August 14, 2017

Chuck Rosenberg
Acting Administrator
Drug Enforcement Administration
Department of Justice
8701 Morrissette Drive
Springfield, VA 22512

RE: Special Registration to Enable the Practice of Telemedicine

Dear Administrator Rosenberg:

The National Council for Behavioral Health (National Council) and the undersigned executive directors of state associations representing community-based providers of mental health and addiction treatment services appreciate the efforts of the Drug Enforcement Agency (DEA) to prevent, detect, and investigate the diversion of controlled substances while ensuring an adequate and uninterrupted supply for legitimate medical, commercial, and scientific needs.

We recognize DEA's job has become increasingly complex given advances in technology that allow for telemedicine and online sales of pharmaceuticals. It is in this context that we write to underscore the importance of the intent of the Ryan Haight Online Pharmacy Consumer Protection Act and request expedited guidance on the DEA's planned special telemedicine registration process. We appreciate your consideration of our comments as you seek to balance the interests of increasing access to controlled substances for legitimate medical use and/or substance abuse treatment as provided for via telemedicine.

About Us

The National Council is the unifying voice of America's community of mental health and addictions treatment organizations. Together with 2,900 member organizations, the National Council serves more than eight million adults and children living with mental illnesses and addiction disorders. We are committed to ensuring all Americans have access to comprehensive, high-quality care that affords every opportunity for recovery and full participation in community life.

The undersigned state associations serve the interests of community behavioral healthcare provider organizations in their states or regions. They represent community clinics and centers that provide services and support for people with intellectual and developmental disabilities, serious mental illness, and substance use disorders.

BACKGROUND

In 2015 DEA announced its intent to issue regulations to permit practitioners to obtain a "special registration to engage in telemedicine," pursuant to the Ryan Haight Online Pharmacy Consumer Protection Act ("Ryan Haight Act"). RIN 1117-AB40. As of the date of this letter, DEA has yet to issue regulations or guidance on the issue, though it has been widely reported that DEA is soon expected to release a rule that would create a special registration class of providers who could prescribe controlled substances over a telemedicine platform.

Many stakeholders – including telemedicine companies, lawyers, healthcare providers, and patients – eagerly await DEA's policy on the issue. We too are eager for DEA's guidance. Nationally, the opiate overdose death rate was over 52,000 per year in 2015 and numerous federally-funded activities are currently underway to assist those living with opioid use disorders to access medication-assisted treatments, some of which are controlled substances and subject to the terms of the Ryan Haight Act. Yet, many Americans living in rural and frontier areas of the country who are suffering from these disorders will not be able to benefit from these life-saving treatments because of the absence of licensed, trained and experienced addiction medicine prescribers in many of these areas. The use of telemedicine to prescribe medication-assisted treatment will provide life-saving access to addiction medicine in these areas, if it can be made available quickly. Meanwhile, mental health prescribers in rural areas and other places across the nation are reporting challenges prescribing common psychiatric medications via telemedicine due to the lack of a special registration process for telemedicine providers.

At the same time, the National Council and undersigned organizations also appreciate DEA's careful evaluation of the issues as we recognize the difficult but critical challenge of needing to craft a policy that both enables access and prevents abuse.

As DEA continues to evaluate the special registration process for remote prescribing, the National Council and undersigned organizations urge DEA to address the unique issues faced by the telemedicine community. In late 2015, the National Council sent the attached comments to DEA regarding remote prescribing via telemedicine. (*See Appendix A.*) In early 2016, we met with DEA Diversion Control Division policy staff to discuss our views. Since that time, we have been awaiting DEA action on the issue.

CURRENT CONSIDERATIONS

Demand for mental health and addiction services far exceeds current system capacity to serve patients. Telemedicine is a vital opportunity to extend both mental health and addiction treatment services to more patients, particularly those living in rural and frontier areas that lack qualified providers.

Considering the ongoing opioid addiction crisis, it is imperative that DEA issue regulations to provide a way for patients to receive medication-assisted treatment (MAT) for substance use disorders via telemedicine. Medication-assisted treatment is a highly effective, evidence-based treatment for opioid addiction that combines the use of medication with counseling and behavioral therapies.

