



The United States Department of Justice

Drug Enforcement Administration



Telemedicine and the Controlled Substances Act

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LEGAL DISCLAIMER

The following presentation was accompanied by an oral presentation on December 13, 2017, 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 provision 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.



DEA Authority

Law

Controlled Substances Act

Regulations

Code of Federal Regulations

Policy

Written Letters, FR Notices



**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



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**

or

A covering practitioner



Covering Practitioner

A practitioner who conducts
a medical evaluation
at the request
of the
Practitioner,



Practitioner

who has conducted **at least one (1)**
in-person medical evaluation of the
patient,
or
an evaluation of the patient through
the practice of telemedicine
within the previous 24 months,



Practitioner

...and

is temporarily unavailable to conduct
the 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.



“Cut Out” for Telemedicine

“...a practitioner engaged in the practice of telemedicine within the meaning of the Act is exempt from the requirement of an in-person medical evaluation as a prerequisite to prescribing ... controlled substances by means of the Internet.”

(Ryan Haight, 74 FR 15603)



“Cut Out” for Telemedicine

“The definition of the ‘practice of telemedicine’ includes **seven distinct categories** (“Exceptions”) that involve circumstances in which the prescribing practitioner might be unable to satisfy the Act’s in-person medical evaluation requirement,...



“Cut Out” for Telemedicine

...yet nonetheless has sufficient medical information to prescribe a controlled substance for a legitimate medical purpose in the usual course of professional practice.”

(Ryan Haight, 74 FR 15603)



In-Person Medical Evaluation

Unless:

*The practitioner is engaged in the
practice of Telemedicine*

21 U.S.C. § 829 (e)(3)



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 the remote practitioner.



Telecommunications System

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



Definition of Telemedicine

(A) is being conducted -

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

OR



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

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)-



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 Secretary..., by regulation, determined to be **consistent with effective controls against diversion and ...**consistent with the public health and safety****



Federal Law and State Law

In part, the definition of telemedicine includes:

“The practice of medicine in accordance with applicable Federal and State laws”.

DEA Registrants must adhere to both sets of laws and regulations.

More Stringent: 21 § C.F.R. 1307.02



A Final Note



Mission

The mission of the Office of Diversion Control is to prevent, detect, and investigate the diversion of pharmaceutical controlled substances and listed chemicals from legitimate channels of distribution...



Mission

... *while* ensuring an adequate and uninterrupted supply of controlled substances to meet legitimate medical, commercial, and scientific needs.



21 C.F.R. § 1306.04 (a)

A prescription for a controlled substance to be effective must be issued for a legitimate medical purpose by an individual practitioner acting in the usual course of his professional practice.



Thank You

