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POLSINELLI

Software as a Medical Device & FDA's Pre-Certification Program

How to Navigate the FDA's Evolving Software Pre-Certification Program in our Digital Health World

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Agenda

- History of software as a medical device
- 21st Century Cures Act
- FDA's Digital Health Pre-Certification Program

History of Software Regulation

- In 1989 FDA published a draft guidance document: “FDA Policy for the Regulation of Computer Products”
  - The earliest comprehensive attempt by the FDA to document its computer software policies
  - Ultimately the agency withdrew the guidance in 2005

History of Software Regulation

- Starting in 2011, the FDA began to release draft guidance documents outlining certain products that were low risk:
  - Medical Device Data Systems, Medical Image Storage Devices, and Medical Image Communications Devices (revised 2015)
  - Mobile Medical Applications (revised 2015)
  - General Wellness Devices (revised 2016)
- For these products, the FDA expressed its intent to exercise enforcement discretion
- Categorized by the intended use / function of the product

21st Century Cures Act

- Signed into law December 13, 2016.
- Among other things, the Act categorically excluded a number of software functions from the FDCA's definition of a "medical device."
  - If the software is not a medical device, it is not subject to FDA oversight.
- Among the excluded categories of software:
  - some probably did not meet definition of a medical device prior to the Act;
  - some had been identified as medical devices, but the Agency exercised "enforcement discretion" to avoid regulating certain functions; and
  - some were regulated prior to the Act, but the contours were murky.

21st Century Cures Act

- Software previously in the "gray zone" of enforcement discretion; now categorically not a device:
  - Software intended for administrative support of a health care facility [FDCA § 520(o)(1)(A)].
  - Software intended for maintaining or encouraging a healthy lifestyle and unrelated to the diagnosis, cure, mitigation, prevention, or treatment of a disease or condition [FDCA § 520(o)(1)(B)].
  - Software intended to serve as electronic patient records to the extent that such records are intended to transfer, store, convert formats, or display the equivalent of a paper medical chart [FDCA § 520(o)(1)(C)].

21st Century Cures Act

- Software previously in the "gray zone" of enforcement discretion; now categorically not a device:
  - Software intended for transferring, storing, converting formats, or displaying clinical laboratory test or other device data and results, findings by a health care professional with respect to such data and results, general information about such findings, and general background information about such laboratory test or other device,
  - unless such function is intended to interpret or analyze clinical laboratory or other device data, results, and findings [FDCA § 520(o)(1)(D)].
  - Examples:
    - Medical device data systems (MDDS)
    - Medical image storage devices
    - Medical image communications devices
    - Laboratory information systems (LIS)

21st Century Cures Act

- Software that previously had no FDA guidance, enforcement was case-by-case; now categorically not a device:
  - Clinical Decision Support (CDS) software
    - Software intended for the purpose of:
      - Displaying, analyzing, or printing medical information about a patient or other medical information (such as peer-reviewed clinical studies and clinical practice guidelines);
      - supporting or providing recommendations to a health care professional about prevention, diagnosis, or treatment of a disease or condition; and
      - enabling such health care professional to independently review the basis for such recommendations;
      - unless the function is intended to acquire, process, or analyze a medical image or a signal from an in vitro diagnostic device or a pattern or signal from a signal acquisition system. [FDCA § 520(o)(1)(E)].

