

A Guide To The DEA's Telemedicine Controlled Substance Rules Post-PHE



A Guide To The DEA's Telemedicine Controlled Substance Rules Post-PHE

The Drug Enforcement Agency (DEA) has issued proposed rules for prescribing controlled substances via telehealth once the COVID-19 public health emergency (PHE) ends. The agency opened the proposed rules for public comment through March 31, 2023.

The DEA suspended the in-person exam requirement for controlled substances when the PHE went into effect in 2020. Providers were allowed to prescribe controlled substances via telehealth as long as the prescription was for legitimate medical purposes. The prescribing physician was also required to act in accordance with applicable federal and state laws.

One of the proposed rules will discontinue the ability for physicians to prescribe controlled substances to patients via telemedicine if the patient has never had an in-person exam, with limited exceptions. The second rule would expand the situations in which providers can prescribe buprenorphine, which is used for pain and withdrawal management.

The proposed rules will not apply to:

- Telemedicine consultations that do not involve the prescribing of controlled medications
- Telemedicine consultations by a medical practitioner who has already conducted an in-person patient examination

This white paper will explore how the proposed rules will affect providers who are currently using telemedicine.



Challenge

The novel coronavirus (COVID-19) was first detected in Wuhan, Hubei Province, People's Republic of China, in December 2019. On January 31, 2020, Secretary of Health and Human Services (HHS) Alex Azar declared COVID-19 a public health emergency¹. The COVID-19 pandemic was officially declared a national emergency on March 13, 2020².

Following the PHE declaration, the DEA announced that registered practitioners could prescribe controlled substances to patients for whom they had not conducted an in-person medical evaluation³. Those allowances remained in place for the past three years. However, HHS announced on February 9, 2023, that the PHE would expire on May 11, 2023⁴.

With the clock winding down on the PHE, the DEA is proposing permanent changes to rules around controlled substances prescribed via telemedicine. Providers will no longer be able to prescribe controlled substances via telehealth without an in-person examination. The rules will purportedly serve as a bridge between the PHE allowances and a post-COVID environment.



However, the change would have several implications for healthcare providers and patients who have relied on telemedicine. Providers would have to start transitioning patients back to in-person visits to receive prescriptions for controlled substances. This could be particularly difficult for patients who live in rural or underserved areas. They may not have easy access to healthcare providers who are authorized to prescribe controlled substances. Patients with mobility issues or lack of transportation may also have trouble accessing healthcare services.

Telemedicine can also be more cost-effective than in-person visits. One study found that a telehealth visit costs about \$79 on average, compared to \$146 for an office visit⁵. These costs could add up quickly for patients who require frequent medication management.

Discontinuing telemedicine prescribing can also have a significant impact on health outcomes. Patients who have been receiving prescriptions via telemedicine may be less likely to adhere to medication if they are required to switch to in-person visits. Previous studies have shown that medication nonadherence causes an estimated 125,000 avoidable deaths per year and \$100 billion in preventable healthcare costs annually⁶.

There is a possibility that parts of the proposed rules could change following the public comment phase. For now, providers should start making preparations for the changes.



Overview



The basis for the DEA's proposed rules is the Ryan Haight Online Pharmacy Consumer Protection Act of 2008 (Ryan Haight Act). The Act prohibits the distribution, dispensation, or delivery of controlled substances over the internet without a valid prescription⁷.

Controlled substances are drugs that are tightly controlled by the government because of their potential for abuse or addiction. These include anabolic steroids, depressants, hallucinogens, opioids, and stimulants⁸.

The Ryan Haight Act requires medical practitioners to conduct at least one in-person medical exam before they can issue a prescription via telemedicine. It provides exceptions for patients in remote areas, but the exceptions have strict requirements.

The Act was established in response to the death of Ryan Haight. The 18-year-old died from an overdose of prescription drugs he bought online. Haight had never met the doctor who prescribed the drugs. The pharmacist who sent Haight the drugs knew he had not been examined by the doctor, but felt the prescriptions were valid⁹.

