

Telemedicine and the Controlled Substances Act

Practitioner Diversion Awareness Conference Antonio R. Guzman, Associate Section Chief January 13 & 14, 2020





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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

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"

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

Landline telephones, facsimile machines, and electronic mail systems do not meet this definition.

is being conducted -

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

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 patient is located,

is being conducted -

• while the <u>patient</u> is being treated by, and in the <u>physical presence of, a</u>

DEA-registered practitioner.

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 patient 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

• 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 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



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Telemedicine

- Practice of medicine by practitioner (not Rph)
- Remote from patient and
- Communicating with patient or health care professional with compliant telecommunications system.

Current Exceptions/Categories involving DEA Registrants

Patient at DEA Registered Hospital/Clinic

Scenario #1

Patient with DEA Registered Practitioner

Scenario #2

Doctor in VA

Patient at DEA Registered Hospital/Clinic in FL

#1



State Authorization Required
DEA Registration in State Required



State Authorization Required

Doctor in VA



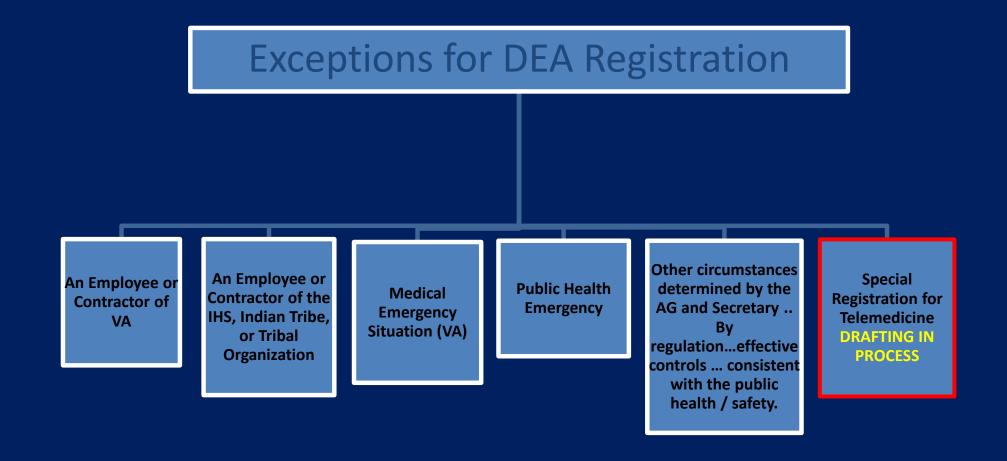
State Authorization Required DEA Registration in State Required

Patient in physical presence of DEA Registered practitioner in FL



State Authorization Required

#2



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

