KING & SPALDING

Client Alert

FDA & Life Sciences Practice Group

December 14, 2017

FDA Releases Long-Awaited Guidances on the Regulation of Digital Health Tools

On December 7, 2017, the Food and Drug Administration (FDA) released three guidance documents that reveal the Agency's current thinking on the oversight of digital health tools. This client alert provides an overview of each of the guidances:

1. Draft Guidance on Clinical Decision Support Software—This draft guidance, entitled "Clinical and Patient Decision Support Software," clarifies FDA's current view regarding what constitutes clinical decision support software (CDS) and the categories of CDS that will be regulated by the Agency.

2. Draft Guidance Modifying Existing Medical Software Policies—This draft guidance, entitled "Changes to Existing Medical Software Policies Resulting from Section 3060 of the 21st Century Cures Act," proposes changes to existing FDA guidance documents related to medical software to ensure that they are consistent with the 21st Century Cures Act and reflect the Agency's current thinking on the regulation of digital health products.

3. Final Guidance on Software as a Medical Device—This final guidance on Software as a Medical Device (SaMD) adopts internationally-recognized principles for analyzing and assessing SaMD and will serve as an initial framework for the Agency in developing its approach to regulating digital health products that constitute a medical device.

The two draft guidances, which address which digital health software functions will and will not be regulated by FDA, will be analyzed first, followed by a discussion of the final guidance on SaMD.

Background on the Regulation of Digital Health Tools

The regulatory framework for digital health tools, and CDS in particular, has long been a gray area in which industry has struggled to identify the agency or agencies with jurisdiction over these new and innovative technologies. In 2012, Congress mandated that a collaborative effort be undertaken by FDA, the Federal Communications Commission (FCC), and the Office of the National Coordinator for Health Information Technology (ONC) at the Department of Health and Human Services. These agencies were charged with drafting a proposed strategy for regulating these products. The risk-

For more information, contact:

Lisa Dwyer
+1 202 626 2393
ldwyer@kslaw.com

Kyle Sampson
+1 202 626 9226
ksampson@kslaw.com

Elaine Tseng
+1 415 318 1240
etseng@kslaw.com

Brady Mickelsen
+1 202 626 5583
bmickelsen@kslaw.com

King & Spalding
Washington, D.C.
1700 Pennsylvania Avenue, NW
Washington, D.C. 20006-4707
Tel: +1 202 737 0500
Fax: +1 202 626 3737

San Francisco
101 Second Street
Suite 2300
San Francisco, CA 94105
Tel: +1 415 318 1200
Fax: +1 415 318 1300

www.kslaw.com

based framework the agencies proposed was documented in the "FDASIA Health IT Report," which was issued in April 2014.[i] That report proposed that FDA (1) take a hands-off approach with regard to most CDS, so as not to stymie innovation, and (2) only regulate CDS that meets the definition of "device" in the Federal Food, Drug, and Cosmetic Act (FD&C Act) and presents some level of risk to patients. Following the 2014 report, FDA stated that it would issue draft guidance explaining how it would regulate CDS in 2015.[ii] FDA did not, however, issue that guidance until last week, on December 7, 2017.

Subsequent to the issuance of the FDASIA Health IT Report, Congress passed the 21st Century Cures Act (Cures Act). The Cures Act, which was enacted in 2016, included a provision, Section 3060(a), which amended Section 520(o) of the FD&C Act to exclude certain software functions from the definition of "device."[iii] The two draft guidance documents issued by FDA last week, on December 7, 2017, are focused on implementing this new definition. First, the CDS draft guidance implements the revised definition by identifying the types of CDS functionalities that: (1) do not fall within FDA's jurisdiction at all because they do not meet the amended definition of "device"; (2) fall within FDA's jurisdiction but will not be actively regulated by the Agency; and (3) fall within the Agency's jurisdiction and will be actively regulated by the Agency. The second draft guidance provides a broader outline of FDA's current thinking on the FD&C Act's definition of device, as amended, and how the revised definition impacts the Agency's previously-issued guidances on medical device software.

Overview of the Draft Guidance on Clinical and Patient Decision Support Software

The draft guidance on "Clinical and Patient Decision Support Software" (CDS/PDS Draft Guidance) is the most long-awaited and controversial of the three guidances issued on December 7, 2017. The CDS/PDS Draft Guidance largely departs from the risk-based approach first outlined in the FDASIA Health IT Report and, instead, adopts an approach based on the ability of the end user to independently review the basis for recommendations provided by the CDS. The draft guidance provides the Agency's definition of CDS based on the amendment to FD&C Act § 520(o)(1)(E) and then divides the types of CDS into three categories, with different levels of oversight.

