33 W Monroe, Suite 1700
Chicago, IL 60603
swillis@ehra.org
Phone: 312-915-9518
Twitter: @EHRAssociation

July 19, 2018

Food and Drug Administration
Attention: Dockets Management Staff (HFA-305)
5630 Fisher's Lane, Rm. 1061
Rockville, MD 20852

Dear Dr. Gottlieb,

On behalf of the more than 30 members of the Electronic Health Record Association (EHRA), we are pleased to share our comments regarding the document *Developing a Software Precertification Program: A Working Model v0.2* (the Working Model), published by the Food and Drug Administration (FDA) in June 2018.

EHRA members serve the vast majority of hospitals and ambulatory care organizations that use electronic health records (EHRs) and other health information and 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 extensive efforts to solicit and address stakeholder input as it refines the Software Precertification Program. Specifically, we appreciated that FDA addressed EHRA's previous request to allow participants the flexibility to self-define their internal units that are subject to the program. Also, EHRA is pleased to see recognition of existing quality management standards (e.g., ISO13485 and 62304) in version 0.2 of the Working Model. The format of version 0.2, with clearly identified changes reflecting prior public comments (marked by large "C"), was helpful and effective.

We ask that FDA consider the following comments in its future revisions to the Working Model, in addition to the guiding principles described by EHRA in our comment letter dated May 31, 2018, which largely remain relevant to version 0.2.

1. The Precertification Program should better accommodate highly configurable software.

Version 0.2 of the Working Model continues to incorporate aspects of the International Medical Device Regulators Forum's (IMDRF) risk categorization framework for software as a medical device (SaMD). As noted in the introduction to Section 5.1, version 0.2 clarifies that the reference to and use of IMDRF categories does not change the intent of FDA for scope of regulated medical devices. This is an important and welcome clarification.

We continue to have concerns with use of the IMDRF framework in the Working Model. The IMDRF risk categorization framework, while complex, provides a reasonable approach for highly specialized software functions that are targeted at specific medical conditions, healthcare contexts, and categories of patients. However, it is not well suited for SaMD that are intended to be customized by sophisticated healthcare organizations and used in a range of clinical settings. Many SaMD functions, particularly those incorporated into broader software suites such as integrated electronic health record systems, are provided as technical frameworks that allow individual healthcare organizations to customize content based on their own clinical judgment, patient populations, and care priorities. The same software function can be configured to provide information of varying levels of significance to be used with a range of healthcare situations or conditions. As a result, simple software functions, such as any basic decision support that remains subject to FDA regulation following finalization of FDA's guidance on Clinical and Patient Decision Support Software, could be treated as risky because of the possibility of their use in sensitive situations.

While it is appropriate for the Precertification Program to incorporate a risk-based framework for determining when "no review" versus "streamlined review" applies, FDA should consider alternatives to the IMDRF classification scheme as currently incorporated into the Working Model. For example, software could be evaluated based on the likelihood that a malfunction will result in death or serious injury. Including an explicit probability factor in the risk analysis would implicitly incorporate the concepts from Table 3 in the Working Model, but would capture more directly the estimated risk associated with a particular SaMD product, taking into account safety guardrails that may accompany use of the product. This type of more direct risk calculation would better accommodate software that may be configured for use to convey important information in critical settings but is unlikely to be a primary contributor to harm events.

2. The appraisal process should avoid unnecessary complexity.

Version 0.2 of the Working Model proposes 12 possible excellence principle elements, each with additional sub-elements and key performance indicators (KPIs). To avoid creating an unnecessarily complex and unwieldy process, EHRA suggests segmenting and triaging the requirements by impact on culture of safety and excellence and, in turn, developing fit-for-purpose requirements for demonstrating organizational excellence. Specifically, we recommend the following order of importance and specificity:

Managing Patient Risk

5. Risk Management: A Patient Safety Focus.

Documentation, including description, process flows, and quantitative measures, should be detailed enough to demonstrate proof of a robust culture of safety and effective practices to uncover and solve patient safety errors. This is the most important domain underscoring the regulatory responsibility of the FDA; and, to be reliable and accepted, the precertification process should reflect the required rigor and assessment.

Development lifecycle that enhances quality products

9. Requirements Management
10. Design and Development
11. Verification and Validation
12. Deployment and Maintenance
7. Measurement, Analysis and Continuous Improvement of Products
6. Configuration Management and Change Control

These aspects of the product development lifecycle should reflect high standards of quality and excellence to demonstrate effective, repeatable practices that deliver reliable and resilient products. The elements and key performance indicators should detail effective practice. As noted in Section 4 (p. 12), reliance on existing development maturity models like ISO 62304 should be encouraged to reduce duplication and redundancy of measuring systems.

