

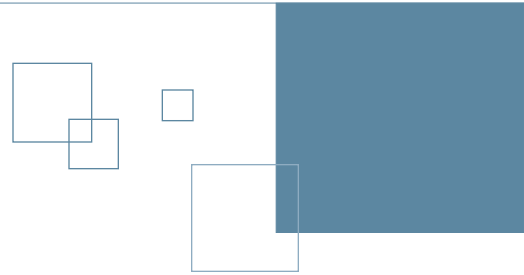
Telemedicine Prescribing of Controlled Substances: What is the Ryan Haight Act?



- » Under the Ryan Haight Act, no controlled substance may be delivered, distributed, or dispensed by means of the internet (including telemedicine technologies) without a valid prescription.¹
- » A valid prescription means a prescription that is issued for a legitimate medical purpose in the usual course of professional practice by: 1) a practitioner who has conducted at least one in-person medical evaluation of the patient; or 2) a covering practitioner.²
- » “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.³
- » Once the prescribing practitioner has conducted an in-person medical evaluation, the Act does not set an expiration period or a mandatory requirement of subsequent annual examinations (although specific drugs may have their own rules for subsequent exams). This should not be construed to imply that one in-person medical evaluation demonstrates that a prescription has been issued for a legitimate medical purpose within the usual course of professional practice. The responsibility for the proper prescribing and dispensing of controlled substances is on the prescribing practitioner.
- » There are some exceptions to the in-person exam requirement, but none readily apply to a telemedicine service where the patient is at his or her home.
- » The DEA is currently drafting a proposed rule that will create a special registration process allowing physicians to prescribe controlled substances via telemedicine without an in-person exam, regardless of the patient’s location.
- » Notwithstanding the DEA federal rules, physicians still must comply with state laws on controlled substance prescribing. If a state law is more restrictive than the federal rules, the more restrictive provisions apply.
- » Physicians must also comply with other state and federal regulations, such as licensure, state DEA registration, etc.
- » The Ryan Haight Act does not apply to all prescription drugs; only controlled substances.

Ryan Haight Act and Federal DEA Regulations

The Ryan Haight Online Pharmacy Consumer Protection Act of 2008 was designed to combat the rogue internet pharmacies that proliferated in the late 90s, selling controlled substances online. The Act took effect April 13, 2009, and the Drug Enforcement Agency issued regulations effective that same date.⁴ The Act essentially imposed a federal prohibition on form-only online prescribing for controlled substances. Although the Act was intended to target “rogue” internet pharmacies, legitimate telemedicine providers who prescribe controlled substances must carefully review the regulations to ensure compliance. Among other things, the Act requires a practitioner to have conducted at least one in-person medical evaluation of the patient, in the physical presence of the practitioner, before issuing a prescription for a controlled substance.



Telemedicine Exceptions to the In-Person Exam Requirement

The Act offers seven telemedicine exceptions to the in-person exam requirement, but they are very narrow and do not reflect contemporary accepted clinical telemedicine remote prescribing practices.⁵ They are summarized as follows:

- (1) The patient is being treated in a DEA-registered hospital or clinic.
- (2) The patient is being treated in the physical presence of a DEA-registered practitioner.
- (3) The telemedicine consult is conducted by a DEA-registered practitioner for the Indian Health Service, who is designated as an Internet Eligible Controlled Substances Provider by the DEA.
- (4) The telemedicine consult is conducted during a public health emergency declared by the Secretary of the U.S. Department of Health and Human Services.
- (5) The telemedicine consult is conducted by a practitioner who has obtained a DEA special registration for telemedicine.
- (6) The telemedicine consult is conducted by a Veterans Health Administration practitioner during a medical emergency recognized by the VHA.
- (7) The telemedicine consult is conducted under other circumstances specified by future DEA regulations.

