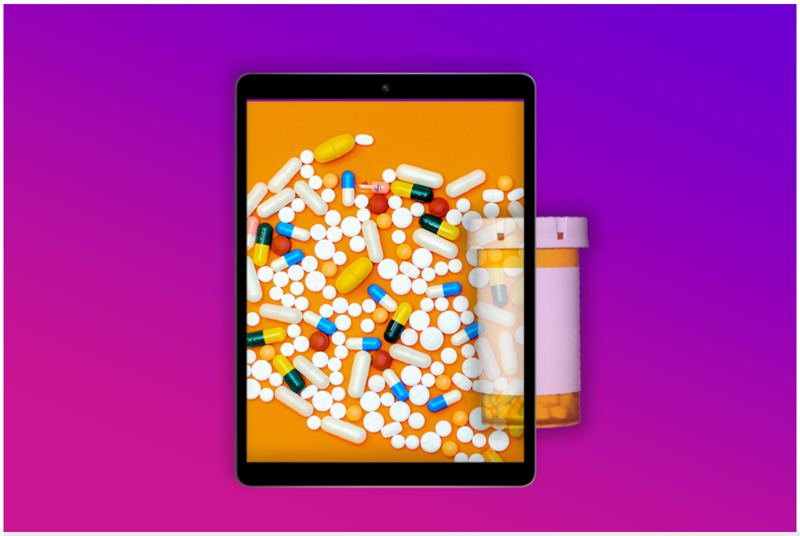
April 07, 2023 09:00 AM | AN HOUR AGO

Digital mental health startups scramble as in-person visit rule looms

LAUREN BERRYMAN



MH Illustration

The trying circumstances of the COVID-19 pandemic underscored the demand for mental healthcare, and a relaxed regulatory environment inspired entrepreneurs and investors to dive into virtual behavioral health services. Now, the circumstances have changed, forcing these young companies to make difficult pivots to new models.

The federal public health emergency declaration is set to expire May 11, and along with it many of the regulatory flexibilities that enabled companies such as Bicycle Health, Done, Ophelia Health and ReKlame Health to gain business. In addition, law enforcement agencies took notice of rising prescriptions for controlled substances—which are popular as drugs of abuse and frequently diverted to the illegal market—and started cracking down on telehealth providers. Cerebral and Done, for example, have been under federal investigation since last year.

The pandemic was never going to last forever, but at least some in the digital behavioral health sector believed the favorable regulatory environment would.

“The industry almost assumed that these flexibilities would be permanent after the [public health emergency] ends,” said Ankit Gupta, founder and CEO of Bicycle Health, which offers remote prescriptions for buprenorphine (also known as Belbuca, Buprenex, Butrans, Probuphine, Sublocade, Suboxone and Subutex) to treat opioid use disorder.

Digital mental health providers that sprang up or expanded during the public health crisis filled a need for patients unable or unwilling to make in-person visits. Research and digital health venture firm Rock Health estimates that digital mental health companies have attracted nearly $60 billion from investors since 2020.

The authorities helped this trend along by waiving or easing regulations governing such as patient privacy and prescriptions for controlled substances including Adderall (also known as amphetamine/dextroamphetamine salts) for attention deficit hyperactivity disorder and the anti-anxiety drug Xanax (also knowns as alprazolam).

Now, the federal government is poised to restrict online prescribing, which means digital-first companies must offer in-person services or risk going out of business. These companies, which have limited funds and leaders with little to no experience managing in-person healthcare, will have to adapt. That could prove difficult for some.

“We can't build brick and mortar locations. We're in too many places, too many counties. We don't have the money to do that,” said Zack Gray, co-founder and CEO of Ophelia Health, which specializes in prescribing opioid use disorder medications.

The executives who run these companies argue that stricter regulation would be bad for patients, as well as for their businesses. “Discontinuing a patient's medication is extraordinarily dangerous because they're going to experience cravings and withdrawal, they'll be tempted to go to the black market, and they're at high risk of overdose and death,” Gray said.

“The challenge that they're facing is figuring out how to quickly transition those models that they built and scaled so quickly during the pandemic, so that they can survive and thrive in the post-pandemic landscape,” said Jeremy Sherer, digital health co-chair at law firm Hooper, Lundy & Bookman. “Part of it is just the nature of startups. You have companies that succeed and companies that fail.”

Enter the DEA

Losing the ability to prescribe medicines remotely would significantly hamper these companies, and that's just what the Drug Enforcement Administration has in mind.

The DEA proposed a rule in February that would restore the pre-pandemic requirement that patients visit clinicians in person to obtain prescriptions for drugs such as Adderall and Ritalin (also known as methylphenidate) for ADHD and buprenorphine.

Under the draft regulation, 30-day prescriptions for Schedule III to Schedule V controlled substances would be available through telehealth, but patients must make in-person appointments to get refills. Patients whose treatments begin before the end of the public health emergency could wait six months before physically visiting a prescriber under the proposal.

“It makes sense that the DEA would be trying to limit over-prescribing of controlled substances based on their mission and their current investigations,” said Libby Baney, a partner at Faegre Drinker Biddle & Reath who specializes in health information technology law. Even as companies transition to hybrid models, the DEA will remain skeptical of digital health companies prescribing controlled substances, she said.

Pivoting operations

The comment period on the DEA’s proposal closed last Friday, leaving companies wondering whether the agency will modify the rule to address their concerns. This uncertainty has companies questioning their next steps. Candace Richardson, an investor in digital health start-ups at venture capital firm General Catalyst, said the regulation will test these companies’ operational readiness.

“The advice I've been giving is to have contingency plans, be prepared to shift, figure out what changes you can wait on doing until maybe next year versus what you need to do now,” Richardson said.

ReKlame Health founder and CEO Evans Rochaste said he is waiting for the final rule. ReKlame Health, which launched in 2020, provides prescribing services aimed at people of color with ADHD, depression, addiction and other conditions in New Jersey, New York and Florida.

Ophelia Health is making contingency plans, but leasing and staffing physical clinics isn’t feasible for the company, which launched in early 2019 and has been operating exclusively via telehealth since the pandemic began, Gray said. The first priority is getting current patients connected to in-person visits, he said. Looking ahead, the company will have to create a process to bring on new patients, and is partnering with a network of DEA-registered providers, he said.

Bicycle Health has a physical location in each of the 32 states where it operates, Gupta said. But the company would be have a hard time accommodating its 20,000 patients in person, and is encouraging them to visit primary care providers. For patients who don’t have one, the company is building partnerships with local clinicians.

Bicycle Health expects to lose 5% of its existing patients and attract 20% fewer new patients as a consequence of the DEA regulation, Chief Medical Officer Dr. Brian Clear said.

Done, an ADHD treatment provider founded in 2019, has made a push to open more physical offices but real estate and labor costs are obstacles, said Done Senior Executive Leader Sean Arroyo. The company expects to have 45 locations in 18 states as of this month and plans to open another 40 offices within the two months, he said.

“In January, we started to make a really hard push knowing this was going to be a transition that had to happen and started making investments because you can't turn things on in 30 days," Arroyo said. "The technology that it takes to build, the personnel that it takes to hire in the environment that we’re in—it’s just expensive.”