March 8, 2019

Division of Dockets Management (HFA-305)
Food and Drug Administration
5630 Fishers Lane, Room 1061
Rockville, MD 20852


To Whom It May Concern:

The Advanced Medical Technology Association (“AdvaMed”) appreciates the opportunity to provide input on the Food and Drug Administration’s (“FDA” or “Agency”) Digital Health Software Precertification Program Working Model version 1.0 (“Working Model”).\(^1\) AdvaMed represents manufacturers of digital health technologies, medical devices, and diagnostic products that are transforming health care through earlier disease detection, less invasive procedures, and more effective treatment. Our members range from the smallest to the largest medical technology innovators and companies.

We applaud FDA for the development of this Working Model and appreciate the Agency’s consideration of the numerous perspectives and comments it received through the docket, as well as from pilot participants and other stakeholders. The program’s intent, as reflected in the Working Model, is consistent with that of industry: The software precertification program must maintain FDA’s rigorous review standards for safety and effectiveness while providing alternative pathways and mechanisms to deliver information where it is most useful for the regulatory decision at hand.

Below we provide high-level feedback on the various sections of the Working Model. A more detailed analysis of these sections is provided in the attached chart.

**Precertification Pilot Program Scope:** As we have commented in the past, we understand FDA’s decision to currently limit the program to software as a medical device (SaMD). However, we believe that the program, in its final form, must also benefit software in a medical device (SiMD).

**Total Product Lifecycle:** We appreciate FDA’s incorporation of a Total Product Lifecycle (TPLC) approach to the Working Model. As FDA states, a TPLC approach is critical to ensure continuous monitoring and evaluation of software performance from design to deployment to reiteration so that patient safety remains the primary focus of the program.

Maintenance of Precertification: We appreciate FDA’s careful consideration of the maintenance and monitoring required to maintain a firm’s precertification status, including factors that could cause a loss of precertification status. Such factors will likely have an impact on companies that are weighing the benefits of being precertified against potential risks for losing their precertification status. We support the approach FDA uses in the Working Model, which utilizes several factors and triggers that would require an additional excellence appraisal, such as the significance of the factor as well as its continued recurrence, resulting in patient and product issues.

Excellence Appraisal: We are pleased to see FDA shift much of the focus of an excellence appraisal concerning an organization’s capabilities, commitments, practices, protocols, processes, and risk management approaches to the company-specific Excellence Appraisal, rather than request such information for product-specific SaMD submissions. We support development of a “Master Organization” file for each precertified software developer of such processes, such as cybersecurity policies and procedures, which should greatly reduce unnecessary duplication and make better use of both Agency and company resources. However, we remain unclear on what the actual Excellence Appraisal application would look like and urge FDA to provide additional clarity.

Key Performance Indicators: We appreciate that FDA recognizes that a “one size fits all approach” to collection of key performance indicators may have its challenges in a diverse health software ecosystem. Indeed, KPIs related to certain organizational domains, such as “people,” will likely need to be evaluated less frequently than KPIs related to other organizational domains, such as “Measurement, Analysis, and Improvement of Processes and Products.” Therefore, we recommend that FDA take a risk-based approach to KPI development and work with organizations to develop a suitable schedule to monitor and evaluate KPIs. It will also be important for FDA to maintain a consistent level of excellence across companies to ensure that precertification signifies to all stakeholders that a precertified company meets a high level of excellence.

Review Pathway Determination: We strongly support that SaMD regulation should be based upon the device’s intended use/purpose and be regulated the same way without regard to its platform (e.g., mobile medical application; cloud; server; or as a module on an analyzer). Further, we agree that SaMD risk should be assessed by the significance of the information to the healthcare decision and the disease/condition.

