Consumer Technology Association™

1919 S. Eads St.
Arlington, VA 22202
703-907-7600
CTA.tech

February 5, 2018

By Electronic Delivery

Dockets Management Staff (HFA-305)
Food and Drug Administration
5630 17 Fishers Lane, Rm. 1061
Rockville, MD 20852.

RE: **Docket No.: FDA-2017-D-6294**
Draft Guidance, *Changes to Existing Medical Software Policies Resulting from Section 3060 of the 21st Century Cures Act*
Comments of the Consumer Technology Association

To Whom It May Concern:

The Consumer Technology Association ("CTA") respectfully submits these comments regarding the Food and Drug Administration's ("FDA" or "the Agency") December 8, 2017, draft guidance document, *Changes to Existing Medical Software Policies Resulting from Section 3060 of the 21st Century Cures Act.*

CTA is the principle trade organization for the consumer technology industry, comprised of more than 2,000 member companies covering a broad range of technology segments. CTA also owns and produces CES® – the world's gathering place for all who thrive on the business of consumer technologies. Profits from CES are reinvested into CTA's industry services. In particular, of relevance to these comments, CTA represents many companies operating in the digital health and medical technology space in the United States. CTA's Health and Fitness Technology Division strives to grow the health, fitness and wellness technology category. We do this in part by working to ensure that health and fitness technology devices, services, and apps operate in a clearly defined regulatory environment that balances innovation with safety and privacy.

CTA thanks FDA for issuing this guidance clarifying how the Agency understands the amended statutory definition of "medical device" as established by the 21st Century Cures Act ("Cures Act"), and how it plans to correspondingly update several existing guidance documents concerning the regulation of medical

software. The forthcoming publication of these updated guidance documents will also be very helpful to industry. More generally, CTA appreciates FDA's recognition of the important and diverse role of software in health care, and endorses FDA's willingness to take a least burdensome approach and focus regulatory oversight on medical devices posing more risk. In keeping with these themes, CTA would like to provide several comments that our members believe may warrant further consideration in order to optimize the usefulness of the final guidance.

I. Overview

Section 3060 of the Cures Act amended Section 520 of the Federal Food, Drug and Cosmetic Act ("FDC Act") to exclude certain software functions from the statutory definition of a "device":

- Software intended for administrative support of a health care facility.
- Software intended for general health and wellness that is not related to the diagnosis, cure, mitigation, prevention, or treatment of a disease or condition.
- Software intended to serve as electronic patient records, if such records are created and used by health care providers, constitute health information technology as certified by the Office of the National Coordinator for Health Information Technology (ONC), and do not interpret or analyze patient records for the purpose of diagnosis or treatment.
- Software intended to transfer, store, convert formats, or display clinical laboratory test or other device data and results, associated findings by a health care professional, general information about such findings, and general background information about a test or device, *unless* such function is intended for interpretation or analysis.
- Certain clinical decision support (CDS) software.

With respect to software intended for administrative support or as electronic patient records, the Cures Act codifies the approach historically taken by FDA, so does not change much in practice. However, the new legislation does raise some questions with respect to the regulation of general wellness products, medical device data systems, and clinical decision support tools. FDA issued separate guidance addressing the regulation of CDS products, and CTA has submitted comments on this topic to that docket. We address the other two categories of products, which are more fully discussed in the subject draft guidance, below.

II. General Wellness

In 2016 FDA issued the guidance document entitled *General Wellness: Policy for Low Risk Devices – Guidance for Industry and Food and Drug Administration Staff* ("*General Wellness Guidance*"). That guidance outlined two categories of general wellness products for which FDA did not intend to exercise active enforcement.

The draft guidance on 21st Century Cures Act changes explains that only one of the two categories of general wellness intended uses set forth in the existing *General Wellness Guidance* is now excluded from the device definition by the Cures Act, namely, those that are not tied to the diagnosis or treatment of a

disease or condition. In the view of our members, it may be worth clarifying in the guidance that many products in this category, including those comprised only of software, may not have met the statutory definition of "device" even before the Cures Act.

