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Changes to Existing Medical Software Policies Resulting from Section 3060 of the 21st Century Cures Act

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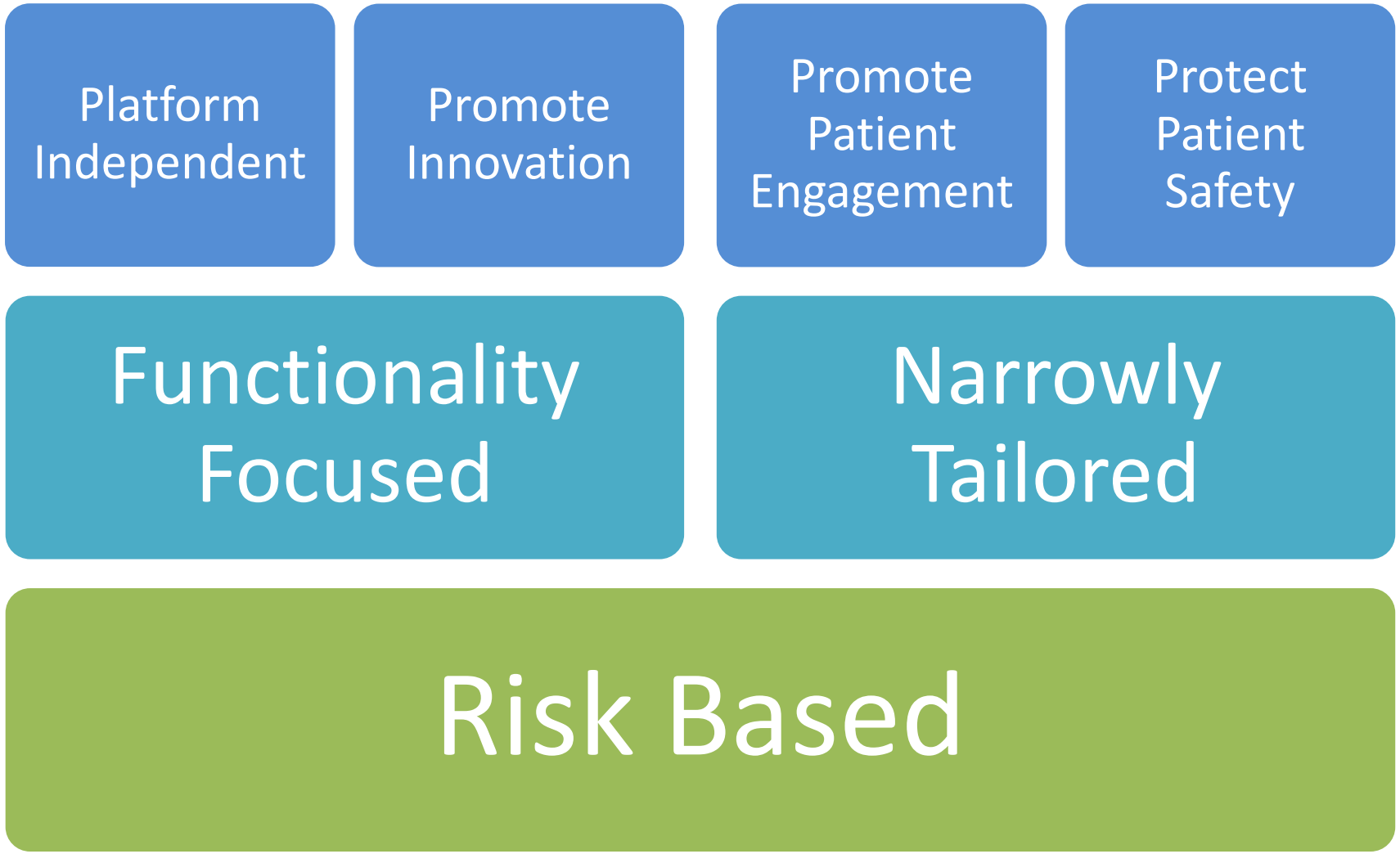
November 14, 2019

Agenda

- Background
- Summary of Final Guidance and Updates to Existing Guidances
- Questions and Answers

Functionality Focused Approach to Software



21st Century Cures Act:
Building on FDA's Digital Health Policy

Recognition of low risk Digital Health products

Codification of existing enforcement discretion policies

Applying a least burdensome approach for device regulation

21st Century Cures Act

- **Section 3060(a) of the 21st Century Cures Act ("Cures Act"):**
  - Amended section 520 of the Federal Food, Drug, and Cosmetic Act (FD&C Act) on December 13, 2016, **removing certain software functions from the definition of device** in section 201(h) of the FD&C Act

- **Final guidance "Changes to Existing Medical Software Policies Resulting from Section 3060 of the 21st Century Cures Act" ("3060 Guidance")**
  - **Provides FDA's current thinking regarding the amended device definition** and the resulting effect the amended definition has on FDA's guidances related to medical device software.

