Introduction to Medical Device Law and Regulation

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FDLI

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

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

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

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

More Wellness Examples

An product that mechanically exfoliates the face, hands and feet to make the skin smoother and softer.

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 . . .

It Depends…

Enforcement Discretion

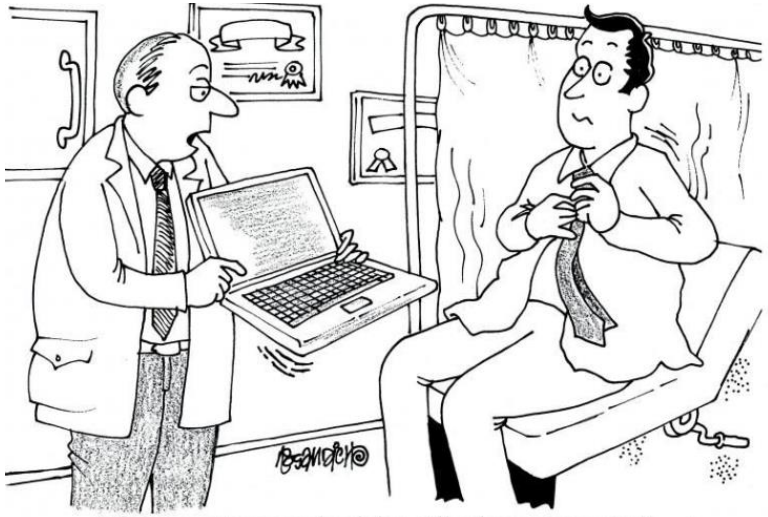
If the product cannot be used in a manner that penetrates or pierces the skin . . .

Not a Device

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

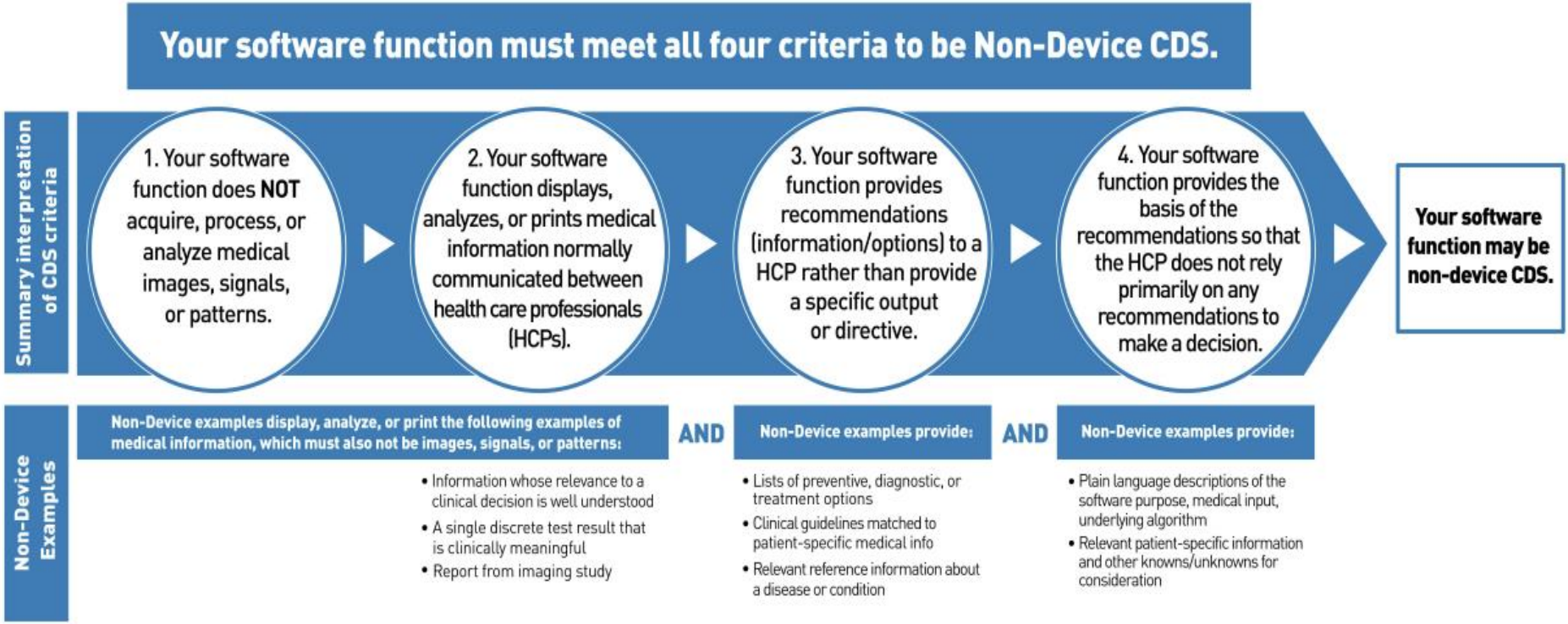
What is Clinical Decision Support (CDS)?

- 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."

