September 13, 2017

Leslie Kux, Assistant Commissioner for Policy

Division of Dockets Management (HFA-305)

Food and Drug Administration

5630 Fishers Lane, Rm. 1061

Rockville, MD 20852

Re: FDA-2017-N-4301, *Fostering Medical Innovation: A Plan for Digital Health Devices; Software Precertification Pilot Program*

Dear Ms. Kux:

As the leading trade association representing the manufacturers of medical imaging equipment and radiopharmaceuticals, the Medical Imaging & Technology Alliance (MITA) is responding to the public docket entitled, *Fostering Medical Innovation: A Plan for Digital Health Devices; Software Precertification Pilot Program*.

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MITA understands the enormous technical and other complexities associated with implementation of device and regulatory schemes. MITA wishes direct continued discussions with FDA on the software precertification pilot program to help ensure its success.

MITA commends the Agency for taking proactive steps in considerations for regulatory review of software products. We acknowledge that medical device software presents challenges for the FDA and encourage the Agency to continue to pursue an efficient, risk-based regulatory framework to streamline manufacturers’ obligations and Agency oversight responsibilities.

MITA encourages the FDA use the pilot to explore the use of external conformity assessment bodies (e.g., IECEE) for software development and change controls using relevant existing international standards. Such an approach would help ensure information about quality and safety using documented external conformity assessment processes. MITA believes that this could be especially useful for cybersecurity controls.

Additionally, MITA and its Members believe that, when implemented appropriately, a pre-certification program for software could reduce regulatory burden on both the manufacturer and the Agency while providing safe and effective medical device software to American patients. However, MITA also notes that developing and implementing such a program will be complicated and the Agency should consider a number of issues and their implications. In this regard, MITA and the Advanced Medical Technology Association (AdvaMed) developed the attached document that represents that consensus of our members on essential tenets we believe FDA should adhere to as it further refines its plan.

\* \* \* \*

MITA Member companies consider themselves partners with FDA in achieving effective and safe outcomes for patients. As such, we count on your careful consideration of this response and look forward to further engaged dialog with us leading to an outcome that meets all stakeholder expectations. If you have any questions, please contact Megan Hayes, Director, Regulatory and Standards Strategy at 703-841-3285 ([mhayes@medicalimaging.org](mailto:mhayes@medicalimaging.org)) or me at 703-841-3235 ([phope@medicalimaging.org](mailto:phope@medicalimaging.org)).

Sincerely,



Patrick Hope

Executive Director, MITA

*MITA is the collective voice of medical imaging equipment and radiopharmaceutical manufacturers, innovators and product developers. It represents companies whose sales comprise more than 90 percent of the global market for medical imaging technology. These technologies include: magnetic resonance imaging (MRI), medical X-Ray equipment, computed tomography (CT) scanners, ultrasound, nuclear imaging, radiopharmaceuticals, radiation therapy equipment, and imaging information systems. Advancements in medical imaging are transforming health care through earlier disease detection, less invasive procedures and more effective treatments. The industry is extremely important to American healthcare and noted for its continual drive for innovation, fast-as-possible product introduction cycles, complex technologies, and multifaceted supply chains. Individually and collectively, these attributes result in unique concerns as the industry strives toward the goal of providing patients with the safest, most advanced medical imaging currently available.*

**Medical Technology Industry**

**Essential Tenets for Software Precertification Program**

Medical device software presents oversight challenges for the U.S. Food and Drug Administration (“FDA” or “Agency”). To foster the development and use of these innovative medical technologies, FDA should employ an efficient, risk-based regulatory framework that streamlines manufacturer’s obligations and the Agency’s oversight responsibilities. Indeed, in a July 28, 2017 Federal Register Notice, FDA announced its Software Precertification Pilot Program (“Pilot”) that will evaluate a new regulatory approach toward software products.[[1]](#footnote-1)

The medical technology industry commends the Agency for announcing this effort and believes such changes could benefit existing software development and foster new innovation across the healthcare industry. To be clear, we believe the Agency’s efforts should include all software under its authority – both Software as a Medical Device (“SaMD”) and Software inside of a Medical Device (“SiMD”).

As FDA develops the Pilot, we believe the Agency should consider how it can update its existing regulations and explore wholly new approaches to regulating these technologies. For example, we believe that the outcome of the Pilot should recommend ways to:

1. Revamp the premarket submission process for SaMD and SiMD so that it is based on the safety risk of the technology and the manufacturer’s demonstration of a commitment to quality and patient safety, while also reducing documentation requirements;
2. Allow for software changes to occur in an expedited fashion while ensuring that potential user risks due to such changes are appropriately mitigated;
3. Streamline post-market surveillance requirements; and
4. Reduce FDA’s own administrative burdens associated with these technologies to focus resources on other critical initiatives.

