



Clinical Decision Support Software

“technology that provides health care providers and patients with knowledge and person-specific information, intelligently filtered or presented at appropriate times, to enhance health and health care”

CDSS and the FDA



Regulated

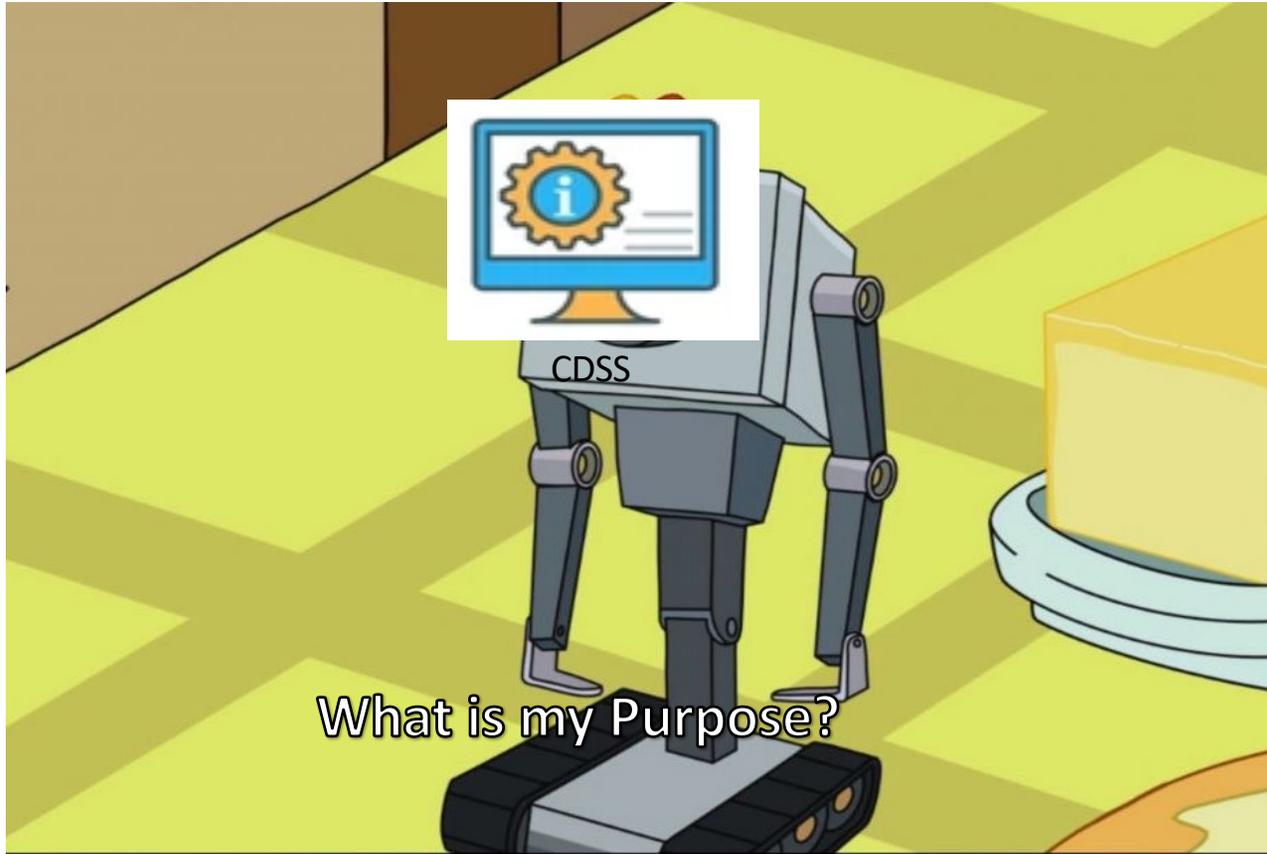


medical device

Maybe ok



Non-device
CDSS

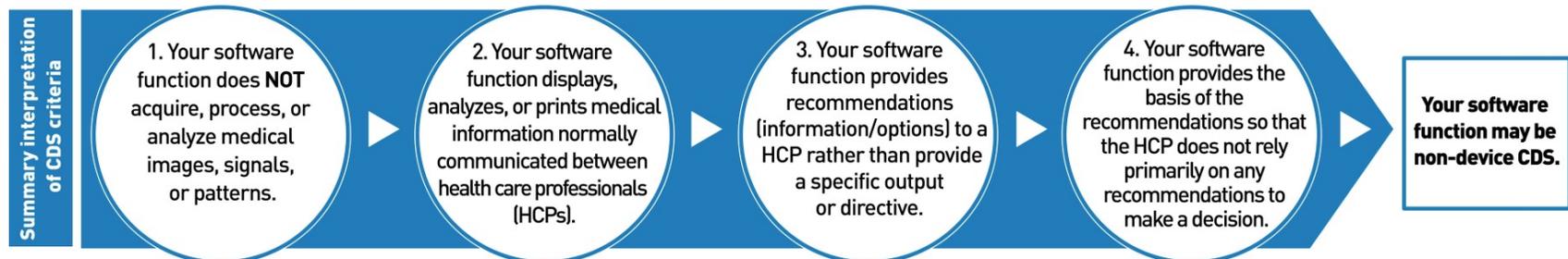


What is my Purpose?

