



The United States Department of Justice

Drug Enforcement Administration



Telemedicine and the Controlled Substances Act

Practitioner Diversion Awareness Conference

Dover, Delaware

June 3-4, 2019



James "Jim" Arnold
Chief, Liaison and Policy
Drug Enforcement Administration



LEGAL DISCLAIMER

The following presentation was accompanied by an oral presentation on **June 3-4, 2019**, and does not purport to establish legal standards that are not contained in statutes, regulations, or other competent law. Statements contained in this presentation that are not embodied in the law are not binding on DEA. Summaries of statutory and regulatory provisions that are summarized in this presentation do not purport to state the full extent of the statutory and regulatory requirements of the cited statutes and regulations. **I have no financial relationships to disclose.**

Fair Use Act Disclaimer

This presentation is for educational purposes only. This presentation may not be further copied or used, with the embedded images and videos, without an independent analysis of the application of the Fair Use doctrine.

Fair Use

Under section 107 of the Copyright Act of 1976, allowance is made for “Fair Use” for purposes such as criticism, comment, news reporting, teaching, scholarship, education and research.

Fair Use is a use permitted by the copyright statute that might otherwise be infringing. Any potentially copyrighted material used in this presentation has been reviewed and found to be used in a manner consistent with Fair Use. A completed Fair Use checklist is attached.

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**

**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)

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**

“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)**



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