Per the CDS/PDS Draft Guidance, the definition of CDS is any function that is:

1. *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. intended for the purpose of displaying, analyzing, or printing medical information about a patient or other medical information (such as peer-reviewed clinical studies and clinical practice guidelines); and

3. intended for the purpose of supporting or providing recommendations to a health care professional about prevention, diagnosis, or treatment of a disease or condition.[iv]

Notably, the Agency has chosen to go a step farther than what is required under the Cures Act, and uses this guidance to express its views on, and largely exclude from regulation, those functions that may be considered patient decision support software (PDS). PDS does not fit within the definition for CDS because it is not intended to provide recommendations to a health care professional. Instead, it is intended to provide recommendations to a patient or caregiver. Thus, the Agency defines PDS to include any software function that is intended for patients or caregivers who are not health care professionals and that also is:

1. *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. intended for the purpose of displaying, analyzing, or printing medical information about a patient or other medical information (such as information derived from peer-reviewed clinical studies and clinical practice guidelines); and

3. intended for the purpose of supporting or providing recommendations to a patient, in terms that are understandable to the patient, about prevention, diagnosis, or treatment of a disease or condition.[v]

Thus, to fall under this draft guidance, the function must qualify as a CDS function or a PDS function as outlined above. The draft guidance then places CDS and PDS into three categories, each with a different level of oversight. The categorization of CDS and PDS is based in part on whether the recommendations provided by the CDS or PDS can be independently reviewed by a decision-maker, such that they are not providing the primary basis for a diagnosis or treatment decision (the Independent Review Requirement).[vi]

FDA's view is that, to satisfy the Independent Review Requirement, the CDS or PDS function must clearly explain: (1) the purpose or intended use of the software function; (2) the intended user; (3) the inputs used to generate the recommendation; and (4) the rationale or support for the recommendation.[vii] Based on the distinction described above, FDA has established three categories of functions:

1. **Functions that are outside of FDA's jurisdiction because they do not meet the amended definition of "device" under the FD&C Act.** These functions meet the three criteria to be considered a CDS function, and they also meet the Independent Review Requirement. Examples of these functions include: "software that provides health care professionals with recommendations on the use of a prescription drug that are consistent with the FDA-required labeling"; and "software that uses rule-based tools that compare patient-specific signs, symptoms, or results with available practice guidelines . . . to recommend condition specific diagnostic tests, investigations or therapy."[viii]

2. **Functions that may meet the amended definition of "device" under the FD&C Act, but for which FDA intends to exercise enforcement discretion.** For the purposes of this draft guidance, functions in this category relate primarily to low-risk PDS. These functions meet the three criteria to be considered PDS, are low-risk, and also fulfill the Independent Review Requirement. Examples include: software that reminds a patient how or when to take a prescription drug, but that does not recommend changes in dose or drug continuation that are not overseen by a health care provider; and software that assists a patient in choosing an appropriate over-the-counter medication based on symptoms and provides appropriate warnings relating to contraindications, such as using multiple medications with overlapping active ingredients.[ix] Though the CDS/PDS Draft Guidance asserts that "some" CDS not exempt from the medical device definition under Section 520(o)(1)(E) will be subject to enforcement discretion, it provides only one specific example: CDS that performs calculations routinely used in clinical practice.[x] The draft guidance makes general reference to other examples in FDA's Mobile Medical Applications (MMA) guidance but does not clarify which examples are relevant. Further, the CDS/PDS Draft Guidance states that the MMA guidance will be revised to conform to the former once the former is finalized, thus further rendering unclear what other medical device CDS might be subject to enforcement discretion. Significantly, unlike for PDS, the draft guidance does not establish a clear principle that enforcement discretion will be applied for CDS that falls within the medical device definition if such CDS is low-risk.

3. **Functions that meet the amended definition of "device" under the FD&C Act, and for which FDA intends to focus its regulatory oversight.** These functions meet the CDS or PDS criteria, but fail to satisfy the Independent Review Requirement. Examples include: software that diagnoses sleep apnea by analyzing breathing patterns from a sleep apnea monitor; and "software that analyzes near-infrared camera signals of a patient intended for use in determining and/or diagnosing brain hematoma."[xi] On the PDS side, an example

would be software that makes recommendations for dosing adjustments of warfarin based on the outcome of a home blood test and published algorithms without direction from, or consultation with, the patient's health care provider.[xii]

Finally, the draft guidance states that, once the guidance is finalized, FDA intends to edit the MMA guidance to ensure that it conforms to the Cures Act and is consistent with the interpretations and policies outlined in this guidance. Notably, the Agency provides as an example, those "mobile apps that use patient characteristics such as age, sex, and behavioral risk factors to provide patient-specific screening, counseling and preventative recommendations from well-known and established authorities," will not be considered devices under the revised policy.

