Telemedicine and the Controlled Substances Act

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The following visual presentation is **not legal advice** and is intended to be used in conjunction with the live presentation given by the author on this particular date.
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

U.S. Drug Enforcement Administration
Office of Diversion Control
“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.

U.S. Drug Enforcement Administration
Office of Diversion Control
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

U.S. Drug Enforcement Administration
Office of Diversion Control
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)
“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,…

U.S. Drug Enforcement Administration
Office of Diversion Control
“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 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.
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

U.S. Drug Enforcement Administration
Office of Diversion Control
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.
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.**
DEA Web-Based Resources
www.DEAdiversion.usdoj.gov

Office of Diversion Control

HOME  REGISTRATION  REPORTING  RESOURCES  ABOUT US

Registration Support
- Call: 1-800-882-9539 (8:30 AM - 6:00 PM)
- Fax: DEA.Registration.Help
- Locate Field Registration Spots
- New Applications
- Renewal Applications
- Registration Changes (Address, Drug, CMEA (Combat Meth Epidemic Act)
- Registration for Disposal of Controls
- Duplicate Certificate Request
- Duplicate Receipt of Registration Order Forms (DEA 222)
- Registration Validation

What's New
Research Triangle Institute (April 18, 2016)
Johnson Matthey, Inc. (April 18, 2016)
Meridian Medical Technologies (April 18, 2016)
Cody Laboratories, Inc. (April 18, 2016)
30-Day Notice (Extension): Reporting and Recordkeeping for Digital Certificates (April 15, 2016)
30-Day Notice (Extension): Report of Mail Order Transactions (April 15, 2016)
Mylan Technologies, Inc. (April 15, 2016)
Final Order: Placement of AL-921 into Schedule I (April 14, 2016)

In The News
Public Safety Alert from Drug Enforcement Administration Counterfeit Hydrocodone Tablets Containing Fentanyl (April 8, 2016)
DEA Agents Arrest Four Men on Federal Charges of Distributing Narcotics, Including Pills Manufactured with a Fentanyl Analogue (March 16, 2016)
Man Sentenced for Distribution of Oxycodeone (March 11, 2016)
Two California Men Plead Guilty to Conspiracy (March 10, 2016)

Quick Links
ARCOS (Automation of Reports & Consolidated Orders System)
Cases Against Doctors
Chemical Control Program
Controlled Substance Schedules
CSOS (Controlled Substances Ordering System)
EPCS (Electronic Prescriptions for Controlled Substances)
DEA Form 105: Report Theft or Loss of Controlled Substances
Find Your Local DEA Office
Mailing Addresses for Topics Related to Title 21 CFR
Medical Missions
Search for an Authorized Collector Location
Submit a Tip to DEA

EMERGENCY DISASTER
Got Drugs?
ALERT
Drug Disposal Boston Postcard

www.usdoj.gov/21cfr/chapter1321/1321_01.htm
Thank You / Questions
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