U.S. FDA Center for Devices and Radiological Health Update

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21st Century Cures Implementation

- Establish Breakthrough Device Pathway
- Change HDE Limit to 8000 Patients
- Streamline Process for 510(k) Exemptions
- Modifications to Classification Panels
- Allow for Central IRBs
- Update CLIA Waiver Guidance
- Recognition of Standards
- Train and Audit Least Burdensome
- Clarify Medical Software Regulation
- Cleaning and Validation Data
<table>
<thead>
<tr>
<th>Provision</th>
<th>Implementation actions completed</th>
<th>Date completed</th>
</tr>
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<tbody>
<tr>
<td>Exemptions (Sec. 3054)</td>
<td>Published lists of Class I and Class II devices exempt from requirement to submit a 510(k)</td>
<td>Final Class I list: April 13, 2017</td>
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<td>Final Class II list: July 11, 2017</td>
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<tr>
<td>Humanitarian Device Exemptions (Sec. 3052)</td>
<td>Published amendment to regulations changing the HDE population limit from 4,000 to 8,000</td>
<td>June 7, 2017</td>
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<td>Central IRB (Sec. 3056)</td>
<td>Published amendment to regulations removing the word “local” where needed to comply with new law</td>
<td>June 7, 2017</td>
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<td>Cleaning/Validation (Sec. 3059)</td>
<td>Published FR Notice identifying reusable device types for which 510(k)s are required to include certain validation instructions for use and validation data regarding cleaning, disinfection, and sterilization</td>
<td>June 9, 2017</td>
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<td>(statutory deadline was June 11, 2017)</td>
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<td>Classification Panels (Sec. 3055)</td>
<td>Published FR Notice soliciting public input for panel membership; finalized “Procedures for Meetings of the Medical Devices Advisory Committee” guidance addressing Cures-related changes</td>
<td>June 23, 2017</td>
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<td>September 1, 2017</td>
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<tr>
<td>Antimicrobial Susceptibility Testing (Sec. 3044)</td>
<td>Held public workshop</td>
<td>September 13, 2017</td>
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FDARA Implementation

USERFEES

- MDUFA 4
- Inspections
- Accessories
- Third Party Servicers
- Pediatric Devices

- Postmarket Surveillance Pilots
- Hearing Aids
- Contract Imaging Agents
- FDA Employee Salaries
- User Fee Reporting
MDUFA 4 Implementation

- Add Performance Goals for Presubmissions and De Novo
- Reduce 510(k) and PMA Average Total Time to Decision
- PMA Approvable and Post-Panel Decisions
- Improve Deficiency Letter Writing
- Enhance Use of Consensus Standards
- Establish Digital Health and Quality Management Programs
- Independent Assessment/Auditing
- Patient Engagement
- Real World Evidence

Launch Date: October 1, 2017
Digital Health Innovation Action Plan

An Integrated Approach

Refine policies & provide guidance
- Issue guidance conforming to software provisions of the 21\textsuperscript{st} Century Cures legislation
- Revise regulations for products that are not devices post 21\textsuperscript{st} Century Cures

Explore new streamlined pathway for software
- Launch an innovative pilot Precertification (Pre-Cert) program to build a new approach to digital health technology, working with our customers and leveraging internationally harmonized principles for software regulation

Building bench strength and expertise
- Build Digital Health unit with right technical expertise
- Launch digital health Entrepreneurs-in-Residence program for building the new paradigm
FDA Pre-Certification for SaMD

A voluntary program that allows manufacturers of Software as a Medical Device (“SaMD”) to demonstrate their embedded Culture of Quality and Organizational Excellence (CQOE) to ultimately participate in a streamlined and predictable FDA regulatory pathway.

**Purpose/Goal**

Allows manufacturers of SaMD with FDA Pre-Cert status (demonstrated culture of quality and organization excellence):

- To have the ability to get SaMD to market faster;
- To iterate based on real world experience;
- To have an excellent regulatory experience; and
- To have regulatory predictability.

**Public health/innovation outcomes**

1. Companies strive for excellence rather than compliance;
2. Promotes high quality and effective innovation;
3. Transparent FDA Pre-Cert status increases user confidence beyond regulatory oversight; and
4. Allows FDA to focus resources on higher risk digital health products.

**Example of CQOE scorecard elements of interest where a company shows commitment towards ...**

- Providing safe patient experience
- Being clinically responsible
- Delivering highest product quality
- Being cybersecurity responsible
- Being proactive v/s reactive
Scope of the Pre-Certification SaMD Pilot

- Manufacturers developing or planning to develop software as a medical device (SaMD) as defined by IMDRF.

**IMDRF SaMD Definition**

*Software intended to be used for one or more medical purposes that perform these purposes without being part of a hardware medical device*

- Limited to maximum of 9 pilot participants.
- Software function not excluded from medical device definition by 21st Century Cures Act.
MDDT Program

Qualification of Medical Device Development Tools (MDDT) Final Guidance issued August 10, 2017


- Voluntary program.
- Reduces regulatory burden in evaluating medical devices.
- Facilitates development and timely evaluation of medical devices.
- Supports regulatory submissions and decision-making (e.g., study population enrichment, reduce or minimize the use of animals using simulations).
- Tool submitters may be a person, group, consortium, or organization (including the federal government).
An MDDT is a method, material, or measurement to assess effectiveness, safety, or performance of a medical device.

Qualification is a conclusion, based on FDA review, that within the context of use (COU), a MDDT can be relied upon to have a specific interpretation and application in medical device development and regulatory review.

Categories of MDDTs:

**COAs:** Instruments that measure how a patient feels or functions (i.e. patient-reported outcome (PRO) for pain severity).

**BTs:** Test or instrument used to detect or measure a biomarker (i.e. instrument or method for measuring blood pressure).

**NAMs:** Non-clinical test model or method measures or predicts device function or in vivo device performance (e.g., in vitro models to replace animal testing).

Benefits of Qualification:

- Innovation
- Collaboration
- Reduce individual resource expenditure
- Bridge gaps between research and development
- Qualified MDDT applied in multiple device submissions
- Efficiency in CDRH review resources
- Minimizes uncertainty in review process
Real-World Evidence

Use of Real-World Evidence to Support Regulatory Decision-Making for Medical Devices Final Guidance issued August 31, 2017


- The guidance defines Real World Data (RWD) and Real World Evidence (RWE) and describes examples of RWD/RWE use for medical devices.
- The guidance clarifies how real world data is evaluated for relevance and reliability to determine whether it is sufficient for generating the types of real-world evidence that can be used in FDA regulatory decision-making for medical devices.
- When sufficiently robust, RWE can potentially be used to support practically any medical device regulatory decision.
THANK YOU