21st Century Cures Act (Section 3060) and FDA Policies

*Amended the definition of "device" in the Federal Food, Drug, and Cosmetic Act to **exclude** certain software functions intended for...*

FDA policies affected/codified

(A) Administrative support;

FDASIA Categories of Health IT
Administrative Functionality

(B) General Wellness;

FDA Policy for Low-Risk General Wellness Products

(C) Electronic Patient Records

FDASIA Categories of Health IT
Health Management Functionality

(D) Transfer, Store, Convert formats, Display related information;

Medical Device Data System (MDDS)

(E) Clinical Decision Support

Policy for Clinical Decision Support Software included in Health Management Functionality

*Addition of 520(o)(2) describes the regulation and assessment of a software product with multiple functions

Objectives

- Present what software functions were excluded from the device definition by the 21st Century Cures Act (Cures Act)

- Explain how FDA's existing software guidances have been updated to reflect the change to the device definition

Overview of Cures Act Software Provisions (Section 3060)

- Defines software **functions** that are **not devices**
- States that the FDA shall **not regulate non-device functions of a product with multiple functions –** but can consider the impact of non-device functions on the device functions
- Provides for the FDA regulation of **software functions that are excluded from the device definition by the Cures Act**, if the FDA finds that it would be reasonably likely to have serious adverse health consequences (substantive and procedural criteria must be met)
- Exclusions from device definition **do not** include software used in the manufacture and transfusion of blood and blood components to assist in the prevention of disease in humans
- A software function may also not be excluded from the definition of a device if it is found that the use of such software function would be reasonably likely to have serious adverse health consequences and the software function has been identified by a final order

Corresponding Changes Reflected in Other Guidance Documents

- 3060 Guidance describes changes that will be made through concurrent Level 2 updates to existing software guidances, including:
  - **Mobile Medical Applications (MMA)**
  - **General Wellness: Policy for Low Risk Devices**
  - **Medical Device Data Systems, Medical Image Storage Devices, and Medical Image Communications Devices (MDDS)**
  - **Off-the-Shelf Software Use in Medical Devices**
  - **Guidance for the Submission of Premarket Notifications for Medical Image Management Devices**

Differences Between the Draft and Final Guidance

Administrative Functions: FDA generally did not consider devices (520(o)(1)(A) of FD&C Act)

Draft 3060 Guidance

- Software functions intended for administrative support of a health care facility are **not devices**
  - Maintenance of financial records,
  - Information about patient populations,
  - Laboratory workflow, etc.

Changes from Draft:

No Change in policy

- Clarified that certain Laboratory Information Systems (LIS) include software functions that remain device

Differences Between the Draft and Final Guidance

General Wellness: Policy for Low Risk Devices (520(o)(1)(B) of FD&C Act)

Draft 3060 Guidance

- General wellness (GW) products that maintain or encourage a "general state of health or healthy activity" - **Excluded from Device definition**

- GW products with intended use related to helping reduce the risk or impact of certain chronic diseases or conditions" – **Not excluded from Device definition, but the FDA continues not to intend to enforce compliance with applicable regulations**

Changes from Draft:

No Change in policy

- Clarified how the two GW categories are affected/unaffected by Cures;
- Noted that hardware products that fit the first category are not excluded from the device definition (but remain under enforcement discretion)

General Wellness Intended Uses

The General Wellness Guidance defines two categories of general wellness intended uses:

Category 1. An intended use that relates to maintaining or encouraging a general state of health or a healthy activity

Category 2. An intended use that relates the role of healthy lifestyle with helping to reduce the risk or impact of certain chronic diseases or conditions and where it is well understood and accepted that healthy lifestyle choices may play an important role in health outcomes for the disease or condition

General Wellness Intended Use: Category 1

- ***Software functions*** for maintaining or encouraging a healthy lifestyle **are now excluded from the device definition** per the Cures Act –
  - As long as the software function is unrelated to the diagnosis, cure, mitigation, prevention, or treatment of a disease or condition.
- ***Hardware*** with general wellness intended uses that meet the device definition **remain devices, but FDA does not intend to enforce compliance with the regulatory controls** for such devices. Refer to the revised General Wellness guidance for FDA's current thinking on these products.

General Wellness Intended Use: Category 2

- If the intended use relates the role of healthy lifestyle with helping to reduce the risk or impact of certain chronic diseases or conditions and where it is well understood and accepted that healthy lifestyle choices may play an important role in health outcomes for the disease or condition, then **the product is not excluded from the definition of the term "device."**
- Refer to the revised General Wellness guidance for current policy.

