



Introduction to Medical Device Law and Regulation

Allison Fulton

Partner | Sheppard Mullin Richter & Hampton, LLP
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The background features a network of light blue circular nodes connected by thin lines. Each node contains a medical icon: a smartphone with a pulse line, a shield with a cross, a first aid kit, a stethoscope, a pill, a laptop with a cross, a heart with an ECG line, surgical instruments, an ambulance, a clipboard, and a robot. The central node is a smartphone with a pulse line.

What does "Digital Health" mean?

What is Digital Health?



Telehealth
platforms



Digital
therapeutics



Medical devices,
including software



Mobile health
applications



Wearables



Remote patient
monitoring



Electronic health
record platforms

Definition, Carve-Outs from 21st Century Cures Act

- Administrative support software for healthcare facilities
- Electronic health records (EHRs)
- Wellness apps and software
- Medical Device Data System (MDDS)
- Software with multiple functions
- Clinical Decision Support (CDS)



Wellness, Defined.

Wellness Products:

1. are intended for only general wellness use, and
2. present a low risk to the safety of users and other persons



Wellness Examples

A software function that plays music to “soothe and relax” an individual (e.g., during hiking) is not a device. A portable product that monitors the pulse rate of users during exercise and hiking is not a device. A portable product that monitors electrical signals produced by the heart (e.g., ECG) to detect a-fib is a device.

Device

A portable product that monitors electrical signals produced by the heart (e.g., ECG) to detect a-fib.

Enforcement Discretion

A portable product that monitors the pulse rate of users during exercise and hiking.

Not a Device

A software function plays music to “soothe and relax” an individual and to “manage stress.”

More Wellness Examples

An app that monitors and records daily energy expenditure and cardiovascular workout activities to improve or maintain good cardiovascular health.

Device

If the product is intended to exfoliate the skin in order to enhance the delivery of a topically applied product containing one or more active pharmaceutical ingredients . . .

Enforcement Discretion

If the product cannot be used in a manner that penetrates or pierces the skin . . .

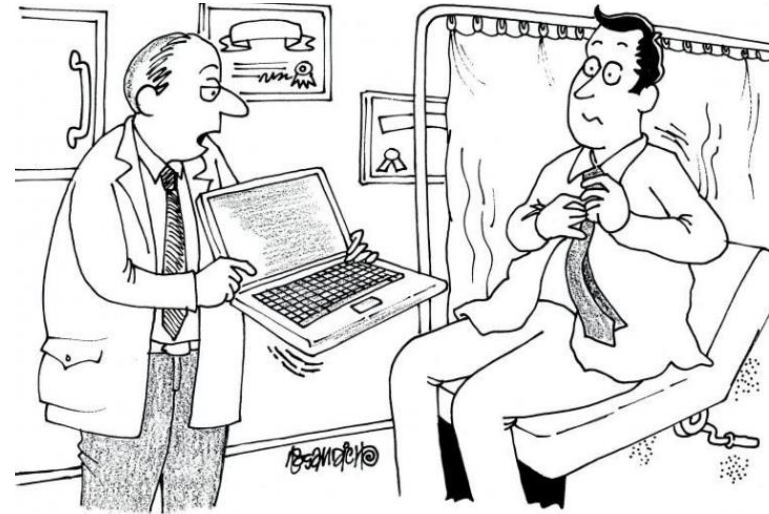
It Depends...

Not a Device

An app that monitors and records daily energy expenditure and cardiovascular workout activities to improve cardiovascular health.

What is Clinical Decision Support (CDS)?

- Software that accesses data (e.g., clinical guidelines, EHRs) and provides clinicians, staff, or patients with intelligently filtered information to enhance health and health care
- Examples
 - A website that asks your symptoms, then provides possible conditions (e.g., cold)
 - Algorithm that analyzes a patient's scan and detects markers/evidence of breast cancer
 - A smartphone app that analyzes a picture of a skin abnormality and provides possible conditions (e.g., Eczema, carcinoma)



"If you want a second opinion, I'll ask my computer."

When is CDS NOT a device?

Your software function must meet all four criteria to be Non-Device CDS.

Summary interpretation
of CDS criteria

1. Your software function does **NOT** acquire, process, or analyze medical images, signals, or patterns.

2. Your software function displays, analyzes, or prints medical information normally communicated between health care professionals (HCPs).

3. Your software function provides recommendations (information/options) to a HCP rather than provide a specific output or directive.

