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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.**

Questions To Discuss

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?

Questions To Discuss

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

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 **<u>practitioner</u>**
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 <u>physical</u> <u>presence</u> 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"

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,

<u>or health care professional</u>

<u>who is treating the patient</u>,

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 <u>two-way</u>, <u>real time interactive communication</u> between the patient and remote practitioner.

Telecommunications System

Landline telephones,

facsimile machines,

and electronic mail systems

do **not** meet this definition.

Definition of Telemedicine

is being conducted -

- while the **patient** is being treated by, and **physically located in a DEA- registered hospital or clinic** and

Definition of Telemedicine

by a practitioner -
- acting in the usual course of professional practice;
- acting in accordance with applicable State law; and
- is registered …in the State in which the <u>patient</u> is located,

Definition of Telemedicine

is being conducted -

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

Definition of Telemedicine

by a practitioner -
- acting in the usual course of professional practice;
- acting in accordance with applicable State law; and
- is registered …in the State in which the <u>patient</u> is located,

Minor "Exceptions" for DEA Registration

- **Employee or Contractor of Veterans Affairs**

- **Indian Health Service**

"Exceptions"

- **Medical Emergency Situation** (Veterans Affairs)

- **Public Health Emergency**

"Exceptions"

- **Special Registration for Telemedicine**

- **<u>Other</u> <u>Circumstances</u>** 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 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)

Ryan Haight Act Overview

On-Line Pharmacy

Valid Prescription
Practitioner has conducted at least 1 in-person medical evaluation - physical
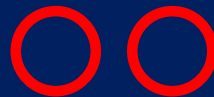
UNLESS INVOLVED IN THE PRACTICE OF TELEMEDICINE

Telemedicine Categories/Exemptions

- By Practitioner / not R.Ph.
- Remote from patient and communicating with patient or health care professional with compliant telecommunications system.
- 7 Exemptions

DEA Registrants

Additional Exemptions

#1

Doctor in VA

Patient at DEA Registered Hospital/Clinic in FL

State Authorization Required
DEA Registration in State Required

State Authorization Required

#2

Doctor in VA

Patient in physical presence of DEA Registered practitioner in FL

State Authorization Required
DEA Registration in State Required

State Authorization Required

Exceptions for DEA Registration

- An Employee or Contractor of VA
- An Employee or Contractor of the IHS, Indian Tribe, or Tribal Organization
- Medical Emergency Situation (VA)
- Public Health Emergency
- Other circumstances determined by the AG and Secretary .. By regulation...effective controls ... consistent with the public health / safety.
- Special Registration for Telemedicine DRAFTING IN PROCESS

Post Questions

1. Are you required to have one in person visit with your patient in order to conduct telemedicine?

   A. Yes
   B. No

Post Questions

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 on-line pharmacies.

   A. True
   B. False

Post Questions

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

Post Questions

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

Post Questions

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