

March 25, 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:

ACTION for PDTs is a multi-disciplinary partnership that works to expand the adoption and coverage of, and access to prescription digital therapeutics (PDTs) for individuals with chronic diseases. We are writing to thank you for introducing **H.R.7051 and S.3791**. We support this legislation as it expands access to innovative therapeutics for patients. We encourage Congress to swiftly adopt this bill and to create Medicare coverage and payment and a new Medicaid payment category for PDTs.

As you know, PDTs are prescription-only software that are regulated by the U.S. Food and Drug Administration (FDA). They deliver standardized, high-quality, and evidence-based therapeutic interventions to prevent, manage, or treat specific diseases and disorders. PDTs must demonstrate safety and effectiveness in randomized clinical trials. They require FDA premarket review and authorization, and they cannot be utilized unless they are prescribed by a licensed healthcare provider.

Bipartisan, bicameral legislation to enable Medicare and Medicaid coverage of PDTs will benefit many vulnerable Americans. PDTs are currently available to treat a wide range of diseases and conditions, including substance use disorders (SUDs), ADHD, cancer, Type 2 diabetes, chronic back pain, and will soon be available to treat chronic stroke, multiple sclerosis, Parkinson's disease, autism, chronic insomnia, and a wide range of mental health and chronic conditions—many of which are common among Medicare beneficiaries.<sup>1</sup> These technologies have already proven effective in addressing the nation's opioid crisis, demonstrating a decline in SUDs, fewer relapses, and greater treatment retention.<sup>2</sup>

These technologies can address an urgent unmet healthcare need in our society and reduce disparities. The COVID-19 pandemic has created disruptions in treatment and demand for virtual care for millions of Americans with chronic conditions. Yet, even before the COVID-19

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<sup>1</sup> Chronic Conditions among Medicare Beneficiaries: A Methodological Overview, Centers for Medicare and Medicaid Services (November 2020), [https://www.cms.gov/Research-Statistics-Data-and-Systems/Statistics-Trends-and-Reports/Chronic-Conditions/Downloads/Methods\\_Overview.pdf](https://www.cms.gov/Research-Statistics-Data-and-Systems/Statistics-Trends-and-Reports/Chronic-Conditions/Downloads/Methods_Overview.pdf) .

<sup>2</sup> Yuri A Maricich, et al., Real-World Evidence for a Prescription Digital Therapeutic to Treat Opioid Use Disorder, *Curr Med Res Opin.*, 2021 Feb; 37(2): 175-183 available at <https://pubmed.ncbi.nlm.nih.gov/33140981/> .

pandemic began, underserved communities with limited healthcare access have existed in both remote rural areas and economically challenged urban neighborhoods. Poor adherence to physician-prescribed protocols can be exacerbated when there is a lack of connection between provider and patient, leading to poorer outcomes and increased healthcare costs.

PDTs help address those access challenges and strengthen patient adherence by offering effective remote care for individuals with chronic conditions, especially in remote areas or economically challenged urban neighborhoods. PDTs provide round-the-clock access to care, keep patients and providers connected, and utilize software and artificial intelligence in lieu of or in conjunction with medications to treat the disease.

A major obstacle to greater use of PDTs stems from the lack of Medicare and Medicaid coverage of these digital tools. This is particularly harmful given that Medicare enrollees tend to have a disproportionate occurrence of serious chronic illnesses.<sup>3</sup> Therefore, legislation is essential. It can provide access to FDA-regulated PDTs for patients and clinicians, allowing for additional healthcare options that can improve outcomes for millions of Americans living with chronic disease, many of whom do not have easy access to conventional in-person clinical care.

Medical and digital science is rapidly evolving, and legislation is necessary to provide wide access to these beneficial advances. Congressional action on your bipartisan measure will allow Americans with chronic conditions to receive high-quality healthcare in their own homes. Thank you again for your leadership and commitment. The undersigned organizations look forward to working with you and your colleagues to advance important legislation. If you have any questions, please contact us at [policy@aimedalliance.org](mailto:policy@aimedalliance.org).

Sincerely,

Aimed Alliance  
Alliance for Patient Access  
American Society for Pain Management Nursing  
Association for Behavioral & Cognitive Therapies  
Below Your Belt  
Behavioral Health Association of Providers  
California Access Coalition  
California Council of Community Behavioral Health Agencies  
California Consortium of Addiction Programs and Professionals  
Caregiver Action Network  
Center for U.S. Policy  
Certification Board for Diabetes Care & Education  
Chronic Disease Coalition  
Diabetes Policy Collaborative  
Healthy Women  
Headache and Migraine Policy Forum

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<sup>3</sup> Chronic Conditions among Medicare Beneficiaries: A Methodological Overview, Centers for Medicare and Medicaid Services (November 2020), [https://www.cms.gov/Research-Statistics-Data-and-Systems/Statistics-Trends-and-Reports/Chronic-Conditions/Downloads/Methods\\_Overview.pdf](https://www.cms.gov/Research-Statistics-Data-and-Systems/Statistics-Trends-and-Reports/Chronic-Conditions/Downloads/Methods_Overview.pdf) .

I-Belong Inc. dba Reach  
Liver Coalition of San Diego  
Lupus and Allied Diseases Association, Inc.  
Mental Health America  
National Association for Continence  
National Hispanic Medical Association  
Partnership to Advance Cardiovascular Health  
People Advocating Recovery  
Shatterproof  
She Recovers Foundation  
The COSHAR Healthy Communities Foundation  
The Kennedy Forum  
The Simon Foundation for Continence  
Triage Cancer  
Young People in Recovery