HIMSS
transforming health through information and technology™

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May 31, 2018

Scott Gottlieb, MD
Commissioner of Food and Drugs
Food and Drug Administration
10903 New Hampshire Avenue
Silver Spring, MD 20993

Dear Commissioner Gottlieb:

On behalf of the Healthcare Information and Management Systems Society (HIMSS), we appreciate the opportunity to respond to the Food and Drug Administration's (FDA) Developing a Software Precertification Program: A Working Model, which issued in April 2018. HIMSS appreciates the opportunity to leverage our members' expertise in offering feedback on the FDA's Precertification Program to help provide a more streamlined and efficient regulatory oversight of software-based medical devices from manufacturers who have demonstrated a robust culture of quality and organizational excellence (CQOE) and committed to monitoring real world performance.

HIMSS is a global voice, advisor, and thought leader of health transformation through health information and technology with a unique breadth and depth of expertise and capabilities to improve the quality, safety, and efficiency of health, healthcare, and care outcomes. HIMSS designs and leverages key data assets, predictive models and tools to advise global leaders, stakeholders, and influencers of best practices in health information and technology, so they have the right information at the point of decision.

HIMSS drives innovative, forward thinking around best uses of information and technology in support of better connected care, improved population health, and low cost of care. HIMSS is a not-for-profit, headquartered in Chicago, Illinois, with additional offices in North America, Europe, United Kingdom, and Asia.

HIMSS supports FDA's drive to modernize its approach to medical device regulation and to rethink the pathway to market for software products which function as medical devices (SaMD). We encourage FDA to continue to innovate on this area in recognition of the increasing role these devices play in care provision and the modern, rapid, and iterative approaches many manufactures use in SaMD development.

HIMSS asks that FDA consider the following while evolving the Precertification Program:

Healthcare delivery is changing and becoming patient-centric.

We encourage FDA to recognize and support the changing nature of healthcare delivery when considering evolving regulatory schemes. This includes a movement from diagnosis and treatment to detection and prevention and a change in the locus of care-delivery from hospitals and clinical offices to the home and other non-traditional spaces. We believe this will require an increased focus on the use of medical devices by patients and consumers, and we ask that FDA make as much information as possible about the Precertification Program and products utilizing this new pathway publicly available in easy to understand formats. Additionally, while we support the five "excellence principles" outlined in the working model, we encourage FDA to change the name of the second principle, "Patient Safety" to the broader category of "Patient Responsibility."

Demographic pressures of an aging population are driving a shift in healthcare from a paternalistic, diagnosis and treatment-based model to a collaborative, prevention and wellness-based model. We encourage FDA to recognize that this change requires more participation by individuals in the planning and delivery of their own healthcare. And that all medical devices, whether SaMD or hardware-based will ultimately be used by, on behalf of, or along with patients themselves. So as part of a new pathway to market, we encourage FDA to assess the manufacturer's capability and willingness to assist the ultimate beneficiary of their product in understanding, utilizing, and benefitting from their products. We feel this is sufficiently different than the existing "patient safety" principle to warrant a new designation that encourages organizations to strive for more than just safety, but to demonstrate an overall commitment to patient-centered design principles, patient access to data collected or generated by the device, and ongoing support for patients using these devices.

The Precertification Program must provide a more efficient, easier to navigate, and fair pathway to market then existing premarket clearance processes

FDA should continue to encourage new manufacturers and innovators to enter the medical device marketplace in order to accelerate the availability of affordable devices for patients. However, two certification levels for organizations, certification at the business-unit level, and nine different risk profiles for devices hint towards a program of sufficient complexity that new market entrants or those comfortable with existing pathways may forego applying for certification entirely. The number of possible review levels in Table 3 might prompt a company to change their product function to reach a "no review" category rather than innovate to the fullest extent and becoming subject to review. HIMSS supports a streamlined level of review scheme such as this, based on existing FDA Class I, II, or III risk categories and consistent with previous FDA policies such as the Medical Device Data System (MDDS) scheme.

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

Regarding the IMDRF risk categories (challenge questions 2.2 – 2.4), while HIMSS recognizes and supports the need for international harmonization of regulatory schemes, we recommend that this new program remain true to previous FDA schemes as much as possible to allow manufacturers and the public to properly evaluate the risks, rewards, and potential costs of the Precertification Program vs. traditional pathway. We ask that FDA, at a minimum, provide a clear mapping of its thinking regarding the equivalence of IMDRF risk categories (non-serious, serious, and critical) to the more familiar Class I, II, and III designations currently in use. Additionally, we ask that FDA clarify how past thinking about software medical devices, and specifically the role of "competent human intervention" in the intended use of a device might affect the risk categorization and relate to the "inform," "drive," and "diagnose/treat" IMDRF designations.

Finally, regarding challenge question 1.5, the two-tier review system has the potential to offer market incumbent companies an unfair market advantage by subjecting their products to a streamlined review process which is not available to an equally capable but less-experienced competitor. We do not feel FDA's intent is to confer or deny market advantages to companies, so we strongly suggest rethinking this scheme and having only one-level of company certification. For similar reasons, in response to Challenge Question 1.10, FDA should also 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.

The Precertification Program should recognize existing quality management certifications

HIMSS applauds FDA for recognizing that Precertification Program can be valuable for companies with a culture of excellence but with limited experience in medical device manufacture. As part of this recognition, we encourage FDA to look positively upon companies that deploy and follow recognized quality systems, even those which are not medical device-specific. These can include companies with ISO 9000-3-based systems or organizations following ISO/IEC 25010-based systems, both specifically designed to support quality software development. We encourage FDA to indicate, clearly, where recognized standards and other special controls are and are not supportive of the precertification goals. In response to challenge question 1.4, we recommend that FDA consider favorably companies that have relied on their quality systems when presented with negative events to demonstrate their commitment to determining root causes and instituting change based on these investigations.

Effective cybersecurity requires comprehensive processes to ensure security risk mitigation occurs at every stage of the product lifecycle

In response to challenge question 2.8, HIMSS recommends the FDA separate health/medical risk determination and cybersecurity assessments. For the purposes of the Precertification Program, the medical risk of the intended use of the device should be the sole element considered for eligibility of a particular product to follow the accelerated pathway to market. HIMSS recommends that the FDA take a holistic approach to the cybersecurity assessment not just of individual products, but as part of the criteria for a manufacturer's demonstration of a culture of excellence for their inclusion in the Precertification Program in the first place. Even low-risk products can be compromised and misused in ways that elevate their overall risk. Strong security requires more

than just the implementation of certain features in a particular product and begins with product conception and design and continues through surveillance and updates once a product is delivered to the end-user. These are organizational characteristics that a manufacturer must possess at all levels, and a strong culture of excellence in this area should lead to meaningful risk assessment and mitigation within individual products.

Overall, HIMSS is eager to work with FDA to help provide more streamlined and efficient regulatory oversight of software-based medical devices. We welcome the opportunity to further discuss these issues in more depth. Please feel free to contact Jeff Coughlin, HIMSS Senior Director of Federal & State Affairs, at 703.562.8824, or Eli Fleet, HIMSS Director of Federal Affairs, at 703.562.8834 with questions or for more information.

Thank you for your consideration.

Sincerely,

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HIMSS