



The Honorable Melony Griffith  
The Honorable Katherine Klausmeier  
Miller Senate Office Building  
Annapolis, Maryland 21401

RE: SB0441 - Maryland Medical Assistance Program - Prescription Digital Therapeutics

Chair, Vice-Chair, and Members of the Committee,

On behalf of the Digital Therapeutics Alliance, we are pleased to SUPPORT your SB0441, which would define "prescription digital therapeutic" as a product, a device, an Internet application, or any other technology approved by the federal Food and Drug Administration that has an approved indication for the prevention, management, or treatment of certain medical conditions, primarily uses software to achieve results, and requires a prescription. This bill also requires the Maryland Medical Assistance Program to provide coverage for prescription digital therapeutics for Program recipients.

The Digital Therapeutics Alliance (DTA) was founded in 2017 as a 501(c)(6) non-profit trade association of industry leaders and stakeholders engaged in the evidence-driven advancement of digital therapeutics. As the leading international organization on DTx thought leadership and education, DTA provides patients, clinicians, payors, and policymakers with the necessary tools to evaluate and utilize DTx products.

Digital therapeutics are transforming healthcare by increasing patient access to safe and effective therapies, by extending clinicians' ability to care for patients, and offering payors scalable and cost-effective interventions.

There are currently 9 FDA approved DTx products, which are prescribed by your healthcare provider and intended to supplement but not replace visits, and unlike the general health apps you see on your phone, these DTx products are proven effective by the FDA and protected under HIPAA.

Digital therapeutics range in capabilities-- from calculating insulin doses to delivering cognitive behavioral therapy, these platforms can help track and manage symptoms as well as improve medication adherence.

To describe just a few—

Freespira is an FDA-cleared therapeutic that incorporates a proprietary sensor, physiological feedback display, and coaching to train patients over 28-days to normalize the respiratory irregularities underlying a key physiological driver of anxiety attacks and PTSD symptoms.

The impact of this PDT? Users were 86% panic attack free immediately post-treatment and 73% panic attack free at 12 months post-treatment. As for PTSD, At 6-months post-treatment, 89% reported significant decrease in symptoms based on CAPS-5 Score (validated PTSD assessment) and 50% were in remission.

Then there is Nervivio, which is a wireless wearable neuromodulation unit controlled by a smartphone app. Treatments with Nervivio are self-administered by the user at the onset of a migraine attack.

The impact? 7 migraine patients out of 10 using Nervivio saw significant pain relief; 4 out of 10 experienced pain freedom.

And EndeavorRx, which is a digital therapeutic indicated to improve attention function as measured by computer-based testing in children ages 8-12 years old with primarily inattentive or combined-type ADHD, who have a demonstrated attention issue.

Patients who engaged with EndeavorRx demonstrated improvements in a digitally assessed measure of sustained and selective attention. EndeavorRx demonstrated improvements in ADHD impairment with responder rates ranging 48\*-50%\*\* after 1-month treatment and 68%\*\* following a second month of treatment.

These digital therapeutics work and this bill would help patients access them. For these reasons, we respectfully request your support for SB 411.