FDA Regulation of Mobile Health Apps

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Device definition

"Device" means an instrument, apparatus, implement, machine, contrivance, implant, in vitro reagent, or other similar or related article, including any component, part, or accessory, which is—

(1) recognized in an official medical compendium;

(2) intended to diagnose diseases or other conditions or to cure, mitigate, treat, or prevent diseases, etc; or

(3) intended to affect the structure or any function of the body

and which does not achieve its primary intended purposes through chemical action within or on the body … and which does not depend upon being metabolized…. FDCA § 201(h)

How is "intent" determined? 21 CFR § 801.4

Software *as* a medical device vs. software *in* a medical device
Int'l Medical Device Regulators' Forum definitions 2013

Cures Act § 3060(a) - 21 U.S.C. § 360j(o)(1) excludes certain software from the device definition

A. Healthcare business software

B. Wellness/healthy lifestyle software that does not diagnose, cure, mitigate, prevent, treat disease

C. Electronic Health Record (EHR) software that does not diagnose, cure, mitigate, prevent, treat disease

D. Medical Device Data System (MDDS) software that does not diagnose, cure, mitigate, prevent treat disease

E. A subset of Clinical Data Support (CDS) software *[and via guidance Patient Decision Support (PDS) software]*

Cures Act § 3060(a) - 21 U.S.C. § 360j(o)(1)(B)

software intended for maintaining or encouraging a healthy lifestyle

Before the Cures Act, FDA's *General Wellness: Policy for Low Risk Devices: Guidance (July 29, 2016)* had defined **general wellness products** as those with:

(1) an intended use that relates to maintaining or encouraging a general state of health or healthy activity [post-Cures Act, this is no longer a device at all]

(2) an intended use that relates to the role of healthy lifestyle with helping to reduce the risk or impact of certain chronic diseases or conditions where it is well understood an accepted that healthy lifestyle affects outcomes

Low risk if: not invasive, not implanted, does not involve intervention or technology that may pose risk unless special controls are applied (e.g., lasers, radiation) [post-Cures Act, continued enforcement discretion for low-risk type 2 above]

21 U.S.C. § 360j(o)(1)(E)
Clinical Decision Support (CDS) software

CDS software has many meanings, but the concept here is:

> software that harnesses patient-specific data + an external source of medical knowledge to support or provide recommendations to healthcare professionals about diagnosis, prevention, treatment of disease

In its December 2017 draft guidance, FDA used its discretion to craft a parallel concept of Patient Decision Support (PDS) software that provides recommendations to patients or non-healthcare-professional caregivers.

FDA intends to adopt an enforcement discretion policy that excludes certain PDS software from regulation as a device.

21 U.S.C. § 360j(o)(1)(E)
Which CDS software is excluded from device definition?

Limitation - Certain CDS software FDA already regulates is ineligible for the exclusion: software that acquires, processes, analyzes signals from diagnostic devices (e.g., software that helps process mammograms to detect suspicious lesions)

Potentially eligible for exclusion – software that harnesses patient-specific data + general medical information to support or provide recommendations to healthcare professionals about diagnosis, prevention, treatment of disease

Exclusion criterion – Is the software intended to enable the healthcare professional to independently review the basis for its recommendations, so that it is not the intent for the healthcare professional to rely primarily on the recommendations to make a clinical diagnosis or treatment decision for an individual patient.

The spectrum of CDS software (and, by analogy, PDS software)

Simplest – relies on existing, established medical knowledge and applies this to individual patient decision-making

Goal: Conform patient decision-making to the existing medical evidence base (clinical practice guidelines, FDA-approved drug labeling, established clinical practice, peer-reviewed literature)

Most advanced – analyzes data from real-world clinical experience to infer new medical knowledge and brings it to bear on patient-specific decision-making

Goal: Push past defects in the existing evidence base, e.g., FDA clinical trials that do not represent real patients, clinical practice guidelines tainted by commercial conflicts, peer-reviewed literature that is biased toward articles where the drug worked

Can advanced CDS software explain itself in terms the physician can understand?

Illuminating precedents

- The alleged “right of explanation” under EU GDPR Art. 22
- Controversial machine-learning facial recognition software
- Explainable artificial intelligence (XAI) in military settings

Is the § 360j(o)(1)(E)(iii) exclusion criterion a workable standard that FDA can apply and enforce?

- *Intent* to enable independent physician review and override
- Impact of known misuse under 21 C.F.R. § 801.4 – known misuse does not generally negate mfr’s statement of intent
- But what if device *could not possibly* be used as intended?

Which PDS software would be subject to FDA's proposed enforcement discretion policy?

FDA will not enforce compliance with regulations if:

1. Doesn't acquire, process, analyze signals from diagnostic devices or signal acquisition system
2. It displays, analyzes or prints patient-specific data + general medical information
3. It supports or provides recommendations to healthcare professionals about diagnosis, prevention, treatment of disease or condition
4. It is intended to enable the patient or non-professional caregiver to independently review the basis for its recommendations, so that it is not the intent that they rely primarily on the recommendations to make decisions for an individual patient.

How could PDS software meet the fourth criterion (transparency to the patient)

The software must clearly explain:

1. The purpose or intended use
2. The intended user (patient, non-healthcare-professional caregiver)
3. The inputs used to generate the recommendation (e.g., patient age, gender, …)
4. The rationale or support for the decision

Intended user must be able to reach the recommendation independently without using the software—e.g., by accessing the same sources the software uses, which must be publicly available and understandable to the user.

Threshold for understanding may be different for laypeople and professionals.

Aspects of transparency

Standards of algorithmic transparency

Access to underlying data the software relies on (to train the algorithm and make recommendations)

Transparent business practices