

Telemedicine and the Controlled Substances Act

Practitioner Diversion Awareness Conference Anaheim, California February 4-5, 2019





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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.

Course Objectives

§ 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?

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?

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?

Ryan Haight Online Pharmacy Consumer Protection Act of 2008

PL-110-425 110th Congress

October 15, 2008

"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

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)

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

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.

(A) is being conducted -

(i) while the <u>patient</u> is being treated by, and <u>physically located in a DEA- registered hospital or clinic and</u>

- (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)-

(B) is being conducted

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

- 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

Medical Emergency Situation (Veterans Affairs)

Public Health Emergency

Special Registration for Telemedicine

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

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

