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October 6, 2015

Imelda L. Paredes
Executive Assistant, Office of Diversion Control
Drug Enforcement Administration
Department of Justice
8701 Morrissette Drive
Springfield, VA 22152

RE: Special Registration to Engage in the Practice of Telemedicine

Dear Ms. Paredes:

The American Telemedicine Association supports the DEA's diversion efforts and applauds the development and use of such an effective piece of legislation to expunge rogue internet pharmacies and the inappropriate prescribing of controlled substances by wayward prescribers without an appropriate clinical evaluation.

As the Ryan Haight Online Pharmacy Consumer Protection Act expressly recognizes telemedicine is increasingly leveraging the power of technology and the internet to offer new mechanisms for legitimate prescribers to obtain sufficient clinical information and work at the top of their professional scope. Consequently, the interpretation of the Act's general prohibition of prescribing controlled substances by means of the internet has become overly restrictive. Therefore, it is time to identify a structured yet flexible framework for appropriate online prescribing that recognizes long-standing practices by legitimate, licensed providers who offer needed medical services to a highly targeted group of patients.

In response to DEA's published agenda item RIN 1117-AB40 stating its intent to create a special registration process for the prescribing of controlled substances via telemedicine, ATA convened a special workgroup from membership within its Telemental Health Special Interest Group.

That workgroup has developed the following suggestions for how a special registration process could be structured to safely enable the prescribing of certain controlled substances via telepsychiatry. These suggestions are intended to find the balance between our country's great need for additional psychiatric resources for mental health care, commonly accepted clinical practices, the evolving landscape of telemedicine technologies, and DEA's charge to protect the safety and wellbeing of our citizens via its drug diversion efforts.

Our proposal contains the following significant elements:

1. Distinctions between telepsychiatry and other forms of telemedicine.

2. The creation of a mechanism for sites and/or prescribers to register to prescribe controlled substances via telemedicine.
3. Suggestions on how to update Form 224 to contemplate telemedicine registration.
4. Suggestions for eligibility requirements of applicants seeking telemedicine registration.
5. Legal and regulatory background information.

As you will note, these suggestions are focused on the practice of telepsychiatry, but the general practice of telemedicine is also contemplated.

We submit this in the interest of timeliness for the Administration's anticipated proposed rulemaking. If time permits, we would like to seek more input from other telemedicine providers, such as those serving hospice patients, for similar parameters.

We would welcome the opportunity to engage in a dialogue about the impact of the Ryan Haight Act on the practice and adoption of telemedicine and thank you in advance for your consideration of these suggestions as you plan the impending special registration process.

Sincerely,

Jonathan D. Linkous
Chief Executive Officer

Proposed Structure for Telemedicine Registration

The following applies only to parameters around the prescribing of DEA controlled substances relative to the Controlled Substance Act. Such guidance shall not be interpreted beyond this scope.

