11-12 MAY 2015 INTERNATIONAL EXHIBITION CENTRE KIPSALA RIGA, LATVIA

mHEALTH SUMMIT | EUROPE
TECHNOLOGY + BUSINESS + RESEARCH + POLICY

IN CONJUNCTION WITH
eHealth week

FROM GARAGE TO MARKET:

US REGULATION OF mHEALTH: FDA, HIPAA AND BEYOND

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Presented by

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Agenda

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1. FDA Regulation of mHealth
2. HIPAA and Beyond

Agenda

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1. FDA Regulation of mHealth
   i. FDA Basics
   ii. What is Regulated and What's Not?
   iii. Clinical Decision Support and the Practice of Medicine
   iv. Hypotheticals
2. HIPAA and Beyond

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FDA Basics

Device Definition

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- Section 201(h) of the Federal Food, Drug, and Cosmetic Act, defines a medical device as:
  - "... an instrument, apparatus, implement, machine, contrivance, implant, in vitro reagent, or other similar or related article, including any component, part, or accessory, which is ... [either]
    - intended for use in the diagnosis of disease or other conditions, or in the cure, mitigation, treatment, or prevention of disease, in man or other animals ... [or]
    - intended to affect the structure or any function of the body of man or other animals."

Intended Use
WHAT DO WE LOOK AT

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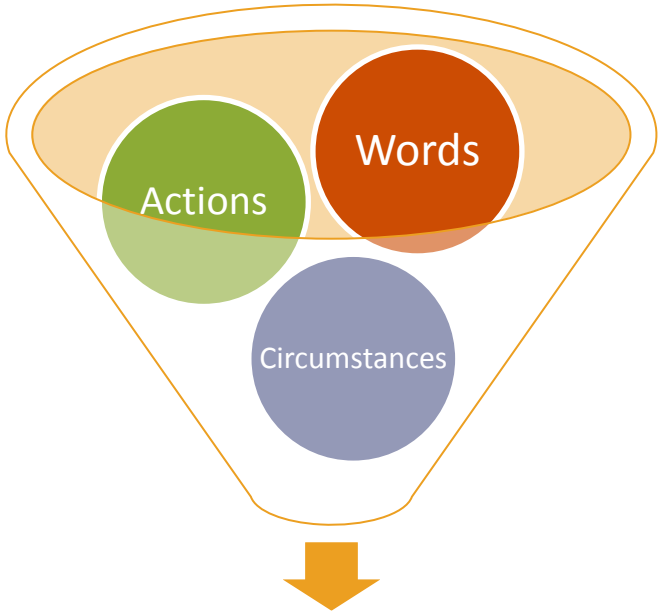

Intended Use
IS THIS A DEVICE?

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FDA: What is Regulated and What's Not?

