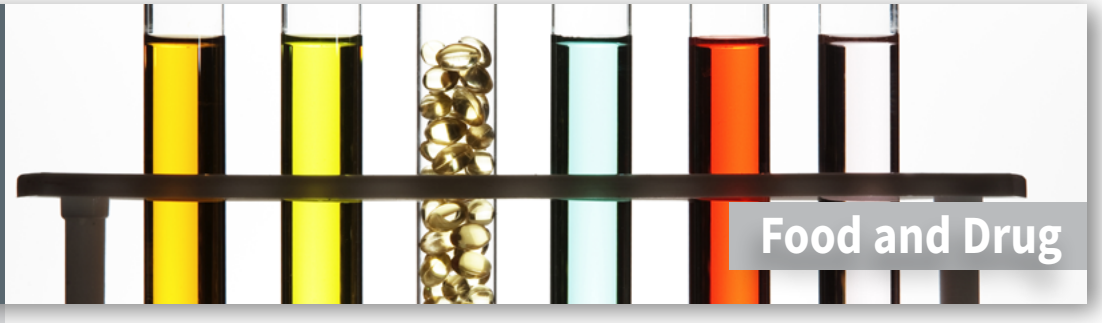

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FDA Guidance on Software as Medical Devices Represents Broader Deregulation Trend

By Michael Gaba, Jean Marie Pechette, and Lidia Niecko-Najjum

The FDA recently published two draft guidance documents to clarify which types of medical software, based on their functionality, are no longer considered medical devices as a result of the changes imposed under section 3060 of the 21st Century Cures Act.

The guidance documents, which were published Dec. 8, are not legally binding on the agency, but they are intended to provide the regulated industry insight as to how the FDA will implement and enforce section 3060. **The provision itself is the culmination of a trend toward less FDA regulation of software technologies that tend to come close to, or brush up against, medical device status.**

What's particularly relevant is that Congress removed swaths of technology from the definition of a medical device, and therefore eliminated the FDA's jurisdiction such that many software developers no longer need to meet the agency's regulatory requirements, and perhaps more importantly, be concerned about living in the nebulous state commonly known as the FDA's zone of "enforcement discretion." The draft guidance documents, unfortunately, do not shed much additional light on the statutory language. **Medical device manufacturers, IT companies, and software developers, therefore, should seek out qualified counsel to help them determine their status vis-à-vis the FDA and the regulatory requirements attendant to that status.**

These draft guidance documents address the following types of software functionality:

1. Software that supports administrative functions
2. Software that encourages a healthy lifestyle
3. Software that serves as electronic patient records
4. Software that assists in transferring, converting formats, displaying or storing data
5. Software that provides limited clinical decision support

The FDA has not yet released its draft guidance to address the "multiple functions" category of software exempt from the Federal Food, Drug & Cosmetic Act. This is the last remaining exempt category under section 3060 of the Cures Act.

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Comments on the "Changes to Existing Medical Software Policies Resulting From Section 3060 of the 21st Century Cures Act" and the "Clinical and Patient Decision Support Software" draft guidance documents are due on Feb. 6, 2018. The comment period affords potentially regulated entities to offer the FDA suggestions on how to provide greater clarity to their guidance.

Proposed Guidance 1: Changes to Existing Medical Software Policies Resulting From Section 3060 of the 21st Century Cures Act

Section 3060 of the Cures Act excluded certain software functions from the definition of a medical device by amending section 520 of the FD&C Act. In this draft guidance, FDA outlines the first four types of software functionality that no longer qualify as medical devices subject to FDA's oversight:

1. **Software intended for administrative support of a health care facility**
   - Examples include processing and maintenance of financial records, claims or billing information, appointment schedules, business analytics, information about patient populations, admissions, practice and inventory management, analysis of historical claims data to predict future utilization or cost effectiveness, determination of health benefit eligibility, population health management, and laboratory workflow.
2. **Software intended for maintaining or encouraging a healthy lifestyle**
   - Examples include software with healthy lifestyle claims, such as weight management, physical fitness, relaxation or stress management, mental acuity, self-esteem, sleep management, or sexual function, when not related to the diagnosis, cure, mitigation, prevention, or treatment of a disease or condition.
3. **Software that serves as electronic patient records**
   - Examples include software functions that are intended to transfer, store, convert formats, or display electronic patient records that are the equivalent of a paper medical chart which meet the following criteria under the FD&C Act Sections 520(o)(1)(C)(i)-(iii):
     i. Such records were created, stored, transferred, or reviewed by health care professionals, or individuals supervised by health care professionals
     ii. Such records are part of information technology certified by the Office of the National Coordinator (ONC) for Health Information Technology Health IT Certification Program
     iii. Such software functions are not intended for interpretation or analysis of patient records, including medical image data, for the purpose of the diagnosis, cure, mitigation, prevention, or treatment of a disease or condition.
   - Notably, FDA does not intend to enforce FDA requirements for software functions not certified by ONC, if they meet the other two criteria.
4. **Software that assists in transferring, converting formats, displaying or storing data.**
   - Examples include Medical Device Data System (MDDS), medical image storage device, and medical image communications device.

Previously, FDA had exercised enforcement discretion over these types of software due to their very low risk and potential benefits to patients from greater innovation.

Importantly, however, under Section 520(o)(3)(A) of the FD&C Act, as amended by Section 3060 of the Cures Act, FDA may reassert its jurisdiction over exempt software functions that encourage a healthy lifestyle, serve as electronic patient records, or assist in displaying or storing data if the Secretary of the Department of Health and Human Services determines, through a defined process, that due to changed circumstances this exempted software would be reasonably likely to have serious adverse health consequences.