For the 2019 pilot, we support FDA’s use of the IMDRF risk categorizations to determine the regulatory path of the SaMD produced by precertified organizations. We believe Table 4, which maps SaMD risk category to a SaMD type (I, II or III), correctly categorizes relevant regulatory pathways. However, as we have stated in our previous comments to this docket, we strongly believe that the IMDRF framework must be adapted to fit the U.S. regulatory paradigm. Furthermore, we welcome additional guidance on how the IMDRF Risk-Categorization Framework and Level of Review map to the existing medical device regulatory classification and product code system. This information will be helpful for non-pilot participants seeking future premarket review and will foster enhanced understanding of
the benefits of the Precertification program.

For purposes of the 2019 pilot, it is appropriate for FDA to confirm the risk category through the review determination. However, we do not believe such an approach is sustainable once the pilot phase is complete. We are also unclear whether this review will be limited to the 2019 pilot phase or whether it will also be an element of the final program. Any delay associated with review determination would degrade the usefulness of being a “trusted” software developer. We support development of modules, decision trees, or other tools that will allow developers to self-determine their risk category. In addition, FDA should strive to develop clear definitions for the three risk categories so that developers are able to correctly self-determine their device’s risk.

Streamlined Review: We are pleased to see that FDA has developed “fit for purpose” regulatory requirements for SaMD, including streamlined submission pathways with iterative, flexible modification pathways. We believe the Agency is correctly considering inclusion of only the most relevant information in a streamlined review and appreciate that the Agency is open to exploring efficient and effective formats in which software developers can provide such information and interaction with FDA, such as templates, web portals, and screen shares. We encourage FDA to maintain this position and to limit the information required for a streamlined review to only necessary product-specific information.

However, in absence of early engagement with the FDA (which can be achieved through existing pathways, such as a Pre-Sub meeting), it is not clear how a submission containing complex clinical performance data could be successfully streamlined in the process described in the Working Model. We encourage FDA to elaborate on its thinking around the provision of clinical performance data.

Additionally, FDA refers to interactive review and automated review but does not commit to a timeline for review, which could lead to questions about the actual benefit precertified organizations should expect from the program. To fully articulate the benefits of the program, we believe a final Decision Summary and letter of substantial equivalence should be provided to the manufacturer within five business days of FDA receiving a confirmation document.

Real World Performance Analytics: FDA’s descriptions of real-world performance analytics (RWPA) require greater clarity and transparency. FDA should adopt a risk-based approach to RWPA plans for SaMD based on the device’s product characteristics and risk categorization. Furthermore, FDA should balance its RWPA expectations with limitations imposed on organizations due to data privacy considerations. For example, during instances in which an organization cannot obtain patient consent, potential approaches to RWPA may be limited and FDA may need to accommodate alternative approaches.

Because precertified organizations would already be monitored through the program, FDA should also consider reducing or eliminating the need for FDA audits for precertified organizations. It is not clear from the current Working Model whether precertification will deliver any benefit in terms of the frequency and depth of surveillance audits conducted at
the manufacturer’s site. A modified audit schedule could help make the program more attractive and drive adoption.

**Training:** FDA should conduct extensive outreach and education to its review staff to ensure complete alignment and buy-in to the precertification program. The success of the program requires alignment within FDA review teams of the overall goals of the program, as well as the vision of a risk-based regulatory framework that includes information from the excellence appraisal, review determination, streamlined review, where applicable, and real-world performance. If review teams continue to require traditional submissions or review pathways in addition to the precertification program’s requirements, there will be no incentive for developers to participate.

**Test Plan and Transparency:** In general, FDA should be as transparent as possible with respect to the evolution of the precertification program and the 2019 pilot, and share publicly its retrospective review of the 2019 pilot.

**Congressional Authorization:** While we applaud the FDA for the advances made regarding the Working Model, it is important to note that many of the potential advantages for precertified organizations, such as no or limited review for certain devices and modifications, may not be fully realized without legislative authorization. Therefore, we request FDA to provide transparency regarding such efforts.

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AdvaMed would like to thank the FDA for its consideration of these comments and looks forward to continuing to work with the Agency on this important issue. Please do not hesitate to contact me at 202-434-7224 or zrothstein@advmed.org if you have any questions.

Respectfully submitted,

/s/

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Attachment