mHealth
FDA 2014-2015

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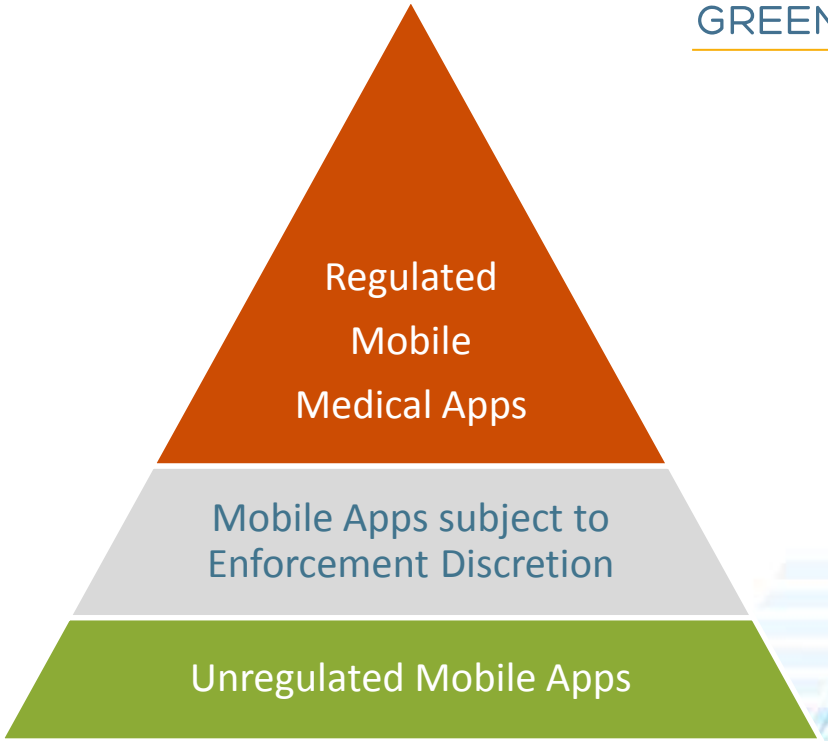
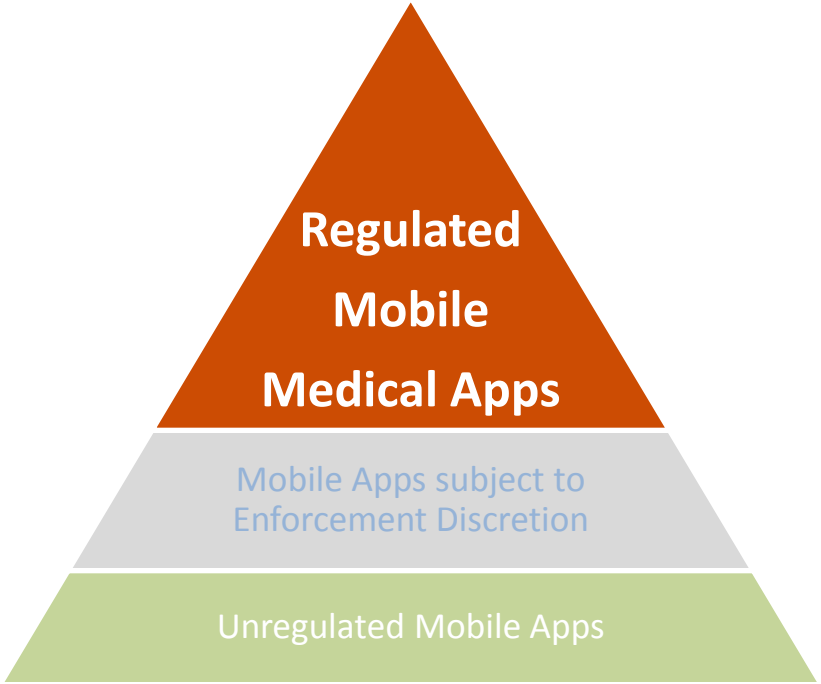
- Risk-Based Approach
- Mobile Medical App Guidance
- FDASIA Report
- MDDS Guidance
- 510(K) Exempt Devices Draft Guidance
- Wellness Draft Guidance
- Accessory Draft Guidance
- Clinical Decision Support*



*FDA priority for 2015

mHealth
WHAT IS REGULATED



- Meets definition of Medical Device
- Accessories to a medical device
- Analyze patient-specific medical device data (some CDS)
- Transform platform into a medical device