Due to an exception in the Act, providers were able to establish a patient relationship and prescribe controlled substances via synchronous, audio-visual interaction during the COVID-19 PHE. Now that the PHE is ending, the exception no longer applies.

The DEA has proposed two new rules around telemedicine prescribing of controlled substances:

- Telemedicine Prescribing of Controlled Substances When the Practitioner and the Patient Have Not Had a Prior In-Person Medical Evaluation¹⁰
- Expansion of Induction of Buprenorphine via Telemedicine Encounter¹¹

Under certain circumstances, the proposed rules would allow practitioners to:

- Prescribe up to a 30-day supply of Schedule III-V non-narcotic controlled medications
- Prescribe up to a 30-day supply of buprenorphine for the treatment of opioid use disorder (OUD)
- Prescribe any schedule of controlled medication when a practitioner has made a "qualifying telemedicine referral" after an in-person medical evaluation

The DEA will waive the in-person exam requirement for 180 days if the practitioner and patient already have a telemedicine relationship and the patient has been receiving prescriptions during the PHE.



Why is the DEA Proposing New Rules Around Telemedicine Prescribing?

COVID-19 brought about significant changes to healthcare delivery. Telehealth was already on the rise, but the pandemic accelerated its adoption. Telehealth use rose as much as 80% in areas where there were a high number of COVID-19 cases¹².

Prior to the pandemic, the DEA had strict regulations in place for prescribing controlled substances. The agency relaxed the regulations during the pandemic to allow healthcare professionals to provide care via telehealth to minimize the risk of infection. However, the DEA intends to revert back to its pre-pandemic regulations once the PHE ends¹³.

Congress previously directed the DEA to create a special registration to prescribe controlled substances via telemedicine in 2008. A second deadline was set in 2018. The agency has yet to establish the special registration process. The DEA believes the proposed rules fulfill the mandates, although it doesn't mention the registration in either rule.