Unfortunately, many rural area providers cannot find qualified MAT prescribers, which include physicians, physician assistants, and nurse practitioners, and are therefore unable to implement MAT. Tele-medication assisted treatment would provide life-saving access to addiction medicine in these underserved areas.

Meanwhile, more than a million tele-psychiatry consultations are estimated to have occurred in the U.S. in 2016, and due to the shortage of psychiatrists in the U.S. the demand for tele-psychiatry is only increasing. As the use and value of tele-psychiatry takes hold in the U.S., it is all the more important that DEA issue regulations to provide a way for patients to receive needed prescriptions via tele-psychiatry encounters.

The National Council and undersigned organizations support the creation of a regulatory pathway that allows patients to receive treatment utilizing controlled substances via telemedicine while balancing the interests of access to care and abuse prevention. Our recommended approach is outlined in the comments we submitted to DEA in 2015, attached here again as Appendix A. Many community addiction and mental health providers do not meet the qualifications to register with DEA under existing registration pathways that would enable them to offer telemedicine services to their patients, though they provide a broad array of important clinical treatment and recovery services. Our position from 2015 as reflected in Appendix A remains our stance today: community mental health and addiction providers need access to a special registration process so that they may register with DEA to prescribe controlled substances used for the treatment of addiction or mental illness to patients in remote locations. As DEA considers the creation of a special registration process for telemedicine providers, it is imperative that this process be inclusive of state-licensed mental health and addiction treatment organizations whose patients receive services via telemedicine.

Additionally, we wish to clarify our prior letter's recommendation that narcotic medications not be prescribed via telemedicine. We do not intend this recommendation to include medication-assisted treatments for addiction such as buprenorphine and methadone. These medications, prescribed either by physicians, physician assistants or nurse practitioners that have received specialty training and waivers, or by specially licensed clinics, support patients' recovery with a steady dosage of medication that reduces cravings and improves functioning. These medications are recognized by the National Institute of Drug Abuse, American Society of Addiction Medicine, American Society of Addiction Psychiatry, and the Substance Abuse and Mental Health Services Administration as essential tools in responding to the opioid epidemic.

DEA registered providers who are certified and permitted to issue such prescriptions by applicable state and federal law should be able to prescribe opioid-based medication assisted therapies for substance use disorders via telemedicine. Increased access to these treatments is consistent with the medical standard of care and the country's heightened efforts to fight the opioid epidemic.

Especially given the opioid epidemic, we continue to believe remote prescribing of controlled substances without a prior in-person medical evaluation should be limited to patients located in a DEA registered facility, including facilities that will register under the forthcoming new special registration process for telemedicine providers. Allowing home-based prescriptions would erode the

Ryan Haight Act and invite rogue online pharmacies posing as telemedicine providers into the market. A simple online search returns websites that sell bottles of Percocet shipped directly to the customer's house for $2 a pill. Currently the National Association of Boards of Pharmacy estimates there are roughly 3,300 active online drug sellers offering controlled substances in violation of existing law. Opening up online prescribing of controlled substances to patients not located in a DEA-registered facility—whether an existing DEA-registered facility or a facility registered under the new special registration process—risks making this problem worse.

For this reason, the National Council and undersigned organizations urge DEA to maintain the Ryan Haight Act's requirement that patients must be located in a DEA-registered facility (whether a clinic, Veterans' hospital, or, as proposed in our comments, an organization such as a state-licensed mental health or addiction organization that has newly registered as a telemedicine site via the special registration process) in order to receive a prescription for a controlled substance via telemedicine. We understand that some stakeholders have encouraged DEA to loosen the location requirement for Veterans so they could get prescriptions for controlled substances via telemedicine without a prior in-person medical evaluation. Although we agree with the goal of increasing Veterans' access to care, we fear allowing prescribers to issue prescriptions for controlled substances in patients' homes (or otherwise outside of DEA-registered facilities) could lead to reduced oversight and increased risk for drug abuse, misuse and diversion in this already vulnerable population. Further, having two different rules for online prescriptions of controlled substances – one for Veterans and one for all other patients – is inconsistent policy and could lead to patient, provider, and industry confusion. As such, we urge DEA to apply the proposed "belt and suspenders" approach outlined in our comments in Appendix A to all patient populations, including Veterans.