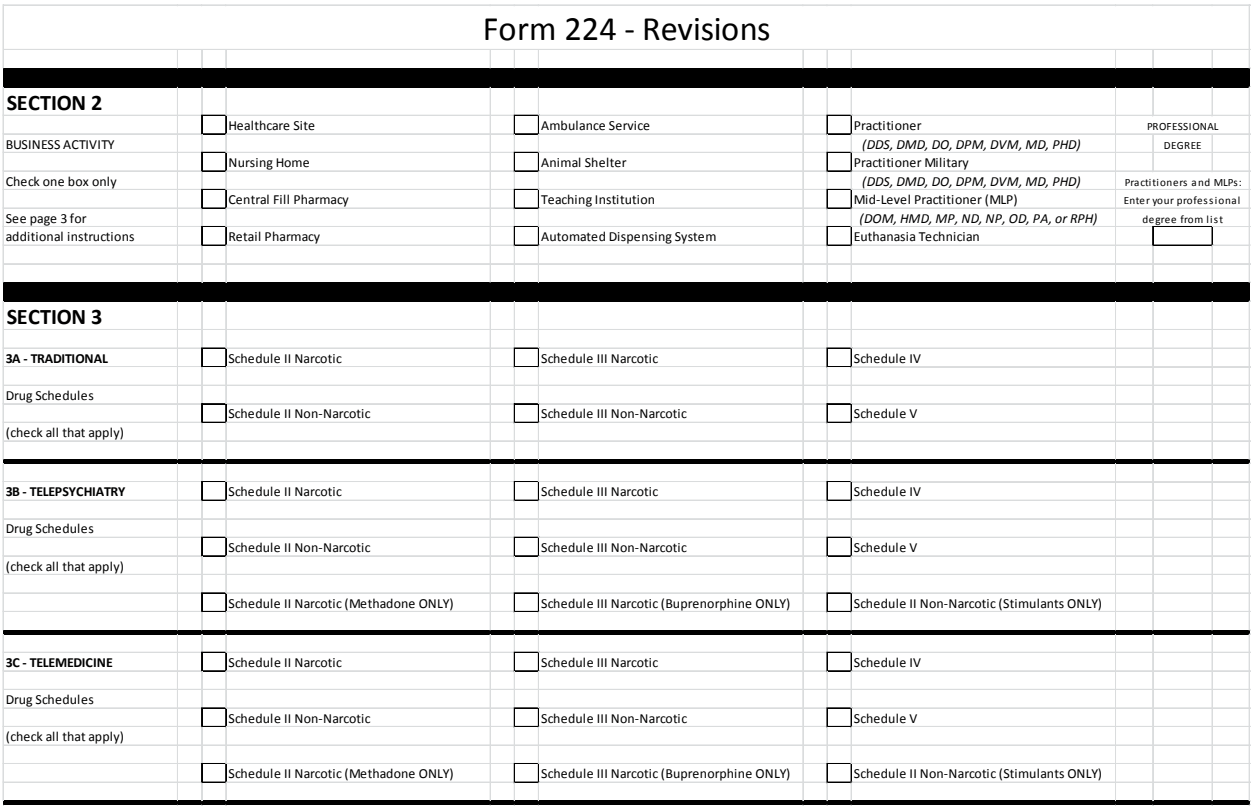
1. Grant federal authority while also recognizing state law (defer to the most restrictive)
   a. DEA registration grants practitioners federal authority to dispense controlled substances based on a telemedicine or telepsychiatry encounter
      i. However, the DEA registered practitioner may only engage in those activities that are authorized under state law for the jurisdiction in which the patient is located, and the remote practitioner must submit to the authority of that state's licensing board.
      ii. When federal law or regulations differ from state law or regulations, the practitioner is required to abide by the more restrictive aspects of both the federal and state requirements.

2. Update current DEA registration process to specify distinctions between traditional, telepsychiatry, and telemedicine prescribing privileges
   a. These options are not mutually exclusive
      i. Applicants can request one or more privileges simultaneously through the existing (though slightly amended) DEA registration process
      ii. Applicants can either request new traditional, telepsychiatry, and/or telemedicine privileges via an initial application (Form 224) or can request telemedicine and/or telepsychiatry privileges be added to their existing registration via the renewal process (Form 224a)
   b. Traditional registration is exactly the same as the current process and standards
   c. Telepsychiatry and telemedicine registration will require the applicant to indicate the schedules and certain types of drugs the applicant may prescribe via telemedicine.
      i. Only psychiatrists or psychiatric nurse practitioners can apply for telepsychiatry registration.

3. Allow sites and prescribers to register for telemedicine and/or telepsychiatry
   a. Site Registrations
      i. Unique to the business entity or practice group
      ii. Can be applied to multiple sites operating under the same Tax ID Number
      iii. Site registration for telemedicine or telepsychiatry would apply to any DEA registered prescriber serving sites of that business entity
         1. Use facility's DEA number
         2. Facility assigns a specific internal code number for each practitioner
   b. Prescriber Registrations
      i. Unique to specific prescribers and their NPI number
      ii. Would continue to be state-specific and linked to their state medical license
      iii. Can be applied to any location served by the prescriber within a state

Proposed Mechanism for Telemedicine Registration

1. Amend Form 224 (initial application) to include new options (see figure below)
   a. Amend Section 2 Business Activity, as follows:
      i. Change "Hospital/Clinic" to "Healthcare Site"
         1. Open this definition to include established medical sites and other settings
         2. This 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, assisted living facilities, and a patient's residence .
         3. This change does not require sites that are not conducting telemedicine or telepsychiatry to register with the DEA
            a) But it creates an option for other sites wanting to do telemedicine to be registered with DEA
   b. Amend Section 3 as follows: (applicants can check multiple options)
      i. Create Section 3A – Traditional
      ii. Create Section 3B – Telepsychiatry
         1. Create options for prescribing authority for certain types of drugs
      iii. Create Section 3C – Telemedicine
         1. Create options for prescribing authority for certain types of drugs



2. Also amend Form 224a (Renewal Application) to include same new options.

Explanation of Proposed Structure

In addition to the normal schedules and delineation of narcotics on the DEA registration application, three additional distinctions have been made for telepsychiatry and telemedicine prescribing on the revised Form 224: stimulants, buprenorphine, and methadone.
We believe that these distinctions are particularly important for telepsychiatry prescribing given the extreme shortage that much of our country faces in accessing psychiatric professionals. Unfortunately, the scarcity of qualified behavioral health professionals is trending in a negative direction as more and more people need behavioral health services while fewer residents enter psychiatry programs and the pool of psychiatrists ages faster than any other medical discipline. Each of these forms of treatment merits close consideration and active monitoring to encourage these services to be performed by the most qualified professionals reasonably available. In many instances, the most qualified professionals may only be available via telepsychiatry.

