MEMO
To: Jim Arnold, Chief, Policy & Liaison, Diversion Control Division, DEA Headquarters
From: The Center for Telehealth & e-Health Law (CTeL)
Re: Suggested Changes to Ryan Haight Act Regulations
Date: February 27, 2018

The Center for Telehealth & e-Health Law (CTeL), a legal and regulatory non-profit research institute, is submitting suggested changes to the Ryan Haight Online Pharmacy Consumer Protection Act (the Act) regulations. Our suggestions are based on conversations that we had with members of the telehealth and behavioral health community.

Our suggestions include:

1. **Permit a Telemedicine Exam.**

   A. Allowing the use of two-way audio-video telemedicine to conduct a physical exam of a patient at an originating site to establish the provider-patient relationship for the purposes of prescribing.

2. **Expansion of Originating Sites.**

   A. **CMS Originating Sites.** Expanding recognized originating sites to include recognized Centers for Medicare and Medicaid Services (CMS) originating sites, in addition to:

   B. **Schools.** Public, charter, private, and parochial K-12 schools; institutions of higher education; early-childhood centers; and other academic institutions; and,

   C. **State or Federal Sites.** Allow any site formally designated by a state government or the federal government as an access point for prescribing of controlled substances.

3. **Special Registration.** The creation of a special registration for telemedicine providers, which would permit them to electronically prescribe controlled substances without first conducting an in-person examination. Instead, they would be able to conduct the first examination via telemedicine for a patient at an originating site.

Each of these is discussed in more detail below.
Section I—The Use of Telemedicine in Physical Examinations

Background

A physical examination of the patient is required, in most states, to establish the practitioner-patient relationship. Except in emergencies, a practitioner-patient relationship must be in place for the practitioner to assess, diagnose, and/or treat the patient, regardless of whether telemedicine is used to deliver care to the patient. All states currently allow for telemedicine by videoconferencing to be used to conduct the physical examination of the patient—to establish the practitioner-patient relationship—as long as the physical examination meets the medical standard of care. Once a valid practitioner-patient relationship exists, the practitioner is under a legal duty to exercise reasonable care in diagnosing and treating the patient.

Seven Rationales

For at least six reasons, the telemedical examination should be accepted for establishing the practitioner-patient relationship for purposes of prescribing controlled substances via a telemedicine platform.

1. **Safeguards Exist to Prevent Inappropriate Prescribing via Telemedicine.** The practitioner is subject to tort liability if a patient is harmed by a breach of the standard of care, as well as licensure board disciplinary action for failure to comply with laws, regulations, or board policy. Additionally, the practitioner remains vulnerable to all the sanctions that can be visited upon him for violations of the Controlled Substances Act. Practically speaking, to restrict the prescribing authority to those physicians who have seen the patient in person will decrease the number of prescriptions that can be written, but will do nothing to reduce the number of inappropriate prescriptions written.

2. **For Purposes of Responsible Prescribing, a Telemedicine Examination is Equivalent to an In-Person Exam.** Clinically, there is little, if anything, relevant to the judgment whether controlled substances are indicated that can be identified by in-person examination that cannot be identified by an exam done at a distance by electronic means. Besides permitting the physician to take a history, videoconferencing also allows the doctor to conduct patient inspection, the first and most important component of a physical exam. In some circumstances, the potential prescriber may also be able to auscultate the heart, lungs, abdomen, vessels, etc. While he is unable to perform palpation and percussion, very few (if any) diagnoses require these techniques today, and none is pertinent to the decision to prescribe controlled substances.

