Welcome to today's

FDA/CDRH Webinar

Thank you for your patience while we register all of today's participants.

If you have not connected to the audio portion of the webinar, please do so now:

Dial: 800-779-8169

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Passcode:**5038387**

Additional net login:
https://www.livemeeting.com/cc/events_vbc1/join?id=PW1374037 &role=attend&pw=5038387

Webinar Objective

- **Share CDRH's perspective and approach on Digital health guidance's**

- **Clarify Final MDDS guidance and the updated Final Mobile Medical Apps guidance**

- **Clarify our proposal in the Draft guidance and solicit public comments**

Digital Health

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Associate Director for Digital Health
Office of Center Director

Center for Devices and Radiological Health

Overview

CDRH's vision and approach	• a patient and innovation focused approach
Mobile apps	• a narrowly tailored and focused approach
MDDS guidance	• Promoting connectivity and interoperability
Draft guidance's	• Proposed approach for "General Wellness" and "Medical Device Accessories"

Vision

- **Patients** in the U.S. have **access** to high-quality, safe, and effective medical devices of public health importance first in the world.

- The U.S. is the world's leader in regulatory science, medical device **innovation** and manufacturing, and radiation-emitting product safety.

- U.S. post-market surveillance quickly identifies poorly performing devices, accurately characterizes real-world performance, and **facilitates** device approval or clearance.

- Devices are legally marketed in the U.S. and remain **safe, effective, and of high-quality.**

- Consumers, patients, their caregivers, and providers have **access to understandable science-based information** about medical devices and use this information to make health care decisions.

Oversight Approach

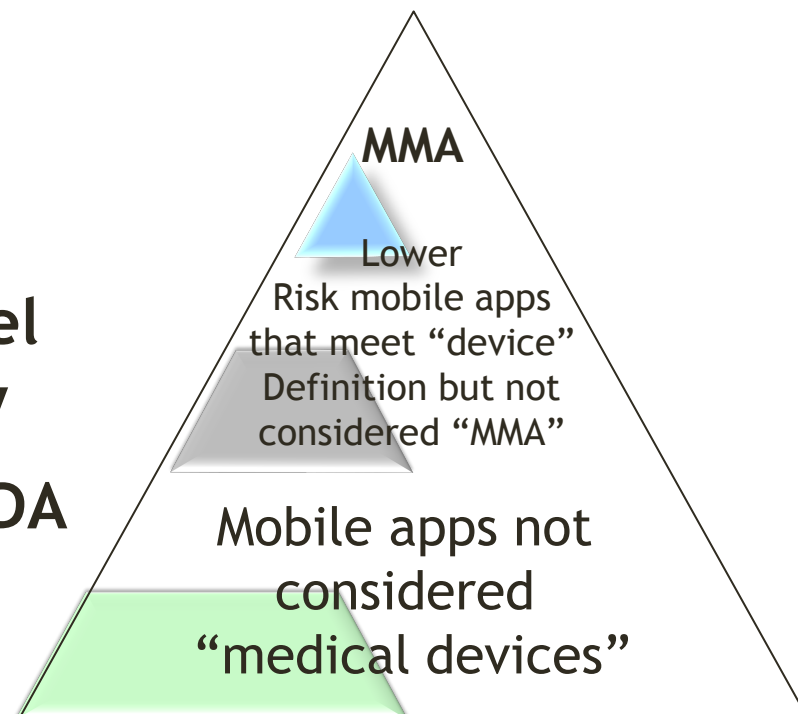|			
Platform independent	Promote innovation	Promote patient engagement	Protect patient safety

Functionality focused	Narrowly tailored

Risk based

Functionality Focused Oversight

- **Focuses only on traditionally regulated functionality**
  - Cleared, approved or otherwise regulated

- **Provides users with same level of assurance of patient safety**

- **Identifies type of apps that FDA does not intend to enforce requirements**

- **Clarifies what is not a device – (Outside of FDA's Jurisdiction)**

MMA

Lower Risk mobile apps that meet "device" Definition but not considered "MMA"

Mobile apps not considered "medical devices"

Mobile Medical Apps (MMA)

- Patient self-management apps
- Tools to organize and track their health information (not for treating or adjusting medications)
- Tools to access to health information document and communicate with health care providers
- Tools that automate simple health care providers tasks

Enforcement Discretion

focus of oversight

MMA

Lower risk mobile apps that meet "device" definition but not considered "MMA"

No regulatory requirements

Mobile apps not considered "medical devices"

