

## **Frustrated telehealth providers say their businesses face ‘doom and gloom’**

Telehealth providers treating opioid use disorder, ADHD, and women’s health issues say the sector is in a state of frustration and chaos as the pandemic-era flexibilities that allowed their businesses to thrive are set to end with no new rules in sight.

With just months to go before the ability to prescribe controlled substances online dramatically changes overnight, the vacuum of information is forcing them to devote significant energy preparing for the unknown. Companies have hired former regulatory officials to understand how hypothetical policies might impact them, and made backup plans based on speculative, third-hand sketches of proposed rules that might replace virtual prescribing flexibilities that began during the pandemic.

A feeling of “doom and gloom” hangs over telehealth entrepreneurs whose care involves controlled substances, according to Nicholas Mercadante, the CEO of PursueCare, which delivers virtual opioid use disorder treatment in 11 states. Planning amid uncertainty consumes time and resources that could be devoted to growing businesses or improving patient care, they claim, while putting more financial strain on startups that are already feeling a post-pandemic pinch.

One telehealth executive told STAT that the new rules would make business “knowingly impossible.” Another said they could force his company to shut down. A third said that companies had considered renting out clinics on a short-term basis, then periodically flying out doctors to conduct dozens of in-person visits in a day.

During the pandemic, the Drug Enforcement Administration, which enforces regulations of controlled substances that have the potential for abuse, temporarily allowed clinicians to write prescriptions for drugs like Adderall, buprenorphine, and testosterone without seeing patients in person. That opening was seized by telehealth companies offering streamlined services users could access from anywhere. Companies

raised investment and expanded their businesses, with advocates cheering on increased access to care.

But DEA's effort to establish post-pandemic restrictions on telehealth prescribing hasn't gone smoothly: After an initial proposed rule was met with criticism, DEA last year extended the pandemic waivers through the end of 2024. The agency so far has not delivered on a promise to issue final rules by this fall — the one-year anniversary of the DEA's last extension came and went last week with no communication from the agency.

Many health care and regulatory experts agree that guardrails for online prescribing of controlled substances are necessary. Drugs with significant potential for addiction can be abused and diverted into the black market. The Ryan Haight Act, which in 2008 enacted in-person requirements for prescribing controlled substances, was named for a teen who died of an overdose after being prescribed Vicodin online. Leaders of companies prescribing stimulants like Adderall to treat attention deficit hyperactivity disorder have been under scrutiny, some having been arrested for fraudulent prescribing.

“The concern may be if there are other companies out there doing what the DEA would perceive as online pill mills,” said Nathaniel Lacktman, a lawyer with firm Foley & Lardner who advises telehealth clients. The DEA did not respond to a request for comment by publication.

But ongoing confusion over what shape guardrails will take has left telehealth companies planning for “the worst case scenario,” said Mercadante. “We just want to know what we have to do,” he said. If new rules requiring in-person care are enacted, the company plans to shift to a hybrid model where it meets patients at partner sites.

Other virtual substance use disorder companies have made similar adjustments, for example by establishing in-person clinics in states that overrode the federal waiver. Pelago has found, said CEO Yusuf Sherwani, that requiring in-person appointments drives up the chance that patients will drop out of its opioid use disorder program.

All that planning may in the short term be moot, as it's become clear that it will be impossible for DEA to finalize new rules by the end of this year.

Most companies assume, perhaps optimistically, that another extension must be coming. Lawmakers, telehealth organizations, and patient advocates have called for continued access to telehealth in recent weeks, especially in the case of buprenorphine prescribing for opioid use disorder. Legislation has been proposed that would enable its continued prescribing.

Without an extension, rules will roll back to the pre-pandemic status quo that required an in-person visit before a provider could prescribe controlled substances over telemedicine.

“They will fall off that telehealth cliff if action is not taken,” said Lacktman.

Today, many companies have been planning around information from a draft DEA rule whose details were leaked in late August. “We’re all working upon just hearsay,” said Lacktman. While its requirements haven’t been confirmed, some telehealth companies say they would make it virtually impossible for their businesses to continue.