3. **Covering Practitioner Authority to Write Prescriptions for Controlled Substances.** Covering practitioners are permitted to write prescriptions for controlled substances. This demonstrates that the in-person evaluation requirement is neither uniformly enforced nor required for standard care. Years ago, solo practice was common; groups, where they existed, consisted of two or three
physicians. Today, the trend is towards larger groups, some with hundreds of members. In many cases, the covering doctor will not have done an in-person evaluation of the patient at any time, never mind in the previous 12 months. In some cases, but not all, he may have access to the patient’s chart, but the law does not so require. Nor does it require that the examiner have special expertise in using telemedicine or in the risk-benefit analysis inherent in prescribing. It requires only that the examining physician be covering for the attending. As it stands, then, the law permits a physician who before the telemedicine consult is a stranger to the patient to examine, diagnose, and treat him; it also allows him, where clinically warranted, and without more, to write a script for controlled substances. No one criticizes this practice; no one has shown any harm from it. If an in-person examination is unnecessary for the doctor specified to take call, there is no logical reason why it should be necessary for any other physician.

4. **Indian Health Service Exception.** An exception is also made for a medical practitioner “(i) who is an employee or contractor of the Indian Health Service, or is working for an Indian tribe or tribal organization under its contract or compact with the Indian Health Service under the Indian Self-Determination and Education Assistance Act [25 U.S.C. 450 et seq.].” This provision was enacted to expand access to care on Native American reservations, which are very often medically underserved. No one would argue that Native Americans are somehow less vulnerable to the risks of taking controlled substances than others; on the contrary, their vulnerability may exceed that of the general population. If access to care is a valid rationale for permitting prescribing without an in-person evaluation, there is no reason why Native Americans are the only citizens who should be able to benefit.

5. **Special Registration Provision for the Care of Veterans.**

   The Act provides for special registration for:

   An employee or contractor of the Department of Veterans Affairs who is acting in the scope of such employment or contract and is registered under section 823(f) of this title in any State or is utilizing the registration of a hospital or clinic operated by the Department of Veterans Affairs registered under section 823(f) of this title…Act, section 831(h)(1)(B)(ii).

   The exception created for prescribers serving our veterans undoubtedly advances the mission of the Department of Veterans Affairs: “To care for him who shall have borne the battle…” If responsible prescribing of controlled substances truly required an in-person evaluation first, surely we would not expose our veterans, after all they have faced, to yet more risk. The rationale behind the exception is to facilitate access to needed care. That same objective should inform our reasoning here.

6. **In–Person Examination Does Not Stop Rogue Pharmacies.** No one denies that, in appropriate circumstances, prescribing controlled substances is not only permissible; it is obligatory. For some
patients, these medicines are indispensable. The Act was never intended to ban their use; rather, it was written to combat rogue pharmacies that make dangerous drugs readily available to patients not under proper medical supervision. The in-person evaluation, however, does nothing to rein in the behavior of such pharmacies; their operators typically do not care, and will not inquire, if the customer has had an in-person evaluation. That is not to say that the law should not strive to identify and eliminate such rogue pharmacies, and to prosecute those who subject patients to dire risk without justification. It does mean, however, that the in-person evaluation requirement, though well intentioned, is the wrong tool for the job.

7. The Current Enforcement of the Act Goes Beyond the Original Concern of the Act. There is no question that at the time of the passage of the Act there was a significant public health issue created by bad actor providers and pharmacies providing scheduled drugs, particularly opioids, via Internet prescribing. Action was required to stem the tide of addiction and overdoses resulting from this crisis, and thus the Act was passed. However, by including all scheduled drugs within the Act, there have been many cases of unintended consequences and treatment limitations, particularly in the area of behavioral health. Many programs aimed at addressing the mental health needs of children in schools and adults in underserved areas are unable to successfully operate under the strictures of the Act. The reason is quite simple: the drugs needed to treat these patients are scheduled drugs, and as they do not have a psychiatrist in their geographic area, and establishing a patient relationship via telemedicine is not allowed, there is no way for these patients to receive the prescriptions they need.

Suggested Draft Language: Proposed Amendments to Ryan Haight Act, 21 USC 829(e)(2)(A)

Note: Bolded words in red are added; words with a strike through them were deleted

Controlled substances dispensed by means of the Internet:

“(1) No controlled substance that is a prescription drug as determined under the Federal Food, Drug, and Cosmetic Act [21 U.S.C. 301 et seq.] may be delivered, distributed, or dispensed by means of the Internet without a valid prescription.

