DIGITAL HEALTH PRE-CERT PILOT PROGRAM UPDATE

Fostering Digital Health Innovation: Developing the Software Precertification Program Public Workshop

Last summer, FDA issued a digital health innovation action plan that outlined FDA's ongoing efforts to support timely access to high quality, safe, and effective digital health products. Since then, FDA has completed several actions in the plan, including issuing two draft guidances (Clinical and Patient Decision Support Software and Changes to Existing Medical Software Policies Resulting from Section 3060 of the 21st Century Cures Act), issuing two final guidances (Software as a Medical Device: Clinical Evaluation and Deciding When to Submit a 510(k) for a Software Change to an Existing Device), and on-boarding Entrepreneurs in Residence. We have also made progress on one of the action plan's most ambitious goals: to reimagine our approach to the oversight of digital health medical devices. Because of software's faster iterative design, development, and validation, traditional implementation of the premarket requirements may impede or delay patient access to advances in software technology that would improve public health. Since issuing the action plan, we have partnered with a range of digital health software companies and other stakeholders to begin developing a precertification program that could replace the need for a premarket submission for certain medical software products and allow for a streamlined review of marketing submissions for others.

The January 30-31, 2018, public workshop marks an important milestone in these efforts, during which FDA is seeking public engagement on lessons learned and next steps.

Overarching Goals of the Digital Health Software Precertification Program

FDA aims to develop a flexible, fit-for-purpose regulatory framework. The Digital Health Software Precertification (Software Pre-Cert) Program would be a voluntary pathway for streamlined regulatory review of software-based medical devices from manufacturers that have demonstrated a robust culture of quality and organizational excellence. The program should:

- Enable a modern and efficient regulatory framework that allows software iterations and changes to occur in a timely fashion;
- Provide a streamlined process for obtaining and maintaining precertification, allowing organizations to continue the customized processes they use to embed a culture of quality and organizational excellence, with minimal translation for regulatory purposes;
- Ensure high quality, safe, and effective software throughout the life of the product, while reducing regulatory burden and regulatory uncertainty, to improve patient and provider access to safe and effective digital health products;

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- Be scalable to organizations of all sizes, enabling measurement of "Key Performance Indicators" (KPI) independent of organization size, deployment strategies, or computing platforms;
- Leverage existing certifications or evaluations that show conformance with best practices and/or recognized industry standards; and
- Be structured to learn and adapt based on the effectiveness of the program, and be sufficiently flexible to withstand the variation in and evolution of software development and management processes in use today or that may exist in the future.

Our iterative approach in developing this program, analogous to a product development approach, is to develop the initial Software Pre-Cert concept and create a "Version 0.1" of the program by the end of calendar year 2018. We plan to test Version 0.1 in 2019 to validate and iterate, leveraging stakeholder input.

Getting There: The Process So Far

When FDA published the Digital Health Action Plan, we issued a Federal Register Notice requesting applications to participate in a pilot program to help us collaboratively develop the Software Pre-Cert Program. To capture the diversity in the digital health space, we selected nine participants representing a range of small and large organizations, traditional tech companies and traditional medical device companies, and an open-source non-profit. FDA developed an initial model for the Software Pre-Cert Program with three key components: (1) precertification, (2) streamlined premarket review, and (3) FDA access to postmarket data collection. The first component, precertification, has been our current focus.

FDA's initial model included excellence principles and common validating perspectives to facilitate understanding how a manufacturer of software that is a medical device approaches, demonstrates, and evaluates excellence. FDA also generated a list of sample appraisal questions, categorized by the identified excellence principles and common validating perspectives.