One of the most common applications of telepsychiatry is the use of video technology to distribute the scarce and valuable services of child psychiatrists into underserved areas. Stimulants are largely considered to be one of the foundational tools of the child psychiatry profession, and telepsychiatry has proven to be one of the most effective tools to enable evaluation and treatment by child psychiatrists within areas of need.

Additionally, as our country struggles with its opiate epidemic, the services of psychiatrists are increasingly being sought within substance abuse clinics, community mental health centers, detox facilities, hospitals, and community clinics to evaluate and manage co-morbid mental health and substance use disorders. Given the increasing prevalence of these issues and the decreasing supply of qualified psychiatric professionals to work within this space, telepsychiatry has increasingly become a valuable tool to connect these sites and consumers with the most qualified professionals to manage these issues via medication-assisted opioid therapy.

We suggested the creation of three distinctions within the DEA's registration process to require the applicant to be specific about its intended use of telepsychiatry and to offer the DEA more options in how it reviews and approves applications and monitors prescribing practices. For instance, DEA may choose to grant special registration authority for stimulant prescribing via telepsychiatry to a board certified child psychiatrist, while denying that same privilege to a teleradiologist. Similarly, DEA may choose to grant authority for a licensed addiction clinic to prescribe buprenorphine via telepsychiatry encounters performed by SAMHSA registered addiction psychiatrists, while denying authority for a general practitioner to prescribe buprenorphine via telemedicine.

Conditions Surrounding Registration for Telepsychiatry

As representatives of the telepsychiatry community, members of ATA's Telemental Health Special Interest Group have outlined basic parameters to govern telepsychiatry practice. Implicit in a proposed structure for a telepsychiatry registration that is distinct from general telemedicine registration is a belief that behavioral health and psychiatric services are unique from many other forms of medicine.

While vital signs and certain other medical indicators should be monitored, psychiatry was not built upon the same sort of hands-on physical examination upon which other medical disciplines rely. Consequently, as psychiatry embraces telemedicine, its toolkit is almost entirely audio-visual interaction and access to records. Telepsychiatry does not require the presence of a facilitator or other diagnostic peripherals. This key differentiator requires a unique framework for telepsychiatry regulation.

Outlined below are parameters that define the foundation of telepsychiatry practice as it relates to DEA registration. This document focuses exclusively on defining parameters specific to the practice of telepsychiatry. Similar parameters may be required for general telemedicine prescribing.

1. For the practice of psychiatry, assuming: a) these conditions are met, b) the prescriber or the prescriber's site has properly registered with the DEA for telepsychiatry prescribing, c) and that the prescription adheres to the schedule and type of drugs indicated on the registration, a telepsychiatry encounter may result in the prescribing of a DEA controlled substance.
2. Telepsychiatry may be used for all patient visits, including initial medical evaluations between a distant site provider and a patient.
3. If the only services provided are related 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 only services provided are related to psychiatry and mental health services.
5. Treatment and consultation recommendations made in an online setting, including issuing a prescription via electronic means, 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

Clearly, the ultimate decision for application eligibility and the approval of registration for certain prescribing privileges rests solely in the hands of the DEA. However, as this new registration is being considered, we postulated that suggestions for eligibility requirements might prove useful, and are therefore offering the following which we believe to be both meaningful and realistic.

To register for telepsychiatry or telemedicine prescribing privileges, an applicant will be assessed along the following parameters:

1. Current and unrestricted license or certification (as applicable for that entity)
    a. Prescribers would be evaluated based on their state medical license
    b. Sites would be evaluated based on either their license or their state certification
        i. Established medical sites would be evaluated on the basis of their state license
        ii. Institutional or group settings would be evaluated on the basis of their state certification

2. Participation in a third-party prescription monitoring program for all telepsychiatry or telemedicine prescribing
    a. Such prescription monitoring program must be made available to DEA as needed for auditing and monitoring purposes

3. Successful completion of a background check showing no history of state or federal sanctions and no history of DEA enforcement actions and no criminal activity
    a. Prescribers evaluated as individuals
    b. Sites would have their officers subject to criminal background checks

