

January 10, 2019

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

Re: Ryan Haight Act Telemedicine Special Registration

Ms. Federico -

This lctcr is submitted in connection with the American Telemedicine Association's recommendations for the forthcoming Ryan Haight Act telemedicine special registration process.

Foley & Lardner's Telemedicine & Digital Health Industry Team has been at the forefront of providing strategic legal, compliance, and business advice to hospitals, healthcare technology companies, and entrepreneurs on the deployment and use of innovative virtual care and digital health services in settings across the United States.

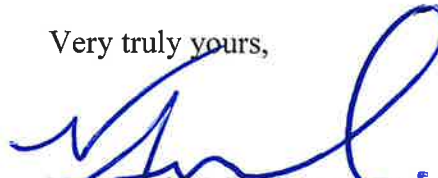
We were therefore encouraged by Congress' passage and the President's signing into law the Special Registration for Telemedicine Act of 2018, as part of the larger SUPPORT for Patients and Communities Act. As you know, the law requires Drug Enforcement Administration (DEA) to promulgate final regulations specifying: (a) the limited circumstances in which a special registration under this subsection may be issued; and (b) the procedure for obtaining a special registration under this subsection. The law sets a deadline of October 24, 2019 for these new regulations.

To Congress' credit, the final version of the SUPPORT for Patients and Communities Act notably changed a clause contained in one of the initial drafts. The draft bill originally required the DEA to issue interim final regulations. Had that version been signed into law, the DEA would have been directed to simply publish the rule and effective date, without considering public comment (which is exactly what happened 10 years ago when DEA published interim final regulations implementing the Ryan Haight Act on April 13, 2009). Fortunately, the final version of the bill signed into law instead sets a one-year deadline for DEA to promulgate final regulations. And the law affords DEA ample time to issue proposed rules, allow a 60 or 90-day period for the public to submit comments, and then promulgate the final regulations.

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We were pleased to help contribute to the ATA's letter (attached) and respectfully ask DEA to give serious consideration to the recommendations as you prepare the regulation. Thank you for your consideration of these comments.

Very truly yours,



Nathaniel M. Lacktman, Esq.

Chair, Telemedicine & Digital Health Industry Team
Foley & Lardner, LLP

Enclosure



January 9, 2019

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

RE: Special Registration for Telemedicine Final Rulemaking

Dear Ms. Federico,

On October 24, 2018, President Trump signed the Substance Use–Disorder Prevention that Promotes Opioid Recovery and Treatment (SUPPORT) for Patients and Communities Act of 2018 (the Act). This package of bills included several sections that strengthen options for the use of telemedicine to address the opioid crisis. We applaud this piece of legislation and provide a series of recommendations to ensure the Act meets its full potential in protecting Americans in crisis.

Section 3232 of the Act on Regulations Relating to a Special Registration for Telemedicine sets a deadline for the Attorney General to activate the provision for special registration for telemedicine, as specified in the Ryan Haight Online Pharmacy Consumer Protection Act of 2008 (RH Act), to come into effect no later than one year after the date of enactment. The telemedicine community has long advocated for activation of special registration to relieve the regulatory impasse that confronts many telehealth prescribers. Activation of the special registration provision will not only allow additional prescribers to use telemedicine to combat the opioid crisis, but also provide the broad range of medical disciplines an avenue to expand access to quality care.

In response to the Act's mandate, the American Telemedicine Association (ATA) has convened a special workgroup from membership within its Telebehavioral Health Special Interest Group. That workgroup has developed five recommendations for how a special registration process could be structured to enable the safe prescribing of certain controlled substances via telemedicine. These suggestions intend to strike the balance between our country's great need for additional behavioral health resources, commonly accepted clinical practices, the evolving landscape of telemedicine technologies, and DEA's charge to protect the safety and wellbeing of citizens via drug diversion. Our recommendations are as follows:

1. Update the current DEA registration process to specify distinctions between traditional and telemedicine prescribing privileges.
2. Allow both sites and prescribers to register for telemedicine.
3. Allow for a public comment period within the one-year timeline for special registration activation.
4. Ensure that telemedicine special registration is not restricted to any single discipline.
5. Allow telemedicine prescribers to apply for DEA registration numbers in multiple states at once.



