

ACTION for PDTs Mental Health and Substance Use Disorders

Prospectus

Mission

ACTION for PDTs: Mental Health and Substance Use Disorders is an alliance of stakeholder organizations working collectively to raise awareness of and expand access to prescription digital therapeutics (PDTs) focused on the needs of patients with mental health disorders (MH) and substance use disorders (SUDs). With ACTION, we seek to achieve the following goals so that patients with MH/SUDs can lead healthier, more productive lives:

- **Adopt** evidence-based, FDA-regulated medical interventions for MH/SUDs
- Provide **comprehensive coverage** of and access to PDTs
- Improved **therapeutic** outcomes
- Drive **inclusion** to reduce inequities, disparities, and social determinants of health
- Provide **options** for patients and providers
- Ensure that **novel technologies** that deliver medical care are adequately regulated to ensure safety and efficacy

Introduction: Addressing an Urgent Need

In Mental Health Treatment

According to the Substance Abuse and Mental Health Services Administration (SAMHSA), one in five Americans ages 18 and above – or about [20.6 percent](#) of adults – experience a mental health (MH) disorder. [Defined](#) as a diagnosable mental, behavioral or emotional condition, MH disorders [include](#) major depressive disorder, attention-deficit/hyperactivity disorder (ADHD), schizophrenia, anxiety, bipolar disorder, and eating disorders – all of which can vary in degree from mild and moderate to severe.

The [burden of mental illness](#) in the U.S. is among the highest of all diseases, and MH disorders are among the most common causes of disability. Recent data show that MH conditions affect Americans of both sexes and all ethnicities from childhood through old age. Today, and estimated [31.7 million women](#), [7.4 million Hispanic Americans](#), [5.2 million African Americans](#), [3.1 million veterans](#), [2.3 million Asian/native Hawaiians and other Pacific Islanders \(NHOPI\)](#), and 260,000 American Indians and Alaska Natives (AI/ANs) have a MH disorder. Additionally, an [estimated 20 percent](#) of people ages 55 or older experience mental health issues, including Medicare beneficiaries ages 65 and older, where studies find that [13 percent](#) report symptoms of depression.

Even more troubling, rates of [anxiety and depression](#) have skyrocketed recently due to the COVID-19 pandemic and other related factors. In fact, [findings reported by the Centers for Disease Control and Prevention \(CDC\)](#) in April 2021 show that the percentage of adults with symptoms of an anxiety or depressive disorder increased from 36 percent in August 2020 to 41.5

percent in February 2021. Yet, many individuals with MH conditions do not receive treatment. For example, in 2019, among the 51.5 million adults with a MH disorder, only [23 million](#) (44.8 percent) received any form of treatment. This is the case even though [Medicaid](#) covers 21 percent of adults with MH conditions and 26 percent with serious MH conditions. Therefore, it is imperative to diagnose a MH condition swiftly and accurately, offer individualized treatment, and provide the tools to monitor the person for adherence to the treatment on a sustained basis.

In Substance Use Disorder Treatment

Characterized by compulsive drug seeking, continued use despite harmful consequences, and long-lasting changes in the brain, substance use disorders (SUDs) are [chronic, relapsing diseases](#) that affect Americans at epidemic levels. As [reported by the National Center for Drug Abuse Statistics](#), in 2018, 29.2 million Americans aged 18 years and over had an SUD, and an estimated 2 million specifically had an opioid use disorder (OUD), including misuse of prescription pain medications, heroin, or fentanyl. Looking at who is impacted, recent data shows that an estimated [7.2 million women](#), [2.9 million Hispanic Americans](#), [2.3 million African Americans](#), [1.3 million veterans](#), [745,000 Asian/NHOPIs](#), and [142,000 AI/ANs](#) are living with SUDs. At the same time, substance use is a growing problem among seniors. From 2018 to 2019 alone, the number of individuals over the age of 65 with an SUD rose by [26 percent](#). This means that nearly [one million adults](#) aged 65 and older live with an SUD. Additionally, approximately [300,000 Medicare beneficiaries](#) are diagnosed annually with an OUD.

