ConnectedHealth

April 29, 2019

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

RE: Prescription Drug-Use-Related Software; Establishment of a Public Docket; Request for Comments *(Docket No. FDA-2018-N-3017)*

The Connected Health Initiative[1] (CHI) appreciates the opportunity to provide input on the Food and Drug Administration's (FDA) draft guidance addressing prescription drug-use-related software (PDURS)[2] (Draft Guidance). CHI also requests a meeting with FDA to provide further insight into our views.

I. Statement of Interest and General Comments of the Connected Health Initiative

CHI is the leading effort by stakeholders across the connected health ecosystem to clarify outdated health regulations, encourage the use of digital health innovations, and support an environment in which patients and consumers can see improvements in their health. We seek essential policy changes that will help all Americans benefit from an information and communications technology-enabled healthcare system. CHI is a long-time active advocate for the increased use of new and innovative digital health tools in both the prevention and treatment of disease. CHI's advocacy reaches across the divisions of the Department of Health and Human Services, as well as other relevant agencies.

[1] For more information, see www.connectedhi.com.

[2] https://www.regulations.gov/document?D=FDA-2018-N-3017-0030.

Internet connected and software-enabled medical devices are radically improving the American healthcare system and will continue to do so. Global consumer spending in health and fitness apps grew three-fold from 2016 to 2018.[3] App-enabled telehealth and remote monitoring of patient-generated health data continues to represent the most promising avenue for improved care quality, reduced hospitalizations, avoidance of complications, and improved satisfaction, particularly for the chronically ill. We agree with the FDA that prescription drug-related use cases should be addressed to realize these benefits. Failed medication adherence alone is responsible for adding $290 billion in costs to the U.S. healthcare system each year.[4] [5] CHI is committed to bringing new trustworthy and innovative technologies into the market to address these and other prescription drug-related challenges to the U.S. healthcare system.

II. Specific Comments and Recommendations of the Connected Health Initiative on the FDA's Draft Guidance

Generally, CHI is concerned with the Center for Drug Evaluation and Research's (CDER) proposed approach to the PDURS in recently-released draft guidance, which would divert from the Center for Devices and Radiological Health's (CDRH) work to modernize the FDA's approach to the regulation of Software as a Medical Device (SaMD). For example, CDER's approach to PDURS would take a situation-based approach, as opposed to the CDRH's risk-based approach to SaMD. Further, CDER's proposed approach to PDURS would expose software developed by a drug company to significantly longer approval timeframes, placing PDURS at an arbitrary disadvantage to SaMD overseen by CDRH. We therefore recommend that the FDA's approach to PDURS be brought into alignment with the widely-supported approach developed by CDRH for SaMD.

[3] http://www.netimperative.com/2019/01/the-state-of-mobile-in-2019-app-spend-worth-double-box-office-market/.

[4] http://www.nehi.net/writable/publication_files/file/pa_issue_brief_final.pdf. Accessed on 31 May 2016

[5] JAMA 2013;310(24):2611-2.

Further specific input from CHI on the draft guidance includes:

- CHI has concerns that CDER's proposed approach to PDURS would be inconsistent with Congress' clear aim to further innovation in the digital health context through the 21st Century Cures Act, which amended Section 503(g)(1)(E) of the Food, Drug, and Cosmetic Act to clarify that "the Secretary shall not determine that the primary mode of action is that of a drug or biological product solely because the combination product has any chemical action within or on the human body."[6] CDER's proposed approach to oversight in the Draft Guidance would peel PDURS away from other digital health tools addressed by CDRH using widely-supported risk-based models solely because PDURS is developed by or on behalf of a sponsor for use with the sponsor's prescription drug or drugs.
- CDER's proposed approach to PDURS does not appear to align with the FDA's "least burdensome" methodology.[7] CDER's proposed approach does not recognize the much more rapid pace of development taking place for SaMD (recognized by CDRH through, for example, its ongoing effort to develop the Software Precertification Program[8]), as opposed to the lengthy drug development process.
- CHI is concerned with CDER's proposal to have all output of PDURS constitute drug labeling "because it accompanies a drug," including "screen displays, alerts, reminders, audio messages, vibrations, or sounds." Noting that there are many features of health software that do not advise on how to use a prescription drug, CHI does not believe that FDA has provided adequate authority for making such a sweeping decision. CHI is similarly troubled by CDER's proposal to include all PDURS output not included in FDA-required labeling as promotional labeling.
- CDER's proposed approach to PDURS would utilize the standard of review utilized for drugs based on labelling, even when the same software may already be cleared by CDRH. CHI is concerned with this proposal to add an additional layer of regulatory review to medical devices already addressed by CDRH guidance.

[6] PL 114-255 Sec 3038(a)(4)(g)(1)(E).

[7] https://www.fda.gov/downloads/MedicalDevices/DeviceRegulationandGuidance/GuidanceDocuments/ucm085999.pdf

[8] https://www.fda.gov/medicaldevices/digitalhealth/digitalhealthprecertprogram/default.htm

We fear the practical effect of CDER's approach to PDURS, should its Draft Guidance be finalized without significant revisions, will be to discourage SaMD developers from working with prescription drug companies which is clearly not in the public interest. CHI urges CDER to consider significant revisions to its Draft Guidance to harmonize the approach taken by FDA to PDURS with the risk-based framework already in place for software-enabled medical devices developed by CDRH, and consistent with the FDA's "least burdensome" approach. As a practical matter, CHI believes that the FDA's approach to PDURS must be built on the extensive work within CDRH to implement the 21st Century Cures Act, address SaMD (including its development of the Software Precertification Program), and other digital health initiatives.

III. Conclusion

CHI appreciates the opportunity to submit its comments to the FDA and urges its thoughtful consideration of the above input. Further, we request a meeting with the FDA to discuss this draft guidance before it advances further.

Sincerely,

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