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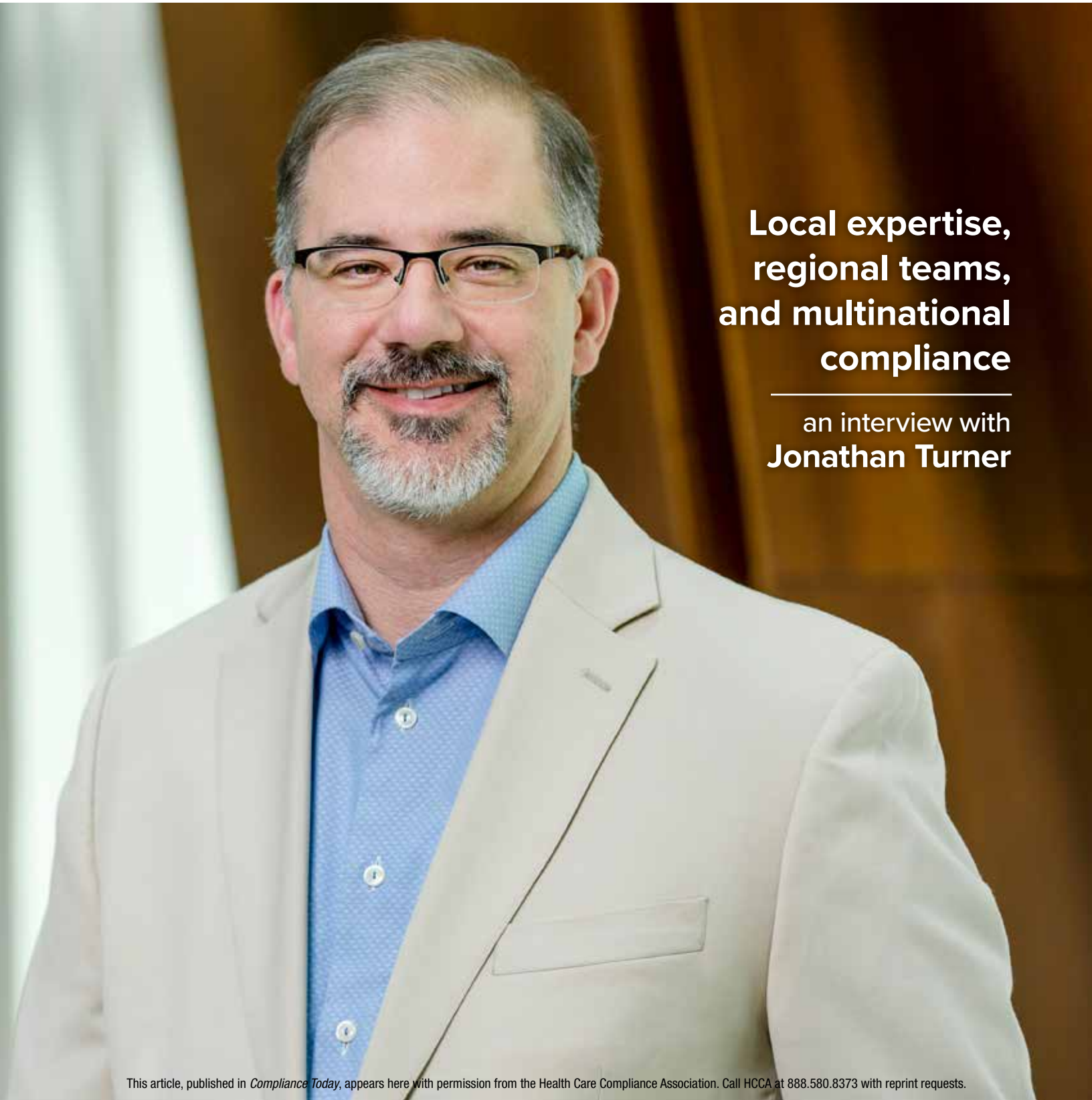

Local expertise, regional teams, and multinational compliance

an interview with
Jonathan Turner

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by Nathaniel Lacktman and Jacqueline Acosta

Compliance issues when prescribing controlled substances via telemedicine

» Telemedicine prescribing of controlled substances is a rapidly-growing practice.
» Only 12 states expressly prohibit telemedicine prescribing of controlled substances.
» Unless exempt, prescribers must be licensed and registered with the DEA.
» Federal law requires an in-person exam, but there are exceptions.
» A common exception applies for DEA-registered hospitals or clinics.