CONCLUSION

The National Council for Behavioral Health and the undersigned state associations of mental health and addiction treatment providers greatly appreciate the DEA's consideration of these comments and stand ready to provide feedback or assistance as you move forward with creating the new special registration process. As you continue to evaluate the issues, please do not hesitate to call on us should you have any questions or if additional input would be of value. The National Council can be reached by contacting: Chuck Ingoglia, Senior Vice President, Public Policy and Practice Improvement, chucki@thenationalcouncil.org or (202) 684-3749.

Thank you for your time and attention to this important matter.

Sincerely,

Chuck Ingoglia, National Council for Behavioral Health
Jim Dill, Alabama Council for Behavioral Healthcare
Emily Jenkins, Arizona Council of Human Service Providers
Paul Curtis, California Council of Community Behavioral Health Agencies
Doyle Forrestal, Colorado Behavioral Healthcare Council

Gian-Carl Casa, The Alliance: The Voice for Community Nonprofits (Connecticut)
C. Thomas Cook, Ability Network of Delaware
Mark LeVota, District of Columbia Behavioral Health Association
Mark Fontaine, Florida Behavioral Health Association
Robyn Garrett, Georgia Association of Community Service Boards
Marvin Lindsey, Community Behavioral Healthcare Association of Illinois
Sara Howe, Illinois Association for Behavioral Health
Janet Stover, Illinois Association of Rehabilitation Facilities
Matt Brooks, Indiana Council of Community Mental Health Centers, Inc.
Shelly Chandler, Iowa Association of Community Providers
Flora A. Schmidt, Iowa Behavioral Health Association
Kyle Kessler, Association of Community Mental Health Centers of Kansas, Inc.
Steve Denny, Kansas Association of Addiction Professionals
Malory Otteson Shaughnessy, Alliance for Addiction and Mental Health Services, Maine & Maine Behavioral Health Foundation
Shannon Hall, Community Behavioral Health Association of Maryland
Tracey Myers-Preston, Maryland Addictions Directors Council
Vic DiGravio, Association for Behavioral Healthcare (Massachusetts)
Robert Sheehan, Michigan Association of Community Mental Health Boards
Brent McGinty, Missouri Coalition for Community Behavioral Healthcare
Debra L. Wentz, New Jersey Association of Mental Health and Addiction Agencies
Andrea Smyth, New York State Coalition for Children's Behavioral Health
Ashley Behrle, New York State Council for Community Behavioral Healthcare
Christy Parque, The Coalition for Behavioral Health, Inc. (New York)
John Coppola, The New York Association of Alcoholism and Substance Abuse Providers, Inc.
Julia Jernigan, Oklahoma Behavioral Health Association
Sheila North, Oregon Prevention, Education, and Recovery Association
Richard Edley, Rehabilitation & Community Providers Association (Pennsylvania)
David Spencer, The Substance Use and Mental Health Leadership Council of RI
Mary-Linden Salter, Tennessee Association of Alcohol, Drug & other Addiction Services
Danette Castle, Texas Council of Community Centers
Richard Nance, Utah Behavioral Health Committee
Julie Tessler, Vermont Council of Developmental and Mental Health Services
Ann Christian, Washington Council for Behavioral Health
Erin Johnson, Wyoming Association of Mental Health & Substance Abuse Centers

cc: Louis Milione, Assistant Administrator, Diversion Control Division
Demetra Ashley, Deputy Assistant Administrator
James Arnold, Liaison & Policy Section Chief, Diversion Control Division

Appendix A

December 2015 Comments to DEA
Re: Special Registration to Enable the Practice of Tele-Psychiatry

December 14, 2015

Imelda L. Paredes
Executive Assistant, Office of Diversion Control
Drug Enforcement Administration
Department of Justice
8701 Morrissette Drive
Springfield, VA 22512

RE: Special Registration to Enable the Practice of Tele-Psychiatry

Dear Ms. Paredes:

The National Council for Behavioral Health, the Texas Council of Community Centers and Optum appreciate the agency's consideration of the attached comments on the Ryan Haight Online Pharmacy Consumer Protection Act's telemedicine provisions. Our comments were inspired by the DEA's published agenda item RIN 1117-AB40, which states the Agency's intent to create a special registration for the prescribing of controlled substances via telemedicine under the Ryan Haight Act.

