



## New Frontiers in Digital Health: Prescription Digital Therapeutics

Today's health care transformations are accelerating through technological innovation. [According to the FDA](#), Digital Health Technologies (DHTs) have the vast potential to improve our ability to accurately diagnose and treat disease and to enhance the delivery of health care for the individual. DHTs are expanding at an incredibly rapid pace. At the forefront of this expansion is a new therapeutic class that uses software as medicine.

### Prescription Digital Therapeutics

The Digital Therapeutics Alliance has defined Prescription Digital Therapeutics (PDTs) as evidenced based software-driven therapeutic interventions that diagnose, prevent, manage, or treat a medical condition – independently or in combination with – medications, devices or other treatments to optimize patient care

and outcomes. PDTs use software to capture information about a patient's symptoms or progress which is shared or remotely accessed by the provider who delivers the medical intervention. Treatment is often based on behavioral and lifestyle changes.

PDTs directly treat and manage serious diseases. They are regulated as medical devices, making them more like drugs and biologics compared to other DHTs, and they offer the ability to safely expand access to evidence-based therapies.

PDTs offer patients additional avenues to overcome treatment access barriers that are often associated with pharmaceutical or in-person therapy. Although they are a category within DHT, they are defined by clinical efficacy and FDA market authorization.

### FDA Authorization Process for PDTs

The FDA categorizes mobile health apps, in general, as Mobile Medical Applications (MMAs). These applications include software that fall under the FDA's enforcement discretion, where manufacturers are not required to submit premarket review applications or register and list their software with the FDA. Software in this category poses minimal risk to patients and consumers. Examples of software in this category include apps that help patients manage a disease without providing specific treatment suggestions.



PDTs are MMAs that do not fall under the FDA's enforcement discretion and are therefore classified and regulated as medical devices. The process of approval for a new PDT requires submission of data to support safety and effectiveness for its intended use. Following FDA review and authorization, health plans and pharmacy benefits managers (PBMs) may decide on coverage options and utilization management, such as step therapy or prior authorization. If a PDT is covered, purchasers may then decide whether or not to offer that PDT in their benefit offerings.

### Prescription Digital Therapeutics

#### Remote Tool

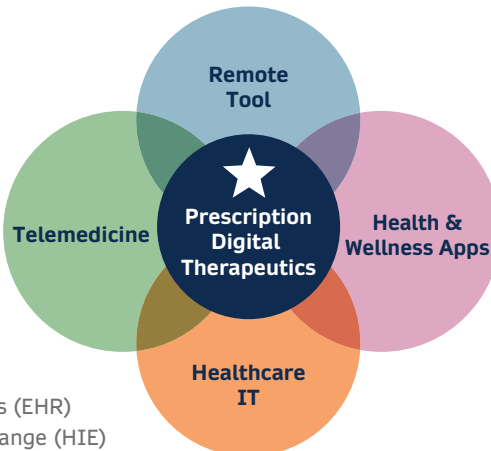
- Collect health data
- Tracked by healthcare professionals

#### Telemedicine

- Video diagnostic consultation
- Remote health services
- Support long-distance healthcare

#### Healthcare IT

- Electronic health records (EHR)
- Health information exchange (HIE)
- Patient portals



#### Health & Wellness Apps

- Promote wellness
- No FDA regulation
- Free/at patient's cost

#### Prescription Digital Therapeutics

- Medical software to treat disease
- Randomized clinical trials
- FDA regulation and authorization

Source: <https://2kw3qa2w17x12whtqxl6s3c-wpengine.netdna-ssl.com/wp>

## PDTs are distinguished from other DHTs in the following ways:

- U.S. Food and Drug Administration (FDA) authorized
- Require a prescription from a health care professional
- Clinically validated for safety and effectiveness in randomized controlled trials
- Held to the same regulatory standards as medical devices
- Developed in compliance with good manufacturing practices