Unfortunately, most of the exceptions have limited utility in contemporary telemedicine arrangements, most notably telemedicine services directly to the patient's home. Some of the exceptions are suitable in institutional telemedicine arrangements.

State Law Requirements

The federal regulations are more stringent than many state laws or state medical board requirements. Some states allow controlled substance prescribing via telemedicine without an in-person exam. But practitioners must comply with both state and federal laws, as the DEA considers a physician who engages in the unauthorized practice of medicine under state law to be someone who is not acting in the usual course of his or her professional practice.⁶ According to the DEA, a controlled substance prescription issued by a physician who lacks the license or other authority necessary to practice medicine within the state is not a valid prescription under federal law.⁷

Forthcoming Rule Changes

The DEA has announced plans to issue a proposed rule that will activate the special registration process allowing physicians to use telemedicine to prescribe controlled substances without an in-person exam. The DEA published a revised notice of rulemaking, stating the proposed rule would be published in January 2017. As of this printing, the proposed rule has not yet been issued.

For More Information

Learn more about how we can help you with telemedicine and health innovation matters. Please contact your Foley attorney or the following:



Nathaniel Lacktman, Esq.

Partner
Chair, Telemedicine & Virtual Care
Practice
Co-Chair, Digital Health Group

Tampa, Florida
813.225.4127
NLacktman@foley.com

www.foley.com/telemedicine

⁵21 CFR 1306.09(a).

⁶21 CFR 1300.04(l)(1); 21 USC 829(e)(2)(A).

⁷21 CFR 1300.04(f); 21 USC 829(e)(2)(B).

⁸21 CFR Part 1300, 1301, 1304, et al.; 74 FR 15596 (April 6, 2009); 21 USC 829.

⁹21 CFR 1300.04(i); 21 U.S.C. 829(e)(3)(A).

¹⁰See, e.g., *United States v. Moore*, 423 U.S. 122, 140-41 (1975).

¹¹21 CFR 1306.04(a); 21 CFR 1306.03(a)(1).

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Telemedicine Prescribing and Controlled Substances Laws

By Nathaniel M. Lacktman
03 April 2017

Health Care Law Today

Editor's Note: This article is the first of a series addressing telemedicine prescribing and controlled substances, designed to give some much needed practical guidance and orientation to established health care providers, hospitals, and entrepreneurs alike.

As providers become more comfortable with delivering care via telemedicine, telehealth, and digital health technologies, some are exploring services beyond low acuity consults. One area of opportunity – and notable confusion – is prescribing controlled substances via telemedicine. This particularly affects specialties that couple chronic disease management with pharmacotherapy. For example, adolescent and adult telepsychiatry, substance abuse/recovery, endocrinology, hormone replacement therapy, and medical weight loss.

Providers are increasingly inquiring about telemedicine prescribing laws and rules, as well as strategies and approaches for business models and service lines that not only satisfy patient needs, but comply with the layers of intersecting state and federal laws on telemedicine, medical practice, fraud and abuse, and controlled substances. Indeed, telemedicine prescribing of controlled substances was one of the [“Telehealth Top 10”](#) for 2015, and has only continued to generate interest since that time.

What is the Federal Ryan Haight Act?

The [Ryan Haight Online Pharmacy Consumer Protection Act](#) was designed to combat the rogue internet pharmacies that proliferated in the late 1990s, selling controlled substances online. The Act took effect April 13, 2009 and the Drug Enforcement Agency (DEA) issued [regulations](#) effective that same date. The Act essentially imposed a federal prohibition on form-only online prescribing for controlled substances. Although the Act was intended to target “rogue” internet pharmacies, legitimate healthcare providers who prescribe controlled substances via telemedicine must carefully review the regulations to ensure compliance.

What Does the Ryan Haight Act Mean for Healthcare Professionals?

