Telemedicine and the Controlled Substances Act

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U.S. Drug Enforcement Administration
Diversion Control Division
Course Objectives

Discuss the Ryan Haight Online Pharmacy Consumer Protections Act.

Discuss the requirements of prescribing controlled substances using telemedicine under Federal law.
Course Objectives

Discuss the requirements of a telecommunications system when using telemedicine.

Discuss practitioners who are exempt from the Ryan Haight Act in-person medical evaluation requirement.
Discuss the telemedicine requirements to abide by both state and federal laws.
At the completion of this block of instruction you will be able to answer the following questions:

1. Does the Ryan Haight Act only apply to on-line pharmacies?
Questions To Discuss

2. For a prescription to be valid it must be issued for a legitimate medical purpose in the usual course of professional practice?

3. Are you required to have one in-person visit with your patient in order to conduct telemedicine?
Questions To Discuss

4. Does e-mail or fax meet the communication requirements for telemedicine?

5. For most practitioners conducting telemedicine the patient must be in:
   (a) DEA registered hospital/clinic or
   (b) in the physical presence of a DEA registered practitioner?
6. When conducting telemedicine does the remote practitioner need to have a DEA registration in the state where the patient is located?
“The Ryan Haight Act”
Amended

The Controlled Substances Act
Basically:

Added New Provisions to the (Controlled Substances Act)
Purpose of the Ryan Haight Act

Prevent illegal distribution and dispensing of controlled substances by means of the Internet.
Controlled Substances Dispensed by Means of the Internet

21 U.S.C. § 829 (Prescriptions) was amended as follows:

No controlled substance may be delivered, distributed, or dispensed without a Valid Prescription.
Valid Prescription

A prescription issued for a legitimate medical purpose in the usual course of professional practice
A Prescription Issued By

A practitioner
who has conducted
at least 1 “in-person medical evaluation”
of the patient

U.S. Drug Enforcement Administration Diversion Control Division
In-Person Medical Evaluation

A medical evaluation that is conducted with the patient in the physical presence of the practitioner.
In-Person Medical Evaluation

Unless:

The practitioner is engaged in the practice of Telemedicine

*21 U.S.C. § 829 (e)(3)(A) *
TELEMEDICINE

“The Basics”
TELEMEDICINE

21 U.S.C. § 802 (54)
Definition of Telemedicine

The practice of medicine in accordance with applicable Federal and State laws by a practitioner (other than a pharmacist) at a location remote from the patient, and
Definition of Telemedicine is communicating with the patient, or health care professional who is treating the patient, using a telecommunications system referred to in 42 C.F.R. § 410.78(a)(3).
Telecommunications System

Multimedia communications equipment that includes, at a minimum, audio and video equipment permitting two-way, real time interactive communication between the patient and remote practitioner.
Telecommunications System

Telephones, facsimile machines, and electronic mail systems do not meet this definition.
Definition of Telemedicine

(A) is being conducted -

(i) while the patient is being treated by, and physically located in a DEA-registered hospital or clinic and
Definition of Telemedicine

(ii) by a practitioner -

(1) acting in the usual course of professional practice;

(2) acting in accordance with applicable State law; and

(3) is registered ...in the State in which the patient is located, unless the practitioner (is)-
Definition of Telemedicine

(B) is being conducted

while the patient is being treated by, and in the physical presence of, a DEA-registered practitioner.
Definition of Telemedicine

a practitioner -

(1) acting in the usual course of professional practice;

(2) acting in accordance with applicable State law; and

(3) is registered ...in the State in which the patient is located, unless the practitioner (is) -
Minor “Exceptions” for DEA Registration

Employee or Contractor of Veterans Affairs

Indian Health Service
“Exceptions”

Medical Emergency Situation

(Veterans Affairs)
“Exceptions”

Public Health Emergency
“Exceptions”

Special Registration for Telemedicine

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“Exceptions”

Other Circumstances determined by the Attorney General and the (HHS) Secretary…
The Remote Practitioner

The remote practitioner must be registered with the DEA:

1. In the state where they are physically located; and

2. In the every state where the patient is located

21 U.S.C. § 822 (e)(1), 21 C.F.R. § 1301.12(a), 71 FR 69478, December 1, 2006
How Can You Do Telemedicine?

(1) Patient is in a DEA Registered Hospital

(2) Patient is in the Physical Presence of a DEA Registered Practitioner

(3) DEA Registered Practitioner Travels to the Residence or Other Physical Location of the Patient
How Can You Do This?

(4) Rent an Office and Have Your Patients Go to the Office Where the DEA Registered Practitioner is Located.

(5) Mobile Van (DEA Registered Practitioner on Board)
1. Are you required to have one in person visit with your patient in order to conduct telemedicine?

A. Yes
B. No
2. Does e-mail or fax meet the communication requirements for telemedicine?

A. Yes
B. No
Post Questions

3. The Ryan Haight Act only applies to online pharmacies.

A. True
B. False
4. When conducting telemedicine does the remote practitioner need to have a DEA registration in the state where the patient is located?

A. Yes
B. No
5. For a prescription to be valid it must be issued for a legitimate medical purpose in the usual course of professional practice?

A. True
B. False
6. For most practitioners conducting telemedicine the patient must be in (a) DEA registered hospital/clinic or (b) in the physical presence of a DEA registered practitioner?

A. True  
B. False
Thank You