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State laws and rules addressing prescribing controlled substances via telemedicine typically fall into three categories:

- States expressly "allowing" telemedicine prescribing of controlled substances without a prior in-person examination;
- States expressly "prohibiting" telemedicine prescribing of controlled substances or prohibiting it unless the prescriber conducted a prior in-person examination; or
- States that are "silent" and neither expressly allow nor prohibit telemedicine prescribing of controlled substances.

Currently, approximately 15 states fall into the first category and have laws or rules explicitly allowing prescribing controlled substances via telemedicine without a prior in-person exam. However, states that explicitly allow the practice often have limitations on the situations when such prescribing is allowed or other requirements that a prescribing physician must meet prior to prescribing controlled substances (e.g., informed consent requirements, patient disclosures). Although a state may allow telemedicine prescribing of controlled substances generally, or allow it in certain situations, there may also be drug-specific restrictions on prescribing, refills, and checking state prescription drug monitoring databases (e.g., suboxone, opioids).

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Approximately 12 states fall into the second category and have laws or rules explicitly prohibiting telemedicine prescribing of controlled substances or prohibit it unless there is a prior in-person examination. For example, New Hampshire prohibits prescribing substances classified in schedule II through IV unless the "prescriber has an in-person practitioner-patient relationship," with subsequent in-person examinations "at intervals appropriate for the patient, medical condition, and drug, but not less than annually."[1]

Georgia prohibits prescribing controlled substances "based *solely* on a consultation via electronic means with the patient."[2] Even in states, like Georgia, with prohibitions on prescribing controlled substances via telemedicine, there may be exceptions allowing it for up to a 72-hour supply (e.g., on-call or covering physicians, emergencies).[3]

The remaining states, approximately 24, fall into the third category and do not have laws or rules expressly permitting nor prohibiting telemedicine prescribing of controlled substances. For example, Illinois law recognizes and allows the practice of medicine via telehealth.[4] However, the Illinois Medical Board has not issued practice standards or guidance with respect to telemedicine prescribing of controlled substances, and Illinois laws and rules are similarly silent. In the absence of express guidance, the best practice is to defer to the professional medical judgment of the prescribing physician in accordance with the applicable standards of care. Compliance professionals should review not only medical board rules, but also pharmacy board rules in this regard, and should frequently review the laws and rules addressing the telemedicine prescribing of controlled substances as these laws and rules are constantly and rapidly changing.

In all states, prescribing via telemedicine must conform with the standard of care. The prescription must be issued for a legitimate medical purpose in the usual course of professional practice. Unless exempt, the prescribing physician must have a license to practice medicine and a DEA registration in the state where the patient is located at the time of the telemedicine consult.

Establishing a valid physician-patient relationship

Any state allowing controlled substance prescribing via telemedicine first requires the prescribing physician to establish a valid physician-patient relationship. For example, Missouri explicitly provides that "prior to prescribing any drug, controlled substance, or other treatment through telemedicine, as defined in section 191.1145, or the internet, a physician shall establish a valid physician-patient relationship."[5]

Some states also specify the type of telemedicine modality required to establish the physician-patient relationship (e.g., interactive audio-video, asynchronous/store and forward). In Missouri, a valid physician-patient relationship may be established "in accordance with evidence-based standards of practice and telemedicine practice guidelines that address the clinical and technological aspects of telemedicine" and the telemedicine technology utilized must be "sufficient to establish an informed diagnosis as though the medical interview and physical examination has been performed in person…."[6]

Missouri defines "telehealth" or "telemedicine" as:

> "the delivery of health care services by means of information and communication technologies which facilitate the assessment, diagnosis, consultation, treatment, education, care management, and self-management of a patient's health care while such patient is at the originating site and the health care provider is at the distant site."