Examples of Regulated mHealth

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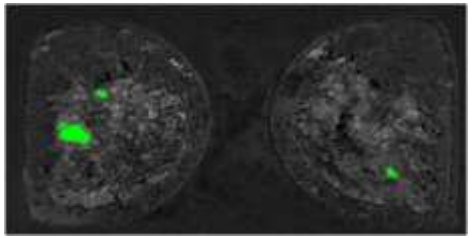
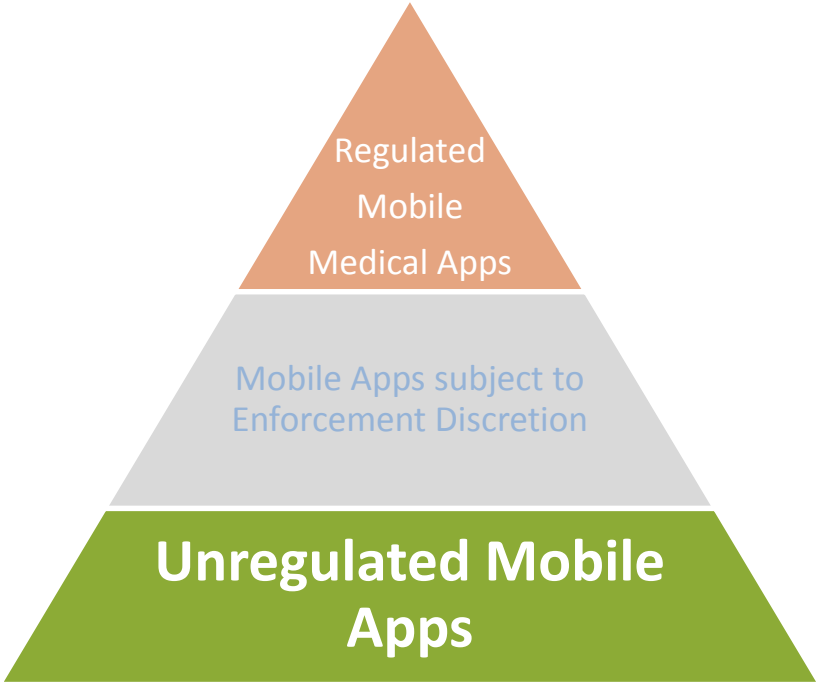


mHealth
WHAT IS NOT REGULATED



- General purpose IT
- Educational tools, medical textbooks
- Facilitate patient access to information
- Administrative products
- Health Management Health IT (Draft FDASIA Report)
- Health and Wellness

Wellness Draft Guidance*

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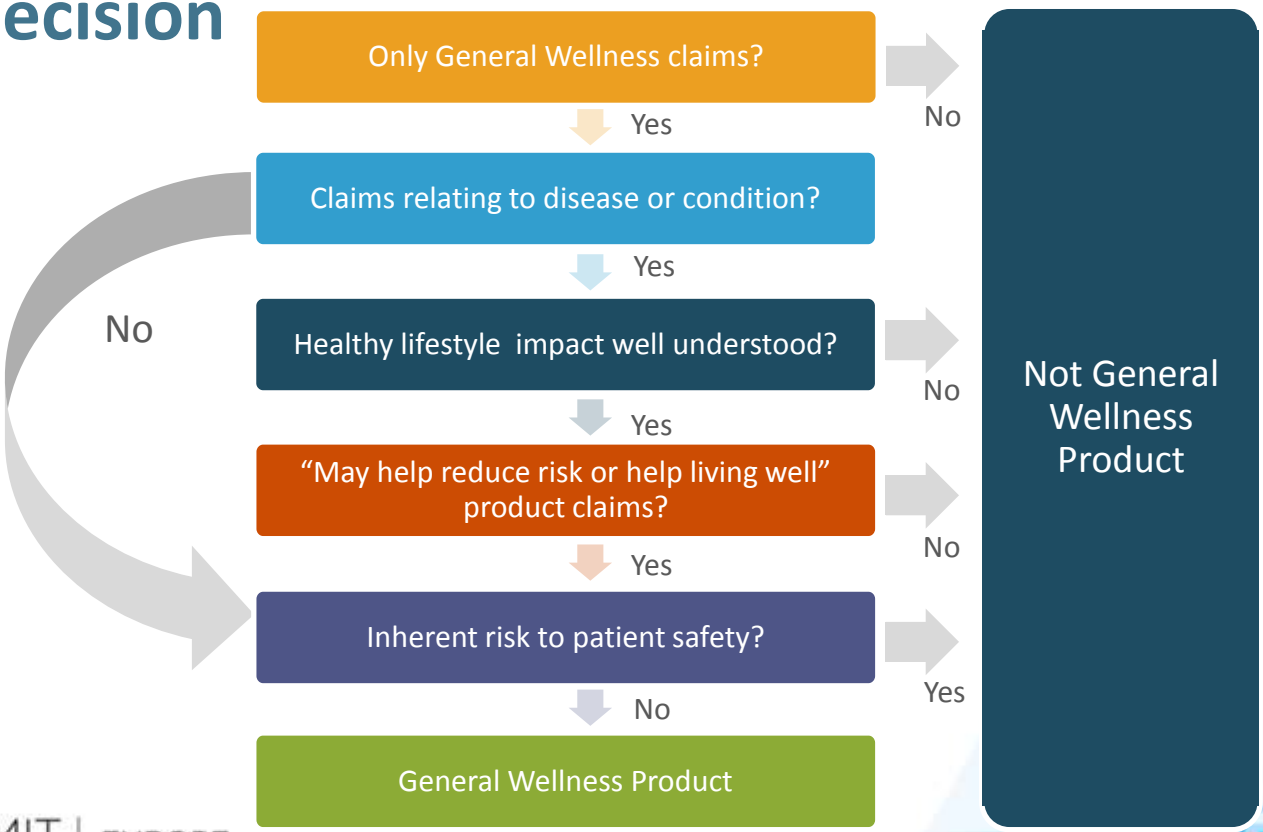
- Unregulated or Enforcement Discretion Wellness Products
  - Intended only for general wellness use
  - Low patient safety risk
- General Wellness Defined
  - Relates to maintaining or encouraging health/healthy activity
  - Associates healthy lifestyle with helping reduce risk or impact of chronic disease or condition where well-established scientifically
- Applies only to CDRH
- Inclusion in guidance does not mean it is safe and effective; still subject to Consumer Product Safety Commission