**Today, there are currently nine FDA-authorized PDTs in the marketplace for the following medical conditions:**

PDT Product	Manufacturer	Therapeutic Area
EaseVRx	AppliedVR	Chronic lower back pain
EndeavorRX	Akili Interactive	ADHD in children ages 8-12 years old
Luminopia One	Luminopia	Amblyopia in children ages 4-7 years old
Mehana IBS	Mahana Therapeutics	Irritable Bowel Syndrome (IBS)
Nightware	Nightware	PTSD Driven Traumatic Nightmares
Regulora	metaMe	IBS-related abdominal pain
reSET	Pear Therapeutics	Substance Use Disorder (SUD)
reSET-O	Pear Therapeutics	Opioid Use Disorder (OUD)
Somryst	Pear Therapeutics	Chronic Insomnia

## PDTs are Similar to Prescription Medications, Yet Different from Apps

Like prescription medications, PDTs are reviewed by the U.S. Food and Drug Administration (FDA) and held to similar standards as traditional medical treatments and medications. With over 300,000 health and wellness apps, fitness and activity trackers and many other devices, they are similar, yet different in the following ways:

	Health & Wellness Apps	Prescription Medication	PDTs
Deliver evidence-based mechanisms of action		✓	✓
Utilize digital technology to improve health	✓		✓
Require randomized controlled trials		✓	✓
Authorized or approved as safe and effective		✓	✓
Reimbursement pathways via a specific product code		✓	✓
Offer real-time feedback for clinicians			✓



## Coverage for PDTs

PDTs are covered through employers, Pharmacy Benefit Managers (PBMs), health plans/carriers or other third-party payors. They may be covered under the medical benefit, the pharmacy benefit or through other forms of contracting.

Ways Employees/Members obtain a PDT

- Prescription from a qualified health care provider
- Authorization or referral by a health care provider
- Eligibility determined by a third party
- Activation code delivered to the employee/ member





## Employer Action Steps

PDTs can offer employers the opportunity to deliver safe, non-invasive, non-drug and cost-effective solutions to support employees and members. Employer benefits include:

- Reductions in the total cost of care
- Increases in member engagement and better access to health care
- Improvements to clinical outcomes
- Enhanced medical treatment experience
- Linkage between patient and clinician improves patient follow-up and has been shown to improve clinical outcomes.
- Ability to utilize data to improve population health

Use these Employer Action Steps, recommendations and tools to help you get started to address Substance Use Disorder (SUD) and Opioid Use Disorder (OUD).

1. Determine the total cost for Substance Use Disorder (SUD) and Opioid Use Disorder (OUD) using the National Safety Council calculator ([www.nsc.org](http://www.nsc.org)) to determine if PDTs might be right for your employees/members.
2. Ask your PBM about their policy for inclusion of PDTs on formulary and for updates on PDTs when they are approved through the [FDA 510K pathway](#).

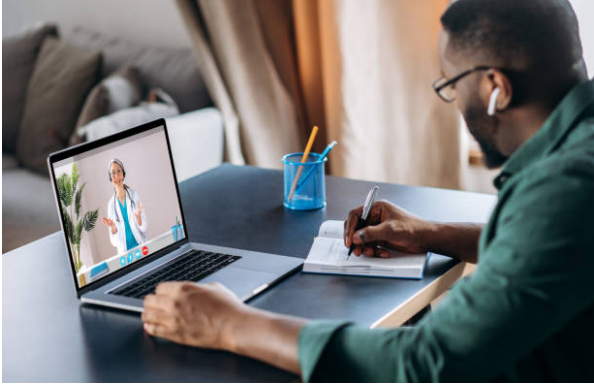
3. Work with your health care partners – benefits consultants/brokers, employee assistance programs (EAP), health plans/carriers/TPAs, pharmacy benefit managers (PBMs), worker compensation and disability vendors and behavioral health providers – to discuss the prevalence and costs of SUD & OUD and their impacts to your organization.
  - a. See sidebar in on *Zeroing in on Substance Use Disorder (SUD) & Opioid Use Disorder (OUD)* providing an overview of the increase in addiction, overdose and deaths and the need for employers to coordinate with vendors to address gaps in care
  - b. Discuss and determine PDT coverage options
4. Communicate the availability of PDTs to your employees/members so they can understand what they are, how they work and how they can help diagnose and treat disease, while enhancing the delivery of health care provided.



