March 8, 2019

Submitted via Regulations.gov

Division of Dockets Management (HFA-305)
Food and Drug Administration
5630 Fishers Lane, Rm. 1061
Rockville, MD 20852

Subject: (FDA-2017-N-4301-0111) Software Precertification Program Working Model Version 1.0; Comments of the American College of Radiology

The American College of Radiology (ACR)—a professional association representing over 38,000 diagnostic and interventional radiologists, radiation oncologists, nuclear medicine physicians, and medical physicists—appreciates the opportunity to provide feedback on the U.S. Food and Drug Administration (FDA) document, "Developing a Software Precertification Program: A Working Model, Version 1.0 - January 2019." We applaud FDA's ongoing efforts to modernize regulatory oversight of digital health products, including Software as a Medical Device (SaMD), and we appreciate the agency's outreach to stakeholders during the development and evolution of the Software Precertification (Pre-Cert) Program.

We note that ACR submitted feedback in response to FDA's targeted questions for stakeholders regarding "version 0.1" of the Pre-Cert Working Model in May 2018. The following addendum reiterates key recommendations for Working Model version 1.0.

Proactively Involve Smaller and Less-Established Developers
To date, the Pre-Cert pilot has primarily supported the participation of medium-to-large medical device and consumer technology companies with extensive resources. We understand these companies are perhaps most willing and able to invest in experimentation. However, smaller and less-established SaMD developers should benefit from the efficiency and flexibility promised by Pre-Cert. We urge the FDA Digital Health Team to proactively seek participation and feedback from such developers moving forward.

Identify Other Ways to Leverage Third Party Validation/Certification/Registries
ACR supports FDA's work to leverage the National Evaluation System for Health Technology (NEST) and other such initiatives to help provide reasonable assurance of the safety and effectiveness of SaMD from precertified companies. Future versions of the Working Model should identify other ways in which qualified third party validation/certification services can contribute to the program, including to the Streamlined Review and Real World Performance (RWP) components. Similarly, FDA should identify ways to recognize qualified, third party clinical data registries contributing to RWP assessments/analytics and ongoing monitoring of SaMD.

For AI/machine learning-enabled SaMD in Pre-Cert and traditional pathways, FDA and developers should work closely with third parties, particularly national specialty societies, to ensure that algorithms are developed to structured use cases that define the inputs, outputs, and clinical

practice deployment considerations. By using structured use cases—such as those curated by the ACR Data Science Institute (DSI)—the agency will know the concept has been vetted and the data elements standardized for consistency, generalizability, and clinical workflow integration. Data sets used by third parties and others to validate AI/ML-SaMD should be diverse (i.e., not a subset of the data/population the algorithm was trained on) and generalizable to widespread clinical practice. Finally, all imaging AI/ML-SaMD should be in a trusted registry program for ongoing performance monitoring.

Participation in third party validation, certification, and registry services can greatly increase healthcare provider trust in SaMD that went to market through Pre-Cert-expedited pathways. Third party services can also better enable participation by smaller and less-established developers.

Remove Effect of Precertification Level on SaMD Review Pathway Determination
Version 1.0 of the Pre-Cert Working Model continues to indicate that a precertified company's status, precertification level, and the IMDRF risk category of the SaMD submission inform the Review Pathway Determination for SaMD from that company. ACR believes that product-specific risk, as represented by IMDRF methodology, is the most important of all considerations. Precertification status is a logical secondary consideration to allow special FDA consideration for scenarios in which a company's maintenance of precertification is under increased scrutiny (for example, after multiple unsuccessful Streamlined Review submissions). However, ACR continues to recommend elimination of the effect of *precertification level* on the Review Pathway Determination—specifically, the ability illustrated in Table 4 of the Working Model for level 2 precertified companies to bypass Streamlined Review for certain type II and type III SaMD and/or major updates.

Table 4. Proposed Level of Review for Level 1 and Level 2 Precertified Organizations' SaMD in Future Pre-Cert Program

IMDRF Risk Categorization		Level of Review for Level 1 and Level 2 Precertified Organizations' SaMD		
Type	**Description**	**Initial product**	**Major changes**	**Minor changes**
Type IV	Critical x diagnose/treat	SR	SR	No Review
Type III	Critical x drive		L1 – SR L2 – No Review	
Type III	Serious x diagnose/treat			
Type II	Serious x drive	L1 – SR L2 – No Review		
Type II	Non-serious x diagnose/treat		No Review	
Type II	Critical x inform			
Type I	Non-serious x drive	No Review		
Type I	Serious x inform			
Type I	Non-serious x inform			

(The arrows indicate the ACR-recommended Streamlined Review extension and removal of the discrepancies between SaMD from level 1 versus level 2 precertified companies.)

While precertification level could conceivably inform the required "elements" of Streamlined Review for SaMD submissions, thereby reducing some of the pre-market administrative burden for level 2 companies and FDA reviewers, it should not play a role in FDA decisions on whether or not type II-and-above SaMD and major updates can go straight to market. This would appear to shift initial responsibility and liability for evaluating SaMD outputs to healthcare providers. Moreover, it could disadvantage level 1 precertified companies (i.e., equal risk SaMD and major updates would be slower and more costly to get to market), and thus discourage innovation and competition from small developers. Finally, the ability to bypass Streamlined Review for type II-and-above SaMD and major updates could unintentionally encourage gaming of the SaMD Definition Statements used for the Review Pathway Determination. Therefore, we recommend FDA take a product-specific, risk-based approach to all SaMD and major updates in the Pre-Cert program by focusing almost exclusively on the IMDRF risk categorization during the Review Pathway Determination to determine if Streamlined Review of the product is warranted.

As always, the American College of Radiology welcomes continued dialog with FDA on issues of shared interest. Please contact Gloria Romanelli, JD, ACR Senior Director of Legislative and Regulatory Relations, and Michael Peters, ACR Director of Legislative and Regulatory Affairs, at (202) 223-1670 or mpeters@acr.org with questions or concerns.

Sincerely,

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Chair, Board of Chancellors
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