Under the Ryan Haight Act, no controlled substance may be delivered, distributed, or dispensed by means of the internet (which, for all practical purposes, includes telemedicine

technologies) without a valid prescription. A valid prescription is one that is issued for a legitimate medical purpose in the usual course of professional practice by: 1) a practitioner who has conducted at least one in-person medical evaluation of the patient; or 2) a covering practitioner. An “in-person medical evaluation” means a medical evaluation that is conducted with the patient in the physical presence of the prescribing practitioner, without regard to whether portions of the evaluation are conducted by other health professionals.

While the DEA has historically viewed the lack of an in-person medical evaluation as a red flag of potential drug diversion, the Ryan Haight Act makes it unambiguous that it is a *per se* violation of the [federal Controlled Substances Act](#) for a practitioner to issue a prescription for a controlled substance by means of the Internet without having conducted at least one in-person medical evaluation, except in certain specified circumstances. Once the prescribing practitioner has conducted an in-person medical evaluation, the Ryan Haight Act does not set an expiration period or a mandatory requirement of subsequent annual re-examinations (although specific controlled substances, such as suboxone, may have their own rules). Of course, this does not mean that conducting one in-person medical evaluation is sufficient in every clinical situation. Even where the practitioner has conducted an in-person exam, a prescription for a controlled substance must still be issued for a legitimate medical purpose by a practitioner acting in the usual course of his or her professional practice.

Can a Health Care Provider Prescribe Controlled Substances via Telemedicine?

The Ryan Haight Act does not prohibit the use of telemedicine to prescribe controlled substances, and a provider may do so if federal and state requirements are met. However, the challenge for many providers is understanding these laws and applying them to the processes of their specific service line or business. There are solutions and approaches that can work for primary care practices, hospitals, telepsychiatry groups, and the like. Moreover, the Ryan Haight Act has seven exceptions to the in-person medical evaluation requirement for when a prescriber is engaged in the practice of telemedicine. For DEA purposes, keep in mind that “practice of telemedicine” is a defined term of art, and the exceptions are technical and specific. Providers should not assume their approach to telemedicine or virtual care does, in fact, meet a “practice of telemedicine” exception under the Ryan Haight Act. The next articles will discuss the practice of telemedicine exceptions under the Ryan Haight Act, as well as state laws.

What’s Next for the Ryan Haight Act?

In 2015, the [American Telemedicine Association](#) sent a letter to the DEA, advocating for provider-friendly changes to federal controlled substance prescribing rules. Disclosure: attorneys in Foley’s telemedicine practice were [contributing authors to the letter](#). The letter urged DEA to open a special registration process allowing psychiatrists and physicians to prescribe controlled substances via telemedicine without the need for an in-person exam. The ATA letter noted that “the interpretation of the [Ryan Haight] Act’s general prohibition of prescribing controlled substances by means of the internet has become overly restrictive.”

In 2016, DEA announced plans to issue a new rule to activate the special registration process

allowing physicians to use telemedicine to prescribe controlled substances without an in-person exam. The most recent notice of rulemaking stated the proposed rule was expected to be published in January 2017. As of this article, the proposed rule has not yet been released, but is anticipated to be published this year.

For more information on telemedicine, telehealth, virtual care, and other health innovations, including the team, publications, and other materials, visit Foley's [Telemedicine and Virtual Care practice](#).

Prescribing Controlled Substances Without an In-Person Exam: The Practice of Telemedicine Under the Ryan Haight Act

By Nathaniel M. Lacktman
17 April 2017

Health Care Law Today

Editor's Note: This article is the second in a series addressing telemedicine prescribing and controlled substances, designed to give some much needed practical guidance and orientation to established healthcare providers, hospitals, and entrepreneurs alike. The [first article](#) addressed federal rules for prescribing controlled substances under the Ryan Haight Act. Subsequent articles will discuss the prescribing controlled substances via telemedicine under state laws.

As providers are becoming more comfortable with delivering care via telemedicine technologies, many of them are looking to explore services other than low acuity triage consults. One area of patient service opportunity – and particular confusion – is prescribing controlled substances via telemedicine.