Environmental Conditions

1. Leadership and Organization Support
3. People
4. Infrastructure and Work Environment
8. Managing Outsourced Processes, Activities and Products

These factors address the overall environment of quality and excellence. Rather than a high level of specificity and data, the proof of effective practices should be made through descriptive summaries and site reviews. We offer that the value of detail from numerous sub-elements and KPIs would be outweighed by the data-gathering burden.

The only remaining domain, *2. Transparency,* may be more effectively addressed through the other domains. For instance, under Requirements Management, the organization can specify how user input is collected and then shared effectively with current and prospective customers.

3. The streamlined premarket review process should avoid requirements for submission of redundant information.

The full list of review elements in a 510(k) submission is listed in Table 5. We understand this was provided for illustrative purposes. It is worth noting that the scope for this premarket notification submission is to support streamlined review for initial products from precertified organizations. The goal, therefore, should be non-redundant information that is specific to the product itself.

In addition, the review elements of cybersecurity processes, configuration management, development environment, life cycle, development testing, traceability, and verification and validation methods would be evaluated at the organizational process level and approved as meeting a robust culture of quality and organizational excellence. Additional explanation of the same environmental factors in a premarket submission would be redundant. Finally, toward the goal of streamlining documentation and avoiding unhelpful formality, the documentation burden should be minimized. Cover letter, device description, device summary, intended use population, indications for use/claims, and executive summary could be condensed into one summary that is specific to the premarket SaMD product.

4. The Precertification Program's data requests should be targeted and sensitive to confidentiality concerns of potential participating companies and their users.

Version 0.2 of the Working Model states, "transparency is one of the key goals of the program, and [FDA expects] all program participants to be transparent in providing information on their SaMD." Accordingly, the program relies heavily on the collection of development data, as well as real world performance data and analytics that would be available on an ongoing basis to FDA. EHRA supports version 0.2's clarification that FDA intends to focus on trend monitoring and analytics, rather than itself gathering raw clinical data. EHRA would like to re-emphasize the importance of assurances that any data collection requests will appropriately respect data privacy and other confidentiality concerns (e.g., intellectual property related) of SaMD developers and their users. Data requirements, at both the premarket and post-market stages, should be subject to a "minimum necessary" principle and tied to specific, meaningful, and actionable information. The overall package of information needed to achieve precertification and support product review must remain manageable. While it would be easy to continuously add on to the data required to support participation in the Precertification Program, each piece of information required should have an incremental value that justifies its inclusion given the overall burden of required evidence.

In addition, FDA should address the concern that otherwise private data or analytics could be subject to public records requests or similar attempts to use the data for purposes other than the pre-certification and product clearance. It is critical to balance the desire to leverage real world data to improve outcomes using the Precertification Program with the need to avoid overly burdensome data collection requirements and to respect confidentiality expectations.

5. The Precertification Program should include commitments to release KPIs about the performance of the program itself.

Two fundamental goals of the Precertification Program are data transparency and data-driven decision-making. Toward that goal, FDA should itself develop and measure program KPIs during the pilot and initial program period to continuously measure and improve the program against its vision and goal. Section 4.4 states that "starting in 2019 during the testing of the Software Precertification Program Version 1.0, the FDA anticipates collecting real-world information on the effectiveness of and ease of appraisal." EHRA suggests that this statement be solidified through a commitment to collect and publish relevant measures, such as:

- Paperwork reduction (average length of traditional 510(k) submissions relative to streamlined review submissions)
- Time from submission to approval in streamlined review process
- Pilot program participant satisfaction

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

Sincerely,

Cherie Holmes-Henry
Chair, EHR Association
NextGen Healthcare

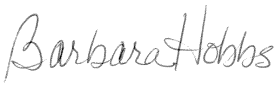
Sasha TerMaat
Vice Chair, EHR Association
Epic

HIMSS EHR Association Executive Committee

Hans J. Buitendijk
Cerner Corporation

Nadeem Dhanani, MD, MPH
Modernizing Medicine

David Heller, JD
Greenway Health



Barbara Hobbs
MEDITECH, Inc.

Rick Reeves, RPh
Evident

Courtney E Tesvich, RN
Nextech

About the EHR Association

Established in 2004, the Electronic Health Record (EHR) Association is comprised of more than 30 companies that supply the vast majority of EHRs to physicians' practices and hospitals across the United States. The EHR Association operates on the premise that the rapid, widespread adoption of EHRs will help improve the quality of patient care as well as the productivity and sustainability of the healthcare system as a key enabler of healthcare transformation. The EHR Association and its members are committed to supporting safe healthcare delivery, fostering continued innovation, and operating with high integrity in the market for our users and their patients and families.

The EHR Association is a partner of HIMSS. For more information, visit www.ehra.org.