ConnectedHealth

March 8, 2019

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

RE: *Comments of the Connected Health Initiative on* Developing a Software Pre-Certification Program: A Working Model (v1.0 - January 2019) *(Fostering Medical Innovation: A Plan for Digital Health Devices; Software Precertification Pilot Program, Docket No. FDA-2017-N-4301)*

The Connected Health Initiative (CHI) appreciates the opportunity to provide input on the Food and Drug Administration's (FDA) *Developing a Software Pre-Certification Program: A Working Model (v1.0 - January 2019)* (Working Model).[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CHI is the leading effort by stakeholders across the connected health ecosystem to clarify outdated health regulations, encourage the use of digital health innovations, and support an environment in which patients and consumers can see improvements in their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 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. CHI's advocacy reaches across the divisions of the Department of Health and Human Services, as well as other relevant agencies. Additionally, CHI is an appointed member of the American Medical Association's (AMA) Digital Medicine Payment Advisory Group, an initiative bringing together a diverse cross-section of 15 nationally recognized experts that identifies barriers to digital medicine adoption and proposes comprehensive solutions revolving

[1] FDA, Developing Software Precertification Program: A Working Model, v1.0 (January 2019), *available at* https://www.fda.gov/downloads/MedicalDevices/DigitalHealth/DigitalHealthPreCertProgram/UCM629276.pdf.

around coding, payment, coverage, and more.[2] CHI is also a board member of Xcertia, a collaborative effort develop and disseminate mHealth app guidelines that can drive the value these products bring to the market and the confidence that physicians and consumers can have in health apps and their ability to help people achieve their health and wellness goals.[3]

CHI is a longtime supporter of the U.S. Food and Drug Administration's (FDA) efforts to modernize and streamline the medical device approval process, particularly for software as a medical device (SaMD), as well as medical devices that utilize software and internet connectivity. In order for Americans to benefit from the latest advancements in medical devices, the FDA's approval process must improve so that time-to-market can be reduced while ensuring patient safety and caregiver trust. The FDA's integral steps of seeking public input at multiple stages, holding of public workshops, and administering its Software Pre-Certification Pilot Program (in which CHI members participated) built towards the Software Pre-Certification Program developed in 2019. CHI continues to support the FDA's efforts to further develop a wider Software Pre-Certification program to speed time-to-market for trusted developers of SaMD.

II. Specific Comments of the Connected Health Initiative on the FDA's Working Model

Building on our support for the FDA's continued work to realize a fully functional Software Pre-Certification Program, we offer the following specific input:

- CHI supports the Working Model's proposed approach to create Master Organization files to include quality assurance, risk management, and other characteristics for Program participants as the primary means for evaluating an organization's approach to developing SaMD. We support this approach as an alternative to collecting information on individual pieces of SaMD produced from a participant's process. CHI believes that this approach is consistent with the spirit of the Software Pre-Certification Program and will avoid the duplicative and overly burdensome data submissions that developers experience in the FDA's legacy approval process.

[2] https://www.ama-assn.org/delivering-care/digital-medicine-payment-advisory-group

[3] http://www.xcertia.org/

- CHI strongly believes that quality assurance and patient safety must be considered and assured in medical devices from the initial stages of design through the device's life. CHI therefore supports the Working Model's proposal to provide for clear accountability and responsibility to address product issues, user issues, constraints, and conflicting priorities throughout the product lifecycle as a key element of demonstrating excellence principles. We note our support for the FDA's development of risk-based key performance indicators for use in the Program and commit to working with the FDA to develop them.
- CHI supports the Working Model's thoughtful approach put forward for Program participants to maintain a demonstration of excellence. CHI supports the Working Model's proposed metrics to revisit demonstrations of excellence. However, CHI urges the FDA to eliminate the proposal in the Working Model to conduct audits of Program participants that would apparently take place in addition to ongoing FDA monitoring efforts. At minimum, we request clarity as to whether audits would serve as the monitoring tool in the Program or if the two concepts are separate functions as envisioned by the FDA.
- CHI commends the FDA's approach to requiring information in useable formats that is reasonably necessary to conduct Program reviews, as opposed to one-size-fits-all data submission requirements utilized in today's device approval process. We urge the FDA to provide as much clarity as possible as to the data it will require on a risk-based approach based on the device's risk categorization and what is permissible. For example, the FDA should clearly articulate how real-world data will be used, consider the burden to developers to provide the data with data privacy restrictions in mind, and should encourage the use of modern formats.
- While CHI fully supports the Software Pre-Certification Program addressing SaMD, we believe that medical devices that incorporate software should likewise benefit from the new process the Program offers. We encourage the FDA to update the Working Model to allow for those developing software that is included in a medical device (SiMD), in addition to those developing standalone SaMD, to participate in the Software Pre-Certification Program. Further, SaMD, whether standalone or as part of another device, should be evaluated consistent with the FDA's finalized guidance for SaMD (namely, based on intended use).
- CHI encourages the development of as much clarity as possible for developers considering participating in the Program. For example, the FDA guidance for developers that would map to the FDA's Program evaluation of excellence in easily understood terms will greatly assist developers in self-assessment exercises.

III. Conclusion

CHI appreciates the opportunity to submit its comments to the FDA and urges its thoughtful consideration of the above input. We look forward to further work with the FDA and other stakeholders towards realizing a successful Software Pre-Certification Program.

Sincerely,

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