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Clarifying clinical decision support: FDA overhauls guidance to focus on risk

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On 27 September 2019 the U.S. Food and Drug Administration (FDA or the agency) released the draft guidance entitled "Clinical Decision Support Software" (CDS guidance), which updates the framework for FDA's oversight of CDS products, substantially revising the draft guidance that was previously released in 2017, "Clinical and Patient Decision Support Software." FDA simultaneously issued a number of final guidance documents updating the medical software regulatory framework developed to implement the 21st Century Cures Act (Cures Act), which we discuss in a companion client update.

The new draft guidance adopts a risk-based framework for evaluating CDS that resembles the approach used by FDA in the "Policy for Device Software Functions and Mobile Medical Applications" guidance. It seeks to clarify FDA's current thinking on the types of CDS software functions that: (1) are not medical devices; (2) meet the definition of a device, but will be subject to FDA's exercise of enforcement discretion (not actively regulated) due to low risk; and (3) are actively regulated. The new draft guidance presents a significant departure from the previously released version, including updates to address industry's concerns with the prior version of the guidance.

Device and nondevice CDS

Building on the statutory language enacted under the Cures Act, the guidance acknowledges that some CDS products will not meet the definition of a medical device. The Cures Act amended Section 520 of the Federal Food, Drug, and Cosmetic Act to exclude certain software functions, including some CDS, from FDA regulation. CDS products are no longer medical devices if they meet four specific criteria. Of these, the most challenging to interpret has been the criterion that the CDS must enable health care professionals (HCPs) to independently review the basis for recommendations presented by the software. The new draft CDS guidance seeks to clarify how this criterion may apply to machine learning and proprietary algorithms. It explains that companies must describe the data used to develop the algorithm and the logic or rationale used by the algorithm to render a recommendation, i.e., inputs used to generate recommendations should be identified, and should be communicated in plain language, so that the intended HCP user is able to independently evaluate the basis for the recommendation.

The draft guidance provides 12 specific examples of types of software that may be considered nondevice CDS functions because they meet all four criteria specified in the Cures Act for falling outside the definition of a medical device. These include, for example:

- Providing HCPs with recommendations on the use of a prescription drug or medical device consistent with the FDA-required labeling.
- Suggesting an intervention or test consistent with clinical guidelines and/or labeling, e.g., suggesting HCPs order G6PD deficiency tests before starting an antimalarial.
- Making chemotherapeutic suggestions based on patient history, test results, and patient characteristics, consistent with clinical guidelines and/or labeling.

In every instance, the critical caveats are that the basis for the recommendations must be described, including data inputs and algorithm sources, such that the HCP need not rely primarily on the software's recommendation and can make an independent, informed judgment about the appropriate clinical approach for the patient in question.

The CDS draft guidance risk categorization

If a CDS product does not meet all four of the Cures Act criteria, then it would be a device CDS and *could* be regulated by FDA. The most significant revision in the new draft guidance to the prior policy is the adoption of a risk-based approach to determining when device CDS would be actively regulated. This came at least partly in response to industry comments to the earlier draft guidance. Specifically, FDA intends to leverage factors developed in "'Software as a Medical Device': Possible Framework for Risk Categorization and Corresponding Considerations" (IMDRF framework) to apply a risk-based policy for defining CDS software functions as devices and determining whether CDS devices are subject to enforcement discretion.

The IMDRF framework, as explained in the draft guidance, deploys two major factors in a matrix to assign risk categorization of Software as a Medical Device (SaMD): (a) the significance of information provided by a SaMD to the health care decision, and (b) the state of the health care situation or condition (i.e., critical, serious, or non-serious). The significance of the information to the health care decision is categorized as (in descending order of risk) "treat or diagnose," "drive clinical management," or "inform clinical management." FDA explains that it only considers software that is used to "inform clinical management" as CDS, because CDS functions – per the Cures Act criteria – are intended to provide information that supports or serves as a recommendation about prevention, diagnosis, or treatment of a disease/condition, but is not necessary to decision-making for a patient's care (CDS guidance at 13 - 14). Accordingly, SaMD functions that "drive clinical management" or "treat or diagnose" are not considered CDS under the Cures Act and are not the focus of this guidance document.

Enforcement discretion and regulatory focus

Building on the risk-based framework, the new draft guidance indicates that FDA does not intend to enforce compliance for device CDS software functions under certain circumstances. Per the draft guidance, the following combinations of intended CDS audience, severity, and transparency would be subject to enforcement discretion:

- Device CDS intended for HCP users for "non-serious situations or conditions" where the user cannot independently review the basis.
- Device CDS intended for the patient or caregiver for "non-serious situations or conditions" and where the user can independently evaluate the basis for the recommendations.

The agency's regulatory oversight will instead focus on:

- CDS intended for HCPs for "serious" or "critical" situation or conditions and not intended to enable independent evaluation of the basis for the recommendation.

- CDS for patient or caregiver use *unless* it is *both* intended for a "non-serious situation or condition" and the user can independently review the basis for the recommendation.

Finally, the guidance provides 20 specific examples of non-CDS device software functions that will fall within the focus of FDA's regulatory oversight because they do not meet the four Cures Act criteria for exclusion from the device definition and are not otherwise considered to be sufficiently low-risk to be subject to enforcement discretion. These examples include software that analyzes and or manipulates data from medical images or physiological signals in order to generate a treatment plan, guide surgery, design custom implants, or aid in diagnosis of a disease or condition.

Patient decision support

The new draft guidance eliminates "patient decision software" as a separate category of clinical decision support tools. The patient decision support concept that was prominent in the previous draft guidance has not entirely disappeared. However, applying the IMDRF risk prioritization framework to this group of products, the draft guidance assigns more conservative oversight focus and enforcement discretion categories if the intended user is a patient or caregiver than if the intended user is an HCP. Moreover, consistent with the statute and the prior draft guidance, only CDS intended for use by HCPs, rather than patients, can fall outside the definition of a medical device and accordingly not be subject to FDA regulation (assuming it meets all of the Cures Act criteria).

Conclusion

FDA's substantially revised draft guidance reflects a significant shift toward a risk-based framework using IMDRF risk categorization from earlier regulatory compartmentalization of "patient" vs. "clinical" decision support software. The move suggests that FDA is listening to industry and trying to clarify pressing concerns, such as the regulation of CDS products that include machine learning or artificial intelligence algorithms. Opportunities to comment further with this newly released – essentially starting anew – draft guidance may prove highly productive toward reaching an effective industry-responsive policy that supports innovation in the CDS space.

Comments to the CDS guidance will be accepted for 90 days (until 26 December) at docket number FDA-2017-D-6569.

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