By contrast, the draft guidance explains that products with an intended use that relates the role of a healthy lifestyle with helping to reduce the risk or impact of certain chronic diseases or conditions remain medical devices. CTA appreciates the draft guidance's affirmation that FDA will continue to apply a policy of enforcement discretion with respect to such functions, as long as they also meet the additional criteria outlined in the *General Wellness Guidance*. CTA agrees that products in this second category under the *General Wellness Guidance* are very low risk and do not warrant FDA time and attention. Having the flexibility to develop tools for these types of applications, without needing to comply with burdensome regulation more appropriate for moderate or high risk medical devices, has been very helpful to industry, speeding development and innovation.

III. FDA Should Clarify the Meaning of "Active Patient Monitoring" and Analysis/Interpretation

CTA appreciates FDA's explicit clarification in the draft guidance that the fourth prong of the Cures Act provision cited above excludes medical device data systems (MDDS), medical image storage devices, and medical image communications devices from the definition of a device. CTA also appreciates the clarification that FDA interprets "clinical laboratory test or other device data and results" in this context to encompass a broad range of potential information, including medical images, waveforms, signals, and other clinical information.

CTA appreciates the approach FDA is taking to regulation of transfer, storage and display of medical device data. In particular, FDA's clarification, on page 12, that these functions will not be regulated "whether or not the use is for immediate clinical action" is helpful. However, because use in "active" or "real-time" patient monitoring has long been a concept in FDA regulation of tools that perform these transfer, storage and display functions (i.e., MDDS tools), it would be helpful for FDA to very clearly explain that use in active patient monitoring would not make such tools regulated. FDA uses the terminology "immediate clinical action" presumably to capture the same concept as the MDDS rule's use of the terminology "active patient monitoring." But given the shift from prior regulatory policy, making this link explicitly clear would be helpful.

Further, the draft guidance emphasizes that while products solely intended to transfer, store, convert formats, and display data and results are not subject to FDA regulation, software functions that also *analyze or interpret* medical data remain medical devices that are statutorily subject to FDA oversight. Nevertheless, FDA does not intend to enforce regulatory requirements for software functions intended to generate alarms or alerts or to prioritize multi-patient displays if they do not trigger immediate clinical action, because the function would then be considered low-risk despite its involving analysis/interpretation. For example, software that provides a notification that a parameter is out of range would not be regulated if it is not intended to alert a caregiver to take an immediate action on behalf of a patient.

CTA applauds this policy approach, but additional examples are needed to illuminate how FDA will prioritize regulation in this area. For instance, it is not clear how the Agency intends to distinguish mere monitoring – which is meant to inform some type of clinical action – from situations that warrant immediate clinical action. Specifically, it would be useful for the final guidance to more fully explain how to interpret "immediate" clinical action, *e.g.,* based on the timeframe in which the action must be taken, the severity of the patient's condition or the impact of not acting, and/or other factors. It would be helpful if FDA could provide examples illustrating this determination.

Further, FDA notes that the Agency "does not intend to enforce requirements under the FD&C Act and implementing regulations for these low risk software functions, such as the analysis of data to provide a notification, for which immediate clinical action is not needed." While this policy position is helpful, it is unclear whether FDA intends to apply enforcement discretion to all software functions that analyze or interpret device data, results and findings where no immediate clinical action is needed. CTA assumes the Agency means the reference to "low risk software functions" to be a description of very specific types of analysis, such as out of range notifications, but the scope of this policy is not yet clear. Numerous other analytical functions exist which are not intended to lead to immediate clinical follow-up and present low risk, such as many types of data trending. One of the examples proposed for addition to the MMA guidance suggests that an important factor in determining the level of regulation may be whether the analysis performed by the software represents a "unique interpretation function." However, no further detail is provided on this distinction. CTA believes industry would appreciate more insight from FDA regarding how it will determine whether an analytical/interpretive software function is sufficiently low-risk to be subject to enforcement discretion.