4. Your software function provides the basis of the recommendations so that the HCP does not rely primarily on any recommendations to make a decision.

Your software function may be non-device CDS.

Non-Device
Examples

Non-Device examples display, analyze, or print the following examples of medical information, which must also not be images, signals, or patterns:

- Information whose relevance to a clinical decision is well understood
- A single discrete test result that is clinically meaningful
- Report from imaging study

AND

Non-Device examples provide:

- Lists of preventive, diagnostic, or treatment options
- Clinical guidelines matched to patient-specific medical info
- Relevant reference information about a disease or condition

AND

Non-Device examples provide:

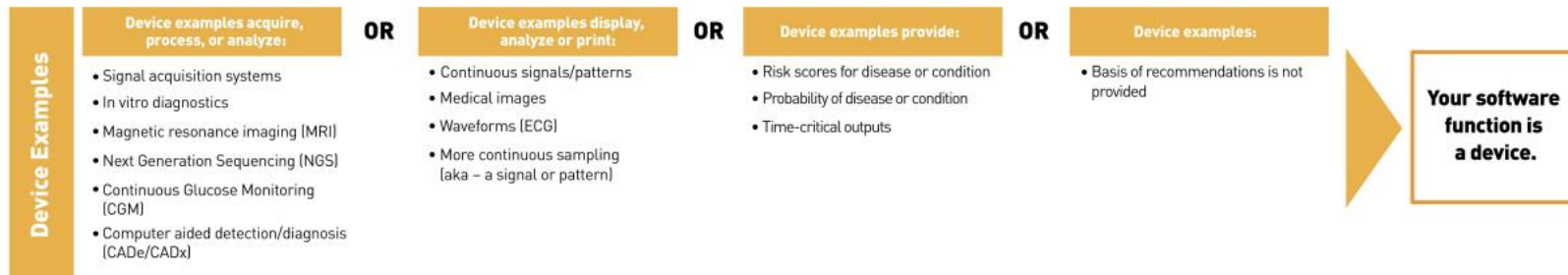
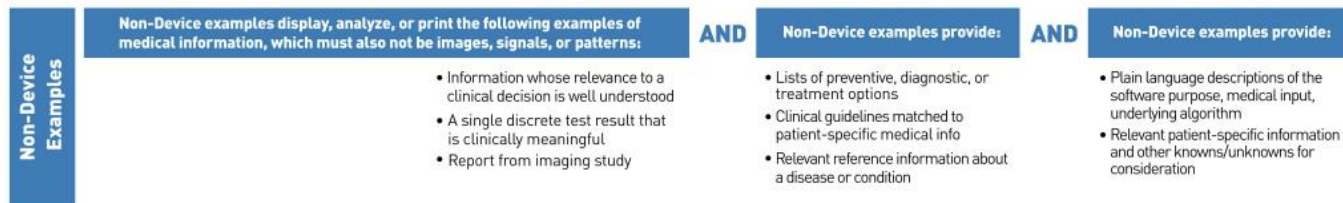
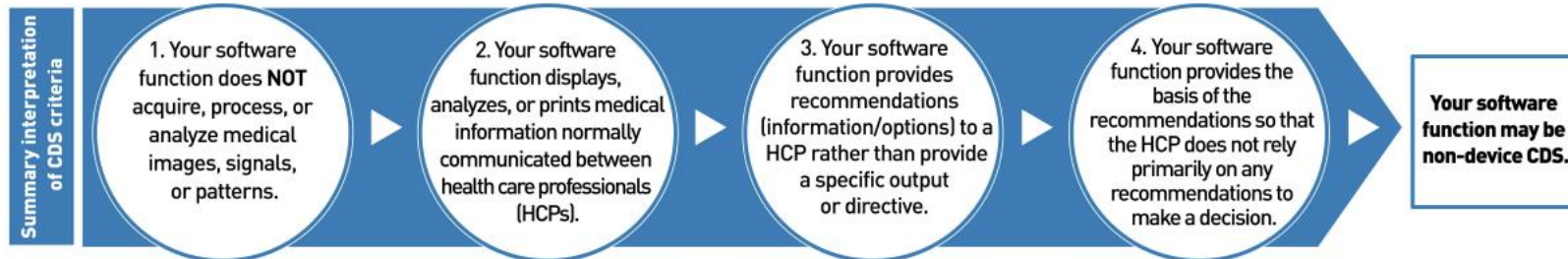
- Plain language descriptions of the software purpose, medical input, underlying algorithm
- Relevant patient-specific information and other knowns/unknowns for consideration

“Non-Device” CDS Examples

- ✓ Software that gives HCPs reminders for preventive care (e.g., breast cancer screening) for a patient based on practice guidelines and using medical information in the patient’s medical record
- ✓ Software that generates list of cholesterol-lowering drugs for HCPs to consider, based on a patient’s cholesterol levels and demographics found in the patient’s EHR.
- ✓ Software that provides HCPs with available treatment options for heart failure patients based on their disease stage and clinical guidelines

When is CDS a device?