Recognizing the DEA's plans for rulemaking on this topic, to develop the position outlined below we consulted with behavioral and mental health experts, national and state provider organizations and trade associations, telemedicine companies, and Internet pharmacy safety stakeholders, anti-prescription drug abuse organizations, and in-house leaders at our various organizations. Central to our policy development process was the recognition that the policy needs to:

1. Ensure patients to have access to psychiatric resources and mental health care, including, if clinically appropriate, prescription drug treatments;
2. Enable continued Agency oversight of and enforcement against rogue online pharmacies and inappropriate prescribing of controlled substances for which Ryan Haight Act was enacted to address; and
3. Not inadvertently open the door to further diversion, misuse, or abuse of controlled substances.

The National Council for Behavioral Health, The Texas Council of Community Centers, and Optum greatly appreciate the DEA's consideration of these comments regarding the creation of a special telemedicine site registration. As your process moves forward, please do not hesitate to call on us should you have any questions or if additional input would be of value. Signatories can be reached by contacting Chuck Ingoglia, Senior Vice President, Public Policy and Practice Improvement, National Council for Behavioral Health available directly at (202) 684-3749.

Sincerely,

Chuck Ingoglia, National Council for Behavioral Health

The following organizations jointly submit the following comments for U.S. Drug Enforcement Administration's consideration regarding the issuance of a prescription for a controlled substance via tele-psychiatry: The National Council for Behavioral Health, the Texas Council of Community Centers and Optum.

ABOUT US

The National Council for Behavioral Health (National Council) is the unifying voice of America's community mental health and addictions treatment organizations. Together with 2,500 member organizations, the National Council serves more than eight million adults and children living with mental illnesses and addiction disorders. The organization is committed to ensuring all Americans have access to comprehensive, high-quality care that affords every opportunity for recovery and full participation in community life.

The Texas Council of Community Centers (Texas Council) represents the 39 Community Centers providing services and supports in communities throughout Texas for people with intellectual and developmental disabilities, people with serious mental illness and people with substance use disorders. The Texas Council's main function is to facilitate policies and changes for mental health, intellectual disability and substance abuse services in Texas.

Optum, part of the UnitedHealth Group family, is a leading information and technology-enabled health services business dedicated to helping make the health system work better for everyone. UnitedHealth Group's workforce of 185,000 people serves the health care needs of more than 100 million people worldwide, funding and arranging health care on behalf of individuals, employers and government. As one of America's most diversified health and well-being companies, we not only serve many of the country's most respected employers, but we are also the nation's largest Medicare health plan - serving nearly one in five seniors nationwide - and one of the largest Medicaid health plans, supporting underserved communities in 24 states and the District of Columbia. Recognized as America's most innovative company in our industry by Fortune magazine for six years in a row, we bring innovative health care solutions to scale to help create a modem health care system that is more accessible, affordable and personalized for all Americans.

BACKGROUND

Earlier this year the U.S. Drug Enforcement Administration (DEA) announced its intent to issue regulations to permit practitioners to obtain a "special registration to engage in telemedicine," pursuant to the Ryan Haight Online Pharmacy Consumer Protection Act ("Ryan Haight Act"). RIN 1117-AB40. As DEA evaluates the special registration process for practitioners, the National Council urges DEA to address the unique issues faced by the tele-psychiatry community. As discussed below, the

signatories support the creation of a pathway – whether through a special registration for the tele-psychiatrist or for the facility – that allows patients to receive robust treatment utilizing non-opioid-based controlled substances via tele-psychiatry.