We welcome the opportunity to engage in a dialogue about the impact of the above recommendations on the practice and adoption of telemedicine to address the nation's public health challenges. Thank you in advance for your consideration.

Sincerely,

A handwritten signature in black ink, appearing to read "Ann Mond Johnson". The signature is fluid and cursive, with a long horizontal stroke extending to the right.

Ann Mond Johnson
Chief Executive Officer

Recommendations for Rulemaking on the Remote Prescribing of Controlled Substances

1. Update the current DEA registration process to specify distinctions between traditional and telemedicine prescribing privileges.

We propose that the existing DEA registration process be updated to allow for special registration for telemedicine. With a small modification to Form 224 and 224a, applicants could select if they are applying for traditional, telemedicine or specifically telepsychiatry privileges. Telemedicine registration would require the applicant to indicate the schedules and types of drugs the applicant is registering to prescribe via telemedicine. Traditional registration would be the same as the current process and standards under this proposal.

The traditional, telemedicine or specifically telepsychiatry distinctions within DEA's registration process will require the applicant to be specific about his or her intended use of telemedicine and offer DEA more options in how it reviews and approves applications and monitors prescribing practices. For instance, the Administration may choose to grant special registration authority for stimulant prescribing via telepsychiatry to a child psychiatrist, while denying that same privilege to a teleradiologist. Similarly, the Administration may choose to grant authority for a licensed addiction clinic to prescribe buprenorphine via telemedicine encounters performed by SAMHSA registered addiction psychiatrists, while denying authority for a cardiologist to prescribe buprenorphine via telemedicine.

We have outlined appropriate parameters for a telepsychiatry-specific registration (we recommend similar parameters be defined for those applying for a general telemedicine registration) and criteria for DEA assessment of special registration in the appendix.

Proposed Mechanism for Telemedicine Registration (see appendix for example):

Amend Section 3 of Form 224 (applicants can check multiple options):

1. Create Section 3A – Traditional
2. Create Section 3B – Telepsychiatry
 - Create options for prescribing authority for certain types of drugs
3. Create Section 3C – Telemedicine
 - Create options for prescribing authority for certain types of drugs

2. Allow both sites and prescribers to register for telemedicine.

We propose that the special registration process be an option for both sites and prescribers.

Prescriber Registration

It is extremely common for both traditional and telemedicine prescribers to work in multiple sites of service throughout their work week, or even day. For example, a geriatric psychiatrist may visit ten different skilled nursing facilities in rotation. Constraining telemedicine registration to any one of those settings limits the prescriber's ability to leverage telemedicine. Special registration that is open to the prescriber resolves this roadblock, since prescribers may now prescribe controlled substances irrespective of their specific location in a state. This proposal would, further, streamline the mechanism of DEA audits, since information about the prescriber (and/or their practice administrator) may now be accessed directly, rather than across many potential disparate sites.

We propose that telemedicine prescriber special registration be:

1. Unique to specific prescribers and their NPI number.
2. State-specific and linked to a prescriber's state medical license.
3. Applicable to any location served by the prescriber within a state.
4. Applicable only to the specific schedule and types of drugs for which the prescriber is registered.

Site Registration

We propose that all venues of care where telemedicine encounters occur have the option to apply for a special registration for telemedicine. These facilities would register to prescribe a specific schedule and type of drug and assign a specific internal code to each telemedicine prescriber, which would enable the DEA to more easily monitor prescribing activity. Community mental health clinics, schools, group homes, correctional programs and skilled nursing facilities today all represent common settings where patients access telemedicine care. Many of these venues where telemedicine encounters commonly occur do not possess a state controlled substance registration but could benefit from a special telemedicine registration to improve access to clinically appropriate care. For example, a community mental health clinic that does not dispense drugs onsite would greatly benefit from a telemedicine registration that allows all prescribers who serve patients within that practice to prescribe controlled substances when appropriate.

