

BACKGROUND:

Prescription Digital Therapeutics (PDTs) are software-based disease treatments designed to directly treat disease, tested for safety and efficacy in randomized clinical trials, evaluated by the FDA, and prescribed by healthcare providers. These therapies are designed and tested much like traditional prescription drugs with one distinction: rather than swallowing a pill or taking an injection, patients are treated with software.

The COVID-19 pandemic and public health emergency 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 are increasingly being used to bridge significant care gaps created by shortages of specialized health providers and geographic barriers in accessing physical healthcare systems.

PDTs provide clinicians and patients with evidence-based remote treatment modalities to treat substance and opioid use disorders, mental health, diabetes and other diseases and conditions. However, there is no clear statutory benefit category to allow for Medicare and Medicaid coverage for PDTs.

The *Access to Prescription Digital Therapeutics Act of 2022* seeks to change this by providing a framework for Medicare and Medicaid coverage of PDTs.

SECTION BY SECTION:

Sec. 1 – SHORT TITLE

Access to Prescription Digital Therapeutics Act of 2022

Sec. 2 – COVERAGE AND PAYMENT OF PRESCRIPTION DIGITAL THERAPEUTICS UNDER THE MEDICARE PROGRAM

This section would define the term “prescription digital therapeutic”; amend Section 1861(s)(2) of the Social Security Act (42 U.S.C. 1395x(s)(2)) to add “prescription digital therapeutics” to the definition of “medical and other health services” for the purposes of Medicare coverage; and set forth the Medicare coverage requirements for prescription digital therapeutics.