THE ISSUE

Through the use of technology, psychiatrists occasionally prescribe controlled substances to patients who are neither (a) in the physical presence of a DEA-registered provider, nor (b) physically located in a DEA-registered facility. The Ryan Haight Act prohibits DEA-registered psychiatrists from issuing a prescription for a controlled substance by means of the Internet, unless an exception applies. Unfortunately, none of the Act's seven categories of telemedicine apply to the scenario that mental health providers and patients regularly face today. As such, the Ryan Haight Act is limiting psychiatrists' ability to provide care to certain patients.

SCENARIO: A patient at a mental health clinic goes into crisis and needs emergency psychiatric care involving a prescription for e.g. diazepam (Valium). There are no psychiatrists on site, so the clinic connects the patient to a psychiatrist via telemedicine. In this case, the psychiatrist is DEA-registered but the clinic is not. If the clinic were registered with DEA, the Act's telemedicine category for "treatment in a hospital or clinic," (21 U.S.C. 829(e)(3)(A)), would apply. In this scenario, none of the Act's other telemedicine categories apply either.

While currently examples like this may be rare, utilization of tele-psychiatry is growing. One million tele-psychiatry consultations are estimated to occur in the U.S. in 2015 and, due to the shortage of psychiatrists in the U.S., the demand for tele-psychiatry will only increase. According to federal health authorities, there are about 4,000 areas nationwide where there is only one psychiatrist for every 30,000 patients. Further, the American Academy of Child and Adolescent Psychiatrists, (AACAP) reports there are approximately 8,300 practicing child and adolescent psychiatrists in the U.S. — and over 15 million youths in need of one. Additionally, use of telemedicine – including tele-psychiatry – will continue to expand as it saves patients and reduces payors costs. According to a 2013 article in iHealthBeat, "a large-scale study involving 98,609 Department of Veterans' Affairs mental health patients from 2006 to 2010 showed that after initiation of telehealth services, patient hospitalization utilization decreased by 25%."

As the use of, access to, and value of tele-psychiatry takes hold in the U.S., it becomes all the more important that DEA issue regulations to provide a way for patients to receive needed prescriptions via tele-psychiatry encounters. At the same time, the regulation should not result in prescriptions being considered valid under the Controlled Substances Act that are solely the result of a form being filled out on a website.

PROPOSED SOLUTION: WHAT DEA CAN DO TO HELP

DEA has the authority to resolve the tele-psychiatry issue via regulation using existing authority. After substantial consideration and consultation with a broad group of stakeholders, we encourage the DEA to establish a new registration process for facilities (e.g. mental health clinics, schools, etc.) that are not currently DEA-registered but which nonetheless serve patients who need to be treated by a DEA-registered provider via telemedicine (including specifically tele-psychiatry).

The Agency could establish this new telemedicine site registration pursuant to their authority to allow for the practice of telemedicine "in any other circumstances that the Administrator [of DEA] and the

Secretary of Health and Human Services have jointly, by regulation, determined to be consistent with effective controls against diversion and otherwise consistent with the public health and safety." 21 CFR 1300.04(i)(7).

CONCEPT: TELEMEDICINE FACILITY REGISTRATION: We encourage DEA to setup a new type of DEA registration for clinics/facilities that are not registered with the DEA under section 303(f), but which nonetheless serve patients who need to be treated by a DEA-registered provider via telemedicine (including specifically tele-psychiatry). One way to do this, for example, is to establish a form similar to Form 224 to allow facilities to register as a "telemedicine site" with the DEA. Locations including but not limited to mental health clinics, group homes, qualified hospice programs, assisted living facilities, juvenile detention centers, and schools should be eligible to apply for telemedicine site registration.

For purposes of the telemedicine site registration, however, we do not believe that a person's individual home should qualify. Allowing individuals to register their homes opens the door to potential abuse. Further, if many patients elected to register their homes as a telemedicine site such could strain the resources of DEA to effectively enforce the Act and prevent abuse. As such, we believe that in order to receive a prescription for a controlled substance via telemedicine (meaning without a prior in-person medical exam), the patient should be located in a regulated location. That location could either be a DEA-registered facility under 303(f) as currently allowed by the Act or a facility registered under the proposed new telemedicine site registration.