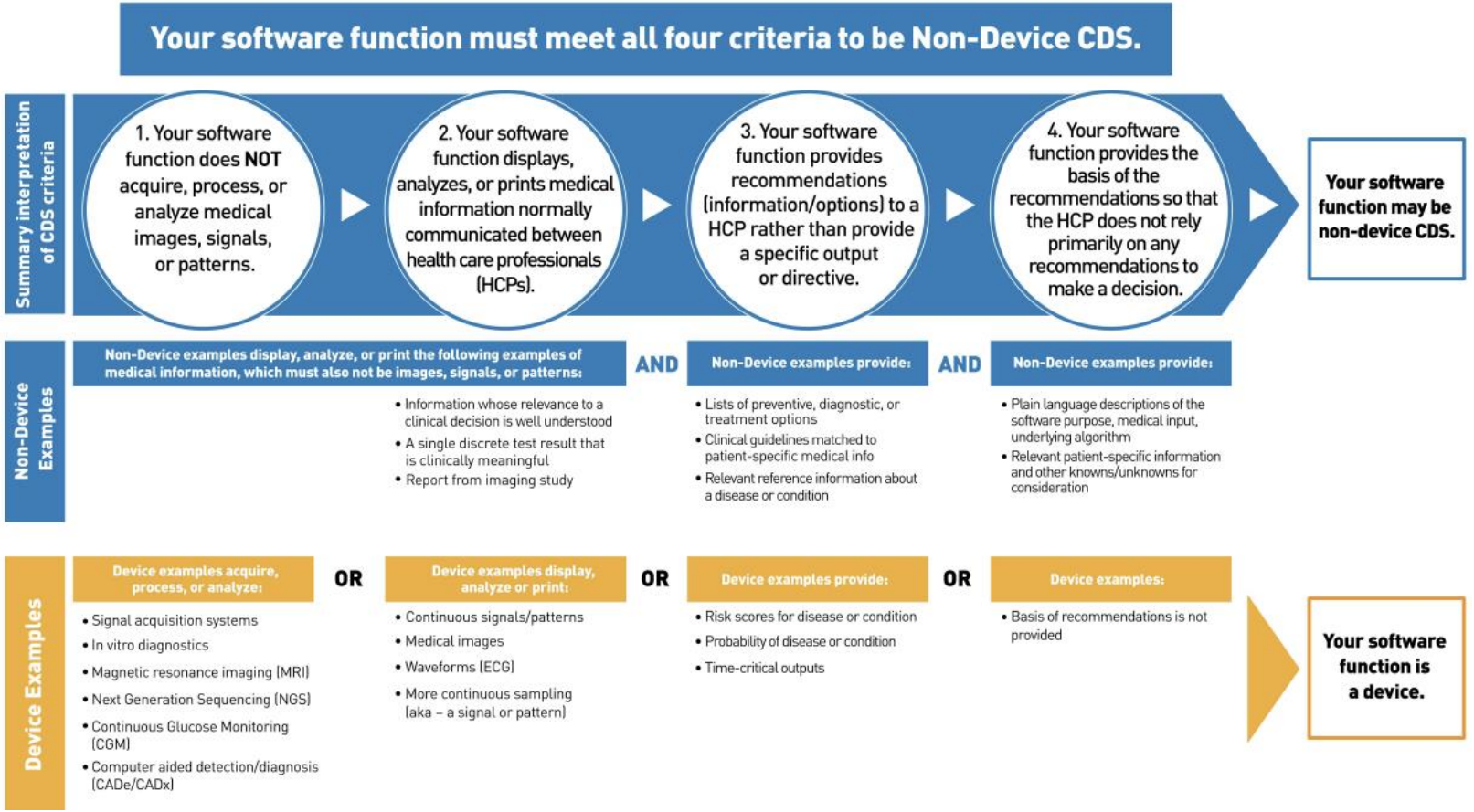
When is CDS NOT a device?



“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?



“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.

CDS Examples

Software 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.

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.

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.

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

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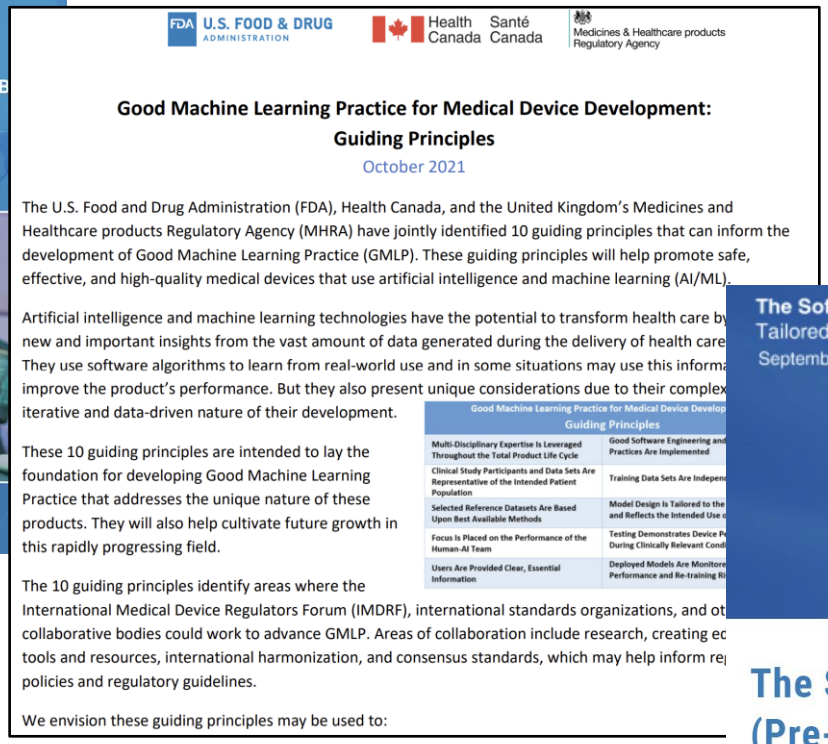
If the Digital Health Product is a Device …

- Establishment registration & device listing
- Premarket notification or approval
- Quality System Regulation / cGMP
- Labeling
- Medical device reporting (MDR) & recalls

Innovative Issues in Digital Health



The Software Precertification (Pre-Cert) Pilot Program Report

Questions?

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