Excellence Principles	Common Validating Perspectives
Patient Safety	Organizational Resource Perspective
Product Quality	Customer Perspective
Clinical Responsibility	Learning and Growth Perspective
Cybersecurity Responsibility	Process Perspective
Proactive Culture	

Table 1. *FDA's original excellence principles and common validating perspectives. In FDA's initial model, each excellence principle could be viewed – and measured – through the lens of each common validating perspective.*

FDA staff spent November and December of 2017 visiting pilot participants for 1.5-2 days each. We sought the participants' perspectives on what makes their companies excellent, what practices and processes they put in place to create and maintain excellence, and how they know that those practices and processes are working. The participants considered how their approaches to excellence align with the excellence principles and common validating perspectives proposed by FDA. We also spent time brainstorming with the pilot participants key performance indicators that could be adopted as objective measures of excellence.

After the site visits, FDA staff compiled what we learned and began to analyze the data. As themes emerged, FDA looked back to existing models of excellence used in other contexts to see how well the themes we heard mapped to those frameworks, and where we could leverage those models in developing our Software Pre-Cert Program.

What FDA Learned from the Site Visits

FDA went into the site visits to learn how digital health companies holistically manage their organizations and to determine whether commonalities with respect to demonstrating, maintaining, and measuring a culture of quality and organizational excellence could be identified.

1. *Questions and desired outcomes from the pilot participants about the program*

Many pilot participants had questions about the pilot process, FDA's vision for the Software Pre-Cert Program, and how the new program would relate to FDA's current regulatory framework. Participants echoed FDA's overarching goals of the program, and agreed that the traditional regulatory approach could hamper innovation in the digital health space. Participants consistently voiced a desire, however, for FDA to preserve existing standards for safety and effectiveness as we adapt regulatory processes to the iterative cycles of digital health products. Participants of all sizes wanted to ensure that the program is scalable across the range of digital health software developers, rather than limiting precertification to large, established organizations. In addition, participants were interested in building a program collaboratively that would:

- Accelerate digital health products and devices and get them to market faster;
- Streamline processes and reduce duplication;
- Empower consumers to make better decisions about their own data;
- Reduce number of submissions for software changes;
- Be transparent as to who is precertified, giving precertified organizations additional credibility in the marketplace;
- Increase innovation in patient-centric medical products; and
- Track and monitor data in an automated fashion.

2. *Common organizational traits – Identifying a culture of quality and organizational excellence*

While each organization FDA visited was unique, FDA staff came away with a sense of the many shared traits among the pilot participants. As examples, these organizations:

- Have agile operational processes, and use their ability to iterate to achieve organizational goals;
- Have values that are communicated and reinforced by leadership, and are understood, articulated, and demonstrated by employees;
- Have engaged leadership and empowered staff;
- Actively engage relevant stakeholders, including users (who may or may not be patients) and clinicians;
- Know their product's users and the use environment;
- Have the right breadth and depth of expertise and capacity to deliver their goals and objectives;
- Have a culture that supports and prioritizes quality, where leadership and staff hold themselves and each other accountable for delivering high-quality products;
- Have effective and transparent modes of communicating within their organization and with appropriate stakeholders to prevent problems and ensure that when problems do occur, they are identified and resolved appropriately;
- Manage new product launches with intensive monitoring around real-world user experiences, and proactively learn from and manage early failures;
- Leverage connectivity, social media and user feedback along with other methods to monitor and ensure the product is working as intended in the real world; and
- Have vigilant cybersecurity processes and practices, and treat user data responsibly.

3. Excellence Principles & Common Validating Perspectives

Through the site visits, FDA aimed to understand the extent to which the practices, processes, and systems created independently by organizations to achieve excellence would align with our proposed framework of excellence principles and common validating perspectives. We found that the excellence principles resonated with pilot participants as key fundamental values. However, it was difficult for most of the pilot participants to identify activities related to the excellence principles through the four common validating perspectives, with many participants preferring to start with their internal organizational structures or major processes. We realized that we needed to modify our model to more closely align with the pilot participants' orientations.