*Draft guidance released 1/16/2015

Wellness Decision Tree



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Wellness Claims Examples

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General Wellness Claims	Regulated Claims
• Claims to promote or maintain a healthy weight, encourage healthy eating, or assist with weight loss goals; • Claims to promote relaxation, boost self esteem or manage stress - no reference to anxiety disorders or disease or condition; • Claims to improve mental acuity, instruction following, concentration, problem-solving, multitasking, management, decision-making, logic, pattern recognition or eye-hand coordination; • Claims to promote physical fitness, help log, track, or trend exercise, measure aerobic fitness, improve physical fitness, develop or improve endurance, strength or coordination, or improve energy; • Claims to promote sleep management, such as to track sleep trends;	• A claim that a product will treat or diagnose obesity; • A claim that a product will treat an eating disorder, such as anorexia; • A claim that a product helps treat anxiety; • A claim that a computer game will diagnose or treat autism; • A claim that a product will treat muscle atrophy or erectile dysfunction; • A claim to restore a structure or function impaired due to a disease, e.g., a claim that a prosthetic device enables amputees to play basketball.

Examples of Unregulated mHealth

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mHealth
THE GRAY AREA: ENFORCEMENT DISCRETION

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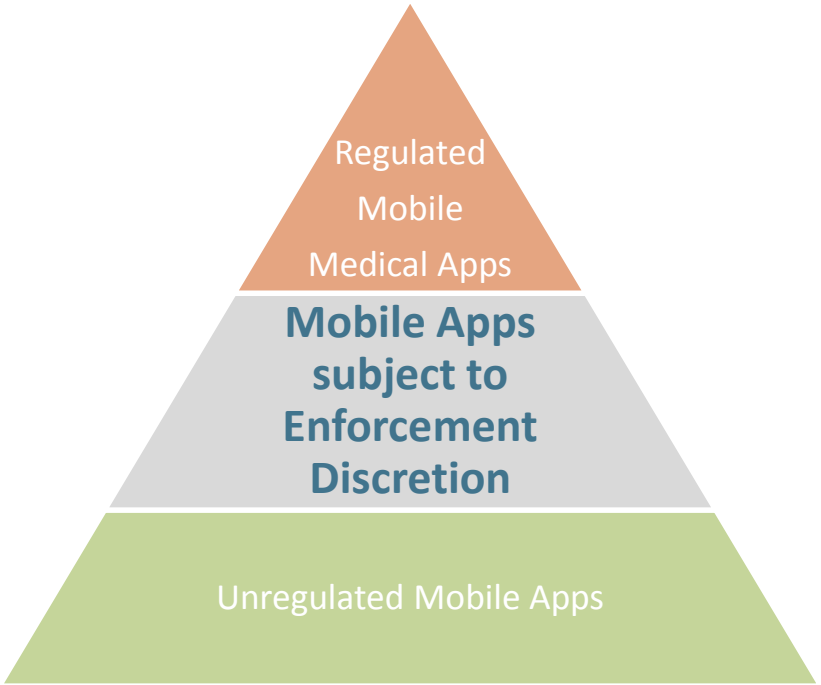