(2) As used in this subsection:

(A) The term “valid prescription” means a prescription that is issued for a legitimate medical purpose in the usual course of professional practice by a practitioner who:

   (i) A practitioner who under the law of the patient’s state has established a valid practitioner-patient relationship with the patient prescribed for; and

   (ii) In so prescribing, has complied with the applicable standard of care, and complied with all applicable state statutes and regulations; and

   (iii) Maintains a valid, current, unrestricted DEA registration. Conducted at least one in person medical evaluation of the patient; or
(B) The term “valid prescription” means a prescription that is issued for a legitimate medical purpose in the usual course of professional practice by—a practitioner who:

i. Has conducted at least one in-person medical evaluation of the patient, which can be accomplished with a telemedicine exam sufficient to satisfy the requirements of state law and conducted via videoconferencing technology on a patient located at an originating site; or

Section II—Expansion of Originating Sites

Background

Section (A) of 21 U.S.C. 802(54) of the Ryan Haight Online Pharmacy Consumer Protection Act (the Act) restricts the site where the patient is physically located to a “a hospital or clinic registered under section 823(f) [1] of this title.” In telemedicine terminology, the site where the patient who is being examined by telemedicine is located is referred to as the “originating site.” Reviewing the registration process for DEA 224, it would appear, given this restriction, that only sites actually dispensing controlled substances can qualify as originating sites. Telemedicine encounters actually occur at many originating sites that do not dispense controlled substances, however, and that therefore would not be legally recognized under the Act. Such a restriction harms providers and patients alike; indeed, patients in rural and underserved areas in need of access to controlled substances have often been unable to obtain their prescriptions owing to the DEA’s current originating-site limitations.

Recommendations

1. Allow CMS originating sites as access points for prescribing of controlled substances.

Since 1996, Congress has recognized certain originating sites for purpose of reimbursement through Medicare. Passed by Congress, and now codified at 42 USC 1834 (m), the following are legally recognized as originating sites, where the patient can be physically located during a telemedicine encounter:

- The offices of a physician or other practitioner
- Hospitals

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[1] 21 U.S.C. 823(f) (2007). Section 823 of the Controlled Substances Act regulates the registration requirements for the manufacturing, distribution, and dispensing of controlled substances in schedule I through schedule V. Section 823(f) specifically provides that the Attorney General shall register practitioners (including pharmacies, as distinguished from pharmacists) to dispense, or conduct research with, controlled substances in schedules II, III, IV, or V. Section 823(f) also permits the Attorney General to modify the registration of pharmacies so registered to permit these pharmacies to dispense controlled substances by means of the Internet.
- Critical Access Hospitals (CAHs)
- Rural Health Clinics (RHCs)
- Federally Qualified Health Centers (FQHCs)
- Hospital-based or CAH-based renal dialysis centers (including satellites)
- Skilled nursing facilities (SNFs)
- Community Mental Health Centers (CMHCs)

Some of these may already be qualified through Section (A) 21 U.S.C. 802(54) (for example, “hospitals”). For purposes of a patient receiving telemedicine services, Congress has recognized these sites as “originating sites”; however, we recommend that these sites be included as eligible originating sites where the patient can be seen via telemedicine for an encounter covered by the Act, regardless of whether the sites are registered and eligible under 21 U.S.C. 802(54).

2. Allow schools as access points for prescribing of controlled substances.

Additionally, while not on the congressionally recognized list of originating sites, we believe that schools should be considered for inclusion. For numerous students and their families in rural and underserved communities, the more than 2,000 school-based health centers throughout the United States provide a lifeline. (Indeed, in some of these cases, school-based providers are the only provider a student sees.) Various studies have demonstrated the positive impact that school-based health programs can have. A 2014 Brigham Young University study, for example, identified cost savings to families as well as lower rates of absence from school. Similarly, a May 2017 Slate article on potential casualties of Affordable Care Act (ACA) repeal also highlighted the safety net that the programs often provide for working families in rural areas—and the bipartisan support that they tend to have among lawmakers who recognize their value.