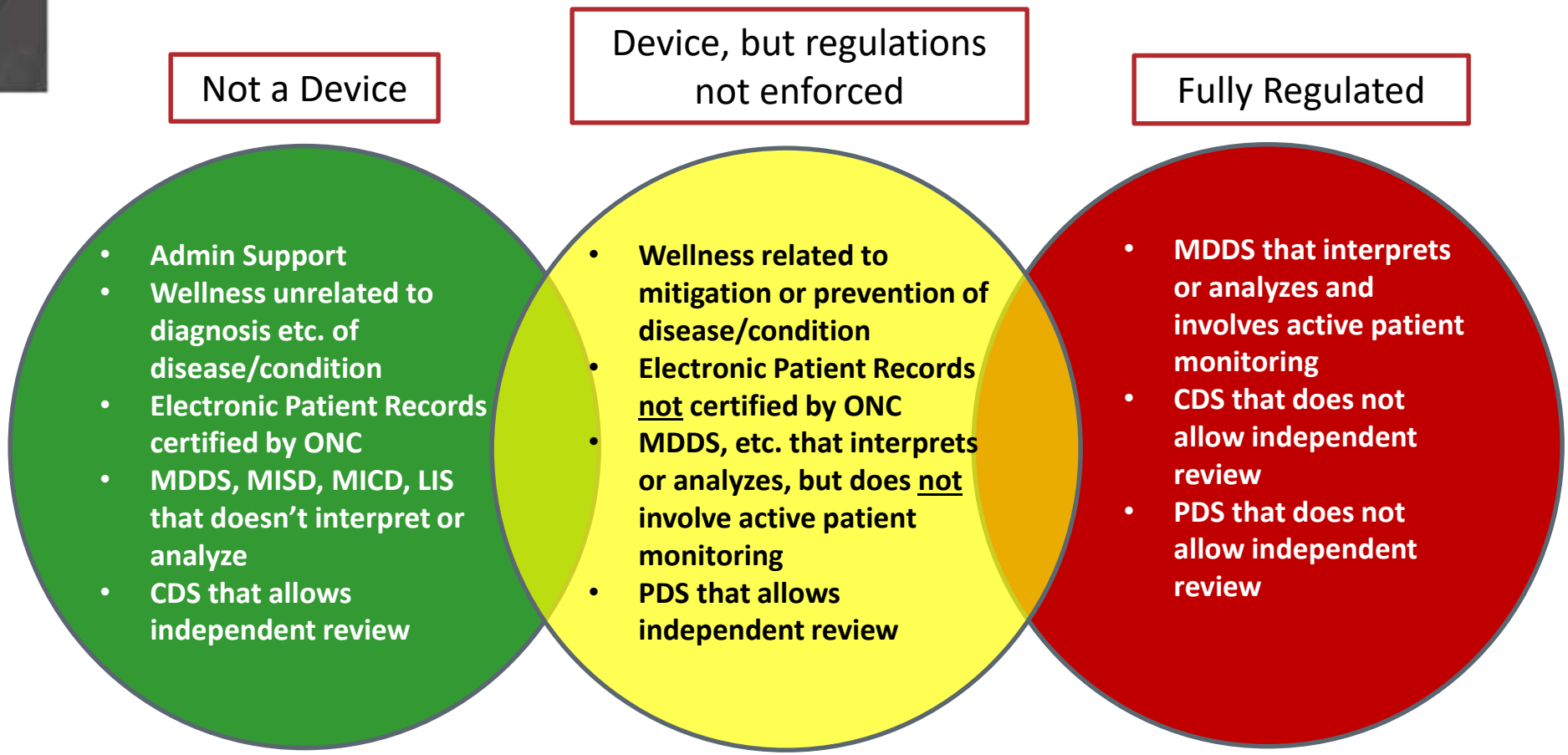
21st Century Cures Act

- **Software products with multiple functions**, where one function does not meet the definition of a device and the other does meet the definition of a device. [FDCA § 520(o)(2)].
  - The Secretary shall not regulate the software function that is not a device;
  - However, when assessing the safety and effectiveness of the function that is a device, the secretary may assess the impact of the non-device function on the device function.

21st Century Cures Act

- The act includes supplemental authority for the FDA to "claw back" and regulate otherwise excluded software products when:
  - Use of the software function would be reasonably likely to have a serious adverse health consequence [FDCA § 520(o)(3)(B)-(C)];
- Congress also clarified that it did not intend for the Act to exclude from regulation:
  - Software used in the manufacture and transfusion of blood and blood components to assist in the prevention of disease [FDCA § 520(o)(4)(B)]; or
  - Software that meets the definition of a Class III device [FDCA § 520(o)(4)(C)].
- Congress also preserved the FDA's ability to exercise enforcement discretion as to any device subject to regulation [FDCA § 520(o)(4)(A)].