- Electronic Health Records
- Patient Portals
- Trending, tracking and sharing data with healthcare providers
- Coaching app – support change in daily environment
- Medication Reminders
- Certain Telemedicine products
- Low Risk CDS
- Medical Device Data Systems

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What is Enforcement Discretion?

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- Informal policy to not require low risk devices to comply with regulatory requirements
  - recommend quality system - sometimes
- Not permanent
  - but changes likely to occur in response to safety issues or other developments and
  - subject to prior public notice to industry

Enforcement Discretion Examples

MEDICAL DEVICE DATA SYSTEM (MDDS)

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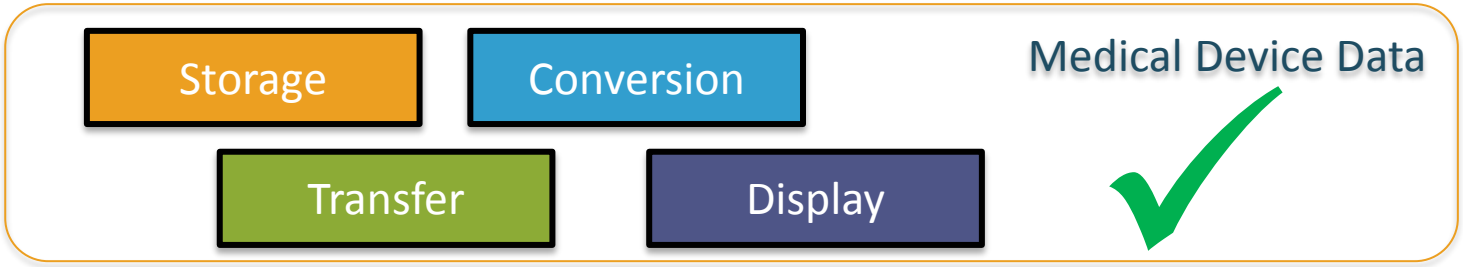

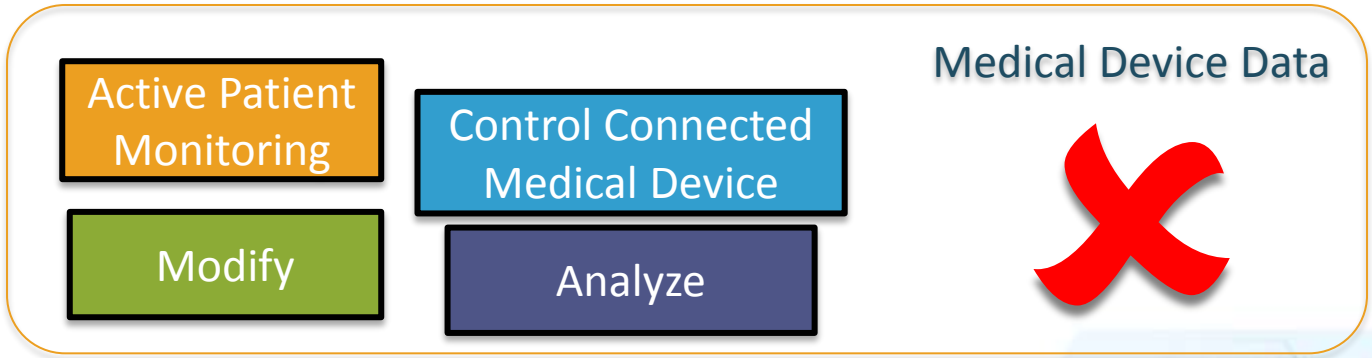

Not active patient monitoring or controlling a device

MDDS
ACTIVE PATIENT MONITORING

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ACTIVE MONITORING	NOT ACTIVE MONITORING
▪ A nurse telemetry station that receives and displays information from a bedside hospital monitor in an ICU. ▪ A device that receives and/or displays information, alarms, or alerts from a monitoring device in a home setting and is intended to alert a caregiver to take an immediate clinical action.	▪ An application that transmits a child's temperature to a parent/guardian while the child is in the nurse/health room of a school. ▪ An application that facilitates the remote display of information from a blood glucose meter, where the user of the meter can independently review their glucose and glucose levels, and which is not intended to be used for taking immediate clinical action

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Clinical Decision Support

What Do We Know About CDS?