Missouri explicitly provides that "telehealth" or "telemedicine" "shall also include the use of asynchronous store-and-forward technology." However, a questionnaire completed by the patient, whether via the internet or telephone, does not constitute an acceptable medical interview and examination for the provision of treatment by telehealth."[7]

In addition, Missouri law statute explicitly states the physician-patient relationship must include:

1. Obtaining a reliable medical history and performing a physical examination of the patient, adequate to establish the diagnosis for which the drug is being prescribed and to identify underlying conditions or contraindications to the treatment recommended or provided;
2. Having sufficient dialogue with the patient regarding treatment options and the risks and benefits of treatment or treatments;
3. If appropriate, following up with the patient to assess the therapeutic outcome;
4. Maintaining a contemporaneous medical record that is readily available to the patient and, subject to the patient's consent, to the patient's other health care professionals; and
5. Maintaining the electronic prescription information as part of the patient's medical record.[8]

Other prescribing limitations

States allowing telemedicine prescribing of controlled substances often have other explicit requirements beyond establishing a proper physician-patient relationship. For example, Ohio law permits telemedicine prescribing of controlled substances, without an in-person examination, subject to certain requirements and situations.[9]

An Ohio physician may prescribe non-controlled substances via telemedicine, without an in-person exam, if the prescribing physician satisfies the following nine requirements:

1. Establishes the patient's identity and physical location;
2. Obtains the patient's informed consent for treatment through remote examination;
3. Requests the patient's consent and, if granted, forwards the medical record to the patient's primary care provider or other healthcare provider, if applicable, or refers the patient to an appropriate healthcare provider or healthcare facility;
4. Completes a medical evaluation through interaction with the patient that meets the minimal standards of care appropriate to the condition for which the patient presents;
5. Establishes a diagnosis and treatment plan, including documentation of necessity for the utilization of a prescription drug, including contraindications to the recommended treatment;
6. Documents in the medical record the care provided, patient's consent, medical information, and any referrals made to other providers;
7. Provides appropriate follow-up care or recommends follow-up care;
8. Makes the medical record of the visit available to the patient; and
9. Uses appropriate technology sufficient for the physician to conduct the above as if the medical evaluation occurred during an in-person visit.[10]

An Ohio physician may prescribe *controlled substances* via telemedicine, without an in-person exam, if the prescribing physician satisfies the nine steps outlined above *and* when one of the following six situations exists:

1. The patient is an active patient of a healthcare provider who is a colleague of the prescribing physician, and the controlled substances are provided through an on-call or cross-coverage arrangement between the healthcare providers. Active patient means that "within the previous twenty-four months the physician or other health care provider acting within the scope of their professional license conducted at least one in-person medical evaluation of the patient or an evaluation

of the patient through the practice of telemedicine as that term is defined in 21 C.F.R. 1300.04."

2. The patient is located in a DEA-registered hospital or clinic;
3. The patient is being treated by, and in the physical presence of, an Ohio-licensed physician or healthcare practitioner registered with the DEA;
4. The telemedicine consult is conducted by a prescribing practitioner who has obtained a DEA special registration for telemedicine;
5. A hospice program physician prescribes the controlled substance to a hospice program patient in accordance with the board of pharmacy rules; or
6. The prescribing physician is the medical director of, or attending physician at, an "institutional facility" (defined in rule 4729-17-01) and
   a. The controlled substance is being provided to a person who has been admitted as an inpatient to or is a resident of an institutional facility, and
   b. The prescription is transmitted to the pharmacy by a means that is compliant with Ohio board of pharmacy rules.[11]

It is important to note that the rule explicitly provides that "[n]othing in this rule shall be construed to imply that one in-person physician examination demonstrates that a prescription has been issued for a legitimate medical purpose within the course of professional practice."[12]

