Telemedicine and the Controlled Substances Act

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James “Jim” Arnold
Chief, Policy and Liaison Section
Drug Enforcement Administration
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

U.S. Drug Enforcement Administration
Diversion Control Division
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

U.S. Drug Enforcement Administration
Diversion Control Division
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)
“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

U.S. Drug Enforcement Administration Diversion Control Division
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.
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) -

U.S. Drug Enforcement Administration
Diversion Control Division
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
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