Finally, on page 13 of the guidance, FDA notes that the following example will be moved from the section discussing the focus of FDA's regulatory oversight to the Appendix discussing examples of mobile apps that are under enforcement discretion:

> Examples of displays of patient-specific medical device data include: display of medical images directly from a Picture Archiving and Communication System (PACS) server and remote display of data from bedside monitors (note that software functions that analyze or interpret medical device data to generate alarms or alerts that are intended to be relied upon in deciding to take immediate clinical action, are subject to regulations associated with such devices)

This example appears to align with the statutory language exempting from regulation tools that transfer, store or display medical device data. Thus, it is unclear why this example would be moved to the enforcement discretion examples list, rather than the list of examples of tools that are not medical devices. Clarification of this point would be helpful.

IV. FDA Should Clarify the Definition of Personal Health Record (PHR)

CTA appreciates that the draft guidance explains that PHR software, which solely functions to help individuals access and organize their health records, and is not intended for use in the diagnosis, cure, mitigation, prevention, or treatment of a disease or condition, is not a device under section 201(h) of the FD&C Act. PHR software of this type can play an important role in helping patients access their healthcare information and become more knowledgeable about their conditions, medications, immunizations and tests and procedures. The position taken by the draft guidance will help to spur needed innovation in these software systems.

At the same time, CTA recommends that the guidance provide further clarification regarding this policy. First, as currently written, the draft guidance appears to suggest that PHR software would potentially become regulated if the information collected by the patient is meant to be reviewed by healthcare professionals. Specifically on page 10 the FDA provides a definition of PHR software as follows:

> "Software functions that enable patients or non-HCPs to create, store, or transfer health records for their own record-keeping purposes that are not intended to be created, stored, transferred or reviewed by a HCP are considered personal health records (PHRs). These software functions in PHR systems that are not intended for use in the diagnosis, cure, mitigation, prevention, or treatment of a disease or condition are not devices under section 201(h) of the FD&C Act."

This definition implies that sharing PHRs with a healthcare professional could transform the PHR into a regulated product. However, given that electronic health records (EHR) are not regulated devices, and the purpose of an EHR is recordkeeping and review by a healthcare professional, it seems likely that this conclusion was not the Agency's intent. In addition, this section appears to be inconsistent with the section below (starting at line 373 page 11) which provides an example of apps which are not medical devices:

> "Mobile apps that enable, during an encounter, a health care provider to access their patient's personal health record (health information) that is hosted on a web-based or other platform"

Thus, further clarification would be helpful.

In addition, it would also be helpful to provide examples of products that would meet the criteria for an unregulated PHR. As outlined in the draft guidance, FDA intends to add language to the MMA guidance describing EHRs that are unregulated (see page 10, line 348). It would be very helpful if examples addressing PHRs could also be added to (or called out in) the MMA guidance. This would assist industry in further differentiating between regulated and unregulated functions.

V. Change to Regulations

The draft guidance is helpful in clarifying which product types FDA now considers to be outside its oversight based on Section 3060 of the Cures Act, and in noting which changes the Agency envisions making to related guidance documents to reflect these interpretations. However, the guidance does not address whether any changes will be made to the governing regulations. For instance, a footnote indicates that the existing classification regulation for medical image communications devices no longer describes a device under the FDC Act, but that certain products regulated under that provision do continue to meet the definition of a device. CTA believes it could be confusing to maintain FDA regulations defining products that current law no longer deems to be subject to FDA oversight. CTA understands that drafting and modifying regulations is time-consuming. Nevertheless, it may be important to take these steps in order to fully realize the implementation of the 21st Century Cures Act – both for clarity and consistency and because FDA guidance, while instructive, is not legally binding.

* * *

CTA appreciates this opportunity to comment on FDA's *Changes to Existing Medical Software Policies Resulting from Section 3060 of the 21st Century Cures Act* draft guidance. CTA supports FDA's efforts to update previously issued guidance documents in the medical device software/digital health space to ensure they align with current law as amended by the Cures Act. We hope that these comments are helpful in explaining some of the industry's questions and recommendations as the Agency prepares the final version of the guidance.

We would be pleased to answer any questions you might have about these comments. Please contact me at 703-907-7544 if CTA can be of any assistance.

Sincerely,

Michael Petricone

Senior Vice President, Government and Regulatory Affairs
Consumer Technology Association