Complying with the federal Ryan Haight Act

In addition to complying with state laws and rules, the prescribing physician must follow the requirements of the federal Ryan Haight Online Pharmacy Consumer Protection Act of 2008 (Ryan Haight Act, see sidebar). Like the Health Insurance Portability and Accountability Act (HIPAA), the Ryan Haight Act requirements must be read in harmony with state law, and the federal requirements control if they are more restrictive than state law. If a state law is more restrictive than the federal rules, the more restrictive provisions apply. Practitioners must comply with both state and federal laws, because 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

Telemedicine exceptions to the federal Ryan Haight Act's in-person exam requirement

The Ryan Haight 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. 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.

practice.[13] 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.[14]

The Ryan Haight 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 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 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.

The Ryan Haight Act was designed to combat the "rogue" internet pharmacies that proliferated in the late 1990s, selling controlled substances online.

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."[15] 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.[16] An "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.[17]

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 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.

Exceptions to the Ryan Haight Act's in-person exam requirement

The Act's in-person exam requirement does not apply to "the delivery, distribution, or dispensing of a controlled substance by a practitioner engaged in the practice of telemedicine."[18] The term "practice of telemedicine" means:

> "the practice of medicine in accordance with applicable Federal and State laws by a practitioner (other than a pharmacist) who is at a location remote from the patient and is communicating with the patient, or health care professional who is treating the patient, using a telecommunications system referred to in section 1834(m) of the Social Security Act (42 U.S.C. 1395m(m)), which practice falls within [one of the seven authorized telemedicine exceptions in the regulation]."[19]

One of those exceptions is when the patient is being treated by, and physically located in, a DEA-registered hospital or clinic.[20]

Conclusion

Understanding the technical aspects of the state and federal laws and rules is fundamental, but it is crucial to bear in mind that, even where the prescribing practitioner has complied with the technical requirements, a prescription for a controlled substance must still satisfy the additional, fundamental prerequisite that it be issued for a legitimate medical purpose by a practitioner acting in the usual course of professional practice.

1. New Hampshire Rev. Stat. Ann. § 329:1-d (IV)(a) Telemedicine. Available at https://bit.ly/2s4BEde
2. Georgia Comp. Rules and Regulations. 360-3-.02(5) Prescribing Controlled Substances. Available at https://bit.ly/2KO0wwV
3. See e.g., Idem
4. Illinois Compiled Statutes: 225 ILCS 150/15 Telehealth Act. Available at https://bit.ly/2xcmFTs
5. Missouri Revised Statutes: V.A.M.S. 334.108, Section 1 Telemedicine or internet prescriptions and treatment. Available at https://bit.ly/2LkItzn
6. Missouri Revised Statutes: V.A.M.S. 191.1146, Sections 1-2 Physician-Patient Relationship. Available at https://bit.ly/2J3ecqu
7. Missouri Revised Statutes: V.A.M.S. 191.1145 Definitions – telehealth services. Available at https://bit.ly/2IDVXIM
8. Ibid, Ref #5
9. Ohio Administrative Code OAC § 4731-11-09 Controlled Substances. Available at http://codes.ohio.gov/oac/4731-11 http://codes.ohio.gov/oac/
10. Idem § 4731-11-09(C)
11. Idem § 4731-11-09(D)
12. Idem § 4731-11-09(E)
13. See, e.g., *United States v. Moore*, 423 U.S. 122, 140-41 (1975). Available at https://bit.ly/2IFm7uP
14. 21 CFR 1306.03(a)(1) Persons entitled to issue prescriptions. Available at https://bit.ly/2IDvtHs
15. Idem 21 CFR 1306.09(a).
16. 21 CFR 1300.04(l)(1) Definitions. Available at https://bit.ly/2x6eOqE
17. Idem: 21 CFR 1300.04(f).
18. 21 USC 829(e)(3)(A) Controlled substances dispensed by means of the Internet. Available at https://bit.ly/2IHxFxC
19. Ibid Ref #16: 21 CFR 1300.04(i).
20. Ibid Ref #16: 21 CFR 1300.04(i)(1).