IMDRF International Medical Device Regulators Forum

U.S. FDA
CENTER FOR DEVICES AND RADIOLOGICAL HEALTH
UPDATE

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21ST CENTURY CURES ACT IMPLEMENTATION

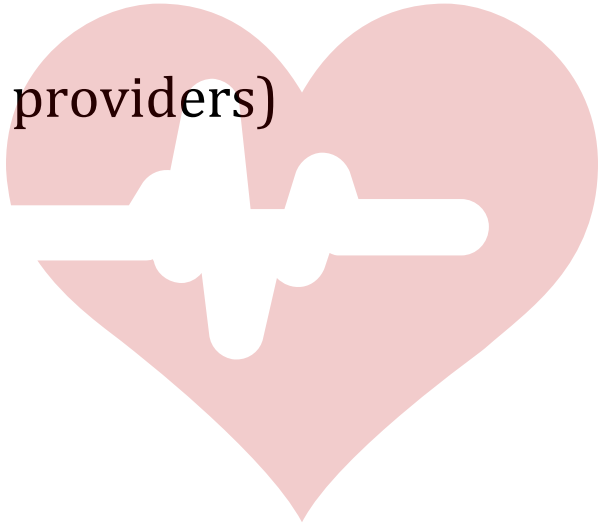
Provision	Implementation activities completed	Date completed
Least Burdensome	Issued draft guidance (not mandated); trained staff	15 Dec 2017
CLIA Waiver	Issued draft guidance	29 Nov 2017
Breakthrough Devices	Issued draft guidance	25 Oct 2017
Classification Panels	Published FR Notice soliciting public input for panel membership; finalized "Procedures for Meetings of the Medical Devices Advisory Committee" guidance including Cures-related changes	23 Jun 2017 (FR notice) 1 Sep 2017 (guidance)
Cleaning & Validation	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	9 Jun 2017
Central IRB	Published amendment to regulations removing the word "local" where needed to comply with new law	7 Jun 2017
Humanitarian Device Exemptions	Amended regulations changing the HDE population limit from 4,000 to 8,000	7 Jun 2017
Exemptions	Published lists of Class I and Class II devices exempt from requirement to submit a 510(k)	Final Class I list: 13 Apr 2017 Final Class II list: 11 Jul 2017
Software	Detailed on subsequent slides	

Digital Health Guidance Documents

Title	Draft or Final	Date Issued	Summary
Multiple Function Device Products: Policy and Considerations	Draft	TBD	Clarifies FDA oversight of products with software functions both within and outside our jurisdiction
Software as a Medical Device (SAMD): Clinical Evaluation	Final	8 Dec 2017	Same as IMDRF document of same title issued 22 Jun 2017
Changes to Existing Medical Software Policies Resulting from Section 3060 of the 21st Century Cures Act	Draft	8 Dec 2017	FDA's current thinking regarding the amended definition of "device" in the Federal Food, Drug, and Cosmetic Act and the resulting effect on medical device software guidances
Clinical and Patient Decision Support Software	Draft	8 Dec 2017	Provides clarity on the scope of FDA's regulatory oversight of clinical decision support and patient decision support software

DIGITAL HEALTH PUBLIC WORKSHOP

- *Fostering Digital Health Innovation: Developing the Software Precertification Program*
- January 30-31, 2018
- Panels
  - Pre-Cert Pilot Participants
  - Health Care Stakeholders (incl. patients, providers)
  - Trade associations
- Breakout Sessions
  - Enablers of Excellence
  - Measuring Results
  - Aggregating & Scoring



FDARA Implementation

- Request for comments on Voluntary Malfunction Summary Reporting Program (26 Dec 2017)
- Accessories guidance (20 Dec 2017): to implement new review timelines and process for accessories
- Pre-Sub guidance (29 Sep 2017): to update timelines related to scheduling meetings and FDA feedback
- Deficiencies guidance (29 Sep 2017): to clarify that a deficiency should include a reference to a regulation, final guidance, or standard

CLINICAL TRIALS

- Final Rule: Human Subject Protection; Acceptance of Data from Clinical Investigations for Medical Devices
  - Issued 21 Feb 2018
  - Requires submission of information about how investigations conform with GCPs
  - Requires a statement regarding compliance with regulations for human subject protection, institutional review boards, and IDEs

- Final Guidance: Acceptance of Clinical Data to Support Medical Device Applications and Submissions
  - Issued 21 Feb 2018
  - Q&A format; provides recommendations to help customers ensure that investigations conducted within the US or OUS comply with the new rule and updated regulations

- Final Guidance: FDA Categorization of Investigational Device Exemption (IDE) Devices to Assist the Centers for Medicare and Medicaid Services (CMS) with Coverage Decisions
  - Issued 5 Dec 2017
  - Updated FDA's criteria for assigning the CMS Category to IDE clinical trials, which supports the Medicare coverage process, especially for early feasibility studies; discusses when it may be appropriate to change categories

New Approaches

- Final Guidance: Deciding When to Submit a 510(k) for a Change to an Existing Device
  - Issued 25 Oct 2017
- Final Guidance: Deciding When to Submit a 510(k) for a Software Change to an Existing Device
  - Issued 25 Oct 2017
- Fostering Medical Innovation: Case for Quality Voluntary Medical Device Manufacturing & Product Quality Pilot
  - Announced in Federal Register 28 Dec 2017
  - Goals: improve patient safety and outcomes, reduce regulatory burden on demonstrating quality assurance, assure safety and effectiveness

2018-2020 Strategic Priorities

- **Employee Engagement, Opportunity, and Success**
- **Simplicity**
- **Collaborative Communities**

https://www.fda.gov/downloads/AboutFDA/CentersOffices/OfficeofMedicalProductsandTobacco/CDRH/CDRHVisionandMission/UCM592693.pdf

THANK YOU