDA's evaluation of the safety and effectiveness of device software functions, which are functions that meet the definition of a device under the Federal Food, Drug, and Cosmetic Act.[1]

I. Statement of Interest and General Comments of the Connected Health Initiative

CHI is the leading effort by stakeholders across the connected health ecosystem to responsibly 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 American healthcare system. For more information, see www.connectedhi.com.

CHI is a long-time active advocate for the increased use of new and innovative digital health tools in both the prevention and treatment of disease and appreciates the FDA's consistent collaboration on digital health-related technologies to responsibly streamline their pathway to the market.

[1] 86 FR 60838.

Medical devices with software functions are radically improving the American healthcare system and will continue to do so. Mobile-app enabled telehealth and remote monitoring of patient-generated health data continues to represent the most promising avenue for improved care quality, reduced hospitalizations, avoidance of complications, and improved satisfaction, particularly for the chronically ill.

CHI is a longtime supporter of the FDA's efforts to modernize and streamline the medical device approval process, particularly for device software functions controlling or part of a hardware device (i.e., Software in a Medical Device, or SiMD) and for devices that are not part of a hardware device (i.e., Software as a Medical Device, or SaMD). We applaud the FDA's release of its Draft Guidance for public input, which provides helpful, timely, and appropriate updates to its 2005-issued version of guidance for premarket submissions for device software functions.

Building on our broad support for the FDA's Draft Guidance, we offer the following specific input:

- We request that FDA consider including additional definitional/scoping language and examples to clearly explain the range of SiMD and SaMD impacted by the guidance document. Further detail explaining the FDA's guidance to areas of high interest to the digital health community, such as artificial intelligence/machine learning (AI/ML), would provide needed context for the guidance's intended audiences, particularly for those developing new SaMD innovations in areas including digital therapeutics. FDA's Draft Guidance can be improved in this respect by adding in examples in Appendix A to account for use cases including clinical decision support software, mobile apps, AI/ML, and devices with multiple functions.

  We also request that FDA's guidance be updated to reflect approaches to software development past the waterfall design approach, and that numerous software development approaches are reflected in the FDA's approach to SiMD and SaMD, including AAMI TIR 45, *Guidance on the use of Agile practices*, which the FDA has already recognized as a consensus standard.

- FDA should ensure that its new guidance on premarket submissions for device software functions reflects that the level of substance and detail in premarket documentation is scaled to the risk posed by the device software function (and not the intended use of either the device software function or the entire device that includes the device software function). Further, a modified version of a previously cleared or approved device that has undergone one or more non-significant changes to software functions since an earlier approval or clearance may not require full re-testing. Such an approach would ensure consistency with FDA's general approach to digital health and risk management as well as key U.S. government policies with which the FDA has long sought to align, such as the National Institute of Standards and Technology's Cybersecurity Framework

risk management tool,[2] and relevant standards including IEC 62304, *Medical Device Software – Software Life Cycle Processes*, and ANSI/AAMI/ISO 14971:2007/(R)2010, *Medical devices – Application of risk management to medical devices*.

Accordingly, FDA's proposed levels of documentation in the Draft Guidance should be revised so that each factor follows this risk-based and scaled approach. As currently drafted, the Draft Guidance would require enhanced documentation for a software device function that is part of a larger medical device which may pose higher risk to a patient despite that software function having no role in creating that higher risk. FDA should ensure that its guidance does not result in excessive and unnecessary documentation requirements that would do little to provide for patient safety.

- Documentation requirements should similarly map to standardized approaches, including ANSI/AAMI/IEC 62304:2006/A1:2016 (with the FDA has already recognized as a consensus standard).
- From a governance standpoint, we encourage FDA to clarify the agency's approach to medical devices cleared or approved before the finalization of new guidance on premarket submissions for device software functions. FDA can best account for such medical devices by assuring its audiences that the FDA's new guidance on premarket submissions for device software functions, once finalized, will not be applied retroactively. Further, those with open submissions to FDA preceding the issuance of the Draft Guidance and relied on the agency's 2005 guidance on premarket submissions for device software functions are expected to continue to rely on such guidance, and have a reasonable grace period that extends beyond the final issuance, accounting for the FDA's new guidance on premarket submissions for device software functions once that new guidance is finalized.

[2] https://nvlpubs.nist.gov/nistpubs/CSWP/NIST.CSWP.04162018.pdf.

II. Conclusion

CHI appreciates the opportunity to submit its comments to the FDA and urges its thoughtful consideration of the above input.

Sincerely,

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