



June 30, 2022

The Honorable Jeanne Shaheen
United States Senate
506 Hart Senate Office Building
Washington, DC 20510

The Honorable Shelley Moore Capito
United States Senate
172 Russell Senate Office Building
Washington, DC 20510

The Honorable Mike Thompson
United States House of Representatives
268 Cannon Office Building
Washington, DC 20515

The Honorable David B. McKinley
United States House of Representatives
2239 Rayburn Office Building
Washington, DC 20515

Re: **H.R.7051** and **S.3791**

Dear Senators Shaheen and Capito and Representatives Thompson and McKinley:

The Digital Therapeutics Alliance is dedicated to expanding adoption, coverage, and access to clinically-validated digital therapeutics (DTx) to improve patient outcomes. We are writing to thank you for introducing **H.R.7051 and S.3791** (the “Access to Prescription Digital Therapeutics Act of 2022”). We support this legislation as it would establish new Medicare and Medicaid benefit categories for prescription digital therapeutics, which are software-based treatments designed to directly prevent, manage, or treat diseases or disorders, tested for safety and efficacy in clinical trials, and regulated by the U.S. Food and Drug Administration (FDA), and prescribed by health care providers. Prescription digital therapeutics undergo rigorous testing and are held to the same standards of evidence and regulatory requirements as traditional treatments like prescription drugs and medical devices, but, the therapeutic intervention is delivered through software.

The Covid-19 pandemic brought to light substantial disparities, particularly related to patient access to health care. Innovative technology has the potential to enable physicians to increase access to high-value care for their patients. Using prescription digital therapeutics as an example, patients prescribed these therapies can obtain access to care they would have otherwise gone without by using an app on their phone or laptop. Allowing more people suffering from a wide range of illnesses and conditions—from alcohol and opioid use disorders, to mental health issues, to chronic conditions like diabetes and Parkinson's disease—to get the care they need is the goal of the Access Prescription Digital Therapeutics Act of 2022.

Health technologies have the potential to improve the lives of Medicare and Medicaid patients, and other high-risk and disadvantaged groups. However, to date, there have only been a few

scenarios where the government pays for digital therapeutics products, and for the most part there is little to no public payor coverage for DTx. Establishing Medicare and Medicaid benefit categories for prescription digital therapeutics is an important first step in closing that gap by ensuring that these evidence-based clinically validated therapeutics reach the people who most need them.

We are grateful for your leadership and commitment to enhancing the availability of these therapies for the many millions of Americans who rely on Medicare and Medicaid for their medical care. This is a critical piece of legislation, and we the undersigned organizations eagerly anticipate working with you and your colleagues to get it through Congress as swiftly as possible. If you have any questions, please contact Sara Elalamy at sara@dtxalliance.org.

Sincerely,

AdvaMed - Advanced Medical Technology Association
Akili Interactive Labs, Inc.
AppliedVR
Astellas Pharma, US
BehaVR, Inc.
Blue Note Therapeutics
Better Therapeutics
Big Health
Click Therapeutics, Inc
Cognito Therapeutics, Inc
CureApp, Inc
Digital Therapeutics Alliance
Digestive Disease National Coalition
Exer Labs, Inc
Freespira, Inc.
Global MD Org Network Corp
Happify Health
HelloBetter
ieso Digital Health, Inc
JOGO Health
Luminopia, Inc.
Limbix
Mahana Therapeutics, Inc
MedRhythms
metaMe Health, Inc
Orpyx Medical Technologies Inc
Orexo US, Inc.
Otsuka Pharmaceutical
Pear Therapeutics
Renalis Health

Renovia Inc
Sidekick Health
Welldoc, Inc
Woebot Health
Yonsei University Health System