4. Key Performance Indicators (KPIs)

FDA's intention is to use some configuration of KPIs to precertify an organization and monitor precertification status. FDA recognizes that there are a variety of successful ways to create and maintain an excellent organization. To allow for companies to maintain the individual approaches that are working for them, FDA posited that we would need a library of KPIs that could be used to measure and monitor the existence of a culture of quality and organizational excellence. No one set of KPIs is going to fit every company.

Through the site visits and engagement with pilot participants and other stakeholders, we quickly learned that not all characteristics of excellent companies are directly and objectively observable. In particular, while many external-facing KPIs appeared to be readily captured and measured, internal KPIs related to culture, process validity, and the consistency with which processes are implemented were more difficult to define. We began exploring with pilot participants indirect or proxy metrics for these types of organizational structures, and are interested in public input on ways of triangulating more easily observable indicators to achieve coverage of these important characteristics.

Review of Other Excellence Appraisal Models

While there were ways in which the site visits reaffirmed FDA's goals and framework, the site visits also highlighted the ways in which our model needs improvement. FDA researched and compared other industry-wide, national, and regional performance management and excellence frameworks that provide to supplement what we learned during the site visits. These include: Balanced Scorecard, the Baldrige Performance Excellence Program, the Capability Maturity Model Integration (CMMI), and the European Foundation for Quality Management (EFQM). These tend to be general, well-recognized frameworks; none are focused specifically on the digital health space. However, the themes they include correlate to FDA's working model, and they reflect detailed approaches that more explicitly aligned to what we heard from the pilot participants. After reflecting on the difficulty pilot participants faced in framing processes, structures, and activities through the lens of our common validating perspectives, FDA restructured the model to frame these elements through five enablers of excellence and four categories of excellence in results and outcomes. The selection of categories, along with the language used to articulate the supporting characteristics for each category, leverages elements from the Baldridge and EFQM frameworks and tailors them for application in a digital health space. The categories, which will shape break-out discussions on Day 2 of the public meeting, are:

Enablers	Results
Leadership Strategy Processes People Partnerships and Resources	Customers Business People Society and Public Health

Table 2. *Five enablers of excellence and four categories of excellence in results and outcomes. FDA restructured the initial model to frame processes, structures, and activities through five enablers of excellence and four categories of excellence in results and outcomes.*

What to Expect at the Public Workshop

We consider the public workshop to be the 10th pilot participant. We cannot build this program to create the right incentives, solve the right problems, and produce the right outcomes for public health without input and collaboration from all stakeholders. As reflected in the agenda, the objectives of the meeting are to 1) allow FDA to provide an update on what we have learned so far; 2) provide the public with an opportunity to hear from the pilot participants, and additional key stakeholders, including patients, providers, payers, investors, assessors, trade associations, and academic institutions; and 3) solicit ongoing input from the public to help build this important program. The first day will involve level setting, information sharing, and opportunity for dialogue. The second day will be a working day, where participants in the public workshop separate into breakout sessions to provide input on various aspects of FDA's working model.

Specifically, in the first breakout session, participants will be asked to identify opportunities to refine and improve a framework for enablers of excellence. During the second breakout session, participants will be asked to identify opportunities to refine and improve a framework of quantitative and qualitative measures that demonstrate performance and outcomes of excellence. During the third breakout session, participants will use draft scorecards and aggregation tools as launching points for discussion on evidence generation, evidence collection, and aggregation methodologies. FDA has posted Software Precertification Program: Excellence Model that includes the framework and supporting material we will use during day 2 of the workshop. FDA encourages attendees to review these materials ahead of time to facilitate productive discussions.

FDA also has a docket for public comment. To adhere to our ambitious timeframe, we are requesting any additional comments on evaluating and measuring a culture of quality and organizational excellence for the precertification element of FDA's software precertification program by **March 1, 2018**.

FDA looks forward to engaging all stakeholders in this important conversation. We recognize the need to develop this program collaboratively, to support innovation that benefits public health, reward excellence in digital health organizations, and ultimately ensure that Americans have timely access to high-quality, safe and effective digital health products.

For more information:

- FDA's Digital Health Program

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