ConnectedHealth

February 6, 2018

Division of Dockets Management (HFA-305)
Food and Drug Administration
5630 Fishers Lane, Room 1061
Rockville, Maryland 20852

RE: *Comments of ACT | The App Association's Connected Health Initiative regarding the Food and Drug Administration's Draft Guidance for Industry and Food and Drug Administration Staff on Changes to Existing Medical Software Policies Resulting from Section 3060 of the 21st Century Cures Act (Docket No. FDA-2017-D-6294)*

ACT | The App Association's Connected Health Initiative (CHI)[1] writes to provide input to the Food and Drug Administration (FDA) as it considers the amended definition of a medical device within the 21st Century Cures Act as well as the effect the amended definition would have on a variety of FDA guidance related to medical device software (Draft Guidance).[2]

CHI is the leading effort by stakeholders across the connected health ecosystem to clarify outdated health regulations, encourage the use of remote patient monitoring (RPM), and support an environment in which patients and consumers can see improvement in their health. We seek partnerships and activities that realize the benefits of an information and communications technology-enabled American healthcare system. CHI members and stakeholders actively participate in the administration of healthcare through connected technologies and medical devices. We strongly believe that by streamlining regulatory processes and providing a clear approach to connected health hardware and software technologies, the FDA can play a central role in creating a cost-effective, patient-centered, and quality-driven healthcare system for all Americans.

[1] http://www.connectedhi.com/

[2] https://www.fda.gov/downloads/MedicalDevices/DeviceRegulationandGuidance/GuidanceDocuments/UCM587820.pdf

CHI appreciates the FDA's recognition of the impact the 21st Century Cures Act has on the range of FDA guidance relied upon by the connected health technology community. CHI members depend on legal and business certainty to increase investment and innovation in the connected healthcare ecosystem, and the FDA's work to update relevant guidance will support that certainty.

The FDA's efforts pursuant to, and around, the 21st Century Cures Act are another example of the agency's willingness to embrace advanced technology and connectivity in the healthcare continuum. We agree with the FDA that the 21st Century Cures Act should not cause major changes in the oversight of connected health technologies, and we generally support the FDA's updates proposed in the Draft Guidance.

Building on the above, CHI offers the following comments to the FDA's proposed changes to various guidance:

- ***Provide clarity around the meaning of "immediate clinical action" in the context of medical device data systems (MDDS)*** – CHI supports the FDA's proposed clarification that "[MDDS], defined as a software, electronic, or electrical hardware that is intended to provide one or more of the following uses, whether or not the use is for immediate clinical action, without controlling or altering the functions or parameters of any connected medical devices: (a) the electronic transfer of medical device data; (b) the electronic storage of medical device data; (c) the electronic conversion of medical device data from one format to another format in accordance with a preset specification; or (d) the electronic display of medical device data" is not a medical device." However, CHI urges the FDA to utilize the same terminology between the Draft Guidance and the various guidances to which it is proposing changes. For example, the FDA's use of the term "immediate clinical action" does not align with the existing MDDS guidance description of MDDS functions that are active and real-time. MDDS that transfers data between devices performing FDA-regulated activities should not be subject to FDA regulation. CHI requests that the Draft Guidance be updated to (1) align with phrasing in existing MDDS guidance; and (2) address the treatment of low-risk MDDS real-time monitoring functions, which are now exempt from FDA regulation, in its discussion and through examples.
- ***CHI Input on FDA proposals to alter or move examples –***
    - CHI supports the FDA's proposal to move three examples from the category of general wellness products that meet the definition of a medical device yet enjoy enforcement discretion to the category of general wellness products that are not medical devices and fall outside of the FDA's regulatory reach.
    - CHI supports the FDA's proposals to move various mobile medical apps (MMAs) from the examples of medical devices that enjoy enforcement discretion to examples of software applications that are exempt from FDA regulation. These changes to the MMA guidance map reflect the changes made to the definition of a medical device in the 21st Century Cures Act.

- CHI recommends that references to personal health records (PHRs) be deleted from pages 16 and 18 of the MMA guidance. On these pages, the FDA currently states that PHRs, as described, will enjoy enforcement discretion. The FDA notes in the Draft Guidance that PHRs are not intended to diagnose or treat diseases and are not medical devices, and should therefore be excluded from FDA oversight rather than enjoy enforcement discretion.
- CHI also recommends that the following MMA guidance examples of software enjoying enforcement discretion be instead characterized as software excluded from FDA oversight:
    - "Mobile apps that provide patients with simple tools to organize and track their health information;"[3]
    - "Mobile apps that are specifically marketed to help patients document, show, or communicate to providers potential medical conditions;"[4]
    - "Mobile apps that provide easy access to information related to patients' health conditions or treatments (beyond providing an electronic 'copy' of a medical reference),"[5] with added context provided in alignment with the FDA's approach to clinical decision support software;
    - "Mobile apps that perform simple calculations routinely used in clinical practice;"[6]
    - "Mobile apps that help asthmatics track inhaler usage, asthma episodes experienced, location of user at the time of an attack, or environmental triggers of asthma attacks;"[7]
    - "Mobile apps that prompt the user to manually enter symptomatic, behavioral or environmental information, the specifics of which are pre-defined by a health care provider, and store the information for later review;"[8]
    - "Mobile apps that record the clinical conversation a clinician has with a patient and sends it (or a link) to the patient to access after the visit;"[9] and

[3] MMA Guidance at 16.

[4] *Id.*

[5] *Id.* at 17.

[6] *Id.*

[7] *Id.* at 23.

[8] *Id*.

[9] *Id.* at 24.

        - "Mobile apps that allow a user to collect, log, track, and trend data, such as blood glucose, blood pressure, heart rate, weight, or other data from a device to eventually share with a health care provider, or upload it to an online (cloud) database, personal or electronic health record."[10]
    - The software described in lines 480-487 of the Draft Guidance, which would be added as an example of software enjoying enforcement discretion, can easily meet the definition of CDS software excluded from the definition of a medical device under the 21st Century Cures Act. The FDA's approach taken in the MMA guidance should be consistent with the text in lines 480-487. CHI recommends that the software described illustrate the distinction made by the healthcare provider to exempt a device from FDA regulation.
- ***Necessary updates to FDA regulations*** – While supporting the FDA's efforts to update its guidance, CHI recommends that the FDA revise its definition of a medical device used within regulations to align with the definition put forth by the 21st Century Cures Act.

CHI appreciates the opportunity to provide input on the FDA's Draft Guidance and requests that our views be considered as the FDA implements necessary updates to various connected health technology-related guidances. We are available to discuss our views further with the FDA.

Sincerely,

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[10] *Id.* at 26.