Along with on-site practitioners who evaluate and treat patients in person, many of these clinics also utilize telemedicine, both as a way of connecting patients with more specialized care and as a way of combating provider shortages, which are widespread in many of the communities that these clinics serve. Some states have already added schools to their lists of eligible originating sites for telemedicine reimbursement; the Medicaid programs in Georgia, New Mexico, and Texas, for example, reimburse for school-based encounters, and legislation signed into law in New York State in September of 2017 expanded the state’s list of eligible originating sites to include schools (public, private, and charter), child care programs, and day care centers. We believe that the DEA should join these states in recognizing the value of school-based telemedicine programs—for students, families, and communities alike.

3. Allow any site formally designated by a state government or the federal government as an access point for prescribing of controlled substances.

Within the realm of health care, there is an abundance of different methods and locations for care delivery. Depending on the type of practice location, the applicable safety mechanisms and quality
oversight regulations can vary dramatically, if they exist at all. At the top of this range are the practice locations regulated under the oversight of a state or federal agency via licensure, registration, or certification requirements. These sites of care delivery already have a thorough oversight system and administration in place to ensure appropriate safety and quality standards are adhered to, thereby allowing flexibility in the prescribing of controlled substances, which might not be appropriate elsewhere. By relying on these already-created oversight systems, telemedicine may be safely implemented in underserved areas and populations.

**Section III—DEA Registry**

**Background**

In 2015, the DEA published a proposed rule that would amend the Act’s regulations to permit the special registration of telemedicine providers to prescribe controlled substances without an in-person visit first. Many stakeholders supported this change, given the additional flexibility that it would give telemedicine practitioners.

More recently, a bipartisan group of senators wrote to the DEA in support of such a special registration, noting that it would make it easier for providers treating rural patients to utilize telemedicine to prescribe medication-assisted treatments for opioid addiction. “While practical steps have been taken and progress has been made, there is more that can be done, and more that should be done to address our nation’s devastating opioid epidemic,” said Sen. Lisa Murkowski (R-AK), in a joint press release with Sen. Dan Sullivan (R-AK) and Sen. Claire McCaskill (D-MO). The senators specifically asked the DEA to permit the prescribing of medication-assisted treatment for opioid addiction without an initial in-person visit—which they noted would be in line with the Trump Administration’s public health emergency declaration—for prescribers granted a special registration to do so. Such providers would be allowed to conduct the initial examination via telemedicine instead. In a January 30 letter to the agency, the senators urged the DEA “to expedite the rulemaking process for regulations authorizing special registration,” noting that this would save valuable time and money for numerous rural Americans who live miles away from treatment facilities.

The creation of such a registry could allow those registered providers to use videoconferencing to conduct a physical exam of a patient at an originating site to establish the provider-patient relationship necessary for prescribing a controlled substance. The registry itself would allow for identification of the provider pool providing these services, and the use of the originating sites would provide an already-established oversight mechanism to ensure patient safety and quality of care. Because of this safeguard, the implementation of such a registry should require only minimal resource expenditure; the registry could be built into current existing registration requirements.
Recommendation

The DEA has a robust system of regulation and oversight concerning the manufacture and use of controlled substances. That framework can undoubtedly be expanded to incorporate these necessary changes. CTeL concurs with the recommendations of Sens. McCaskill, Murkowski, and Sullivan, as well as the other stakeholders who have encouraged the DEA to expedite the rulemaking process for the special telemedicine registration. We believe that it could go a long way toward alleviating the need for opioid addiction treatment in rural and underserved communities.

Conclusion

The goal of the Ryan Haight Act (the Act) was to protect the public from rogue pharmacies that make dangerous drugs readily available to patients not under proper medical supervision. While the Act and its regulations were written with the best of intentions, some of those regulations are serving to stifle the use of telemedicine to care for patients, at a time when many—including those impacted by the opioid addiction epidemic—are living in areas with provider shortages. CTeL welcomes the DEA’s request for stakeholder feedback on ways that the Act might be improved, and we look forward to working together to do so.