March 13, 2021

Via Docket Submission

U.S. Department of Health and Human Services
Daniel Barry, Deputy General Counsel
200 Independence Avenue, SW
Washington, DC 20201

Re: 86 FR 4088 – Making Permanent Regulatory Flexibilities Provided During the COVID-19 Public Health Emergency by Exempting Certain Medical Devices From Premarket Notification Requirements

Dear Mr. Barry,

On behalf of the Digital Therapeutics Alliance (DTA), we are submitting comments related to Health and Human Services' '*Making Permanent Regulatory Flexibilities Provided During the COVID-19 Public Health Emergency by Exempting Certain Medical Devices From Premarket Notification Requirements*'[1] (86 FR 4088), published on January 15, 2021.

As referenced in proposed rule HHS 86 FR 4088, in April 2020, FDA issued the, '*Enforcement Policy for Digital Health Devices For Treating Psychiatric Disorders During the Coronavirus Disease 2019 (COVID-19) Public Health Emergency*'[2] (EUA). This EUA permits device manufacturers to commercialize certain products without premarket clearance provided that the manufacturer complies with specific controls set forth in the guidance (including labeling verification and validation, disclosure requirements, cybersecurity protections, and labeling limitations).

Although DTA supports the overall goal of the April 2020 EUA to provide patients with access to certain digital therapeutics (DTx) and other medical devices during the Covid-19 public health emergency (PHE), it is important for existing or more appropriately tailored regulatory pathways to be reinstated following this emergency period. This is necessary since HHS 86 FR 4088 proposes stripping Class II devices on the list from premarket notification requirements without implementing other controls to protect public health and safety.

Therefore, the Digital Therapeutics Alliance – the leading global non-profit trade association of industry leaders and stakeholders dedicated to broadening the understanding and adoption of digital therapeutics into healthcare – does not support HHS 86 FR 4088 as currently proposed.

[1] https://www.govinfo.gov/app/details/FR-2021-01-15/2021-00787/summary
[2] https://www.fda.gov/media/136939/download

It is critical for the agency to address the following issues related to HHS 86 FR 4088:

1) Under this proposed rule, companies could market digital health products that deliver varying degrees of medical interventions to patients without sufficient regulatory oversight. We are concerned that HHS 86 FR 4088 could result in companies making confusing, ambiguous, or potentially unsubstantiated clinical claims when marketing their products. This would erode trust and confidence in the rapidly evolving digital therapeutics industry, while potentially diminishing long-term quality.

2) Another concern is that HHS 86 FR 4088 could impact existing product market access pathways, including: 1.) digital therapeutics that have obtained FDA clearance under the de novo pathway, but may now be subject to permanent exemption, 2.) products subject to the 510(k) pathway that have received clearance using one of these predicate devices, and 3.) products currently under development intending to utilize a predicate device that may now be subject to permanent exemption. If HHS 86 FR 4088 moves forward, it would be critical for HHS to address short- and long-term impacts on these categories of products.

3) Regarding the proposed rule's reference to the FDA's Manufacturer and User Facility Device Experience (MAUDE) database, HHS' exclusive reliance on data in the MAUDE database for this proposed rule is flawed and incomplete. MAUDE is a collection of individual reports from manufacturers, importers, and medical device users. Since the database has no mechanism to identify or correct missing, erroneous, or incomplete information, its value should not be elevated beyond a reference tool.

We therefore propose the following steps for HHS and FDA:

1) DTA believes that FDA provides critical value to patients, clinicians, and payors in assessing and validating the safety and efficacy of digital therapeutic devices – some of which are included in this proposed rule. Since we cannot support HHS 86 FR 4088 as presented, HHS and FDA should work with DTA and similar organizations to develop appropriate and necessary pathways for DTx product review and access in the post-PHE period. This will ensure a greater balance between patient access and appropriate oversight of DTx clinical indications, product claims, safety, and efficacy.

2) It is also necessary for the agency to develop a continuity of care pathway for patients, caregivers, and clinicians who've had access to certain digital therapeutics during the PHE period under the April 2020 EUA. Given the importance of this discussion, DTA hopes to work directly with FDA and HHS to develop the necessary solutions and pathways.

Overall, DTA is encouraged by HHS' efforts to improve regulatory standards and oversight, particularly as they relate to providing increased patient access to high-quality digital therapeutics. However, we are concerned about the potential negative impacts on patients with regard to product safety and efficacy, plus devalued end user confidence, if certain digital therapeutics are permanently exempt from FDA premarket notification requirements through HHS 86 FR 4088. In the long-term, if patients, caregivers, and clinicians are negatively impacted following the acceptance of this proposed rule, undertaking a formal reversal

process will be much more difficult than proactively working with DTA and fellow industry leaders now to create more targeted, appropriate regulatory and patient access pathways.

Thank you for the opportunity to provide commentary on this proposed rule. We look forward to ongoing conversations and working with you on future proposals to provide patient access to safe and effective digital therapeutics to patients, caregivers, and clinicians.

Sincerely,

Megan Coder, PharmD, MBA
Executive Director
Digital Therapeutics Alliance
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Reference: DTx Definition and Industry Principles

Digital therapeutics (DTx) are products that "deliver evidence-based therapeutic interventions to patients that are driven by high quality software programs to prevent, manage, or treat a medical disorder or disease. They are used independently or in concert with medications, devices, or other therapies to optimize patient care and health outcomes".[3] Digital therapeutics differ from wellness apps and other general digital health products given their mechanisms of action, intended use, levels of risk, and rigor of clinical evaluation to ensure a safe and effective offering to patients.[4]

All products claiming to be a digital therapeutic should adhere to these foundational industry principles:

1) Prevent, manage, or treat a medical disorder or disease
2) Produce a medical intervention that is driven by software
3) Incorporate design, manufacture, and quality best practices
4) Engage end users in product development and usability processes
5) Incorporate patient privacy and security protections
6) Apply product deployment, management, and maintenance best practices
7) Publish trial results inclusive of clinically meaningful outcomes in peer-reviewed journals
8) Be reviewed and cleared or certified by regulatory bodies as required to support product claims of risk, efficacy, and intended use
9) Make claims appropriate to clinical evaluation and regulatory status
10) Collect, analyze, and apply real world evidence and/or product performance data

[3] https://dtxalliance.org/wp-content/uploads/2021/01/DTA_DTx-Definition-and-Core-Principles.pdf
[4] https://dtxalliance.org/wp-content/uploads/2021/01/DTA_DTx-Product-Best-Practices_11.11.19.pdf