Differences Between the Draft and Final Guidance

Electronic Patient Records: (520(o)(1)(C) of FD&C Act)

Draft 3060 Guidance

- For the record to be excluded from the device definition it must
  - Be created/reviewed by HCPs,
  - Certified under ONC Health IT Certification Program, and
  - Not intended for interpretation or analysis for the purpose of diagnosis, cure, mitigation, prevention, or treatment of a disease or condition
- **FDA does not intend to enforce the requirements** for records that are not certified under the ONC Health IT Certification Program
- Personal health records (not created/reviewed by HCPs) are **not devices**

Changes from Draft:

No Change in policy

- Created sections to describe each of exclusion criteria
- Added examples as requested by comments

Differences Between the Draft and Final Guidance

Transfer, Store, Convert Formats, Display Data and Results: (520(o)(1)(D) of FD&C Act)

Draft 3060 Guidance

- Software functions that transfer, store, convert formats, and display device data and results describe functions included in the Medical Device Data Systems (MDDS) regulations and MDDS guidance
- MDDS functions were under enforcement discretion per MDDS guidance
  - MDDS guidance did not distinguish between hardware and software functions
  - MDDS regulation includes both hardware and software in the identification
- Included reference to our policy for alarms/alerts/flags, because MDDS regulation refers to active patient monitoring

Changes from Draft:

- Clarifies that only software MDDS functions are excluded from device definition
  - MDDS hardware remains under enforcement discretion (except specialized medical display hardware)
- Clarifies that software MDDS functions are excluded from the device definition whether or not they are intended for active patient monitoring
- Refers to Clinical Decision Support (CDS) draft guidance for discussion of alarms/ alerts/ flags
  - CDS draft guidance describes alarms/ alerts/ flags as device functions (they analyze medical device data, so are not excluded per 520(o)(1)(E) “1st criterion”)

MDDS Guidance: Software Functions

- ***Software functions that are solely intended*** to transfer, store, convert formats, and display medical device data or results, **are now excluded from the device definition per the Cures Act and considered Non-Device-MDDS.**
  - These non-device software functions may or may not be intended for active patient monitoring.
  - Software functions intended to interpret or analyze clinical laboratory test or other device data, results, and findings are not considered MDDS and are not excluded from the device definition.

MDDS Guidance: Hardware

- ***Hardware products that are solely intended*** to transfer, store, convert formats, and display medical device data or results **are considered Device-MDDS, but FDA does not intend to enforce compliance with the regulatory controls** for such devices.
  - Provided that the hardware function is limited to assisting the following software functions: electronic transfer, storage, conversion of formats, or display of medical device data.
- ***Specialized medical display hardware devices***, e.g. for digital mammography, radiology, pathology, and ophthalmology **have NOT been considered Device-MDDS and are NOT excluded from the device definition by the Cures Act**.

MDDS Guidance: General Purpose Products

- ***Software functions and hardware products that are NOT intended by the manufacturer for a device function*** under 201(h) of the FD&C Act, e.g. general purpose hardware IT infrastructure intended for data transfer (e.g. network router), data storage (e.g. network storage (NAS)), conversion of data (e.g. PDF software), and display of data (computer monitor) **do not meet the definition of a device for either the software or hardware functions** and therefore are not regulated as devices.

Changes to MMA Guidance

- Where the previous guidance referred to “mobile application,” the new guidance refers to “software function.”
- Several examples from Appendix B (enforcement discretion) have been moved to Appendix A (not medical devices).
  - Including General Wellness, Electronic Patient Records, and MDDS functions.
- Examples in Appendix C (regulatory oversight) have been revised.

Changes to Off-the-Shelf Software Guidance

- Section 3.2.2 titled, “Exemption of Laboratory Information Management Systems,” has been removed from the guidance.
  - Section is specific to Laboratory Information Systems (LIS) and Laboratory Information Management Systems (LIMS).
- Some terminology and citations updated.

Medical Image Management Devices Guidance

- Guidance withdrawn because some software functions described in the guidance no longer meet the definition of a device, as amended.
  - For the limited subset of Medical Image Management Devices that continue to meet the definition of a device, CDRH encourages manufacturers to reference the most recent FDA-recognized versions of relevant voluntary consensus standards instead.

Stakeholder Feedback Requested

Stakeholder feedback requested on the revised Draft Guidance: Clinical Decision Support Software (https://www.fda.gov/regulatory-information/search-fda-guidance-documents/clinical-decision-support-software)

- In response to comments, FDA adopted risk-based approach to regulation of Device CDS informed by the International Medical Device Regulators Forum (IMDRF) Framework
- No longer proposing to use a separate category for Patient Decision Support Software
- Clarifying interpretation of Cures criteria for exclusion from device definition

Open for comment until December 26, 2019 at www.regulations.gov under docket number FDA-2017-D-6569

Resources

Guidance documents discussed in this webinar:

- Changes to Existing Medical Software Policies Resulting from Section 3060 of the 21st Century Cures Act
- Policy for Device Software Functions and Mobile Medical Applications *(originally titled Mobile Medical Applications)*
- General Wellness: Policy for Low Risk Devices
- Off-The-Shelf Software Use in Medical Devices
- Medical Device Data Systems, Medical Image Storage Devices, and Medical Image Communications Devices

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Questions?

For Digital Health questions: digitalhealth@fda.hhs.gov

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