Your software function must meet all four criteria to be Non-Device CDS.



“Device” CDS Examples

- ✓ Software function that analyzes sound waves captured when users cough or recite certain sentences to diagnose bronchitis or sinus infection.
- ✓ Software function that identifies patients with possible diagnosis of opioid addiction based on analysis of patient-specific medical information, family history, prescription patterns, and geographical data.
- ✓ Software function that analyzes signals from a trans-abdominal electromyography device, a fetal heart rate monitor, and an intrauterine pressure catheter to determine timing of a C-section intervention for an “at term” pregnant woman.

Software that uses a COPD patient's age and average perspiration rate (e.g., heart rate, eye movement, breathing rate) from wearable products for the HCP to consider (e.g., office visit, spirometry) to evaluate disease progression.

Device

Software function that uses a patient's image sets (e.g., CT, magnetic resonance (MR)) to create an individual treatment plan for review by an HCP for patients undergoing radiation therapy treatment.

Device

Software function that analyzes multiple signals (e.g., perspiration rate, heart rate, eye movement, breathing rate) from wearable products to monitor whether a person is having a heart attack or narcolepsy episode.

Not a Device

Software that analyzes a COPD patient's age and average number of steps walked per day in order to provide a list of follow-up options for the HCP to consider (e.g., office visit, chest CT, spirometry) to evaluate disease progression.

If the Digital Health Product is a Device ...

Establishment registration & device listing

Premarket notification or approval

Quality System Regulation / cGMP

Labeling

Medical device reporting (MDR) & recalls

Innovative Issues in Digital Health



Artificial Intelligence/Machine Learning (AI/ML)-Based Software as a Medical Device (SaMD) Action Plan

January 2021



Good Machine Learning Practice for Medical Device Development:

Guiding Principles

October 2021

The U.S. Food and Drug Administration (FDA), Health Canada, and the United Kingdom's Medicines and Healthcare products Regulatory Agency (MHRA) have jointly identified 10 guiding principles that can inform the development of Good Machine Learning Practice (GMLP). These guiding principles will help promote safe, effective, and high-quality medical devices that use artificial intelligence and machine learning (AI/ML).

Artificial intelligence and machine learning technologies have the potential to transform health care by providing new and important insights from the vast amount of data generated during the delivery of health care. They use software algorithms to learn from real-world use and in some situations may use this information to improve the product's performance. But they also present unique considerations due to their complex, iterative and data-driven nature of their development.

These 10 guiding principles are intended to lay the foundation for developing Good Machine Learning Practice that addresses the unique nature of these products. They will also help cultivate future growth in this rapidly progressing field.

The 10 guiding principles identify areas where the International Medical Device Regulators Forum (IMDRF), international standards organizations, and other collaborative bodies could work to advance GMLP. Areas of collaboration include research, creating educational tools and resources, international harmonization, and consensus standards, which may help inform regulatory policies and regulatory guidelines.

We envision these guiding principles may be used to:

Good Machine Learning Practice for Medical Device Development Guiding Principles	
Multi-Disciplinary Expertise Is Leveraged Throughout the Total Product Life Cycle	Good Software Engineering and Practices Are Implemented
Clinical Study Participants and Data Sets Are Representative of the Intended Patient Population	Training Data Sets Are Independent
Selected Reference Datasets Are Based Upon Best Available Methods	Model Design Is Tailored to the Intended Use of the Device
Focus Is Placed on the Performance of the Human-AI Team	Testing Demonstrates Device Performance During Clinically Relevant Conditions
Users Are Provided Clear, Essential Information	Deployed Models Are Monitored for Performance and Re-trained As Needed

The Software Precertification (Pre-Cert) Pilot Program: Tailored Total Product Lifecycle Approaches and Key Findings

September 2022



The Software Precertification (Pre-Cert) Pilot Program Report

Questions?



Allison Fulton

Partner

Washington DC

202.7472195

afulton@sheppardmullin.com