Updates from the DEA

National Association of State Controlled Substance Authorities
Scottsdale, Arizona
Tuesday, October 30, 2018
Opioid Drug Treatment

The Comprehensive Addiction and Recovery Act of 2016

“CARA”

July 22, 2016

Public Law 114-198
Opioid Drug Treatment

Qualifying Practitioners
(Qualifying Physicians)
(DATA Waived Doctors)

Qualifying Other Practitioners
(Nurse Practitioners)
(Physician Assistants)
Opioid Drug Treatment

Qualifying Practitioners
(30, 100, 275 Patients)

Qualifying Other Practitioners
(30, 100 Patients)
Dispensing Buprenorphine

- Administer, Dispense, and Prescribe as Allowed by Federal and State Law and Regulations.

- “Active Script, Active Patient”
Total Prescriptions Filled: Buprenorphine 2009-2017

 IMS Data
Opioid Treatment Programs (OTPs)

*As of October 25, 2018: DEA Data
DEA Registered Opioid Treatment Programs (OTP)

Total: 1,662

Drug Enforcement Administration, Diversion Control Division

Updated September 18, 2018
DEA Registered Qualifying Practitioners

*As of October 25, 2018 (NPs and PAs as of 01/01/2017)
### Qualifying Practitioners (US)

<table>
<thead>
<tr>
<th>Category</th>
<th>Number</th>
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<tbody>
<tr>
<td>Practitioner DW-30</td>
<td>30,293</td>
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<td>Practitioner DW-100</td>
<td>9,535</td>
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<td>Practitioner DW-275</td>
<td>4,639</td>
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<tr>
<td>Nurse Practitioner DW-30</td>
<td>6,285</td>
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<tr>
<td>Physician Assistant DW-30</td>
<td>1,623</td>
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</tbody>
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As of October 25, 2018
New Regulatory Clarity

• Pending New Regulation Clarity
  – EPCS
  – Mobile Treatment Vans
  – Mobile Doctors
  – Partial Fill Regulations
  – One Page DEA Form 222
  – Special Registration for Telemedicine
  – EMS
Options for Hospitals

21 C.F.R. 1306.07:

- Register as an NTP
- Three Day Rule (Withdrawal)
- Incidental Adjunct to Medical/Surgical Treatment
- DATA Waived (Qualifying Practitioner)
Revised Manuals

Narcotic Treatment Manuals

Practitioners Manual

Pharmacy Manual

Researcher’s Manual
National Emergencies

DEA Registrants

Domestic or International disasters such as Hurricanes, Earthquakes, Floods, Tornadoes, and Typhoons.
National Emergencies

http://www.DEAdiversion.usdoj.gov

At the Above Listed Homepage Click on Tab at the Bottom of the Home Page Titled:

Click on: Natural.Disaster@usdoj.gov
Factory Visit Photos
Domestic Control of Marihuana

For marijuana to be moved from Schedule I to another schedule, the substance/drug requires an accepted medical use.

The definition of currently accepted medical use was litigated, Alliance for Cannabis Therapeutics v DEA (D.C. Cir 1994)
“Five Part Test for Currently Accepted Medical Use”

Five Part test:

1) The drug’s chemistry must be known and reproducible;

2) There must be adequate safety studies;

3) There must be adequate and well-controlled studies proving efficacy;

4) The drug must be accepted by qualified experts; and

5) The scientific evidence must be widely available

Marinol - Yes
Marijuana - No
Domestic Control of Marihuana

- State laws, anecdotal reports, position statements do not fulfill these criteria.
- The U.S. Department of Health and Human Services (HHS) is the sole domestic entity with the authority to approve medications for use by humans and animals.
Marihuana is a Schedule I Controlled Substance Under Federal Law.
Recent Examples of Drugs Participating in the Process

• Drug sponsor conducted clinical trials and collected the information required of the FDA

• DEA registered the researchers and the sponsor conducted their studies
Epidiolex®