The following Essential Tenets developed by the Advanced Medical Technology Association (“AdvaMed”) and Medical Imaging & Technology Alliance (“MITA”) more fully describe these concepts and should underlie the foundation of the Precertification Program (“Program”). We recognize FDA is at the initial stages of developing the Pilot. As a result, we offer these Essential Tenets as a preliminary guide that we intend to update and modify, with the input of the Agency and other stakeholders, throughout the Program’s development process.

1. **General Tenets**
   1. The Program should eventually address all software within FDA’s jurisdiction, including SaMD and SiMD.
   2. The Pilot should include a broad representation of SaMD device types and risk types. For example, we recommend the Agency consider including at least one *in vitro* diagnostic device, one Premarket Approval (“PMA”) device, and one 510(k) device.
   3. All elements of the Program should be administered or governed (if outsourced) by the FDA. FDA is best equipped to evaluate risks associated with various types of medical devices.
   4. The Program should enable the Agency to focus its resources appropriately based on the risk of the product or device while also enabling patients to have access to innovative products and product improvements as quickly as possible.
2. **Premarket Program Administration, Eligibility, and Authorization**
   1. Participation in the Program should be voluntary; manufacturers should be permitted to submit premarket information through FDA’s current regulatory processes (e.g., the 510(k) program).
   2. Program requirements should be such that a broad range of manufacturers would be eligible for participation, including large and small manufacturers as well as established firms and start-ups. Careful consideration should be undertaken to ensure that participation requirements do not eliminate these types of manufacturers.
   3. The Program should reduce the complexity of the process for both initial submissions and product changes based on a risk assessment and other relevant criteria.
      1. For software technologies subject to the Agency’s 510(k) review program, the Program should, at a minimum, provide an exemption or streamlined premarket review and modification submission requirements.
      2. For software technologies that require PMA, the Program should, at a minimum, offer a streamlined process of such submissions and required supplements.
      3. For product changes that do not include a change to intended use, the Agency should allow the manufacturer to use their approved process to initiate necessary software changes in a timely and efficient manner.
   4. Participation in the Program should be time-limited and periodically reviewed. Continued participation in the program must be predicated on compliance with program requirements, which should be made clear to participating firms.
   5. Manufacturers should be required to inform FDA of any material changes to information that was relied upon to gain authorization to participate in the Program, including the sale, acquisition and divestiture of such eligible firms and products.
   6. *Authorization criteria*: Criteria established to determine a manufacturer’s eligibility for the Program should be transparent and objectively evaluated. FDA should consider the following criteria when evaluating a manufacturer’s suitability for participation in the Program:
      1. The manufacturer’s culture of quality and experience in designing, delivering and maintaining quality medical software or other software technologies, including its organizational response to postmarket surveillance (e.g., Medical Device Reports (“MDRs”), MedWatch, recalls, safety communications, warning letters, and cybersecurity vulnerabilities).
      2. Documentation that demonstrates a company’s verification and validation processes, including the firm’s maturity and capabilities for change controls, and organizational response to inspection outcomes. However, a manufacturer should not be required to obtain third-party certification (e.g., Capability Maturity Model Integration (“CMMI”)).
      3. Use of consensus standards for the software development lifecycle and/or process assessments.
3. **Postmarket Efficiencies**
   1. The Program should contemplate mechanisms to allow authorized manufacturers to issue software patches and other updates prior to, or in conjunction with, any required reports to the FDA to ensure customers receive such updates as quickly as possible.
   2. The Program should provide exemption from or streamlined reporting requirements; criteria should clearly describe situations in which streamlined reporting is not acceptable.
      1. The Program should immediately permit authorized manufacturers to submit malfunction reports, as required, for eligible devices on a quarterly, summary basis.

We encourage the Agency to coordinate with a variety of stakeholders throughout the Pilot, especially to establish metrics for success and to develop solutions to any challenges identified during the Pilot to ensure that the ultimate Program meets the needs of all stakeholders. The medical technology industry believes FDA’s commitment to the Program is an important step towards fostering the development and use of these innovative technologies. We believe these essential tenets will ensure the Agency’s Program ultimately provides a more efficient, risk-based regulatory framework for SaMD and SiMD technologies. We again commend the Commissioner for the announcement of and commitment to developing the Program, and look forward to working with the Agency throughout its development process.

1. Fostering Medical Innovation: A Plan for Digital Health Devices; Software Precertification Pilot Program (July 28, 2017), *available at* https://www.federalregister.gov/documents/2017/07/28/2017-15891/fostering-medical-innovation-a-plan-for-digital-health-devices-software-precertification-pilot. [↑](#footnote-ref-1)