Overview of the Draft Guidance on Changes to Existing Medical Device Software Policies Resulting from Section 3060 of the 21st Century Cures Act

While the CDS/PDS Draft Guidance focused on Section 520(o)(1)(E) of the FD&C Act, this draft guidance (the Technical Changes Draft Guidance) focuses on interpreting and implementing Section 520(o)(1)(A)-(D) of the Act. These provisions, like those in Section 520(o)(1)(E), exclude certain software functions from the definition of "device."

In a press release announcing issuance of these guidance documents, FDA Commissioner Scott Gottlieb stated that the Technical Changes Draft Guidance makes clear "that certain digital health technologies—such as mobile apps that are intended only for maintaining or encouraging a healthy lifestyle—generally fall outside the scope of the FDA's regulation. Such technologies tend to pose a low risk to patients, but can provide great value to consumers and the healthcare system."[xiii] This draft guidance, in addition to providing FDA's interpretation of the amended definition of "device," proposes numerous changes to previously published FDA guidance documents. These changes are based on four categories of products that the Cures Act exclude from the definition of "device."

Under Section 520(o)(1)(A)-(D), the definition of "device" in the FD&C Act, does not include:

1. **Software intended for administrative support of a healthcare facility**, including the processing and maintenance of financial records, billing information, appointment schedules, business analytics, information about patient populations, future utilization or cost-effectiveness, determination of health benefit eligibility, population health management, and laboratory workflow;

2. **Software used for maintaining or encouraging a healthy lifestyle** that is unrelated to the diagnosis, cure, mitigation, prevention, or treatment of a disease or condition;

3. **Software that serves as electronic patient records**, including patient-provided information, to the extent that such records are intended to transfer, store, convert formats, or display the equivalent of a patient medical chart, so long as, among other things, the software is not intended to interpret or analyze patient records for the purpose of the diagnosis, cure, mitigation, prevention, or treatment of a disease or condition; and

4. **Software for transferring, storing, or converting formats, or displaying clinical laboratory information**, or findings by a health care professional with regard to such information, unless the software's function is to interpret or analyze clinical laboratory information, results, and findings.

Based on this amended definition, the Technical Changes Draft Guidance proposes technical changes to four previously published guidance documents: (1) General Wellness: Policy for Low Risk Devices; (2) Mobile Medical Applications; (3) Off-the-Shelf Software Use in Medical Devices; and (4) Medical Device Data Systems, Medical Image Storage Devices, and Medical Image Communications Devices. The changes made to these previously-issued guidance

documents largely involve the rearrangement of certain examples between lists of products against which FDA intends to enforce regulatory requirements, those against which the Agency does not intend to enforce regulatory requirements, and those that it cannot regulate because they fall outside the FD&C Act's definition of "device." The draft guidance also states FDA's intention to withdraw the Guidance for the Submission of Premarket Notifications for Medical Image Management Devices.

In addition to these technical changes, FDA articulates certain broader policy positions based on the amended "device" definition. Two of these broader policy positions are notable. First, FDA states that, with respect to software used for maintaining or encouraging a healthy lifestyle, the Agency intends to continue to exercise enforcement discretion for software functions that have an intended use related to the role that a healthy lifestyle plays in reducing the risk or impact of a disease or condition, so long as the function presents a low risk to the safety of users and other persons. Second, the Agency states that, for software that serves as electronic patient records, it does not intend to enforce the requirement under FD&C Act § 520(o)(1)(C)(ii), which mandates that the records be part of information technology certified by the ONC Health IT Certification Program, so long as the function meets the other requirements of that section.

Overview of the Final Guidance on Software as a Medical Device

As part of its suite of digital health guidance documents released last week, FDA issued final guidance on Software as a Medical Device (SaMD Guidance), which was issued in draft form in October 2016. While the two draft guidance documents discussed above focus on which software functions will not be considered "devices" under the FD&C Act, the SaMD Guidance provides a framework for FDA oversight of software that is considered to be a medical device. The SaMD Guidance is the result of FDA's efforts, in collaboration with several other countries through the International Medical Device Regulators Forum (IMDRF), to harmonize regulatory approaches to digital health devices. Commissioner Gottlieb, in the press release announcing the issuance of these guidance documents, stated that the SaMD Guidance "establishes common principles for regulators to use in evaluating the safety, effectiveness and performance of [SaMD] . . . [and] provides globally recognized principles for analyzing and assessing SaMD, based on the overall risk of the product."[xiv]

As Commissioner Gottlieb noted, the SaMD Guidance provides principles that FDA intends to use as an initial framework as it develops its regulatory approach and expectations for oversight of SaMD. The SaMD Guidance does not, however, establish recommendations or requirements for specific regulatory situations, and it does not modify the Agency's expectations regarding regulatory submissions. Thus, for industry, the guidance will serve primarily as insight into the Agency's current thinking on how it may develop and revise its regulatory approach to digital health software that is considered a medical device under the FD&C Act.