Non-Device CDSS Purpose

- Not intended to analyze medical images, signals, or patterns
- Intended for displaying, analyzing, or printing medical info
- Intended for supporting or providing recommendations to a healthcare professional
- Intended for enabling the healthcare professional to independently review the basis for recommendations that the software presents

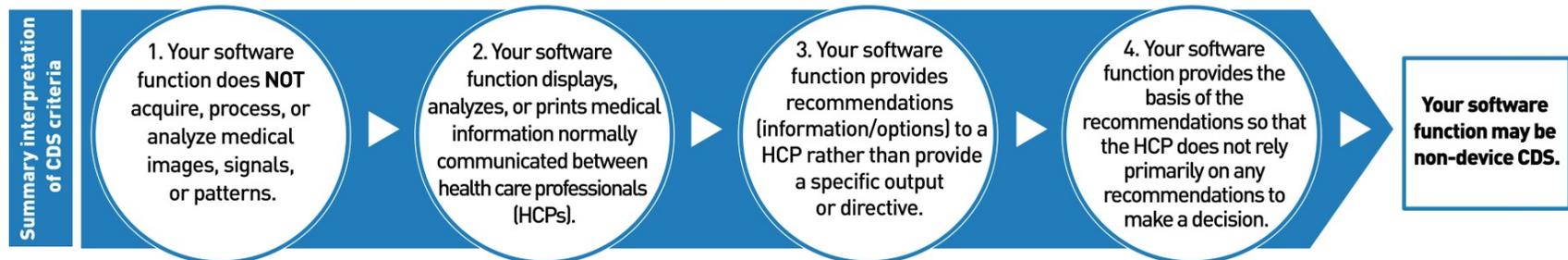
Your software function must meet all four criteria to be Non-Device CDS.



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Requirement 4

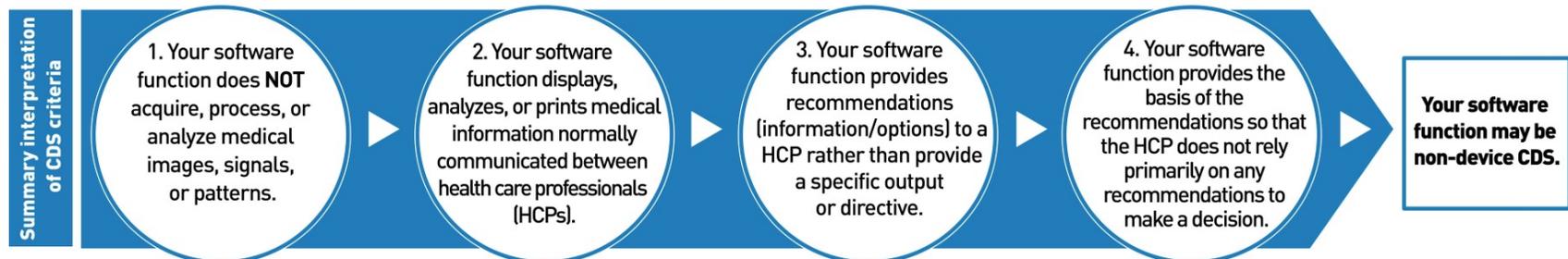
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- Clearly identify the intended use, user, and patient population
- Provide a plain language description of the underlying algorithm development
 - Summary of the logic or method relied upon (AI/ML techniques)
 - Description of the data relied upon
 - Description of the results of clinical studies
- Will provide the practitioner with known/unknowns for consideration
 - Missing, corrupted, or unexpected input data values

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Non-device CDSS...

a practitioner uses the CDSS to make a diagnosis/recommendation...

The diagnosis/recommendation ends up being wrong and someone is harmed



“Some of my medical advice may prove to be wrong in 20 years, so just ignore that part.”

- A 63-year old patient at a hospital was given an alpha/beta blocker as treatment for an acute myocardial infraction
- At discharge, the practitioner was given a CDSS alert to start a beta blocker in all discharged patients with a diagnosis of AMI who did not have a beta blocker in their medication list
- The practitioner thus prescribed a beta blocker
- The patient became sick due to having two drugs which had beta-blocking activity
- Upon review it was found that the CDSS logic did not consider that alpha/beta blockers have beta-blocker activity



Medical Malpractice

1. Physician-patient relationship existed
2. The defendant (physician) failed to conform to “good medical practice”
3. The defendant’s negligence caused the plaintiff’s injury

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Good Medical Practice

A general practitioner owes his or her patient that degree of care and skill possessed by the average qualified practitioner, taking into account the advances in the profession and resources available to the physician

Would the average practitioner have been able to identify the mistake made by the CDSS?

Liability for the non-use of a CDSS?

CDSS gave alert and practitioner ignored it

Design Defect

a design defect occurs when **foreseeable risks** associated with the product could have been minimized by the adoption of **a reasonable alternative design**

- Don't need the safest design possible, but the safest alternative design which has the same benefit
 - A cost benefit analysis

Learned intermediary doctrine

Say a ML model is trained on a MIT students that uses vital signs and laboratory readings to recommend treatment for hypertension

- What are the foreseeable risks here?
 - The model may be improperly trained for the target demographic
 - Risk that the laboratory readings may be wrong

Assume that this product has now been released

- Are you failing to mitigate a foreseeable risk by not having an evolving product?



We can help 😊



School of Law

Technology Law Clinic