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Contains Nonbinding Recommendations

Mobile Medical Applications

Guidance for Industry and Food and Drug Administration Staff

Document issued on: September 25, 2013

The draft of this guidance was issued on July 21, 2011.

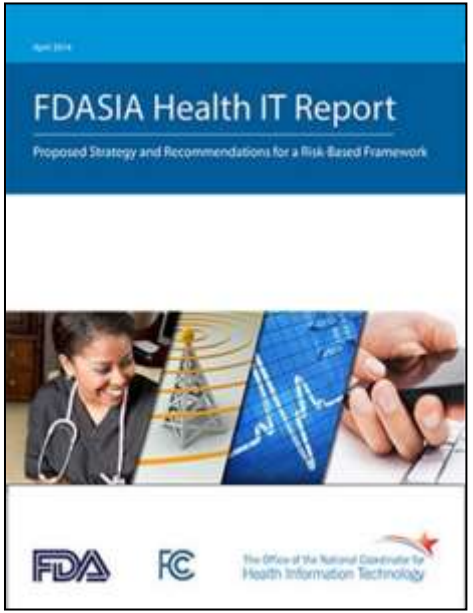
For questions regarding this document, contact Bakul Patel at 301-796-5528 or by electronic mail at Bakul.Patel@fda.hhs.gov. For questions regarding this document concerning devices regulated by CBER, contact the Office of Communication, Outreach and Development (OCOD), by calling 1-800-835-4709 or 301-827-1800.

CDRH | CBER

U.S. Department of Health and Human Services
Food and Drug Administration

Center for Devices and Radiological Health

Center for Biologics Evaluation and Research



IMDRF International Medical Device Regulators Forum

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Clinical Decision Support

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Information

- Data from a medical device
- Environmental data (e.g., pollen count, temp.)
- Demographic data (e.g., age, sex, socio-economic status)

Conversion

- Algorithms (fixed or iterative)
- Formulae
- Database look-ups or comparisons
- Rules or associations

Clinical Decision

- Patient-specific
- Actionable result

The Challenge of CDS

WHERE'S LINE BETWEEN …

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- Regulated Medical Device vs. Practice of Medicine
- Decision Support vs. Workflow Automation
- Active Monitoring vs. Telemedicine
- Time Sensitive Care vs. Real - Time Data Sharing
- Treatment vs. Care Coordination vs. Population Health

Other CDS: Draft FDASIA Report Proposal

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Not FDA Regulated

- Evidence-based clinician order sets tailored for a particular condition, disease, or clinician preference;
- Most drug dosing calculations; Drug formulary guidelines;
- Reminders for preventative care
- Calculation of prediction rules and severity of illness assessments (e.g., APACHE score, AHRQ Pneumonia Severity Index, Charlson Index);
- Duplicate testing alerts;
- Suggestions for possible diagnoses based on patient-specific information retrieved from a patient's EHR.

FDA Regulated

- Computer aided detection/diagnostic software;
- Remote display or notification of real-time alarms (physiological, technical, advisory) from bedside monitors;
- Radiation treatment planning;
- Robotic surgical planning and control;
- Electrocardiography analytical software.