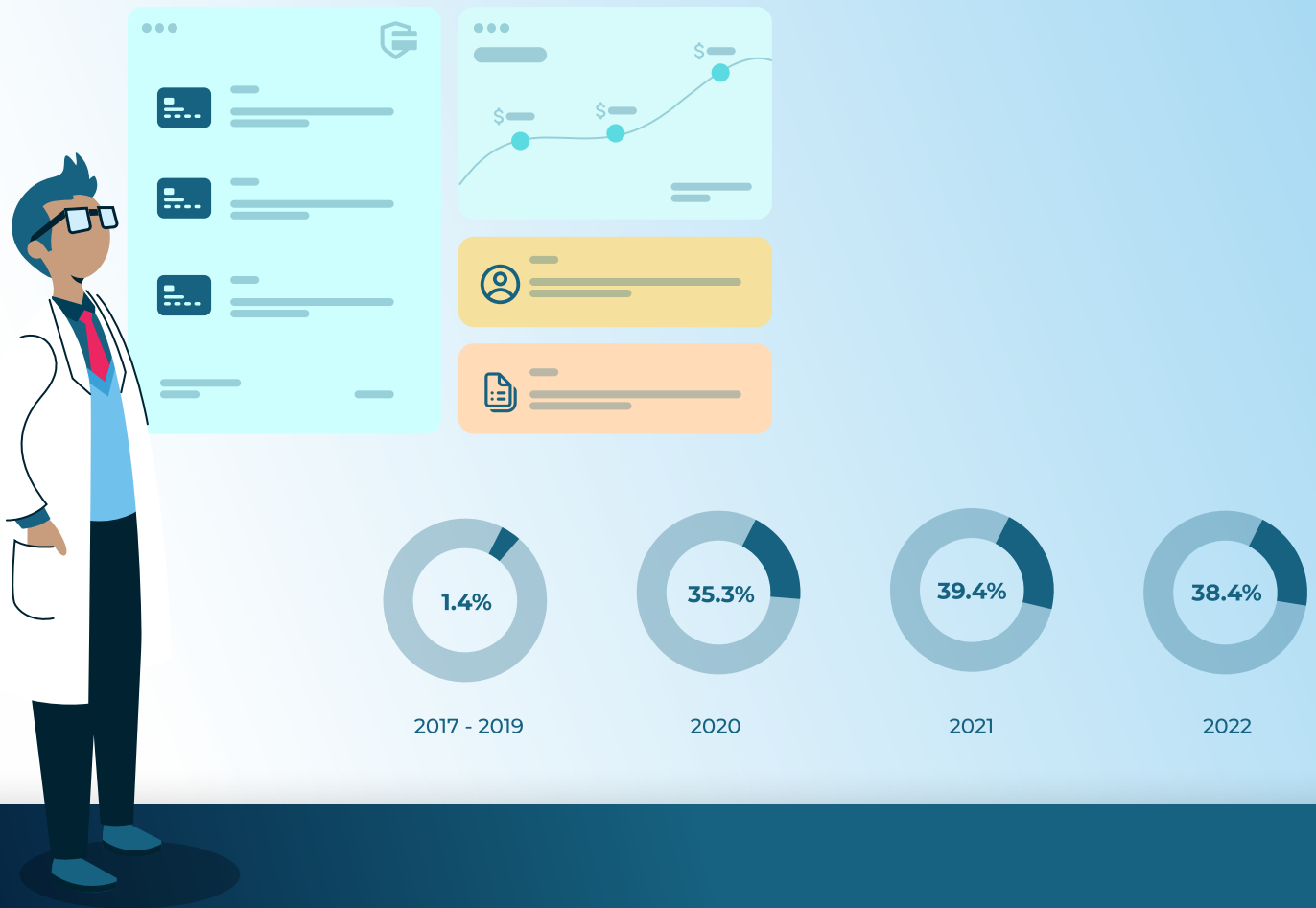
The DEA's proposed rules are not without controversy from healthcare providers and public health experts.

The American Telemedicine Association has said the rules are "more restrictive than necessary¹⁴." The organization also said the rule changes could leave patients without access to needed medications. Other companies that use remote prescribing have urged the agency to reconsider its proposed rules to avoid potential disruptions in medication¹⁵.

Lawmakers also voiced concerns that the buprenorphine proposed rule will worsen the opioid crisis¹⁶. Buprenorphine is one of only three drugs approved in the U.S. to treat OUD. It is one of two that doctors are allowed to prescribe directly to patients. The proposed rule would require an in-person examination for telehealth patients who need more than a 30-day prescription of the medication.

Missing even one dose of buprenorphine can cause withdrawal symptoms. This could potentially cause patients to seek out illicit drugs, leading to abuse, overdose, or even death. Congress members said any restrictions on buprenorphine access would be "a step in the wrong direction."





How Did the Pandemic Affect Telemedicine Prescribing?

The relaxed regulations on telemedicine prescribing during the pandemic increased access to controlled substances. Stimulant prescribing via telehealth increased from 0.5% to 1.4% between 2017 and 2019. That percentage rose to 35.3% in 2020, 39.4% in 2021, and 38.4% in 2022¹⁷. But the DEA's proposed rules could lead to a dramatic decrease in those percentages. The proposed rules do not extend flexibilities for virtual prescribing of controlled substances like Adderall and Ritalin without an in-person exam.

A report from the National Institutes of Health also found that patients with OUD who received telehealth services had a lower risk of overdosing¹⁸. The expanded access to buprenorphine also allowed them to continue their treatment.

How Can Healthcare Organizations Prepare for Changes in Telemedicine Prescribing?

The DEA's proposed rules aren't finalized yet, so healthcare providers have some time to prepare. The public comment phase provided an opportunity for providers to voice their concerns, and there is a possibility that the agency will make revisions.