Our Post-Cures World



FDA's Digital Health Pre-Certification Program

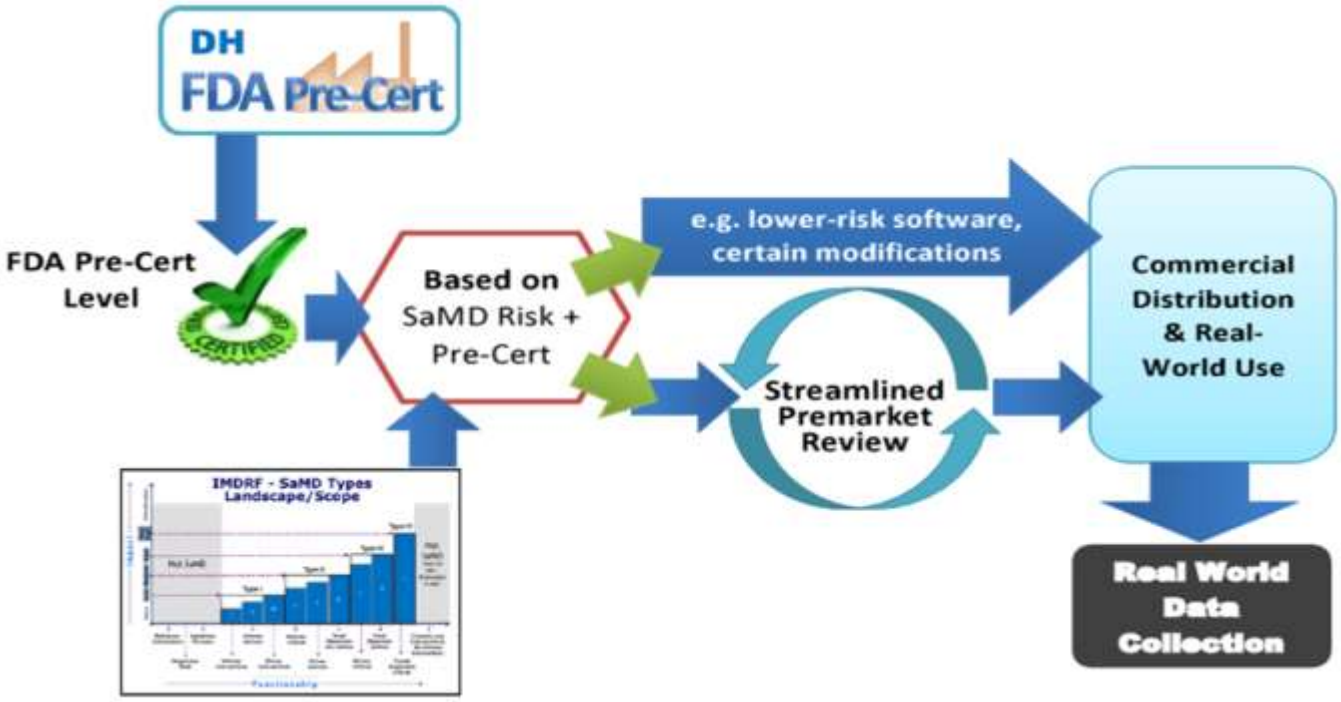
- Goals
  - Keep pace with innovation – be innovative!
  - Be an enabler not a disabler
  - Be flexible and nimble
  - Promote Culture of Quality and Organizational Excellence (CQOE)
  - Do not compromise mission
    - Continue to ensure safety & efficacy

FDA's Digital Health Pre-Certification Program

- FDA as Innovator
  - Focus on software developer/manufacturer
  - Do not try to evaluate each SaMD
  - Fundamental shift
    - Quality developer = quality product

Does this Picture Paint 1,000 Words?

High-level concept of the reimagined regulatory process using FDA Pre-Cert for Software



Source: FDA, *Software Precertification Program Model.*

FDA's Digital Health Pre-Certification Program

- Push for organizational quality
- Consistent with CDRH Director Shuren's broader mission
- Don't settle for compliance
- > CQOE score leads to < burden to clear SaMD
  - Excellence Appraisal

FDA's Digital Health Pre-Certification Program

- The Volunteers
  - Apple
  - Fitbit
  - Johnson & Johnson
  - Pear Therapeutics
  - Roche
  - Samsung
  - Tidepool
  - Verily

FDA's Digital Health Pre-Certification Program

- What the Volunteers Agreed to:
  - Provide FDA access to measures for developing, testing, and maintaining software products and demonstrating CQOE measured by KPI
  - Collect real-word post-market data and provide it to the FDA
  - Meet with FDA for real-time consultation
  - Be available for site visits from FDA officials
  - Provide information about the firm's quality management system

FDA's Digital Health Pre-Certification Program

- Excellence Appraisal -- under development
- EA leads to pre-certification – 2020 earliest
- Mock EA developed for 2019 testing
- EA Criteria to be based upon 5 excellence principles:
  - Patient safety
  - Product quality
  - Clinical responsibility
  - Cybersecurity responsibility
  - Proactive culture

FDA's Digital Health Pre-Certification Program

- How is FDA going to implement this reimagined program?
  - Relying on existing regulatory authority
  - Leaning heavily on de novo pathway
    - Implications, e.g., intended uses
  - Anticipates needing new authority from Congress
    - For ultimate "streamlined pre-cert 510(k)"

FDA's Digital Health Pre-Certification Program

- "We're flying the plane as we build it"
- How do you get a seat on the plane?
  - Existing authority
  - Build extra seats?
    - 2019 Test Plan Solicitation – May 22nd

