

# Prescription Digital Therapeutics: Introducing Software as Medicine

## ***Software as medicine* can revolutionize how we manage behavioral health and substance use disorders, both during the COVID crisis and beyond**

The COVID-19 pandemic has presented an undeniable and unprecedented public health crisis for our nation and world over the past 18 months – and not just for those who have been infected with the novel coronavirus. The prolonged need to socially distance and connect virtually has had a profound impact not only on people’s livelihoods and their sense of safety and security, but also their ability to access necessary medical and behavioral health care services and support.

The silver lining is that the pandemic’s restrictions on our normal way of life have rapidly accelerated the pace of innovation to address some of the most pressing challenges in health care. New tools are being rapidly deployed and adopted, particularly in the case of digital health, which is increasingly being used to extend needed care across geographic, social, or economic barriers.

Notably, this swift embrace of digital tools and telehealth during the COVID crisis has enabled the growth of the innovative field of prescription digital therapeutics (PDTs), evidence-based medical interventions using software that can be accessed on a tablet or smartphone to prevent, manage, or treat a range of diseases and disorders.<sup>1</sup> Considered a new category of therapeutics, PDTs deliver high-quality, adjunctive diagnostic care and treatments that do not require patients to travel to a health care facility or hospital.

PDTs are similar to traditional therapeutics in several ways, in that they are:

- regulated by the Food and Drug Administration (FDA) and are tested for safety and efficacy, developed using strict quality standards, and labeled according to FDA requirements

- only available to patients when prescribed by a licensed healthcare provider and must be used under clinician supervision
- eligible to be priced and reimbursed similar to traditional medication via federal, state, and commercial insurers

PDTs are cleared by FDA for a number of diseases and disorders, but those approved to help impact substance use disorders (SUDs) and behavioral health issues are particularly vital, given that most behavioral diseases aren't just an interplay of chemicals that can be fixed solely with pills or injections — they often require cognitive therapy to address and interrupt complex behavioral patterns. Given COVID restrictions, many patients may have less willingness to participate in more traditional means to treat and manage their disease, which typically includes a number of in-person clinician visits to receive cognitive therapy and additional hospital visits.

Here in California, people seeking treatment for behavioral health conditions often face limited access to care and the demand for these services is growing:

- By the end of this decade, California will face a projected shortage of 41% fewer psychiatrists than needed and 11% fewer psychologists, LMFTs, LPCCs, and LCSWs than needed
- There have been significantly increased levels of adverse mental health conditions, substance use, and suicidal ideation because of the COVID-19 pandemic
- 9.2% of California adults age 27 and older reported a SUD in the past year, compared with 7.7% nationwide and drug deaths in California increased by more than 45% from December 2019 to December 2020

These alarming statistics, coupled with the UCSF study's projected provider shortage, demonstrate the power that PDTs potentially have to act as a lifeline to patients who otherwise would not be able to access care.

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<sup>1</sup>Digital Therapeutics Alliance, [Understanding DTx](#), accessed 10/12/21

<sup>2</sup>University of California, San Francisco, [California's Current and Future Behavioral Health Workforce](#), accessed 10/13/2021

<sup>3</sup>California Health Care Foundation, [Medi-Cal Behavioral Health Services: Demand Exceeds Supply Despite Expansions](#), accessed 10/13/2021

<sup>4</sup>Substance Abuse and Mental Health Services Administration, [2018-2019 National Survey On Drug Use And Health: Model-Based Prevalence Estimates \(50 States And The District Of Columbia\)](#), accessed 10/13/2021

<sup>5</sup>Centers for Disease Control and Prevention, [Provisional Drug Overdose Death Counts](#), accessed 10/13/2021