4. Requested privileges in alignment with professional credentials
    a. Only psychiatrists or psychiatric nurse practitioners can request telepsychiatry privileges
        i. Must have completed an approved psychiatry training program as per ABPN

Legal and Regulatory Precedent

Background of the Ryan Haight Act

The Ryan Haight Online Pharmacy Consumer Protection Act of 2008[1] amended the federal Controlled Substances Act by adding a series of new regulatory requirements and criminal provisions designed to combat the proliferation of "rogue Internet sites" that unlawfully dispensed controlled substances by means of the Internet. Congress passed the Act "to prevent the Internet from being exploited to facilitate such unlawful drug activity."[2] The Act was enacted on October 15, 2008 and was effective April 13, 2009. The DEA issued interim final regulations on April 6, 2009, effective April 13, 2009.[3]

The Ryan Haight Act prohibits the distributing, dispensing, or delivery of controlled substances by means of the "Internet" without a valid prescription.[4] In short, the Act requires a practitioner to conduct at least one in-person medical evaluation of the patient before remote prescribing any controlled substances. The term "in-person medical evaluation" means a medical evaluation that is conducted with the patient in the physical presence of the practitioner, without regard to whether portions of the evaluation are conducted by other health professionals.[5]

The Act was intended to target rogue Internet pharmacies and online prescription drug trafficking. Congress passed the Act "precisely because of the increasing use of prescription controlled substance by adolescents and others for nonmedical purposes, which has been exacerbated by drug trafficking on the Internet."[6] Unfortunately, the broad language of the Act and the lack of a subsequent telemedicine special registration process have created a barrier for patients to receive care from legitimate telemedicine providers who engage in remote prescribing in full compliance with current standards of practice and state law. This is in part because the Ryan Haight Act is eight years old and has not kept pace with the rapid developments in telemedicine-based practices since that time. The regulations provide seven exceptions to the in-person exam requirement.[7] However, the exceptions are very narrow and do not reflect contemporary accepted clinical telemedicine remote prescribing practices. In particular, the exceptions do not align with direct-to-patient delivery models frequently used by patients in areas such as telepsychiatry (e.g., where the patient is at his or her home at the time of the telemedicine consult).

The lack of a DEA special registration process for telemedicine-based practitioners is a significant issue. Unfortunately, since the DEA issued its interim final rule eight years ago, no such special registration regulations have been issued, nor have changes been made to existing regulations to account for modern telemedicine prescribing practices.

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[1] 21 U.S.C. §829.
[2] 74 FR 15596, 15597 (April 6, 2009).
[3] *See* 21 CFR Part 1300, 1301, 1304, *et al.;* 74 FR 15596 (April 6, 2009).
[4] 21 CFR 1306.09(a); 21 CFR 1300.04(l)(1); 21 USC 829(e)(2)(A).
[5] 21 CFR 1300.04(f); 21 USC 829(e)(2)(B).
[6] Senate Report 110-521 http://www.gpo.gov/fdsys/pkg/CRPT-110srpt521/html/CRPT-110srpt521.htm
[7] 21 CFR 1300.04(i).

The purpose of the Act's in-person exam requirement is not to promote best practices in clinical remote prescribing, but to curtail illegal online prescription drug trafficking. Indeed, "the main reason Congress enacted the Ryan Haight Act was to bring an end to the rogue websites that hire unscrupulous practitioners to write prescriptions without a legitimate medical purpose and outside the usual course of professional practice."[8]

It is important to note that defining the special registration provision makes no changes to the heart, purpose, and intent of the Act, and ATA's suggestions are in alignment with the spirit, language, and intent of the Act and DEA's planned special registration process. Nothing is these suggestions is intended to reduce DEA's power of diversion enforcement against rogue websites or unscrupulous practitioners.

Federal Law

In a review of all published federal case law, our members found no informative court decisions addressing the Ryan Haight Act's (or its regulation's) language specific to telemedicine or the application and scope of the in-person exam requirement. To the extent there are published cases, the prescribing practitioners fell far below the acceptable requirements for prescribing, typically using an online form with no examination. *See, e.g., United States v. Maye*, 2014 U.S. Dist. LEXIS 56455 (W.D.N.Y. Apr. 23, 2014) (Physician operating Internet pharmacy issued prescriptions for controlled substances based on patient medical questionnaires; physician never personally met, consulted with, or examined any patients.).

State Law

Medical boards throughout the U.S. are increasingly seeing the value in telemedicine as a clinical delivery tool, and as such are regulating telemedicine comparably to in-person care. Additionally medical boards recognize that tools, such as video-conferencing and store-and-forward, enable physicians to obtain sufficient and appropriate clinical and other information to provide a specific medical service including prescriptions.

