A Very Fine Line — Split Decision: FDA Issues Draft Guidance on Clinical Decision Support Software

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From his 1986 "Back in the High Life" album, Steve Winwood sings, "It's a fine line, a very fine line – split decision." In fact, that's what many medical device companies will face as they review the Food and Drug Administration's recently-issued draft guidance document on "Clinical Decision Support Software" (CDS).[1] The draft is a continuation of the agency's efforts to define how it intends to regulate this type of software and includes recent changes to the Federal Food, Drug and Cosmetic Act (FDC Act). The 21st Century Cures Act amended the FDC Act to exclude certain software functions from the statutory definition of a device. Comments are due to FDA by December 26.

This Bulletin summarizes the highlights of the draft and provides AGG's observations.

Summary of Draft Guidance

On September 27, 2019, FDA issued the draft guidance, "Clinical Decision Support Software," which supersedes a 2017 guidance on the subject.

- The focus of the guidance document is that FDA intends to regulate CDS that meets the statutory definition of a medical "device."
- FDA intends to apply a risk-based approach to regulation; CDS products that present low risk would not be subject to active regulation by the agency.
- The framework categorizes the risk presented by medical device software using two factors: (1) the seriousness of the health condition (i.e., critical, serious or not serious), and (2) the significance of the information to the health care decision (i.e., whether the information informs clinical management, drives clinical management, or treated or diagnosed a patient).[2]
- According to FDA, software that does more than inform clinical management, such as driving clinical decisions or determining a diagnosis, goes beyond CDS and will be subject to active regulation.
- In contrast, the agency does not intend to enforce compliance with the FDC Act if the software function is a Non-Device CDS product, regardless of the platform on which the software is run. The following are the conditions that must be met:
    - not intended to acquire, process, or analyze a medical image or a signal from an in vitro diagnostic device or a pattern or signal from a signal acquisition system;
    - intended for the purpose of displaying, analyzing or printing medical information about a patient or other medical information;
    - intended for the purpose of supporting or providing recommendations to a healthcare professional (HCP) about prevention, diagnosis, or treatment of a disease or condition; and
    - intended for the purpose of enabling an HCP to independently review the basis for the recommendations that such software presents, so that it is not the intent that the HCP rely primarily on any of such recommendations to make a clinical

1 The draft can be accessed at https://www.fda.gov/regulatory-information/search-fda-guidance-documents/clinical-decision-support-software

2 This framework follows from the International Medical Device Regulators Forum Software as a Medical Device: Possible Framework for Risk Categorization and Corresponding Contributions.

diagnosis or treatment decision regarding an individual patient.[3]

- In addition, FDA will not enforce compliance if the Device CDS software functions, which are intended to inform clinical management, are for non-serious situations or conditions and that are also intended for the HCP or patient to be able to independently evaluate the basis for the software's recommendations.
- FDA provided examples of CDS products that would (and would not) likely be subject to regulation:
  - software that calculates the dimensions of a skin lesion, and compares those dimensions to a database of images to identify whether the lesion is malignant or benign, would not be exempt (and thus would be subject to regulation)
  - a software that detects a genomic variance, and compares the variance to a large set of genomic data, would not be exempt (and thus would be subject to regulation)
  - CDS that is for patient use to support or provide recommendations to patients or caregivers to prevent, diagnose, or treat a disease or condition, as opposed to use by an HCP, would not be exempt from regulation (and thus would be subject to regulation)
  - software that provides HCPs with recommendations on the use of a prescription drug (or medical device) that are consistent with the FDA-required labeling, and where the software describes the recommendations, such that the HCP does not rely primarily on the software's recommendation, would not be subject to FDA regulation
  - software that makes chemotherapeutic suggestions to an HCP based on patient history, test results and patient characteristics, and describes the basis for the recommendation, such that the HCP does not rely primarily on the software's recommendation, would not be subject to FDA regulation
- FDA provided the following as examples of CDS software, that although they would meet the definition of "device" under the FDC Act, would not be subject to active regulation (i.e., enforcement discretion), because they present low risk (the CDS product informs clinical management for non-serious conditions):
  - machine learning algorithm, for which the logic and inputs are not explained, that trends and classifies patient-specific data (e.g., blood test results, weight) to alert HCPs to potential triggers that may be indicative of cholesterol management issues
  - software that provides information to a patient about the use of a prescription drug that is consistent with the FDA-required labeling and the patient's prescription, such as reminding the patient how or when to take a prescribed drug
  - software that assists a patient in identifying over-the-counter cold or allergy medications to consider purchasing based on symptoms.
- In contrast, FDA intends to actively regulate software that informs clinical management for serious or critical conditions, such as:
  - machine learning algorithms, for which the logic and inputs are not explained, that identifies hospitalized, type 1 diabetic patients at increased risk of postoperative cardiovascular events
  - software that is intended to perform image analysis for diagnostically differentiating between ischemic and hemorrhagic stroke
  - software that uses a patient's image set (e.g., MRI) to create an individual treatment plan for radiation therapy
  - software that detects and highlights abnormalities in an image and assesses associated disease severity
- Even where FDA will exercise enforcement discretion, the agency recommends that companies create a quality management system and apply good cyber hygiene consistent with FDA's digital health guidance documents.

AGG Observations

- While the draft guidance is not legally binding, it represents FDA's current thinking on the issue of CDS products.
- A review of the draft allows a company to evaluate its regulatory strategy to determine whether it can find a way to exempt its product from FDA regulation or if it will require a marketing application; if a marketing application is required, a question then may be whether there is a predicate device to which a finding of substantial equivalence can be made or whether a de novo application is an option and, if a marketing application is needed, the company may consider whether a meeting with the agency could be useful. The label claims will be important

3 As noted, the 21st Century Cures Act amended the FDC Act to remove certain software functions from the statutory definition of "device."

here.

- The agency will accept comments to the draft until December 26, so those interested in letting FDA know what they think should speak up now.

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