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May 31, 2018

Food and Drug Administration
Docket No. FDA-2017-N-4301
5630 Fishers Lane, Rm. 1061
Rockville, MD 20852

Dear Dr. Gottlieb,

On behalf of the 34 members of the Electronic Health Record Association (EHRA), we are pleased to share our comments regarding the document *Fostering Medical Innovation: A Plan for Digital Health Devices; Software Precertification Pilot Program* published by the Food and Drug Administration (FDA) in April 2018.

EHRA members serve the vast majority of hospitals and ambulatory care organizations that use electronic health records (EHRs) and other health information technology to deliver high quality, efficient care to their patients. EHRA operates on the premise that the rapid, widespread adoption of health information and technology (IT) has and will continue to improve patient care quality, as well as the productivity and sustainability of the healthcare system.

We appreciate FDA's recent efforts to modernize its approach to regulating software that qualifies as a medical device (SaMD), including recognition that traditional medical device premarket clearance and approval pathways are not well suited to the iterative nature of software development. While most traditional EHR functions do not fall within the statutory definition of "medical device," the establishment of a well-defined and efficient premarket pathway for software modules that do qualify as SaMD could bolster a culture of innovation for health information and technology in the United States. We appreciate FDA's extensive efforts to seek stakeholder input on this topic.

To create a precertification program that will be attractive to and well-used by health IT suppliers that develop SaMD, we ask that FDA consider the following principles as it works with pilot participants to finalize its initial version of the software precertification program (the Precertification Program).

1. *The Precertification Program should remain voluntary.*

EHRA supports FDA's statement that the Precertification Program is envisioned to be a voluntary pathway to market for SaMD developers. We strongly encourage FDA to continue to allow companies the flexibility to choose whether to use the Precertification Program or traditional premarket regulatory processes. Companies should not be penalized, directly or indirectly, for choosing one pathway or the other.

2. *The Precertification Program must be less burdensome than existing premarket clearance and approval processes.*

To encourage companies to use the new Precertification Program, it is important that the program is less time, resource, and information-intensive than traditional clearance pathways, such as the 510(k) notification process. In evaluating whether this goal has been met, FDA should consider the full spectrum of companies that produce SaMD. There are significant differences between a small start-up that focuses exclusively on SaMD applications and a large company for which SaMD represents a fraction of their overall product suite. Many EHRA members that develop SaMD fall into the latter category. If the Precertification Program has a broader scope or requires that companies generate and share significantly more information than is currently required for a 510(k) notification, companies may choose to either continue to use the 510(k) process, despite its drawbacks as applied to software, or forgo development of SaMD entirely. Either outcome would defeat the purpose of the Precertification Program.

To mitigate this risk, EHRA supports FDA's statement in the Precertification Working Model that it anticipates allowing companies to seek precertification of individual business units or centers of excellence, rather than requiring precertification at the corporate level. FDA should allow companies full discretion to determine the scope of their covered business units, so long as a unit has internally-defined and understood boundaries. It would be a mistake for FDA to require that a business unit meet specific criteria to qualify as separate from non-precertified parts of the company. A company's organizational structure may reflect its culture, business philosophy, and "secret sauce" for producing high quality products. If FDA requires a company to implement artificial separation of its SaMD unit in order to keep the scope of precertification manageable, it may impede the shared development and other factors that have led to the company's success.

3. *The Precertification Program should avoid unnecessary complexity.*

Much of the public discussion regarding the Precertification Program has centered on the variation of methods for producing high quality, safe SaMD; FDA and the initial pilot participants want to capture that flexibility in the program's requirements. EHRA agrees that overly prescriptive requirements could defeat the purpose of the program. However, complexity could also become a barrier to entry for the Precertification Program. It is important to balance the desire to tailor the program closely to individual companies and applications with the need to create a framework that is predictable for potential participants and minimizes complexity. The Precertification Program should not include so many sub-pathways and nuances that specialized expertise is necessary to navigate it.

Specifically, the Precertification Program should only have one level, rather than the two that are currently contemplated. So long as a company is able to meet the initial and ongoing requirements of the Precertification Program, it should not be relevant for certification status whether that company has an established track record in delivering SaMD. While that important distinction may drive potential purchaser and consumer behavior, it is unnecessary to capture it in precertification status. An appropriate post-market feedback and de-certification framework could address the risk of precertifying companies without extensive medical device experience.