The National Safety Council's (NSC) Employer [Substance Use Cost Calculator](#) offers a way to easily calculate the costs and prevalence in your employee/dependent population using national data. It requires very little information – just enter the number of employees, if they are in one state or throughout the U.S. and your industry group. Results offer estimates of the costs of lost time, job turnover and retraining and health care. It also provides an estimate of the prevalence of opioid use disorder in your employee population. Users that don't have their own data can still use the calculator to get a framework of the prevalence and costs for their organization.



## PDTs – Example of a Patient Journey



PDT's can help providers better communicate and collaborate with patients to address any potential gaps in health care.

1. Patient meets with clinician (in person or virtually) who determines if a PDT is appropriate
2. Clinician writes prescription
3. Patient confirms identity and onboards with 2 texts



4. Text 1 is sent in real time to verify and obtain patient authorization via digital signature on phone
5. Text 2 is sent with access code to enable patient to download PDT and get started

6. Patient works independently and with clinician and completes recommended lessons – e.g. four per week for 12-weeks
7. Clinician/care team continue to meet with patient (in person or virtually) as part of their ongoing outpatient treatment
8. If a patient / Clinician dashboard is available with the PDT, the clinician can review the dashboard to determine patient progress, modules completed, triggers and make adjustments to the patient treatment plan

## References & Resources

1. [FDA: What is Digital Health? \(2022\)](#)
2. [Pear Therapeutics: Prescription Digital Therapeutics Digest \(2021\)](#)
3. [PCMA: Digital Therapeutics - Pharmacy Care Innovation and Implications for Policy \(2021\)](#)
4. [NIH: Role of Digital Therapeutics and the Changing Future of Healthcare \(2020\)](#)
5. [FDA: Device Software Functions Including Mobile Medical Applications \(2019\)](#)

## Zeroing in on Substance Use Disorder (SUD) & Opioid Use Disorder (OUD)

In 2020, the U.S. recorded the largest number of drug overdoses ever for a 12-month period. Increases in drug overdose deaths appear to have accelerated during the COVID-19 pandemic. In early 2021, the American Medical Association reported that there was a 45% drop in prescribing opioid drugs over the past decade. Overdoses have been driven by illicit drugs – mainly fentanyl, fentanyl analogs, cocaine. In the majority of states, overdoses have increased by 30% or more and there has been a 30% increase in deaths due to these overdoses.

- SUD involves the misuse of caffeine, tobacco/nicotine, alcohol, prescription medication misuse (e.g., opioids, sedative, hypnotics, stimulants), marijuana and inhalants.
- Opioid Use Disorder (OUD) involves the misuse of prescribed opioid medications, use of diverted opioid medications and/or use of illicitly obtained heroin.



SUD affects more than 20 million Americans and 1.6 million people in the U.S. are living with OUD. Billions of dollars in medical and direct health care costs can be attributed to untreated SUD and OUD annually. These disorders are costly both financially and in their impact on families and friends. The first FDA-approved PDT was in 2017 (SUD), following by (OUD) in 2018 and Alcohol Use Disorder (AUD) in 2021.

Treating SUD and OUD is complicated because of the stigma and complexity of the disorder. Many people have other medical and psychiatric conditions, along with a shortage of providers and a lack of stakeholder education. As a result, only a small percentage of those needing help receive effective treatment.

Given the dramatic increase in addiction and overdose deaths, along with no new treatment modalities for SUD/OUD brought to the market, PDT's can help providers better communicate and collaborate with patients to address any potential gaps in health care.



## About MBGH

MBGH is one of the nation's leading and largest non-profit employer coalitions. Members are represented by human resources and health benefit professionals for over 140 mid, large and jumbo self-insured public and private companies who provide health benefits for more than 4 million lives, with employer members spending over \$12 billion annual on health care. Since 1980, members have used their collective voice to serve as catalysts to improve the cost, quality and safety of health care benefits.

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