As discussed in greater detail in the [first article in this series](#), the [Ryan Haight Online Pharmacy Consumer Protection Act](#) was designed to combat the rogue internet pharmacies that proliferated in the late 1990s, selling controlled substances online. Although the Act was intended to target “rogue” internet pharmacies, legitimate healthcare providers who prescribe controlled substances via telemedicine must carefully review the regulations to ensure compliance. Among other things, the Act requires a practitioner to have conducted at least one in-person medical evaluation of the patient prior to issuing a prescription for a controlled substance.

However, the Ryan Haight Act contains an important exception to the in-person exam requirement for practitioners engaged in the “practice of telemedicine.” Indeed, there are seven separate “practice of telemedicine” exceptions under the Act. They are technical, and providers should not assume their approach to telemedicine or telehealth does, in fact, meet an exception under the Ryan Haight Act. Providers must devote the resources to really understanding these laws and how to apply them to their business or services.

Practice of Telemedicine Under the Ryan Haight Act

The Act contains the following “practice of telemedicine” exceptions:

(1) **Treatment in a hospital or clinic.** The practice of telemedicine is being conducted while

the patient is being treated by, and physically located in, a hospital or clinic registered under section 303(f) of the Act (21 U.S.C. 823(f)) by a practitioner acting in the usual course of professional practice, who is acting in accordance with applicable State law, and who is registered under section 303(f) of the Act (21 U.S.C. 823(f)) in the State in which the patient is located, unless the practitioner:

(i) Is exempted from such registration in all States under section 302(d) of the Act (21 U.S.C. 822(d)); or

(ii) Is an employee or contractor of the Department of Veterans Affairs who is acting in the scope of such employment or contract, and registered under section 303(f) of the Act (21 U.S.C. 823(f)) in any State or is utilizing the registration of a hospital or clinic operated by the Department of Veterans Affairs registered under section 303(f);

(2) Treatment in the physical presence of a practitioner. The practice of telemedicine is being conducted while the patient is being treated by, and in the physical presence of, a practitioner acting in the usual course of professional practice, who is acting in accordance with applicable State law, and who is registered under section 303(f) of the Act (21 U.S.C. 823(f)) in the State in which the patient is located, unless the practitioner:

(i) Is exempted from such registration in all States under section 302(d) of the Act (21 U.S.C. 822(d)); or

(ii) Is an employee or contractor of the Department of Veterans Affairs who is acting in the scope of such employment or contract, and registered under section 303(f) of the Act (21 U.S.C. 823(f)) in any State or is using the registration of a hospital or clinic operated by the Department of Veterans Affairs registered under section 303(f);

(3) Indian Health Service or tribal organization. The practice of telemedicine is being conducted by a practitioner 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; who is acting within the scope of the employment, contract, or compact; and who is designated as an Internet Eligible Controlled Substances Provider by the Secretary of Health and Human Services under section 311(g)(2) of the Act (21 U.S.C. 831(g)(2));

(4) Public health emergency declared by the Secretary of Health and Human Services. The practice of telemedicine is being conducted during a public health emergency declared by the Secretary of Health and Human Services under section 319 of the Public Health Service Act (42 U.S.C. 247d), and involves patients located in such areas, and such controlled substances, as the Secretary of Health and Human Services, with the concurrence of the Administrator, designates, provided that such designation shall not be subject to the procedures prescribed by the Administrative Procedure Act (5 U.S.C. 551–559 and 701–706);

(5) Special registration. The practice of telemedicine is being conducted by a practitioner who has obtained from the Administrator a special registration under section 311(h) of the Act (21 U.S.C. 831(h));

(6) Department of Veterans Affairs medical emergency. The practice of telemedicine is being conducted:

(i) In a medical emergency situation:

(A) That prevents the patient from being in the physical presence of a practitioner registered under section 303(f) of the Act (21 U.S.C. 823(f)) who is an employee or contractor of the Veterans Health Administration acting in the usual course of business and employment and within the scope of the official duties or contract of that employee or contractor;

(B) That prevents the patient from being physically present at a hospital or clinic operated by the Department of Veterans Affairs registered under section 303(f) of the Act (21 U.S.C. 823(f));

(C) During which the primary care practitioner of the patient or a practitioner otherwise practicing telemedicine within the meaning of this paragraph is unable to provide care or consultation; and

(D) That requires immediate intervention by a health care practitioner using controlled substances to prevent what the practitioner reasonably believes in good faith will be imminent and serious clinical consequences, such as further injury or death; and

(ii) By a practitioner that:

(A) Is an employee or contractor of the Veterans Health Administration acting within the scope of that employment or contract;

(B) Is registered under section 303(f) of the Act (21 U.S.C. 823(f)) in any State or is utilizing the registration of a hospital or clinic operated by the Department of Veterans Affairs registered under section 303(f); and

(C) Issues a controlled substance prescription in this emergency context that is limited to a maximum of a five-day supply which may not be extended or refilled; or

(7) **Other circumstances specified by regulation.** The practice of telemedicine is being conducted under any other circumstances that the Administrator 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.

How Useful Are the Ryan Haight Act Exceptions for Telemedicine?

Some of the exceptions are very narrow and do not account for current clinical telemedicine practices. However, others are well-suited to institutional telemedicine arrangements. And others are of use to only a limited subset of practitioners or particular environments (e.g., public health emergency, Indian tribal organization). One exception requires a patient-site telepresenter who is also registered with the Drug Enforcement Agency (DEA) (and presumably independently able to prescribe controlled substances for the patient).

Overall, the exceptions have limited utility in contemporary telemedicine arrangements, most notably telemedicine services directly to the patient's home. For that reason, the exceptions do not easily align with direct-to-patient service models frequently sought 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 main exception designed to accommodate this type of telemedicine practice – the special registration – has not yet been implemented by the DEA.

The DEA seems to recognize the exceptions [have not kept pace](#) with the rapid developments in telemedicine-based practices. To be fair, Congress gave the DEA a very brief window to draft regulations in order to implement the Act within the short time period between the passage of the Act and its effective date (only six months). The DEA's interim final rule was effective a mere nine days after it was published, leaving no time for public comment. Fortunately, DEA has announced plans to activate the special telemedicine registration provision (exception #5). This would allow practitioners to use telemedicine to prescribe controlled substances without the *per se* in-person exam. The new rule is anticipated to be published this year.

If I Meet an Exception, Can I Prescribe Controlled Substances Without Any In-Person Exam?

No, not necessarily. Whether the exam is conducted in-person or via the practice of telemedicine, a prescription for a controlled substance must always be issued for a legitimate medical purpose by a practitioner acting in the usual course of his or her professional practice. Moreover, practitioners must comply with both federal and state laws, as DEA considers a physician who engages in the unauthorized practice of medicine under state law to be someone who is not acting in the usual course of his or her professional practice. For example, according to DEA, a controlled substance prescription issued by a physician who lacks the license or other authority necessary to practice medicine within the state is not a valid prescription under federal law.

Some states prohibit the prescribing of controlled substances via telemedicine, but [others do allow it](#). The remaining states are silent, or allow/disallow its use in certain specialties (e.g., cannot be used in connection with treatment of chronic nonmalignant pain). The federal and state laws must be read in harmony with each other (not unlike how HIPAA interacts with more restrictive state medical privacy laws). Understanding how these layers intersect will enable providers to see the pathways and approaches available to compliant prescribing of controlled substances via telemedicine. This is particularly useful for those telemedicine providers in specialties that involve chronic disease management with pharmacotherapy, for example, adolescent and adult psychiatry, substance abuse/recovery, endocrinology, hormone replacement therapy, and medical weight loss.

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