

October 12, 2022

The Honorable Joseph R. Biden
President of the United States
White House
1600 Pennsylvania Avenue
Washington, DC 20500

Dear President Biden:

Americans are grateful that the COVID-19 pandemic is slowly coming to an end in America. We appreciate your Administration's leadership in providing the resources, flexibility, and regulatory relief to directly respond to the pandemic and address the unique challenges faced by patients and health care providers across the nation. In particular, myriad strategies and efforts – including expanded telehealth services – have helped to maintain access to care throughout the Public Health Emergency (PHE) and ensured that patients have continuity of primary and specialty care, including prescription therapies. On behalf of the patients and providers we represent, we are writing to respectfully urge you to direct the Office of Management and Budget (OMB) to release the [proposed rule for a Special Registration to Engage in the Practice of Telemedicine](#), which has been pending review at the agency since March 17, 2022.

Overview

As you know, because of the various PHE-related waivers and flexibilities, more Americans have been able to access telehealth services for behavioral (e.g., mental health, substance use disorders) and physical health care needs. This experience has demonstrated telemedicine's power in advancing equity and reaching patients – many who previously were underserved. Moreover, patients, providers, and payers all now have a lived experience that validates telehealth as an important and valuable patient-centered option for individuals and families.

Based on indicators from your administration, it is likely that the PHE will expire in January 2023, and at that time, a number of critical waivers and flexibilities will sunset. While Congress may act to extend some policies, we are very concerned that the flexibility currently afforded to providers to prescribe controlled substances via telehealth without first having an in-person visit will expire without the Drug Enforcement Agency (DEA) having taken action to provide a “special registration” for telemedicine for certain providers who have the need to utilize telemedicine for prescribing controlled substances for patients with whom they have not previously had an in-person examination.

The Office of Information and Regulatory Affairs (OIRA) has 90 days from when it receives the notice of a proposed rule to act on the proposal, plus an additional 30 days. OIRA has failed to act within the prescribed 120-day timeline, given that the proposed rule was received in mid-March. Moreover, DEA has ignored all inquiries as to the status of the

proposed rule, and there is no line of sight into when OIRA will release the proposed rule for public comment. There is no reasonable expectation that a proposed rule will be released for public comment any time soon. This delay is particularly concerning given that for the past 14 years, the DEA – along with the Department of Justice and Health and Human Services – have all failed to provide the regulatory guidelines for a special registration as called for in the *Ryan Haight Online Pharmacy Consumer Protection Act of 2008 (Act)*.

Background

More than a decade ago, Congress anticipated the benefits of telemedicine for *both* physical and behavioral health services when it originally enacted the *Ryan Haight Act*. At the time, Congress also recognized the need to ensure that when telemedicine is used for prescribing certain medications, additional safeguards should be in place. To that end, the *Act* included a provision mandating the DEA provide a “special registration” for certain health care providers who have the need to utilize telemedicine for prescribing controlled substances for patients with whom they have not previously had an in-person examination. Shamefully, 14 years and three Administrations later, DEA has never proposed any regulations for implementing the “special registration” called for in the *Act*.

In 2018, because of the unconscionable delay in promulgating the “special registration,” Congress passed the SUPPORT Act, which included a provision that specially mandated the Attorney General, within 12 months of enactment, promulgate final regulations “specifying the circumstances” and “procedure” for practitioners to obtain the “special registration” found in the original *Act*.¹ The Attorney General has never acted on the Congressional mandate.

Congress witnessed the explosion of telehealth during the COVID-19 pandemic, and in the FY 2021 Consolidated Appropriations Act directed the DEA to complete the mandate of promulgating the limited circumstances and procedure of health practitioners obtaining a “special registration” under the *Act* and to “brief the Committees on the status of these regulations not later than 30 days after the date of enactment.” Despite clear Congressional directive, DEA again has yet to take any of the required actions.

More recently, on May 4, 2022, the House Energy and Commerce Committee bipartisan leadership wrote to the DEA Administrator Anne Milgram demanding that the DEA fulfill its “legal obligation to meet Congressional mandates” and “to immediately put forth the “special registration” regulations under the *Act* to ensure essential access to care that constituents in each of districts and tens of thousands – if not millions – of patients across the nation.” Administrator Milgram has not responded to the bipartisan correspondence.

¹ See Chapter 4 - Special Registration for Telemedicine Clarification in the SUPPORT Act, P.L. 115-271 (2018).

The Public Health Imperative for a Special Registration

With the flexibility granted by the PHE over the past two years, patients have received continuity of care and accessed the prescriptions they need to manage their conditions; the experience reported by both prescribing practitioners and patients is that outcomes are better due to improved access and reduced barriers to care. We know from providers and patients that much of this expanded access has benefitted underserved individuals and rural communities, and this advancement of equity must be sustained.

Further, numerous independent studies have shown that mental health and substance abuse services delivered via telehealth have greatly expanded access. Moreover, while other outpatient telehealth services utilization had declined, behavioral health care patients maintain a high level of utilization of telehealth services. As we look to a time soon when the declaration of the PHE will expire and current flexibilities will terminate, we must have in place a “special registration” process by which providers can be authorized to continue to treat new patients via telehealth and prescribe controlled substances if clinically indicated.

Yet, despite the public health imperative, the DEA and Attorney General remain silent on this matter. With all-time record rates of mental health issues, substance use disorders, and other behavioral health challenges, we – as a nation – must ensure continuity of care for those most in need. Now is the time for your Administration to release the proposed regulation and work with all stakeholders to develop and implement the “special registration” under the *Act*, which would allow some medically licensed practitioners to meet with new patients via telehealth to prescribe controlled substances after the patient’s identification and prescription history has been reviewed and validated.

We thank you for your attention to our concerns and look forward to hearing from you soon regarding your plans to address this critical public health, access to care, and equity issue.

Sincerely,

The Undersigned Organizations

American Association of Psychiatric Pharmacists (AAPP)

American Society of Consultant Pharmacists (ASCP)

Anxiety and Depression Association of America

Cancer Support Community

Done Global Inc.

Done Health P.C.

HealthyWomen

National Association for Behavioral Healthcare (NABH)

Schizophrenia & Psychosis Action Alliance

Spina Bifida Association