Untreated SUDs create a significant burden to the economy. It is estimated that untreated SUDs cost the nation approximately [\\$442 billion](#) each year in health care costs, lost productivity, and criminal justice costs. SUDs can also have a devastating impact on families. According to a [2017 Pew Research Center survey](#), 46 percent of adults reported having a family member or close friend with an SUD. Moreover, evidence has demonstrated that some individuals may have [a greater risk](#) of developing an SUD if they grow up in a home affected by a family member's history of substance use.

Yet, the reality is that less than [20 percent](#) of individuals receive treatment, even though SUDs are treatable diseases and [treatment has been shown to reduce associated health and social costs](#) by far more than the cost of the treatment itself. Among the 1.2 million individuals 65 and older who reported having an SUD in 2019, [only 284,000](#) received any SUD treatment. Similarly, focusing on the estimated 55.9 million Americans who are Medicaid beneficiaries, nearly [12 percent](#) have an SUD, but only [8 percent](#) receive SUD treatment. Thus, expanded access to effective SUD treatment is critical to reducing the toll of substance use disorders, including fewer overdoses and deaths.

In Greater Access to Prescription Digital Therapeutics (PDTs)

People living with both MH and SUDs often [respond to treatment](#) differently, and [successful outcomes](#) often depend upon a person staying in treatment and adhering to a combination of medication and behavioral therapies for an extended period. Thus, there is an urgent need to reduce the barriers and improve access to individualized treatments, including expanded coverage and availability of evidence-based interventions that prevent relapse and treat co-occurring conditions.

Among the many [barriers](#) that impede quality care are a shortage of providers and treatment facilities, especially in states with large rural populations and in urban health care deserts. In these areas, it may be difficult to coordinate and access comprehensive treatment, which could include individual and group counseling, inpatient and outpatient treatment, case management, and medication, as well as additional services and programs.

Additionally, adherence to the treatment protocol can be a significant problem, especially to ensure individuals stay on the treatment plan long enough to reap its full benefits. Considering this challenge, prescription digital therapeutics (PDTs) are emerging as an effective technology to provide 24/7 treatment and improve treatment adherence. Using prescription software applications to deliver evidence-based cognitive behavioral therapy (CBT), PDTs allow patients to access mental health treatment on a tablet or smartphone at their convenience. PDTs are prescribed by health care practitioners, backed by safety and efficacy data from clinical trials, and approved or cleared by the U.S. Food and Drug Administration (FDA) for use. With respect to SUDs, PDTs are designed to be adjunctive to other types of treatment provided by a health care professional, such as face-to-face counseling, CBT and/or prescription medicines. Additionally, PDTs give providers access to secure, asynchronous or real-time data from patients, so clinicians can monitor progress and manage the personalized treatment plans.

Yet, several obstacles are impeding patient access to PDTs for individuals with MH/SUDs, such as legislative and regulatory barriers, insurance coverage, education, and awareness. Accordingly, federal and state lawmakers and policymakers must be educated on the need for comprehensive coverage and access to PDTs. This includes the need to create a new Medicare benefit category specifically for PDTs that could also pave the way for Medicaid and private payers to offer similar coverage. Additionally, patients and providers must be educated on the benefits and availability of PDTs for individuals with MH/SUDs.

Purpose

ACTION for PDTs: Mental Health and Substance Use Disorders is committed to six areas of purpose:

1. Adoption

The “A” in ACTION stands for “Adoption.” With the goal of encouraging adoption of PDTs as evidence-based, FDA-regulated medical interventions, ACTION for PDTs will serve as a resource for patients with MH/SUDs, treating providers, payers, lawmakers, and policymakers. Specifically, the collaborative will provide stakeholders with the latest information on the capabilities of PDTs in preventing, managing, and treating MH/SUDs as well as the clinical improvements associated with PDTs and their cost-savings to the health system. Additionally, the collaborative will seek to educate state stakeholders on PDT adoption as states look for new and innovative solutions to address the opioid crisis.

