February 22, 2019

Kathy L. Federico
Acting Section Chief, Regulatory Drafting and Support Section / Diversion Control Division
Department of Justice
Drug Enforcement Administration
8701 Morrissette Drive
Springfield, VA 22152

**RE: Special Registration for Telemedicine under the Ryan Haight Act**

Dear Action Section Chief Federico:

I am writing today on behalf of the National Council for Behavioral Health (National Council) and our 3,000 community-based mental health and addiction treatment member organizations. Together, our members serve over 10 million adults, children and families living with mental illnesses and addictions each year. The National Council is committed to all Americans having access to comprehensive, high-quality care that affords every opportunity for recovery.

Amid our nation's continuing opioid epidemic, the Drug Enforcement Agency (DEA)'s mission to protect public safety through the enforcement of controlled substances laws and regulations is absolutely critical in preventing the diversion and misuse of controlled substances. Your work is especially challenging in the digital age as illegal online drug sellers are rampant. The Ryan Haight Online Pharmacy Consumer Protection Act (Ryan Haight) (PL 110-425), passed into law in 2008, was created to give DEA the tools to address this problem.

However, just as essential to addressing the opioid epidemic is the ability of health care providers to treat patients with opioid use disorder according to the clinical standard of care, which includes the prescription of medication-assisted treatment (MAT), a controlled substance. Due to MAT's status as a controlled substance, only specifically registered and qualified providers and specialists may legally prescribe and dispense MAT, and the population currently in need of MAT far exceeds the existing availability of providers authorized to prescribe it. This is especially true in more remote areas, which are often hardest hit by the epidemic.

*Fortunately*, telemedicine can help bridge this gap by creating access to care for those who otherwise may go without or endure substantial delays in receiving mental health and addiction treatment. *Unfortunately*, current limitations on telemedicine prescribing of controlled substances leave patients without that option.

**Community addiction and mental health treatment centers are uniquely positioned to safely and effectively treat patients with mental illness and addiction using telemedicine for remote prescribing, but are severely limited in doing so by DEA's current policy.**

**The DEA has the ability and authority to immediately solve access issues for patients with opioid use disorder and other behavioral health conditions by updating and carefully, narrowly expanding the exceptions that currently limit the use of telemedicine.**

Building on our letters to the DEA in 2015 and 2017 on this topic (attached), this letter outlines options available to DEA to immediately address the opioid epidemic and ensure that the public health benefits of telemedicine are achieved without compromising public safety.

***CURRENT LAW PERMITS USE OF TELEMEDICINE TO PRESCRIBE CONTROLLED SUBSTANCES UNDER THE RYAN HAIGHT ACT***

The original Ryan Haight Act recognized the need to maintain access to telemedicine through its inclusion of limited exceptions for the prescribing of controlled substances via telemedicine without a prior in-person patient medical evaluation.

The Act's most often used telemedicine exception permits a remote practitioner acting in the usual course of professional practice and in accordance with state law to prescribe controlled substances to a patient remotely if two conditions are met: [1]

1. The remote practitioner is registered with the DEA under section 303(f) of the Controlled Substances Act in the state where the patient is located; [2] and
2. The patient is being treated by, and physically located in, a hospital or clinic also registered with the state and the DEA under 303(f).

The first part of this exception does not pose a problem for community addiction and mental health treatment centers as they understand the need to use remote practitioners who are registered with DEA in in the state where the patient is.

The challenge arises under the current interpretation of the second part of this statutory exception. **Despite the fact that community addiction and mental health treatment centers are clinics, they are rarely able to register with the DEA as a clinic under this exception.**

[1] 21 U.S.C. § 802 (54)(A) (2018).
[2] Section 303(f) of the Controlled Substances Act is found in 21 U.S.C. § 823(f) (2018). It requires the Attorney General "to register practitioners (including pharmacies, as distinguished from pharmacists) to dispense, or conduct research with, controlled substances in schedule II, III, IV, or V."

***COMMUNITY ADDICTION AND MENTAL HEALTH TREATMENT CENTERS ARE UNIQUELY POSITIONED TO PROVIDE CARE VIA TELEMEDICINE, BUT CANNOT UNDER CURRENT DEA POLICY***

The National Council for Behavioral Health (the National Council), with 2,900 community addiction and mental health treatment center member organizations, serves more than eight million adults and children living with mental illnesses and substance use disorders. National Council member organizations provide a range of mental health and addiction treatment services including:

- Psychiatric crisis services, inpatient hospitalization, outpatient medication and psychotherapy, case management and assertive community treatment, and treatment for trauma and post-traumatic stress disorders;
- Programs for the prevention of addictions, violence, and suicide; community education; early intervention; and jail diversion and prison re-entry initiatives;
- Addiction disorder treatment programs, including detoxification, residential, and intensive outpatient care;
- Evidence-based interventions, including supported work and housing, illness self-management, and family psychoeducation; and
- Specialized community mental health services for children, including therapeutic foster care, multi-systemic therapy, functional family therapy, and mentoring and respite services.

