SQUIRE PATTON BOGGS

FDA Draft Guidance on Clinical and Patient Decision Support Software Issued

Recently, the US Food and Drug Administration (FDA) published a notice of availability for the Clinical and Patient Decision Support Software – Clinical and Patient Decision Support Software – Draft Guidance for Industry and Food and Drug Administration Staff (Draft Guidance). The Draft Guidance provides clarity on the scope of FDA's regulatory oversight of two important areas: clinical decision support software (CDS) intended for healthcare professionals, and patient decision support software (PDS) intended for patients and caregivers who are not healthcare professionals.

Medical device and software manufacturers with products that may influence medical decision-making should study the Draft Guidance, as it reflects FDA's current regulatory thinking.

The purpose of the Draft Guidance is to identify the types of decision support software functionalities that (1) do not meet the definition of a "device" as amended by the 21st Century Cures Act (Cures); (2) may meet the definition of a "device" under Cures, but for which FDA does not intend to enforce compliance with applicable regulatory requirements, including, but not limited to, premarket clearance and premarket approval; and (3) "devices" that will be the focus of FDA's regulatory and enforcement oversight.

Section 3060(a) of Cures amended section 520 of the Food, Drug, and Cosmetic Act[1] to exclude certain software functions from the definition of a "device," thereby reducing the regulatory obligations applicable to such software. Specifically, under Cures, CDS that meets all four of the following criteria is excluded from the definition of a medical device:

1. Software that is 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
2. Software that is intended for the purpose of displaying, analyzing or printing medical information about a patient or other types of information (such as a peer-reviewed clinical studies and clinical practice guidelines)
3. Software that is intended for the purpose of supporting or providing recommendations to a healthcare professional about prevention, diagnosis or treatment of a disease or condition
4. Software that is intended to enable a healthcare professional (HCP) to independently review the basis for the recommendations that the software presents, so that it is not the intent that such HCP rely primarily on any of such recommendations to make a clinical diagnosis or treatment decision regarding an individual patient[2]

Cures does not apply to PDS, which refers to software that a patient or non-HCP caregiver may use to help make a medical decision. PDS implicates a much different balance of risks and benefits because the software must make up the difference between a lay patient and a physician's education and training. With respect to PDS, the fourth criteria should allow patients or their non-HCP caregivers to independently review the software's recommendation. FDA states that it intends to exercise its enforcement discretion when a PDS meets all of the above criteria, despite technical violation of applicable regulation.

FDA does not single out any one of the four criteria as being more important, but it does identify the fourth criteria as the lynchpin of its analysis. Therefore, manufacturers seeking apply the Draft Guidance must ensure that an HCP or a patient (or their non-HCP caregiver) can reach the same recommendation as the software, without relying primarily on the software to arrive at that decision. In practice, this means that the software functions must clearly explain (1) the purpose or intended use of the software function; (2) the intended user (e.g., patient, non-HCP); (3) the inputs used to generate the recommendations (e.g., patient age and gender); and (4) the rationale or support for the recommendation.

The Draft Guidance provides many examples that manufactures can review to help understand how these criteria will be evaluated in practice. For example, software that simply identifies drug allergy contraindications based on FDA-approved labeling, or identifies patients who meet the clinical definition of a disease based on test results, are no longer medical devices. On the other hand, software that conducts analyses of a patient and, for example, uses such analyses to create treatment or surgical plans, will continue to be a medical device under the Draft Guidance.

Either electronic or written comments on the Draft Guidance may be submitted to FDA by February 6, 2018, to ensure that the FDA considers all comments on the Draft Guidance before it begins work on the final version. You can submit electronic comments through regulations.gov or submit written comments to the Dockets Management Staff (HFA-305), Food and Drug Administration, 5630 17 Fishers Lane, Rm. 1061, Rockville, Maryland 20852. Identify all comments with Docket No. FDA–2017–D–6569.

If you have any questions regarding the Draft Guidance, please contact the authors noted or your regular firm lawyer.

Contacts

John E. Wyand
Partner, Washington DC
T +1 202 626 6676
E john.wyand@squirepb.com

Elliot R. Golding
Partner, Washington DC
T +1 202 457 6407
E elliot.golding@squirepb.com

Sarah H. Stec
Associate, Washington DC
T +1 202 457 6304
E sarah.stec@squirepb.com

1 21 U.S.C. § 360j.

2 21 U.S.C. § 360j(o)(1)(E).