Benefits of the proposed telemedicine site registration:

- Gives the DEA transparency into the business practices of clinics/facilities not otherwise registered with the DEA under section 303(f) but who nonetheless have patients on-site that need treatment via telemedicine involving the issuance of a prescription for a controlled substance.
- Gives DEA jurisdiction over the clinics/facilities for violation of the Ryan Haight Act should the clinic/facility fail to comply with the requirements of the new, proposed telemedicine site registration. Having registered with DEA, however, should not be interpreted as a safe-harbor from DEA action, just as provider registration with the DEA does not shield a doctor from DEA enforcement should he/she otherwise be violating the law.
- Balances the burden that is placed on the provider (in this case, the psychiatrist) with a corresponding onus on the clinic/facility. Psychiatrists already must be registered with DEA in order to prescribe controlled substances.
- Gives DEA jurisdiction over two parts of the encounter – the provider and the facility – which both benefits the Agency's enforcement abilities and is consistent with the Act's "belt and suspenders" approach of allowing telemedicine treatment in a hospital or clinic registered with the DEA. 21 CFR 1300.04(i)(1).

For sites that have a clientele for whom it is foreseeable that a patient may need telemedicine care, DEA registration seems reasonable to require. However, some sites might not have the reasonable

foresight to register with DEA and then be faced with an emergency situation that requires patient treatment via telemedicine. The signatories acknowledge this reality and could be comfortable with the Agency crafting an exception to the site registration requirement for emergency situations so long as the emergency exception is sufficiently tailored to avoid creating a loophole that could be exploited by rogue actors. If written too broadly, patients could simply claim they had an "emergency" and then get prescriptions for controlled substances from the comforts of their homes from DEA-registered providers who either didn't know the patient was lying or didn't care.

FACTORS TO CONSIDER: In evaluating telemedicine site applications, the signatories encourage the Agency to consider the following factors, among other things, which would give the DEA insight into the location's likelihood of compliance with the Act:

- The facility's typical purpose (school, clinic, recreational center, jail, etc.);
- The facility's compliance history with any applicable local, state or federal laws and registration requirements;
- The background, record and compliance history of the facility's owners and key personnel (no significant prior discipline); and
- The background, record and compliance history of the providers with whom the facility historically works (no significant prior discipline).

ADDITIONAL VIEWS OF THE SIGNATORIES

Separate from the proposed telemedicine site registration, the signatories wish to share our views on the following other issues the Agency may be contemplating while thinking about new telemedicine rules:

1. In all instances, providers should not be permitted to issue a prescription for an opioid-based controlled substance based on a telemedicine encounter (again, we mean without a prior in-person patient medical evaluation). Where opioids are involved, the risks for prescription drug abuse and diversion are simply too great.

2. The DEA's regulation should not allow prescriptions being considered valid under the Controlled Substances Act that are solely the result of a form being filled out on a website. Online forms alone should still be considered insufficient to establish the doctor-patient relationship that is necessary to issue a valid prescription.

3. DEA should require greater transparency of telemedicine sites/platforms and any associated providers. Specifically, we would like the Agency to require the conspicuous display of key information on the website/platform that providers utilize to make contact with patients. Such information should include accurate information about the telemedicine website/platform's owner/operator, location and contact information, and all practitioner names and licensure information. Further, the website/platform's domain name (to the extent one is used) must accurately reflect the identity of the business and may not be registered anonymously (i.e. with privacy or proxy services). This level of transparency would greatly help to promote

accountability and prevent bad actors.

The National Council, the Texas Council and Optum appreciate the DEA's consideration of these comments regarding the creation of a special telemedicine site registration. As your process moves forward, please do not hesitate to call on us should you have any questions or if additional input would be of value.

Sincerely,

The National Council for Behavioral Health
The Texas Council of Community Centers
Optum