In this guidance, FDA proposes to make certain changes to the following previously published agency guidance documents to be consistent with section 3060 of the Cures Act:

- General Wellness: Policy for Low Risk Devices
- Mobile Medical Applications
- Off-The-Shelf Software Use in Medical Devices
- Medical Device Data Systems, Medical Image Storage Devices, and Medical Image Communications Devices

FDA also proposes to withdraw the Guidance for the Submission of Premarket Notifications for Medical Image Management Devices.

Proposed Guidance 2: Clinical and Patient Decision Support Software Draft Guidance for the Industry

In the second proposed draft guidance, FDA addresses the fifth type of software functionality exempted under section 3060 of the Cures Act: software that provides physicians or patients limited decision support. FDA discusses the type of decision support software functionalities that: (1) do not meet the definition of a device as amended by the Cures Act; (2) may meet the definition of a device but for which FDA does not intend to enforce compliance with applicable requirements of the FD&C Act, including, but not limited to, premarket clearance and premarket approval requirements; and (3) FDA intends to focus its regulatory oversight on.

As noted above, the decision support software falls into two categories: (1) clinical decision support software intended for healthcare professionals and (2) patient decision support software intended for patients and caregivers who are not healthcare professionals. **Because the FD&C Act only pertains to clinical decision support software, meaning products intended for health care professionals, FDA proposes to adopt an enforcement discretion policy for patient decision support (PDS) software that generally parallels the enforcement policy for CDS software functionalities described below.**

FDA defines "clinical decision support" software (or CDS) functions to mean those that meet the first, second, and third criteria of section 520(o)(1)(E) of the FD&C Act; FDA explains that CDS is excluded from a definition of a device when its function meets the fourth criterion:

- **Criterion 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.
- **Criterion 2:** Intended for the purpose of displaying, analyzing, or printing medical information about a patient or other medical information.
- **Criterion 3:** Intended for the purpose of supporting or providing recommendation to a health care professional about prevention, diagnosis, or treatment of a disease or condition.
- **Criterion 4:** Intended for user to be able to reach the same recommendation on his or her own without relying primarily on the software function.

In this draft guidance, FDA provides somewhat dated examples (for instance, an algorithm that relies on one published clinical guideline) of CDS functions that are not devices (meet all four criteria under section 520(o)(1)(E)), examples of CDS and other software functions for health care professionals that remain devices (generally, software on which health care professionals rely in clinical decision making), and an example of PDS functionality that will not be excluded (e.g. software that makes recommendations on blood thinner dosing).

To be CDS software exempted from the FD&C Act, the FDA emphasizes the importance of the intended user to be able to reach the same recommendation without relying primarily on the software. The examples offered don't really shed light on how this standard would apply to fairly sophisticated algorithms. The agency goes on to state that the sources behind the software must be identified to the intended user and easily accessible. Interestingly, the guidance appears to be using software transparency, i.e., the ability to see the inputs to algorithms and apply them, as a proxy for determining whether that software should be regulated as a medical device or excluded from the FD&C Act. The greater the transparency, the smaller the risk, on the premise that the physician or consumer can independently verify the software's recommendation (and vice versa). This guidance is silent, however, on the risk profile of software once it is judged to be a medical device. Perhaps the FDA will clarify this point in its final guidance, but until then, software developers should presume that the risk associated with

the disease or condition posing the greatest risk to patient health, being evaluated by the software, would drive its risk classification.

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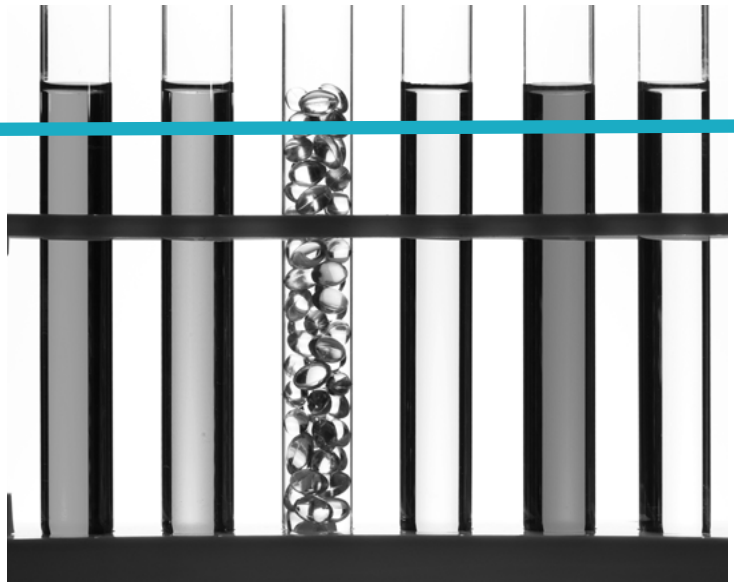
Along with the two proposed guidance documents discussed above, FDA also finalized the "Software as a Medical Device: Clinical Evaluation" guidance, delineating globally recognized principles for analyzing and assessing Software as Medical Device (SaMD) based on the overall risk of the product.

In its Dec. 8 statement, FDA announced that next it plans to issue draft proposed guidance on FDA oversight of products with both software functions that fall under FDA's medical device oversight and software functions that do not. FDA is also planning to finalize proposed guidance on "Deciding When to Submit a 510(k) for a Software Change to an Existing Device."



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