We propose that telemedicine site special registration be:

1. Unique to the business entity or practice group.
2. Applicable to multiple sites operating under the same Tax ID Number.
3. Applicable to any DEA registered prescriber serving sites of that business entity.
 - a. Use facility's DEA number.
 - b. Facility assigns a specific internal code to each practitioner (for activity, prescribing tracking & audit).
4. Applicable only to the specific schedule and types of drugs for which that site registers.

Proposed Mechanism for Telemedicine Registration (see appendix for example):

Amend Section 2 Business Activity to change "Hospital/Clinic" to "Healthcare Site"

Opening this definition to include established medical sites and other settings would allow the option for registration of other common sites of service including, but not limited to, residential treatment facilities, halfway houses, jails, juvenile detention centers, prisons, group homes, rehabilitation centers, schools, qualified hospice programs, and assisted living facilities.

To be clear, this proposed change would not require sites that do not conduct telemedicine to register with the DEA; yet, it does create the option for sites who seek to practice telemedicine to register with the DEA in order to be appropriately monitored and controlled.

We further recommend that Form 224a (Renewal Application) be amended to include the same options.

3. Allow for a public comment period within the one-year timeline for special registration activation.

We urge the inclusion of a public comment period prior to the finalization of telemedicine special registration. The Ryan Haight Act was enacted without a public comment period, which resulted in the challenges the DEA and telemedicine communities now seek to address. In a previous Senate amendment to the Act, a "period of not less than 60 days for comments on the proposed regulations" was outlined; however, in the finalized version, inclusion of this public comment period was removed. Absent a public comment period, there is risk that published regulations might not align

with the best interests of patients.¹ Therefore, it is paramount that the healthcare and telemedicine communities have the opportunity to review and comment on proposed special registration regulations before they become effective.

We also encourage the DEA to review the matter of federal preemption as it pertains to special registration to minimize potential sources of legal conflict between prescribers, states, and federal regulators.

4. Ensure that telemedicine special registration is not restricted to any single discipline.

The aim of the SUPPORT for Patients and Communities Act is to increase access to substance use disorder (SUD) treatment through activation of special registration. The ATA applauds this important and timely objective and is enthusiastic about the potential to leverage telemedicine to address the opioid crisis with increased participation from behavioral health providers.

A wide range of disciplines, including child and adolescent psychiatry, endocrinology, and emergency medicine, also rely on appropriately prescribing controlled substances and, therefore, should not be excluded from the special registration provision.

Child and Adolescent Psychiatry: An example of a discipline that would benefit from telemedicine special registration is child and adolescent psychiatry. Telepsychiatry has proven to be one of the most effective tools to enable evaluation and treatment by child and adolescent psychiatrists within areas of need. Child and adolescent psychiatry also has extreme shortages of providers that telemedicine helps to relieve. Among the child and adolescent population, ADHD diagnoses are one of the most common. In order to treat ADHD, stimulants are largely considered to be one of the foundational tools of the child psychiatry profession. However, the majority of ADHD stimulant medications, such as Adderall, Vyvanse, and Ritalin are Schedule II controlled substances. Without the special registration process, child and adolescent psychiatrists are restricted from providing medications to treat the most prevalent child and adolescent mental health diagnosis via telemedicine.

The limitations around remote prescribing of controlled substances go beyond the opioid crisis—they impact the quality of care that patients can receive from providers across many care situations. Thus, special registration should be formulated so that telemedicine can address all applicable health care issues.

5. Allow telemedicine prescribers to apply for DEA registration numbers in multiple states at once.

The Controlled Substances Act requires a separate registration for each principal place of business or professional practice where controlled substances are manufactured, distributed, or dispensed, as set forth in 21 U.S.C. § 822(e). A separate application is required for each state in which the telemedicine prescriber is anticipated to practice. These separate applications are inefficient, especially when one considers that telemedicine prescribers often practice in multiple states and serve multiple settings in order to leverage telemedicine. The potential for DEA to receive inconsistent addresses and locations for prescribers under the current registration process makes it more difficult for DEA agents to monitor prescriber activity and get in contact with prescribers when necessary.