Policy actions by medical boards in Maine, Massachusetts, and Minnesota have demonstrated the importance of streamlining medical practice standards for telemedicine providers. These boards broadly define telemedicine and provide no distinct rules, protocols, or standards for telemedicine providers to follow. Moreover, states like North Carolina, North Dakota, and Virginia have made enhancements to existing policies allowing duly licensed physicians to uphold practice standards when using clinically appropriate internet prescribing for controlled and non-controlled substances alike.

For instance, the North Carolina Medical Board issued guidance in November 2014 that allows a licensed physician to prescribe for a patient whom the licensee has not personally examined. This guidance states: "Prescribing for a patient whom the licensee has not personally examined may be suitable under certain circumstances… an appropriate prescription in a telemedicine encounter where the threshold information to make an accurate diagnosis has been obtained, or

[8] 74 FR 15608

prescribing an opiate antagonist to someone in a position to assist a person at risk of an opiate-related overdose."[9]

The North Dakota Board of Medicine is considering revised regulations that would allow a licensee to perform a telemedicine examination or evaluation for the purposes of prescribing, not including opioids for pain control.[10] If the federal restrictions were lifted, ND licensees would be permitted to prescribe controlled substances for mental health treatment such as psychotropic drugs and stimulants.

Earlier this year, the Virginia General Assembly enacted HB 2063 which authorizes the Board of Medicine to allow licensees to prescribe Schedule VI when a practitioner-patient relationship is established using "face-to-face interactive, two-way, real-time communications services or store-and-forward technologies" and all of the following conditions are met:

a) the patient has provided a medical history that is available for review by the prescriber;
b) the prescriber obtains an updated medical history at the time of prescribing;
c) the prescriber makes a diagnosis at the time of prescribing;
d) the prescriber conforms to the standard of care expected of in-person care as appropriate to the patient's age and presenting condition, including when the standard of care requires the use of diagnostic testing and performance of a physical examination, which may be carried out through the use of peripheral devices appropriate to the patient's condition;
e) the prescriber is actively licensed in the Commonwealth and authorized to prescribe;
f) if the patient is a member or enrollee of a health plan or carrier, the prescriber has been credentialed by the health plan or carrier as a participating provider and the diagnosing and prescribing meets the qualifications for reimbursement by the health plan or carrier pursuant to § 38.2-3418.16; and
g) upon request, the prescriber provides patient records in a timely manner in accordance with the provisions of §32.1-127.1:03 and all other state and federal laws and regulations.[11]

After thoughtful consideration of the intent of the Act and the unintended consequence of the Act creating an artificial barrier that restricts the clinical practice of legitimate telemedicine-based practitioners, we respectfully submit that the following proposal is as consistent as possible with both Federal and State law around telemedicine.

Recognizing the authority of States to regulate the practice of medicine and the fact that updating Federal regulation around telemedicine may produce certain inconsistencies, for the purposes of prescribing controlled substances via telemedicine, we propose that the practitioner must always submit to the more restrictive of the two, as is consistent with existing legal standards for preemption.

[9] North Carolina Medical Board Position. November 2014. Contact with patients before prescribing.
[10] North Dakota Board of Medicine draft regulations. September 2015. Chapter 50-02-15 Telemedicine.
[11] Virginia General Assembly 2015. Chapter 115 §§38.2-3418.16 and 54.1-3303 of the Code of Virginia.

Conclusion

The Ryan Haight Act was immensely effective in granting authorities new tools to define and prosecute unscrupulous internet pharmacies. Unfortunately, an unintended consequence of this tool was a limitation on the legitimate practice of telemedicine. Telemedicine and telepsychiatry have evolved considerably since the inception of the Act such that the seven exceptions are nowhere near representative of the whole of telemedicine practice, and these practices will continue to evolve as technology improves and as prescribers embrace more and more new tools. Similarly state regulations around telemedicine have increasingly grown in sophistication such that medical boards are closely and carefully defining and monitoring the practice of telemedicine. The ongoing application of the Ryan Haight Act to legitimate telemedicine is simply no longer appropriate. The most straightforward way to refocus the Act is to complete its special registration process for telemedicine prescribing.

The structure, guidelines, definitions, and criteria we suggested offer a meaningful yet flexible DEA registration process for telepsychiatry while also laying a framework upon which other telemedicine practitioners can build.

We would be happy to offer additional comment, explanation, or resource material as DEA evaluates its options, and we look forward to working collaboratively toward a final solution.