Mobile apps that meet "device" definition that are either intended
- To be used as an accessory to already regulated medical device, **or**
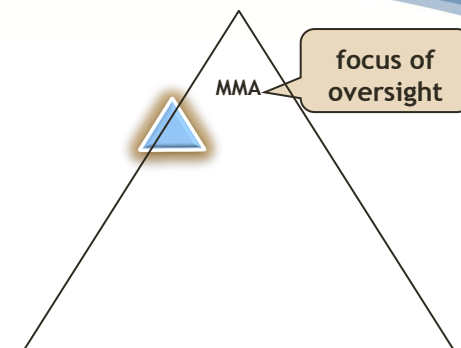- To transform a mobile platform into a regulated medical device.

02/24/2015

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Mobile medical apps (MMA)

focus of oversight

MMA

"mobile medical app" is a mobile app that meets the definition of device in section 201(h) of the Federal Food, Drug, and Cosmetic Act (FD&C Act) ; and either is intended:

–   to be used as an accessory to a regulated medical device; **or**

–   to transform a mobile platform into a regulated medical device

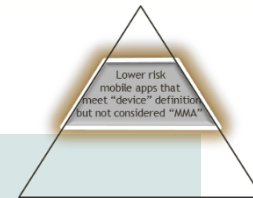*Examples in Section V-A + Appendix C*

Mobile Medical Apps

1. Mobile apps that are an extension of one or more medical devices by connecting to such device(s) for purposes of controlling the device(s) or displaying, storing, analyzing, or transmitting patient-specific medical device data.

2. Mobile apps that transform the mobile platform into a regulated medical device by using attachments, display screens, or sensors or by including functionalities similar to those of currently regulated medical devices.

3. Mobile apps that become a regulated medical device (software) by performing patient-specific analysis and providing patient-specific diagnosis, or treatment recommendations.

Mobile Apps –(not considered MMA)
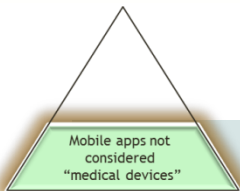
Mobile apps – NOT Medical Devices	Mobile apps – NOT Focus of Oversight
• Library of clinical descriptions • Medical flash cards • Certification or recertification preparation apps; • Games to train health professionals in advanced CPR skills. • Allow users to input pill shape, color or imprint and displays pictures and names of pills that match this description; • Find the closest medical facilities; • Help guide patients to ask appropriate questions to their physician • Track, review and pay medical claims and bills online; • Manage or schedule hospital rooms or bed space	• Help patients (i.e., users) self-manage their disease or conditions without providing specific treatment or treatment suggestions; • Provide patients with simple tools to organize and track their health information; • Provide easy access to information related to patients' health conditions or treatments; • Help patients document, show, or communicate potential medical conditions to health care providers; • Automate simple tasks for health care providers; or • Enable patients or providers to interact with Personal Health Record (PHR) or Electronic Health Record (EHR) systems.

FDASIA Health IT Report

Public and workgroup feedback

- *Agencies should address ambiguities*

- *Agencies should reevaluate current regulation*

Proposed further Clarity on

- **Distinction between wellness and disease-related claims**

- **Medical device accessories**

April 2014

FDASIA Health IT Report

Proposed Strategy and Recommendations for a Risk-Based Framework

FDA   FCC   The Office of the National Coordinator for Health Information Technology

U.S. Food and Drug Administration
Protecting and Promoting Public Health

Final MDDS Rule
(§ 21 CFR 880.6310) Feb 15, 2011

... intended to provide one or more of the following uses, without controlling or altering the functions or parameters of any connected medical devices:

 (i) The electronic transfer of medical device data;

 (ii) The electronic storage of medical device data;

 (iii) The electronic conversion of medical device data from one format to another format in accordance with a preset specification; or

 (iv) The electronic display of medical device data.

- Does not include devices intended to be used in connection with active patient monitoring.

Federal Register / Vol. 76, No. 31 -- *http://www.gpo.gov/fdsys/pkg/FR-2011-02-15/pdf/2011-3321.pdf*

Revaluating Current Regulations

- **MDDS and medical Image storage and communication device**
  - Generally were considered lower risk - class I
  - Systems that record, share, and use of medical device data have become a significant in a connected healthcare system
  - These inter-communication functionality is foundational in an interoperable digital health ecosystem.