FDA's Digital Health Pre-Certification Program

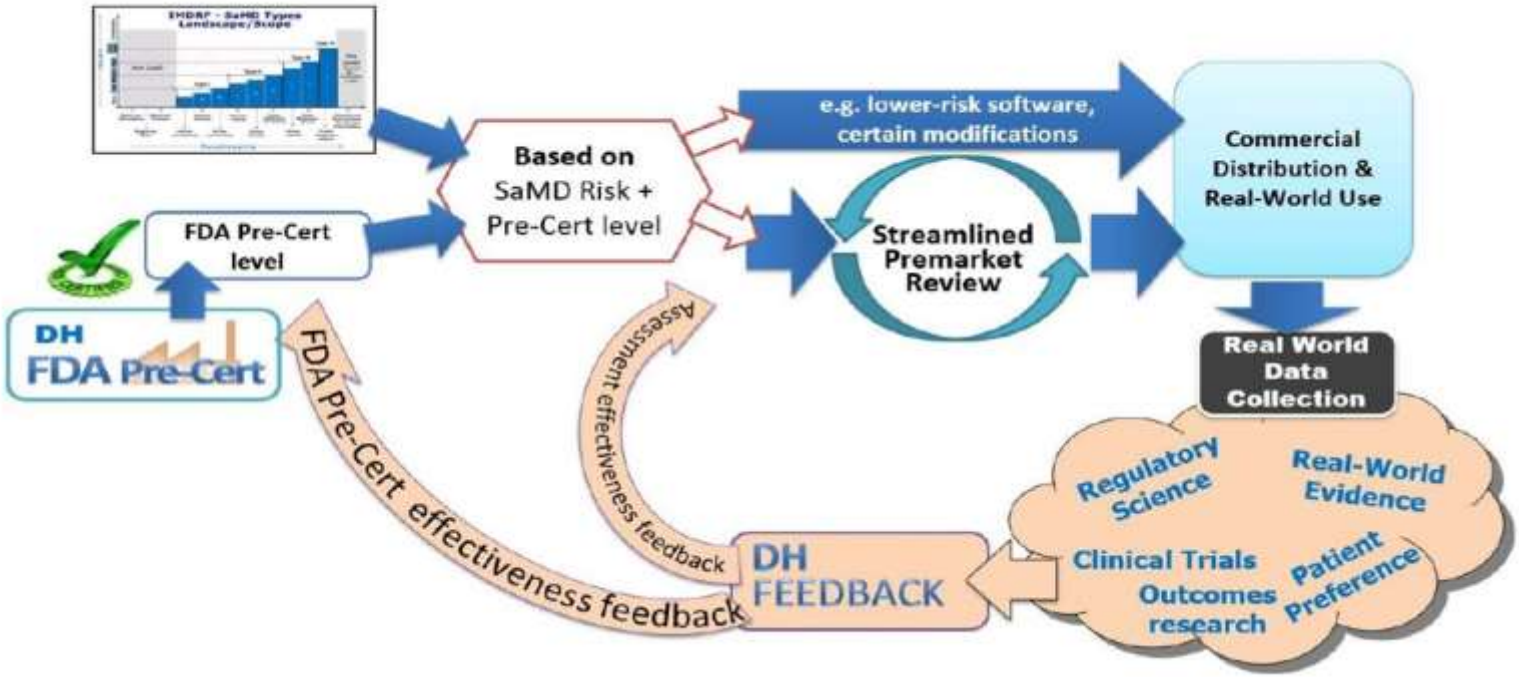
- 2019 Test Plan Solicitation (beyond the 9 Volunteers)
  - FDA ISO software organizations that
    - Are planning to submit a de novo request or 510(k) for SaMD prior to June 2020
    - Represent a broad spectrum of software developers
  - Large and small firms
  - Who develop a range of products, including low and high-risk SaMD
  - Not considered to be traditional medical device manufacturers

FDA's Digital Health Pre-Certification Program

- 2019 Mid-Year Update
  - FDA is engaged in side-by-side analysis
    - Proposed Pre-Cert pathway v. traditional pathway
  - What the FDA is evaluating during the 2019 Test Plan
    - The ability to provide an equivalent reasonable assurance of safety & effectiveness
    - The value proposition of enhanced communications between FDA & sponsors
    - Overall progress in program development and maturity
  - Retrospective Testing Completed
  - Prospective Testing in Progress

Does this Picture Paint 1,000 Words?

High-level concept of the reimagined regulatory



Source: FDA, *Software Precertification Program Model.*

Questions?

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