2. Coverage and Access

The “C” in ACTION stands for “Coverage and Access.” To allow for adequate adoption of PDTs for MH/SUDs, health plans must provide comprehensive coverage of and access to PDTs. Yet, despite the medical benefits of PDTs to patients with MH/SUDs, there is currently no statutory benefit category that allows for Medicare coverage of PDTs. The impact extends far beyond seniors because Medicare policy serves as a model for state Medicaid programs and commercial insurance plans. Thus, without an established benefit category, coverage decisions will remain largely ad-hoc, impeding many patients from benefitting from this innovative technology. To remove this roadblock, legislative and regulatory actions that create a pathway for comprehensive coverage and access to PDTs for qualifying patients with MH/SUDs are necessary. As such, the collaborative will educate Congress on the need to create a new benefit category for PDTs, similar to the pathway Congress created for Medicare reimbursement of mammography screening. Until Congress took this legislative action, the Centers for Medicare and Medicaid Services did not have authority to cover the costs of mammograms for Medicare beneficiaries. The same is now the case for PDTs.

Additionally, the collaborative will educate on the need for regulations to modernize and accelerate coverage and reimbursement so that patients have timely access of PDTs for MH/SUDs.

3. Therapeutic Outcomes

The “T” in ACTION stands for “therapeutic outcomes.” PDTs are used independently or in concert with medications, devices, or other therapies [to optimize patient care and improve therapeutic outcomes](#). The collaborative will advocate for prescription digital therapeutics given the emerging evidence, which shows that PDTs can improve outcomes in a wide range of mental health conditions as well as substance use disorders.

4. Inclusion

The “I” in ACTION stands for “Inclusion.” PDTs can play a vital role in addressing health inequities, disparities, and social determinants of health (SDOHs) for patients with MH/SUDs. [SDOHs](#) are conditions in the environments where people are born, live, learn, work, play, worship, and age that affect a wide range of health, functioning, and quality-of-life outcomes and risks. SDOHs include transportation and access to health care. SDOHs prevent underserved communities from accessing quality care, leading to health inequities and disparities. Research has shown that SDOHs can be a contributing factor to MH/SUDs, in particular. Accordingly, the collaborative will encourage the adoption of PDTs so these therapies can be used to address SDOHs and improve health equity by providing accessible treatment to all patients in real-time and from any location.

5. Options

The “O” in ACTION stands for “Options.” There is no one-size-fits-all approach that works for patients with MH/SUDs. Practitioners and individuals with MH/SUDs need all available FDA-regulated treatment options at their disposal for the treatment of these conditions. Therefore, the collaborative will advocate for policies that ensure patients with MH/SUDs, in consultation with their providers, have access to all effective PDTs for their condition so they can choose the one best suited for them without unnecessary interference or barriers from policymakers and third-party payers.

6. Novel Technology

The “N” in ACTION stands for “Novel Technology.” Novel technology is critical to the evolution of mental health and addiction medicine. In encouraging the adoption of PDTs, it is important to understand that these therapeutics are regulated by the FDA, similar to traditional medicine. They must go through rigorous clinical trials establishing positive patient outcomes in order to receive FDA approval or clearance. For this reason, ACTION for PDTs will educate stakeholders, so they fully comprehend the significance of clinical rigor and testing to ensure safety and efficacy of PDTs.

Join Us

ACTION for PDTs’ members include a diverse group of like-minded organizations and individuals working toward the common goal of improving adoption and coverage of and access to PDTs. These include:

- Patient and caregiver advocacy groups
- Health policy organizations
- Professional associations
- Research, innovation, and technology organizations
- Individual patients, caregivers, and loved ones
- Individual health care providers and academics
- Commercial supporters

If you are interested in joining ACTION for PDTs, please click [here](#).

Contact Us

If you have questions, please visit us at www.aimedalliance.org/ACTIONforPDTs or contact us at ACTIONforPDTs@gmail.com.

Funding and Independence

ACTION for PDTs: Mental Health and Substance Use Disorders is spearheaded by Aimed Alliance. Aimed Alliance's list of funders can be found here: <https://aimedalliance.org/supporters/>.

ACTION for PDTs: Mental Health and Substance Use Disorders shall, at all times, retain full independence and control over its activities and content. Should the coalition obtain funders, the entity shall not be directed or otherwise influenced by the commercial interests of a funder or potential funder. While the coalition may advocate for improved access to PDTs, it shall not advocate for specific products.

About Aimed Alliance

Aimed Alliance is a 501(c)(3) non-profit health policy organization that works to protect and enhance the rights of health care consumers and providers. We achieve this mission by conducting legal research and analysis; developing sound, patient-centered policy recommendations; and disseminating its findings to inform policymakers and increase public awareness.

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