Patients who have received a telemedicine-only exam will not be "grandfathered" from the in-person exam when the PHE ends. However, the proposed rules have created a new term for patients to whom this applies: "telemedicine relationship established during the COVID-19 public health emergency." A telemedicine relationship exists if:

- Between March 16, 2020, and May 11, 2023
- A practitioner prescribed a controlled substance based on a telemedicine encounter
- The practitioner did not conduct an in-person exam of the patient

If such a relationship exists and the patient has received prescriptions during the PHE, the DEA will waive the in-person exam requirement for 180 days.

In the interim, healthcare providers should review state and federal regulations. This will ensure they remain in compliance with all applicable rules. Providers may also need to consider weaning patients off of the medications before the PHE ends. Others may have to stop prescribing controlled substances altogether.



Some healthcare companies, however, have found creative solutions to the in-person requirement. One virtual care company sent providers to self-created pop-up clinics to fulfill in-person requirements in Alabama¹⁹. Another said it can use its office for in-person visits, or work with affiliated clinicians to perform in-person exams before referring patients back to the company.

Providers who are currently using telehealth services for controlled substance prescribing can continue to do so through the end of the public health emergency. It will remain to be seen what, if any, changes the DEA will make to its proposed rules after reviewing public comments. In the meantime, platforms like Mend can help ensure patients are still able to receive needed healthcare services and reduce the risk of lapses in medication. To discover how Mend can help your organization provide patients with the care they need, [schedule a demo](#) today.

References

- 1 <https://www.phe.gov/emergency/news/healthactions/phe/Pages/2019-nCoV.aspx>
- 2 <https://trumpwhitehouse.archives.gov/presidential-actions/proclamation-declaring-national-emergency-concerning-novel-coronavirus-disease-covid-19-outbreak/>
- 3 <https://www.dea.gov/press-releases/2020/03/20/deas-response-covid-19>
- 4 <https://www.hhs.gov/coronavirus/covid-19-public-health-emergency/index.html>
- 5 <https://www.healthaffairs.org/doi/full/10.1377/hlthaff.2016.1130>
- 6 <https://www.thepermanentejournal.org/doi/10.7812/TPP/18-033>
- 7 <https://www.congress.gov/bill/110th-congress/house-bill/6353>
- 8 <https://www.cancer.gov/publications/dictionaries/cancer-terms/def/controlled-substance>
- 9 <https://abcnews.go.com/GMA/story?id=128153&page=1>
- 10 <https://www.federalregister.gov/documents/2023/03/01/2023-04248/telemedicine-prescribing-of-controlled-substances-when-the-practitioner-and-the-patient-have-not-had>
- 11 <https://www.federalregister.gov/d/2023-04217>
- 12 <https://www.beckershospitalreview.com/telehealth/led-by-covid-19-surge-virtual-visits-will-surpass-1b-in-2020-report.html>
- 13 <https://www.dea.gov/press-releases/2023/02/24/dea-announces-proposed-rules-permanent-telemedicine-flexibilities>
- 14 <https://www.americantelemed.org/press-releases/ata-and-ata-action-call-deas-proposed-rule-on-controlled-substances-overly-restrictive-fear-consequences-in-patient-care/>
- 15 <https://www.fiercehealthcare.com/telehealth/deas-proposed-telehealth-rules-tighten-covid-era-remote-prescribing-regulations>
- 16 <https://www.statnews.com/2023/03/02/advocates-lawmakers-warn-that-biden-telehealth-rule-will-worsen-opioid-crisis/>
- 17 <https://www.trillianthealth.com/behavioral-health-trends-shaping-the-health-economy>
- 18 <https://www.trillianthealth.com/behavioral-health-trends-shaping-the-health-economy>
- 19 <https://digitalhealth.modernhealthcare.com/digital-health/remote-prescribing-limbo-federal-covid-19-emergency-ends>