• June 25, 2018

• FDA Approved Epidiolex®

• 1st Pharmaceutical Grade CBD Product derived from Cannabis in an FDA approved medication.
Epidiolex®

• Approved for the treatment of Lennox-Gastaut syndrome
  Dravet syndrome

• Two serious and rare forms of epilepsy that appear at an early age.
Epidiolex®

Schedule V

Approved by FDA on
Monday, June 25, 2018

Scheduled by DEA on
Friday, September 28, 2018
Placement in Schedule V of Certain FDA-Approved Drugs

FDA-approved drugs that contain CBD derived from cannabis and no more than 0.1 percent tetrahydrocannabinols into Schedule V
Marihuana

DEA continues to support legitimate medical and scientific research on marijuana and its derivatives, extracts and synthetic versions.

To date, the DEA has not denied any application to conduct FDA approved research with marijuana.
Marihuana

- As of October 10, 2018, DEA has approved a total of 692 researchers nationwide to perform research with Schedule I controlled substances.

- Approximately 499 of those researchers are conducting research with marijuana, marijuana extracts, and/or THC.
What’s New?
H.R.6

SUPPORT for Patients and Communities Act

115th Congress (2017-2018)

October 24, 2018
Substance Use-Disorder Prevention that Promotes Opioid Recovery and Treatment for Patients and Communities Act or the SUPPORT for Patients and Communities Act
I. Provisions Amending the Controlled Substances Act

II. Provisions Requiring the Promulgation of DEA Regulations

III. Provisions Requiring Consultation with DEA
Provisions
Amending
the Controlled Substances Act
Section 3204:

Delivery of a Controlled Substance by a Pharmacy to be Administered by Injection or Implantation
Section 3204:

1. Amends the CSA to allow a pharmacy to deliver a controlled substance directly to a practitioner to be administered to a specific patient for injection or implantation maintenance or detoxification treatment.

2. Will allow delivery to a practitioner at the location listed on the practitioner's certificate of registration.

3. **14 Days to Administer**
Delivery to a Practitioner’s Office

DEA has already provided exceptions for some substances (for the treatment of Opioid Addiction):

• Investigational buprenorphine product RBP-6000
  Indivior

• Probuphine (buprenorphine) implant
  Braeburn Pharmaceuticals

• Implanted intraspinal pumps
  Advanced Infusion Solutions (AIS)
New Products

Sublocade™
(buprenorphine extended-release)
injection for subcutaneous use
Subdermal Buprenorphine Implant

- Trade name - Probuphine
- Manufactured by Titan Pharma
- Small, solid “rod” (26 mm × 2.5 mm)
- Made from a mixture of ethylene vinyl acetate
- Contains about 80 mg Buprenorphine
- Buprenorphine released over 6 months
- Benefits
  - Decreased risk of diversion and accidental pediatric exposure
  - Improved adherence, convenience

Presented at the national CME "OST: Policy and Practice" on 18th-19th April 2015 at AIIMS, New Delhi
New Products
Section 3222:

Disposal of Controlled Substances of a Hospice Patient by Employees of a Qualified Hospice Program
Section 3222:

- **Three specific circumstances** when an employee of a qualified hospice program may assist with disposal of the controlled substances:

  1. The disposal occurs after the death of a person receiving hospice care

  2. The controlled substance is expired
3. Change of care of the patient only in instances where the employee is a DEA registrant and the practitioner of the patient

- Disposal shall occur onsite and in accordance with all applicable Federal and State law
Chapter 7:

Using Data to Prevent Opioid Diversion
Amends the CSA to provide drug manufacturers and distributors with access to anonymized information through the Automated Reports and Consolidated Ordering System (ARCOS) to assist in identifying, stopping, and reporting suspicious orders of opioids.
Chapter 7:

• The following anonymized data will be made available via ARCOS Quarterly

1. Total Number of competitors who have sold a particular controlled substance to a prospective customer (pharmacy or practitioner)

2. Quantity and type of opioids distributed
“Anonymized”

“anonymized”

• Make anonymous

• Remove identifying particulars so that the original source cannot be known
Chapter 7:

• A bi-annual reporting requirement to provide a standardized report to regulatory, licensing, attorneys general, and law enforcement agencies of States.

