ALERT

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FDA Releases Software Precertification Working Model

On April 26, 2018, the U.S. Food and Drug Administration ("FDA") released an initial working model for its Software Precertification ("Pre-Cert") Pilot Program. The Pre-Cert Program is an effort by FDA to develop a new, more streamlined regulatory framework for software as a medical device ("SaMD") developed by manufacturers who have demonstrated a robust culture of quality and organizational excellence, and who are committed to monitoring real-world performance of their products once they are introduced into the U.S. market. Under the program, manufacturers that demonstrate these qualities may qualify for either an exemption from premarket review for lower risk SaMD products, or a faster review of higher risk products.

Though details are subject to change, the working model identifies five "excellence principles" on which eligible manufacturers will be evaluated for initial precertification, which are: (i) product quality, (ii) patient safety, (iii) clinical responsibility, (iv) cybersecurity protection, and (v) proactive culture with respect to surveillance, assessment of user needs, and continuous learning. FDA has not yet settled on a mechanism for conducting precertification, but the working model envisions a voluntary application process through which a company will submit to FDA information that objectively demonstrates commitment to the above-listed principles. After initial precertification, FDA expects there to be a mechanism for monitoring and maintaining precertification status.

As has been true generally across FDA's digital health endeavors, the working model notes that FDA is actively seeking public engagement on this topic. The working model includes specific questions to the public related to various components of the model, and presents an opportunity to help shape the regulation of medical software.

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