TO: The Honorable Melony Griffith, Chair
Members, Senate Finance Committee
The Honorable Clarence K. Lam

FROM: Angie Gochenaur, Director of Government Affairs, Pear Therapeutics

DATE: February 28, 2023

RE: **SUPPORT** – Senate Bill 441 – *Maryland Medical Assistance Program - Prescription Digital Therapeutics*

Pear Therapeutics (US), Inc. ("Pear") welcomes the opportunity to provide public comment on Senate Bill 441 (Lam). Pear is a commercial-stage healthcare company pioneering a new class of software-based medicines, sometimes referred to as Prescription Digital Therapeutics ("PDTs"), which use software to treat diseases directly. Our vision is to advance healthcare through the widespread use of PDTs with an initial focus on supporting patients struggling with behavioral and mental health conditions. In particular, Pear's reSET® and reSET- O® are the first mobile applications to be authorized to treat disease by the FDA. These products specifically treat Substance Use Disorder ("SUD") and Opioid Use Disorder ("OUD"), respectively[1,2].

PDTs are prescribed by a licensed prescriber, either alone or in combination with drugs. Similar to pharmaceuticals, PDTs undergo rigorous clinical development via clinical trials designed to seek FDA authorization to safely and effectively treat disease. PDTs are evidence-based therapeutic interventions that are driven by high quality software programs to prevent, manage, or treat a medical disorder or disease. PDTs are only available via consultation with a licensed healthcare professional who then prescribes the digital therapeutic as clinically appropriate. PDTs are designed to expand access and convenience for patients and improve reach for clinicians. Additionally, PDTs may lower cost for payors by reducing and/or augmenting human intervention, providing for more efficient care. PDTs can help mitigate many treatment barriers by offering accessible and consistent evidence-based treatments, available to patients 24/7.

To treat serious disease, it is imperative that the treatments patients use are recommended by a licensed provider or fit within an existing care plan. Whether it is a pill, electronic device, or mobile app - treatments for serious disease must adhere to a high standard as patients trust these products to improve their health outcomes. Provider recommendation is important, yet there are hundreds of mobile apps that purport to help treat disease - and we know that providers do not have the time to vet all of them. FDA authorization provides a smaller set of already vetted products for providers to review - products which have been shown to have a statistical

correlation with positive health outcomes. Being prescription-only means that manufacturers cannot reach patients without the provider involved. In other words, the only way that manufacturers can support patient access is by educating providers and payers on the clinical value the product provides to patients. Products available directly to consumers can use direct-to-patient marketing techniques without undergoing the level of clinical rigor that PDTs are subject to. The incentives are therefore different for PDT manufacturers - where PDTs are judged by their clinical value to patients and other apps can be judged by their ability to market well to patients.

In summary, Senate Bill 441 is a bill which further expands Maryland's leadership role in pioneering the use of FDA authorized prescription digital therapeutics to treat serious disease. This bill further supports providers by giving them more evidence-based and vetted tools to support patients and does so in a way that integrates these tools directly into care plans for patients. PDTs can help make care more accessible for people who struggle with conditions and provide support in times when providers may not be available. Pear supports this legislation and applauds the state of Maryland for its continued commitments to patients.

Respectfully,
Angela Gochenaur
Director, State Government Affairs

References

1. reSET Clinician directions for use. Pear Therapeutics, Inc. 2020.
2. reSET-O Clinician directions for use. Pear Therapeutics, Inc. 2020.