• Nothing in this chapter should be construed to absolve a DEA registrant from the responsibility of identify and report suspicious orders.
Chapter 8:

Opioid Quota Reform
Chapter 8:

- Amends the CSA to strengthen DEA’s discretion in setting opioid quota by codifying changes outlined in the April 2018 notice of proposed rulemaking and outlines an annual reporting requirement to congress regarding manufacture and aggregate production quota increases.
Chapter 8:

- DEA may establish APQ, MQ, and/or PQ in terms of pharmaceutical dosage forms to avoid the overproduction, shortages, or diversion of a controlled substance

  - MQ deadline changed from October 1 to December 1

  - Estimated amount of diversion shall be considered when setting APQ, MQ, and/or PQ
Chapter 8:

- Congressional annual reporting requirement due:
  
  - For any year for which the approved APQ for a covered controlled substance is increased
  
  - An anonymized count of manufactures issued MQ and number of manufactures who received increases in MQ from previous year
Chapter 9:

Preventing Drug Diversion
Chapter 9:

- Requires DEA to establish a centralized database for collecting reports of suspicious orders within one year of enactment of this law.
Chapter 9:

• Defines and adds the term ‘suspicious order’ to the CSA

• DEA shall establish a centralized database for collecting reports of suspicious orders

• A standardized report to be made available to regulatory, licensing, attorneys general, and law enforcement agencies of States within a reasonable period of time
Chapter 9:

• A call for State AG’s to provide access to DEA regarding PDMP data
Section 3201:

Allowing for More Flexibility with Respect to Medication-Assisted Treatment for Opioid Use Disorders
Section 3201:

• Amends the CSA to increase the number of patients a DATA waived practitioner may treat and eliminates the time limitation for specific practitioner types to be considered a ‘Qualified Practitioner’.

• Permanently codifies the 275 patient limit for DATA waived practitioners
Section 3201:

- **Eliminates** time limitation (**Sunset Provision**) for nurse practitioners and physician assistants to become qualifying practitioners

- **Imposes** a 5 year time limitation (**Sunset Provision**) on clinical nurse specialists, registered nurse anesthetists, and certified nurse midwives to become qualifying practitioners
Section 3202:

Medication-Assisted Treatment for Recovery from Substance Use Disorder
Section 3202:

• Amends the CSA to expand the type of practitioners that may obtain a DATA waiver with respect to medication-assisted treatment (MAT).

• A physician who graduated from an accredited school of allopathic medicine or osteopathic medicine may obtain a DATA waiver with respect to medication-assisted treatment (MAT).
Provisions Requiring the Promulgation of DEA Regulations
Section 2003:

Every Prescription Conveyed Securely

- Requires updated DEA regulations for the biometric component of multifactor authentication with respect to electronic prescriptions of controlled substances (EPCS).
Chapter 4:

Regulations Relating to a Special Registration for Telemedicine
Requires a DEA regulation that contains both the limited circumstances and procedure for obtaining a special registration for telemedicine.
Provisions Requiring Consultation with DEA
Section 3212:

• Programs and Materials for Training on Certain Circumstances Under which a Pharmacist may Decline to Fill a Prescription

• HHS, in consultation with DEA, shall develop materials explaining circumstances under which a pharmacist may decline to fill a prescription for a controlled substance.
Section 8215:

• Provider Education

• DEA, in coordination with HHS, shall provide a report outlining additional steps recommended to limit the over-prescribing of opioids by medical practitioners and clearly identify how DEA can help to regulate registrations for the dispensing of controlled substances.
A Final Note
The mission of the Diversion Control Division 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.
The DEA is primarily responsible for Enforcing the CSA

Providing for the Public Health and Safety
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
Contact Information

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