¹ *The process of federal rulemaking typically starts with a proposed rule, published and shared with the public. The public is then generally given a period of 90 days to read the proposed rule and submit comments to the federal agency. The agency must then read, consider, and publicly respond to every single comment. Afterward, the comments and responses are published for the public to review. This procedure is iterative and allows the public to comment on and suggest changes to the regulation before it is finalized. In contrast, an act sent directly to the President's desk could mean published rules and an effective date without consideration or response to public comments.*

Our recommendations are that prescribers seeking a special telemedicine registration for multiple states should not need to provide an in-state address for each of those states, but instead would list the single address of their home state practice and select any number of states where they are already licensed when completing the DEA application form. Medical boards do not require physicians to have an in-state brick and mortar address in order to obtain a medical license, and DEA should follow that same approach for applicants with multistate telemedicine footprints. However, if an applicant does have brick and mortar locations in multiple states and/or plans to purchase controlled substances and have them sent to those address(es), then such address(es) should be listed on the application. But a prescriber with a single office located in New York, with a telemedicine only footprint that also covers additional states, should need only list her single New York address and should not be required to obtain in-state addresses in those other states.

Permitting prescribers to fill out a single form using a single address of record, even when applying for DEA registration numbers in multiple states, will make it easier for DEA to monitor an ever-more diverse and mobile prescriber workforce. Finally, since many telemedicine prescribers have practice administrators that support their credentialing and registrations, this singular address will make getting in touch with that prescriber easier for all involved.

DEA registration costs and fees would remain the same under this proposal; however, both prescribers and the DEA would face a lessened administrative burden, which would allow more prescribers to care for more individuals.

Conclusion

Telemedicine has the potential to impact the opioid crisis in a significant way, and at the same time address a number of other patient health issues. With the passage of SUPPORT for Patients and Communities Act and the explicit deadline to create a special registration for telemedicine, DEA has the opportunity to make several measured changes that would catapult the reach of telemedicine to resolve critical public health need. In summary, our recommendations:

1. Update the current DEA registration process to specify distinctions between traditional and telemedicine prescribing privileges.
2. Allow both sites and prescribers to register for telemedicine.
3. Allow for a public comment period within the one-year timeline for special registration activation.
4. Ensure that telemedicine special registration is not restricted to any single discipline.
5. Allow telemedicine prescribers to apply for DEA registration numbers in multiple states at once.

Appendix

Suggested Conditions Surrounding Registration for Telepsychiatry

Outlined below are parameters specific to the practice of telepsychiatry. Only psychiatrists or psychiatric nurse practitioners would be able to apply for the proposed telepsychiatry registration.²

- 1) For the practice of psychiatry, assuming these conditions are met: (a) the prescriber or the prescriber's site has properly registered with the DEA for telepsychiatry prescribing, and (b) the prescription adheres to the schedule and type of drugs indicated on the registration, a telepsychiatry encounter may result in the prescribing of a controlled substance without a prior in-person visit.
- 2) Telepsychiatry may be used for all patient visits, including initial medical evaluations between a distant site provider and a patient.
- 3) If the services provided relate only to psychiatry and mental health, a patient site presenter is not required, except in cases of prescribing for behavioral emergencies.
- 4) Telepsychiatry services may be conducted within an established medical site, institutional/group setting, or the patient's private home if the services provided relate only to psychiatry and mental health services.
- 5) Treatment and consultation recommendations made in an online setting, including issuing a prescription via the internet, will be held to the same standards of acceptable medical practices as those in traditional in-person clinical settings.
- 6) An online questionnaire; or questions and answers exchanged through email, electronic text, or chat; or telephonic evaluation of or consultation with a patient are inadequate for initial medical evaluations.
- 7) Under no circumstances may a telepsychiatry encounter be used as the basis for the prescribing of opioid-based pain medication, regardless of a prior in-person medical evaluation, unless the patient is enrolled in a hospice program.

