

Take Action to Continue Access to Critical Medications Prescribe via Telehealth

The prescribing flexibilities extended by the Drug Enforcement Administration (DEA) to providers prescribing controlled substances have been a lifeline for people managing depression, anxiety, ADHD, substance abuse disorder, and other mental health conditions. Without an extension of these flexibilities, many patients could lose access to necessary medications and face significant delays in receiving care. We need intervention from Congress to avoid a treatment cliff.

Extend DEA Teleprescribing Flexibilities for Two-Years

Please include in the end of year funding package a two-year extension of the DEA prescribing flexibilities to allow time to promulgate rules for a Special Registration process that allows for clinically appropriate patient care to take place via telemedicine. Patients have been receiving prescriptions via telehealth for almost four years, and an abrupt end would interrupt patient care.

What are the Pandemic Prescribing Flexibilities?

During the COVID-19 pandemic, DEA instituted <u>telehealth prescribing flexibilities</u> in March 2020 to minimize in-person contact, allowing the prescriptions of Schedule II, III, and IV medications to be prescribed remotely. This gave patients the ability to receive needed medications without having to travel to their provider office, which was particularly helpful for patients with mental health and substance use disorders who have to travel far to see a provider, patients who are homebound, patients who have child or parent caregiving responsibilities, and others who simply cannot see their provider frequently. The DEA has extended the flexibilities twice since the public health emergency ended.

Why a Special Registration Process?

In 2008, Congress <u>amended</u> the *Controlled Substances Act* to prevent distribution of controlled substances over the internet. To allow for legitimate prescribing of clinically appropriate medications, Congress granted authority to the DEA to establish a special registration process for health care providers to evaluate patients, and safely prescribe medications via telemedicine. Per the 2008 *Ryan Haight Act*, providers must see a patient in person prior to teleprescribing a controlled substance. To establish the special registration process DEA must promulgate a rule.

What is Required for a Special Registration for Telemedicine?

Congress established three general requirements that practitioners must meet while using the special registration to deliver, distribute, dispense, or prescribe controlled substances via telehealth:

- The practitioners must demonstrate a legitimate need for the special registration.
- The practitioners must be registered to deliver, distribute, dispense, or prescribe controlled substances in the state where the patient is located.
- The practitioners must maintain compliance with federal and state laws when delivering, distributing, dispensing, and prescribing a controlled substance.

What Steps has DEA Taken to Promulgate Regulations?

Despite the enactment of the *Ryan Haight Act* in 2008 and a further directive from Congress in the 2018 SUPPORT for Patients and Communities Act requiring the Attorney General in consultation with the Secretary of Health and Human Services to within one year promulgate final regulations, DEA did not take action for 16 years.

- March 1, 2023: DEA published the <u>proposed rule</u> Telemedicine Prescribing of Controlled Substances When the Practitioner and the Patient Have Not Had a Prior In-Person Medical Evaluation that received over <u>35,000 comments</u> many of which were highly critical of the proposal.
- May 10, 2023: DEA issued a <u>temporary rule</u> as the PHE ended on May 11, 2023 extending the pandemic flexibilities for six months through November 11, 2023.
- September 12 and 13: DEA hosted <u>listening sessions</u> to inform the development of updated regulations.
- October 2023: DEA issued a second extension through December 31, 2024

DEA's revised proposed rule has yet to be released. Given the expiration of the flexibilities is fast approaching more than 340 organization sent a <u>letter</u> to the White House asking for DEA to issue another two-year extension. Because it is not clear that DEA is willing to issue another extension, a <u>letter</u> was also sent to Congress asking for a two-year extension should DEA not act expeditiously.

What has been Congressional Support of Permanent Special Registration Process?

Members of Congress from both chambers have been pressing DEA for more than a decade to promulgate special registration rules that balance access to care with diversion control. There are at least six bipartisan letters that have been sent to the DEA since 2020, including a bipartisan Senate letter for permanency, a bipartisan Senate letter with concerns about the previous proposed rulemaking, a bipartisan House letter urging for a rule that fulfills DEA's congressional mandate, among others. Additionally, several members of Congress have requested DEA to commit to addressing telemedicine prescribing for controlled substances in hearings, including the Health Energy & Commerce Committee, House Appropriations Committee, Senate Appropriations Committee, Senate HELP Committee, and others.

Evaluation of the Teleprescribing Flexibilities

On August 31, 2022, the *Centers for Disease Control and Prevention (CDC), National Institutes of Health (NIH), and the Centers for Medicare & Medicaid Services* (CMS) published a collaborative study, which found that Medicare beneficiaries and providers that used the COVID-19 flexibilities related to telehealth services, including teleprescribing of controlled substances, were associated with positive impacts on patient outcomes.

About the American Association of Psychiatric Pharmacists

The <u>American Association of Psychiatric Pharmacists</u> (AAPP) is a professional association representing nearly 3,000 psychiatric pharmacists nationwide. They are specialty pharmacists, and most are Board Certified Psychiatric Pharmacists (BCPPs) who specialize in psychiatry, substance use disorders (SUDs), and psychopharmacology. Psychiatric pharmacists have deep understanding of medications for OUD as well as the commonly co-occurring psychiatric illnesses. Our members integrate into teams of health care professionals, making a difference in overall costs, treatment efficiencies, patient recovery, and quality of life.