Similarly, while it would be reasonable for FDA to consider the International Medical Device Regulators Forum's (IMDRF) SaMD risk categorization framework when deciding how to classify particular SaMD function, or when deciding whether to apply enforcement discretion, FDA should not incorporate that framework into the Precertification Program itself. The number of parameters and classifications included in the IMDRF's framework would create unnecessary complexity, particularly when combined with two potential levels of precertification. Moreover, SaMD is often highly configurable, and the IMDRF framework is not well suited for SaMD that can be customized by healthcare organizations and used in a range of clinical settings. The exact same software function could be available for use in both non-serious and critical settings for a variety of clinical decision-making and could be configured to display a range of content at the user's discretion. The IMDRF framework introduces a level of complexity, inconsistent with program goals, that outweighs value of the specificity. It could lead to the over-classification of very simple software functions and unnecessary variation in classification across products and companies.

For example, the level of review grid proposed on page 10 of the Precertification Working Model contains 33 potential outcomes based on twelve different parameters. This level of complexity could preclude certain companies from participating in the Precertification Program unless they can afford to hire outside expertise. FDA and the pilot participants should instead consider a simpler model, such as the following framework that loosely matches the existing medical device regulatory regime:

FDA Medical Device Class	Initial Product	Major Changes	Minor Changes
I	No review	No review	No review
II	Streamlined review	No review	No review
III	Streamlined review	Streamlined review	No review

This is still a risk-based framework that could take into account the IMDRF factors where appropriate, but it keeps a lot of the complexity in the initial classification decision, rather than incorporating it into the Precertification Program. Similar to the current 510(k) and pre-market approval regime, FDA could require different levels of data to support Class II and Class III precertification. In addition, FDA could decide that the greater transparency associated with the Precertification Program would justify re-classifying certain lower-risk class II SaMD functions to class I.

For similar reasons, in response to Challenge Question 1.10, FDA should avoid attempting to establish product-specific requirements under the Precertification Program. Given the pace of innovation in health IT, product-specific requirements would be time-intensive to create and prone to falling out of step with advancing technology.

4. ***The Precertification Program should leverage existing quality management system certifications.***

In response to Challenge Question 1.1, the Precertification Program should build on existing third party medical device certification frameworks, such as ISO 13485:2016 and the Medical Device Single Audit Program (MDSAP). By doing so, the Precertification Program would be adopting a well-understood and flexible quality framework that companies could prepare to be measured against. Use of these certifications, which are already viewed by FDA as an indication that quality system and organizational excellence requirements are met, can help preserve resources and avoid duplication. For purposes of tailoring requirements to SaMD, it is better for the Precertification Program to clarify that certain requirements within these more general medical device standards are unnecessary for SaMD, rather than develop an entirely new and untested standard.

5. ***The Precertification Program should leverage outputs from existing quality management system certifications.***

It is critical that FDA and the pilot participants establish a defined and predictable scope of data that is required to support precertification so that companies can make an informed choice whether to participate. Any data required should map to a discrete objective of the Precertification Program. It would be impossible for the program to become the arbiter of all aspects of product quality that could be relevant to the public. Instead, FDA and the pilot participants should identify a specific list of objectives that map to existing medical device requirements, such as whether the company (a) uses appropriate testing methods to confirm its SaMD meets pre-established requirements; (b) has a system for reliably identifying, classifying, and addressing anomalies; and, (c) has a process for post-market safety monitoring that meets minimum standards. FDA should ensure that review staff have clear guidance on what data is and is not required for precertification.

Additionally, the Precertification Program should focus data requirements on outputs that are generated through use of the established quality system frameworks described above (e.g., complaint handling data, corrective action, and preventive action (CAPA) tracking and resolution). To avoid dis-incentivizing companies from participating, the Precertification Program should not require new types of data or studies (such as the type of clinical evaluation proposed under the IMDRF framework) that would not be required of the same class of device under the traditional Quality System Regulation and premarket clearance or approval framework.

Finally, while it is appropriate for the Precertification Program to include robust post-market surveillance requirements, FDA should avoid significantly expanding the types of post-market data that must be reported and should ensure that any reporting requirements respect the privacy of SaMD users also. The Precertification Program should not require specific functions, such as real world performance data (RWPD) collection functions, within the SaMD itself. SaMD developers must retain flexibility to tailor any data collection mechanisms to the nature of their software, the context in which it is used, and data privacy concerns. Automated data return requirements could threaten the privacy of SaMD users and lead to other unintended consequences, such as conflicts with other regulatory and contractual confidentiality obligations. For example, users may avoid precertified SaMD due to concerns about mandatory data sharing and the risk that otherwise private data could

become subject to public records requests. It is important that the Precertification Program not impose specific design requirements that could impede innovation and quickly become obsolete.

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Thank you for this opportunity to comment. EHRA and its members strongly believe in the power of health information and technology to support safe and high quality healthcare. We are committed to identifying and capitalizing on opportunities to ensure that innovative software has an efficient pathway to reach providers and patients.

Sincerely,

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