However, it is often not possible for these community addiction and mental health treatment centers to have a DEA-registered provider on site where the patient is located. Telemedicine is the perfect solution because these centers can safely care for patients and provide all the other services and support they need; the provider registered to prescribe controlled substances is the only thing they are missing in person.

Community addiction and mental health treatment centers are legitimate places to receive health care services and are licensed, operated, authorized, certified, or otherwise recognized by their states. In some cases, these centers are even quasi-state or local government entities. However, they are not currently authorized to *prescribe or dispense* controlled substances under state law *because they do not prescribe or dispense controlled substances*.

Most hospitals and clinics obtain controlled substances authority, or 303(f) registration, because most hospitals and clinics engage in prescribing, dispensing or conducting research with controlled substances. Community addiction and mental health treatment centers do not typically prescribe, dispense or conduct research with controlled substances. Therefore, states have had no need to grant these centers controlled substances authority and their license, authorization, certification, or other recognition does not typically include a state controlled substance authorization.

Here lies the barrier for community addiction and mental health treatment centers, who could otherwise safely expand access to prescribing of controlled substances via telemedicine.

**Community addiction and mental health treatment centers would like to be able to register with the DEA in order to comply with the Ryan Haight Act's requirement that the patient be located in a hospital or clinic registered under 303(f)[3], but are not currently able to do so.** To be clear, these centers seek the ability to register with DEA for the mere purpose of complying under the telemedicine exception; DEA registration will not change the fact that these centers will not be prescribing or dispensing controlled substances themselves.

The solution is allowing community addiction and mental health treatment centers a process with the DEA that achieves the goal of limited expanded access to care. **Requiring that each state change its laws to allow all community addiction and mental health treatment centers to be authorized to *prescribe* or *dispense* controlled substances is <u>not</u> a practical solution as the centers do not currently perform these functions, nor want to.** Further, expecting each state to change its controlled substance laws would be overly onerous on both the states and the community. This is especially true at the height an epidemic during which there were more than 72,000 overdose deaths last year alone.[4]

***Recommendation for Limited Telemedicine Special Registration under Ryan Haight***

Recognizing the need to carefully expand the telemedicine exceptions allowed under Ryan Haight, in October Congress required that the DEA create this Special Registration process as Section 3232 of H.R. 6, the SUPPORT for Patient and Communities Act.[5] If implemented carefully, as DEA is currently contemplating doing, telemedicine can be used appropriately without opening the floodgates to diversion of controlled substances.

**The National Council recommends that the DEA create a Special Registration process for practitioners who have authority from their state to operate as community addiction and mental health treatment centers to act as a site for patients to receive remote prescribing services via telemedicine.** The National Council recommends that this registration only be permitted for remote practitioners who are registered under 303(f) in the state where the patient is located.

***Other Authority to Ensure Telemedicine Availability in Appropriate Settings under Ryan Haight***

In addition to the pending Special Registration process, the DEA has other existing authority to solve the problem facing community behavioral health facilities attempting to expand access to

[3] 21 U.S.C. § 823(f) (2018).
[4] National Institute on Drug Abuse Overdose Death Rates, https://www.drugabuse.gov/related-topics/trends-statistics/overdose-deaths-rates (last visited Dec. 18, 2018).
[5] Substance Use-Disorder Prevention that Promotes Opioid Recovery and Treatment for Patients and Communities Act, Pub. L. No. 115-271 (2018).

care for their patients. Under the existing telemedicine exception for hospitals and clinics, the DEA could simply change the registration process to include community addiction and mental health treatment centers, with appropriate recognition but not necessarily controlled substances authority from their state, as qualifying clinics.

The Ryan Haight Act provides yet another way DEA could allow these centers to utilize telemedicine to increase access to care. The Act's definition (54)(G) of telemedicine includes: *"Any other circumstances that the Attorney General and the Secretary have jointly, by regulation, determined to be consistent with effective controls against diversion and otherwise consistent with the public health and safety."*[6] The National Council believes that working with community addiction and mental health treatment centers to solve this registration issue would be consistent with effective controls against diversion and with the public health and safety.

***CONCLUSION***

The National Council looks forward to working with the DEA to ensure that patients have appropriate access to medically appropriate controlled substances in a manner that is carefully controlled to prevent diversion. To further discuss, please contact Chuck Ingoglia, Senior Vice President, The National Council for Behavioral Health, at chucki@thenationalcouncil.org and (202) 684-3749.

Sincerely,

Linda Rosenberg
President and CEO
National Council for Behavioral Health

Enclosures

cc: Admiral Brett Giroir, Assistant Secretary for Health, U.S. Department of Health and Human Services

[6] 21 U.S.C. § 802 (54)(G) (2018).