- **Proposed draft guidance (June 2014) intended to**
  - Provide continued clarity in Digital Health
  - Narrowly focus on higher risk products
  - Create and impetus for devices to share data and ultimately become interoperable with other systems

Public feedback

- **Majority of the comments indicated the following:**
  - Supported the deregulatory policy for MDDS
  - Suggested specific edits to the language to clarify
  - Asked to clarifying the exclusion criteria of "active patient monitoring" that would make products to be NOT considered MDDS
  - Asked to supplement the final guidance with permanent regulations

- **In response to the feedback - the final guidance :**
  - Maintains the proposed policy without any changes
  - Added additional language in the background section from the published final MDDS rule –
    - added definition of the MDDS from the published rule
    - Added clarifying language, primarily from the preamble of the MDDS rule related "active patient monitoring"
  - Made the edits as proposed to MMA guidance to reflect MDDS policy

MDDS Final Guidance (Feb 9, 2015)

The FDA does not intend to enforce compliance with the regulatory controls that apply to the following devices:

- MDDS subject to 21 CFR 880.6310,

- Medical image storage devices subject to 21 CFR 892.2010, and

- Medical image communications devices subject to 21 CFR 892.2020.

MDDS does not include --

A. Products that are intended for active patient monitoring i.e.

  – clinical context requires a timely response

  – The clinical condition (disease or diagnosis) requires a timely response

B. Modifies the medical device data, and

C. Control the functions or parameters of any connected medical device.

U.S. Food and Drug Administration
Protecting and Promoting Public Health

Updated MMA Guidance
(notable changes) (Feb 9, 2015)

Mobile Medical Apps	Mobile apps under enforcement Discretion

Further narrows apps defined as MMA …

- Mobile apps that are an extension of one or more medical devices by connecting to such device(s) for purposes of controlling the device(s) *or for use in active patient monitoring* or ~~displaying, storing,~~ analyzing~~, or transmitting patient-specific~~ medical device data.

Includes

- MDDS -- Intended to transfer, store, convert format, and display medical device data in its original format from a medical device (as defined by MDDS regulation 880.6310 OUG).

- Examples previously added to website

Addressing evolving Mobile apps landscape

- **Web page for mobile medical apps**
  - http://www.fda.gov/MedicalDevices/ProductsandMedicalProcedures/ConnectedHealth/MobileMedicalApplications/default.htm

- **FDA, on this website intends to have a list of**
  - example types that we intend to exercise enforcement discretion, regulate or have considered not devices.

- **Provide internal coordination to maintain consistent policy decisions related to mobile medical apps**

- **Questions related to mobile medical apps –**
  MobileMedicalApps@fda.hhs.gov

Draft General Wellness guidance – Policy for Low Risk devices

PROPOSES A POLICY THAT

- Does not intend to examine low risk general wellness products to determine whether they are "devices" within the meaning of the FD&C Act, or

- If they are "devices", FDA does not intend to enforce compliance to regulatory requirements for devices under the FD&C Act

PRODUCTS COVERED UNDER THE PROPOSED POLICY

A. Products intended for <u>only</u> general wellness use, **and**

B. Products inherently present a very low risk to users' safety.

❑ **PRODUCTS INTENDED FOR GENERAL WELLNESS USE CAN BE MARKETED**
  - ❑ without any reference to diseases or conditions, or
  - ❑ with a disease-related general wellness claims that contain references where it is well understood that healthy lifestyle choices may reduce the risk or impact of a chronic disease or medical condition.

Draft Accessories guidance

DEFINES "ACCESSORIES" NARROWLY --

- **Accessory:** A device that is intended to support, supplement, and/or augment the performance of one or more parent devices.

- **Parent Device:** A finished device whose performance is supported, supplemented, and/or augmented by one or more accessories.

PROPOSES A POLICY THAT

- Classification of accessories will be similar to the risk-based classification that FDA applies to all medical devices, and
  - Risk of an accessory are the risks that it presents when used with the corresponding parent device as intended

- Allows for a de novo submission requesting FDA to make a classification determination for new accessory types.

In Summary

Digital Health

- Beneficial to drive better health outcomes

- Enables patients empowerment

- Enables efficient health care – processes and decisions

FDA's Policies Drive Towards...

- Promoting patient engagement technologies

- Providing regulatory clarity by using focused regulatory oversight

- Understanding and addressing stakeholder needs and expectations

Questions on Draft Guidance?

Division of Industry and Consumer Education:
DICE@fda.hhs.gov

Slide Presentation, Transcript and Webinar Recording will be available at:

www.fda.gov/CDRHWebinar under the "Past Webinars and Stakeholder Calls-2015" tab.