Considerations for Industry

Although these three guidance documents together provide a more comprehensive view into FDA's current thinking on digital health, the most significant implications for industry likely will arise from the CDS/PDS Draft Guidance. As noted above, the CDS/PDS Draft Guidance does not exempt low-risk CDS devices from oversight to as great an extent as the Agency and its counterparts had signaled in 2014.

Failure to more fully implement the risk-based approach for CDS oversight raises important concerns for the digital health industry. Low-risk software may be forced to comply with burdensome and unnecessary requirements simply because it employs a proprietary computer algorithm to generate a recommendation for the physician to consider a certain diagnosis based on patient-specific symptoms. This creates the potential for undue regulation of many novel

products that employ innovative technologies, such as artificial intelligence and machine learning capabilities, but are unlikely to pose any significant threat to patient health or safety.

Importantly, the CDS/PDS Draft Guidance and the Technical Changes Draft Guidance are in draft form, and FDA is accepting comments on both until February 6, 2018. Industry participants may wish to consider submitting comments on these concerns and other issues as the Agency further develops its policy positions and works toward issuing final guidance documents.

King & Spalding would be pleased to provide you with additional information as you consider these new developments.

* * *

Celebrating more than 130 years of service, King & Spalding is an international law firm that represents a broad array of clients, including half of the Fortune Global 100, with 1,000 lawyers in 20 offices in the United States, Europe, the Middle East and Asia. The firm has handled matters in over 160 countries on six continents and is consistently recognized for the results it obtains, uncompromising commitment to quality and dedication to understanding the business and culture of its clients. More information is available at www.kslaw.com.

This alert provides a general summary of recent legal developments. It is not intended to be and should not be relied upon as legal advice. In some jurisdictions, this may be considered "Attorney Advertising."

---

[i] U.S. FOOD & DRUG ADMIN., FED. COMMUNICATIONS COMM'N & OFFICE OF THE NAT'L COORDINATOR FOR HEALTH INFO. TECH., FDASIA HEALTH IT REPORT: PROPOSED STRATEGY AND RECOMMENDATIONS FOR A RISK-BASED FRAMEWORK (2014), *available at* https://www.fda.gov/downloads/AboutFDA/CentersOffices/OfficeofMedicalProductsandTobacco/CDRH/CDRHReports/UCM391521.pdf.

[ii] U.S. FOOD AND DRUG ADMIN, CDRH FISCAL YEAR 2015 (FY 2015) PROPOSED GUIDANCE DEVELOPMENT (2015).

[iii] The term "device" is defined in the FD&C Act as "an instrument, apparatus, implement, machine, contrivance, implant . . . or other similar or related article, including any component, part, or accessory, which is . . . [1][a] intended for the use in diagnosis of disease or other conditions, or in the cure, mitigation, treatment, or prevention of disease in man or other animals, or . . . [b] intended to affect the structure or any function of the body of man or other animals . . . and [2] which does not achieve its primary intended purposes through chemical action or within the or on the body" 21 U.S.C. § 321(h).

[iv] U.S. FOOD & DRUG ADMIN., DRAFT GUIDANCE, CLINICAL AND PATIENT DECISION SUPPORT SOFTWARE 5 (2017), *available at* https://www.fda.gov/ucm/groups/fdagov-public/@fdagov-meddev-gen/documents/document/ucm587819.pdf; *see also* 21 U.S.C. § 361j(o)(1)(E).

[v] Draft Guidance, CLINICAL AND PATIENT DECISION SUPPORT SOFTWARE, *supra* n. 4 at 6.

[vi] 21 U.S.C. § 361j(o)(1)(E)(iii); *see also* Draft Guidance, CLINICAL AND PATIENT DECISION SUPPORT SOFTWARE, *supra* n. 4 at 5.

[vii] Draft Guidance, CLINICAL AND PATIENT DECISION SUPPORT SOFTWARE, *supra* n. 4 at 8, 12.

[viii] *Id.* at 8-9.

[ix] *Id.* at 12-13.

[x] *Id.* at 11.

[xi] *Id.* at 10.

[xii] *Id.* at 13.

[xiii] SCOTT GOTTLIEB, STATEMENT FROM FDA COMMISSIONER SCOTT GOTTLIEB, M.D., ON ADVANCING NEW DIGITAL HEALTH POLICIES TO ENCOURAGE INNOVATION, BRING EFFICIENCY AND MODERNIZATION TO REGULATION (2017), *available at* https://www.fda.gov/NewsEvents/Newsroom/PressAnnouncements/UCM587890.htm.

[xiv] *Id.*