AMA
AMERICAN MEDICAL ASSOCIATION

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The Honorable Scott Gottlieb, MD
Commissioner
U.S. Food and Drug Administration
10903 New Hampshire Avenue
Silver Spring, MD 20993

Dear Commissioner Gottlieb:

On behalf of the physician and medical student members of the American Medical Association (AMA), I applaud the leadership of the U.S. Food and Drug Administration (FDA) and your efforts to identify and test modernization options for oversight of digital health tools. The AMA is strongly committed to clinical transformations that improve patient access to high quality care by leveraging rapid advances in digital health tools. We are very interested in the FDA's various initiatives and welcome the opportunity to provide preliminary comments on the precertification program pilot for software as a medical device (SaMD). The FDA has indicated that this option could replace the need for a premarket submission for certain products and allow for decreased submission content and/or faster review of the marketing submission for other products.

We support the FDA's modernization efforts in principle, but strongly urge the FDA to establish, at a minimum, quarterly updates and discussions with physician organizations so that significant changes to current regulatory oversight standards and processes, as well as all relevant trade-offs and risks, are well-understood. Since digital health tools that are subject to FDA oversight will increasingly cut across medical specialties (unlike many current medical devices which are specialty-specific), we recommend that the FDA reassess historic engagement patterns and consider how physician organizations may become more engaged and involved in FDA processes.

The FDA is evaluating whether digital health developers who demonstrate a culture of quality and organizational excellence (CQOE) based on objective criteria should be pre-certified. The FDA is considering further that pre-certified developers could qualify to market their lower-risk devices without additional FDA review or with a more streamlined premarket review. We are well aware that the volume and rapid-cycle iterative improvements in SaMD dictate a new approach that would allow the FDA to streamline oversight for lower risk products while allocating scarce resources to the highest risk regulated digital health tools. We believe focusing on whether a company or organization excels in software design, development, and validation (testing) are important components. But we also believe that the track record of the developer for all of their products is equally important; thus, post-market active sentinel capabilities with organized feedback loops easily captured by regulators as well as developers are essential. This collection of real-world data post-market should be mandatory to affirm the regulatory status of the product, not simply to support new and evolving product functions. Furthermore, the ability

and obligation to rapidly communicate to providers and patients and correct defects or problems with SaMD should also be a mandatory capability for all pre-cert eligible developers.

In considering objective criteria to demonstrate CQOE, the FDA may want to examine the elements for an effective compliance program from the U.S. Sentencing Commission. These elements are used throughout the health care industry to help prevent and reduce inappropriate activity. For example, the element "Implementing written policies, procedures and standards of conduct" involves developing a general corporate statement of ethical and compliance principles that will guide the company's operations along with compliance-related policies and procedures based on areas of risk.

Additionally, it will be important to balance the evaluation of developer business practices, including CQOE based on key performance indicators (KPI); with the extent developers incorporate product design principles and guidelines. Industry-recognized principles and guidelines are key components in developing safe and effective products. It is our experience that when technology design is not tightly integrated with a core set of principles and guidelines, products' effectiveness, safety, security and operability are negatively impacted. While the FDA's pilot appraisal model captures product quality metrics at an organizational level, it is unclear if the final pre-cert program will emphasize the adoption of specific software design elements based on industry-recognized principles and guidelines. We urge the FDA to clarify that a product's quality should not be considered solely a subcomponent of CQOE, but rather an essential aspect of an organization's pre-cert demonstration process. The FDA should consider methods to reasonably evaluate a developer's assertion of design principle and guideline adoption.

As a threshold matter, any new SaMD oversight framework should be risk-based and developed to promote transparency and to ensure safety, efficacy, cybersecurity, privacy, and risk mitigation while advancing innovation. Gag clauses that prevent public disclosure of adverse events caused by SaMD are contrary to public policy and must be deemed illegal.

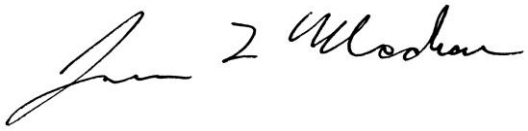
Pre-cert developers should also be evaluated with regard to the extent to which they engage physicians, physician organizations, patients, and consumers to collaborate and to obtain input on design, development, validation, and implementation of SaMD and communicate clearly about the relative risk, intended and expected uses, and limitations of their products, while adhering to rigorous standards and best practices for quality product design, development, and implementation. Developers seeking pre-cert status for SaMD used in the clinical care process should also be evaluated with regard to the extent that they develop products that are informed by real-world workflow, human-centered design and usability principles, and patient needs.

Developers should not inappropriately shift risk downstream to patients/consumers, physicians, and allied health professionals who use SaMD. The oversight/liability framework must align incentives so those best positioned to have knowledge of SaMD risks and best positioned to minimize harm through design, development, validation, and/or implementation are incentivized to do so. Protections should be established for the clinically appropriate use and reliance on SaMD by physicians and should be coupled with preservation of the physician's discretion to utilize or direct the use of the most appropriate diagnostic and treatment options. Where regulatory oversight is limited, black-box, proprietary SaMD with no algorithmic or dataset transparency should be subject to strict liability, particularly if not reviewed by an independent third party such as the FDA or an accreditor.

The AMA also strongly supports efforts by the FDA to encourage and support the role of third-party certification in facilitating FDA determinations about pre-certification. As the volume of SaMD increases, it is essential that the footprint of third-party accreditors with both technical and clinical expertise expand capacity to ensure that high quality and validated digital health tools are available to physicians, patients, and consumers. Greater developer transparency and/or utilization of third-party validation, including compliance with government regulation, should reduce liability.

We welcome an additional ongoing discussion. If you have questions, please contact Shannon Curtis, Assistant Director of Federal Affairs at shannon.curtis@ama-assn.org or 202-789-8510.

Sincerely,



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