Among other requirements, the circulated rule would force teleprescribers to check prescription drug monitoring programs in all 50 states for each patient receiving a script for a controlled substance. That is “knowingly impossible in the status quo,” said Stephanie Strong, CEO of substance use disorder company Boulder Care, because no nationwide infrastructure exists to check those databases. That’s “a major blow to telehealth from the DEA’s perspective.”

The rule reportedly would also require providers to see 50% of their controlled substance patients in person. In that case, “we’d have to shut down,” said Zack Gray, CEO of Ophelia, which will conduct more than 100,000 online-only visits for opioid use disorder this year, unless it could cobble together a dramatically different workforce. Telehealth leaders told STAT any version of an in-person prescribing requirement would lead some number of companies to shut down.

Others would need to dramatically revise their business and staffing model. “I’ve heard a million different ideas tossed out,” said Rafid Fadul, CEO of digital health services company Zivian, which advises several companies that prescribe controlled substances. Some would try to rent

clinics on a daily or weekly basis in areas with large populations of patients, flying their doctors out to staff them on a short-term basis for physical exams. Another plan includes going directly to people's homes to conduct in-person visits. "They're all pricey, they're all creative," said Fadul.

Until recently, some companies did not understand they were going to be subject to the DEA's rules, and are scrambling to catch up. Some women's health and menopause-focused telehealth companies are circulating petitions, trying to protect their ability to prescribe.

Joanna Strober, co-founder of Google Ventures-backed menopause company Midi, said she wasn't even following the regulations closely until recently. Midi, like several other telehealth startups, sprang up at the beginning of the pandemic once prescribing rules were relaxed.

"I read the news about the leaked DEA memo and I was just shocked that they would think about this," she told STAT. "I have not been politically active at all, but perhaps that was a mistake. I had not really realized they could go back that far in terms of rolling back things."

Strober and Midi have circulated a Change.org petition urging DEA to reconsider the limitations, naming several treatments Midi prescribes for customers that could be impacted, including testosterone for low libido, gabapentin for hot flashes, sleep aids and anxiety medications.

Congress classified testosterone, a steroid, as a controlled substance in 1990 following concerns about athletes using it non-medically for muscle growth; Lawmakers including Sen. Ed Markey (D-Mass.) have called for its reclassification to preserve access to gender-affirming care, though they have not emphasized its role in women's health, Strober said. Gabapentin, prescribed for nerve pain and seizures, is controlled in some states but not federally due to potential harm when combined with other drugs, such as other opioids. Strober said Midi prescribes gabapentin to breast cancer patients who can't take hormonal treatments.

The petition has racked up almost 14,000 signatures. Strober said she's also met virtually with bipartisan members of Congress in recent weeks to raise awareness about the DEA proposal's impact on women's health.

If the limitations do take hold, companies like Midi and Plume, a gender-affirming care company, may have to find brick-and-mortar locations to evaluate patients in-person, or send clinicians out to patients' homes, among other models. "It's a big TBD on that one," said Jerrica Kirkley, co-founder and chief medical officer at Plume, which has been tracking the potential limits on teleprescribing for years as it relates to hormone therapy, HIV management, and other treatments. Through advocacy and comments on public proposals, she said, Plume has been "deeply involved in it and certainly following all the recent evolutions with the leaked report."

The lack of stability has knock-on effects for telehealth businesses, said Gray. Staffing telehealth providers becomes more difficult as employees question their career stability in the face of new regulations, and investors similarly start to run scared the longer the industry waits for clarity.

Collectively, impacted businesses have turned to industry alliances including the American Telemedicine Association and the Alliance for Connected Care to advocate for action before the end of the year. Some speculate another two-year extension of telehealth flexibilities will be wrapped into an end-of-year legislative package, aligning with a similar extension to Medicare reimbursement flexibilities for telehealth visits.

Another option is that DEA will be compelled to again extend the flexibilities for a year or longer to allow enough time for a finalized rule to pass.

In the long term, telehealth leaders agree that a strong system is necessary to ensure that controlled substance prescribing provides clinical benefit while protecting against the potential for abuse and diversion.

"I understand why they're doing these regulations, because there are bad actors," said Fadul. "But the solution right now needs a surgical scalpel to delicately solve it rather than a butcher's knife."