Suggested Criteria to Consider When Evaluating Applications for Special Registration

The evaluation of application eligibility and approval of registration for certain prescribing privileges rests solely in the hands of the DEA but we have provided the following requirements as a proposed baseline of eligibility to register for telepsychiatry or telemedicine prescribing privileges, an applicant could be assessed along the following parameters:

- 1) Prescribers carry a current and unrestricted license or certification (as applicable for that entity).
 - a. Prescribers are evaluated on the basis of a valid state medical license.
 - b. Sites are evaluated on the basis of either their license or state certification.
 - i. Established medical sites are evaluated on the basis of their state license.
 - ii. Institutional or group settings are evaluated on the basis of their state certification.
- 2) The provider participates in a third-party prescription drug monitoring program for all telepsychiatry or telemedicine prescribing.
 - The prescription drug monitoring program must be made available to DEA as needed for auditing and monitoring purposes.
- 3) The prescriber completes a background check that shows no history of state or federal sanctions, no history of DEA enforcement actions, and no criminal activity.
 - a. Prescribers are evaluated as individuals.
 - b. Sites subject officers to criminal background checks
- 4) The requested privileges are in alignment with professional credentials
- 5) Psychiatrists or psychiatric nurse practitioners alone may request telepsychiatry privileges
 - Must have completed an approved psychiatry training program

Suggested Form 224 Revisions

Form 224 - Revisions				
SECTION 2				
BUSINESS ACTIVITY	<input type="checkbox"/> Healthcare Site	<input type="checkbox"/> Ambulance Service	<input type="checkbox"/> Practitioner <i>(DDS, DMD, DO, DPM, DVM, MD, PHD)</i>	PROFESSIONAL
	<input type="checkbox"/> Nursing Home	<input type="checkbox"/> Animal Shelter	<input type="checkbox"/> Practitioner Military <i>(DDS, DMD, DO, DPM, DVM, MD, PHD)</i>	DEGREE
Check one box only	<input type="checkbox"/> Central Fill Pharmacy	<input type="checkbox"/> Teaching Institution	<input type="checkbox"/> Mid-Level Practitioner (MLP) <i>(DOM, HMD, MP, ND, NP, OD, PA, or RPH)</i>	Practitioners and MLPs: Enter your professional degree from list
See page 3 for additional instructions	<input type="checkbox"/> Retail Pharmacy	<input type="checkbox"/> Automated Dispensing System	<input type="checkbox"/> Euthanasia Technician	
SECTION 3				
3A - TRADITIONAL	<input type="checkbox"/> Schedule II Narcotic	<input type="checkbox"/> Schedule III Narcotic	<input type="checkbox"/> Schedule IV	
Drug Schedules (check all that apply)	<input type="checkbox"/> Schedule II Non-Narcotic	<input type="checkbox"/> Schedule III Non-Narcotic	<input type="checkbox"/> Schedule V	
3B - TELEPSYCHIATRY	<input type="checkbox"/> Schedule II Narcotic	<input type="checkbox"/> Schedule III Narcotic	<input type="checkbox"/> Schedule IV	
Drug Schedules (check all that apply)	<input type="checkbox"/> Schedule II Non-Narcotic	<input type="checkbox"/> Schedule III Non-Narcotic	<input type="checkbox"/> Schedule V	
	<input type="checkbox"/> Schedule II Narcotic (Methadone ONLY)	<input type="checkbox"/> Schedule III Narcotic (Buprenorphine ONLY)	<input type="checkbox"/> Schedule II Non-Narcotic (Stimulants ONLY)	
3C - TELEMEDICINE	<input type="checkbox"/> Schedule II Narcotic	<input type="checkbox"/> Schedule III Narcotic	<input type="checkbox"/> Schedule IV	
Drug Schedules (check all that apply)	<input type="checkbox"/> Schedule II Non-Narcotic	<input type="checkbox"/> Schedule III Non-Narcotic	<input type="checkbox"/> Schedule V	
	<input type="checkbox"/> Schedule II Narcotic (Methadone ONLY)	<input type="checkbox"/> Schedule III Narcotic (Buprenorphine ONLY)	<input type="checkbox"/> Schedule II Non-Narcotic (Stimulants ONLY)	