Clinical Decision Support is Regulated Today

TRADITIONAL FACTORS CONSIDERED

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Competent Human Intervention

New Capabilities or Intended Uses

Transparency

Individualized Patient Care Recommendations

Time to reflect

Display, create, sound alarm or detect alarm conditions

How the Software Contributes to the User's Decision-Making

Real Time, Active, or Online Patient Monitoring Functions

Output is Provided or Manipulated in a novel or Non-Traditional Manner

CLINICAL DECISION SUPPORT

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Hypotheticals

Smartwatch with a HR Monitor

www.heavy.com

- Description of the device:
  - The smartwatch includes sensors capable of measuring the wearer's heart rate
- Intended use:
  - To be used by athletes to capture heart rate and can be paired with an app that can help the user calculate in and out of target ranges and track measurements over time as part of training program. Data can be shared by user.
  - Can be paired with an app that uses the wearer's heart rate to monitor and provide feedback about the user's level of stress and provides suggestions on managing stress.
  - Can be paired with an app called "Coming Back from That Heart Attack" which is otherwise identical to the app described in the first bullet.
    - The app is updated and now provides articles on recovering from a heart attack.
    - A feature is added to this app which will allow it to alert the wearer and/or the wearer's doctor in the event the wearer's heart rate is out of the target range for more than a set period of time.

Diabetes Tracking App

- Description of the device:
  - App allows users to enter their blood glucose data.
  - App can read QR codes for food labels, provide carb count, meal options and recipes.
- Intended use:
  - To help individuals with diabetes maintain a healthy life style:
    - by allowing users to track their blood glucose, food intake and exercise
    - by providing reminders at pre-set times regarding blood glucose readings
  - To help individuals with diabetes calculate the amount of insulin to be administered based on:
    - Food intake
    - Individualized correction factors including blood glucose measurements, weight and target blood glucose levels

www.diabeticnerd.com

apps.structiva.com

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HIPAA and Beyond

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Overview

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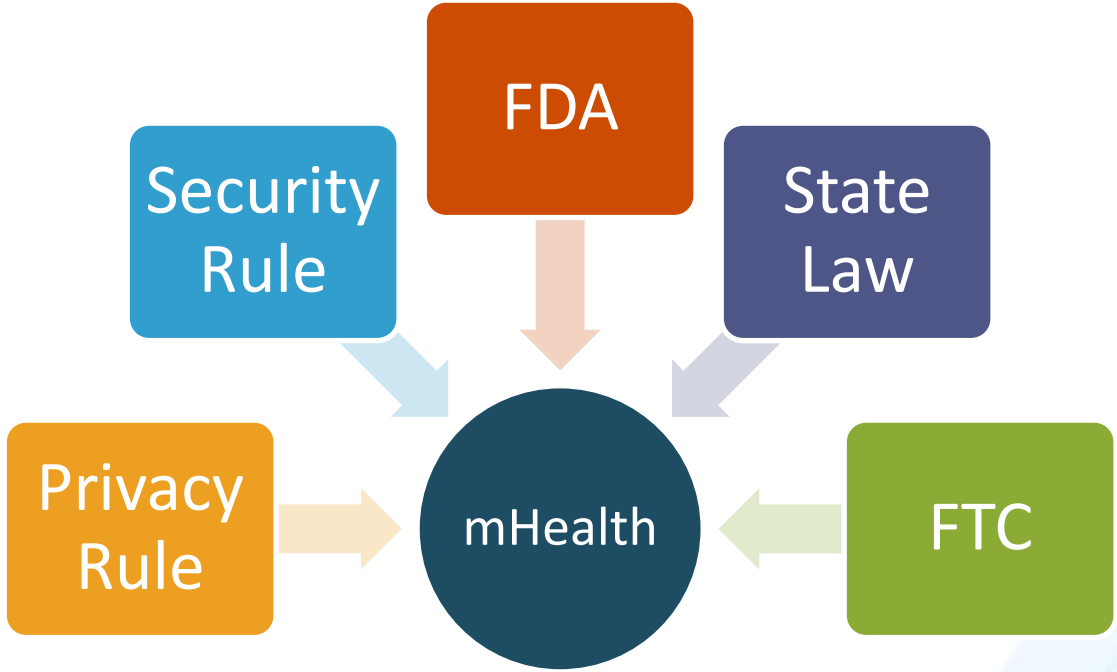

Take Away

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Applicability
- Multiple Regulatory Frameworks Apply

Risk
- Cybersecurity is Real Risk for Device/Health Industry

Be Ready
- Compliance and IT/Development No Longer Separate

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