Updates from the DEA

National Association of State Controlled Substance Authorities
Richmond, Virginia
October 23, 2019
DEA Tasking and Tools

Controlled Substances Act Implementing Regulations Policy
Opioid Drug Treatment

The Comprehensive Addiction and Recovery Act of 2016
“CARA”
July 22, 2016
Public Law 114-198
Opioid Drug Treatment

Qualifying Practitioners
(30, 100, 275 Patients)

Qualifying Other Practitioners
(30, 100 Patients)
Opioid Drug Treatment

The SUPPORT Act of 2018

Expanded the types of healthcare professionals who could prescribe buprenorphine products for OUD

Authorized the delivery of a prescribed buprenorphine OUD treatment product to place of administration.
Opioid Drug Treatment

The number of DATA waivered practitioners has expanded significantly from 27,719 in 2015 to 70,020 today.

There has been a slower but still significant increase in OTPs such that there are 1,756 including 3 added just last week.
New Regulatory Guidance

• Pending New Regulation Clarity
  – EPCS (2018 Support Act)
  – Mobile Treatment Vans
  – Mobile Doctors
  – Partial Fill Regulations (2016 CARA)
  – One Page DEA Form 222
  – Special Registration for Telemedicine (2018 SUPPORT Act)
  – Emergency Medical Services (2017 Act)
OUD Treatment

21 C.F.R. 1306.07:

What can a hospital do?

What can a practitioner do?

Issues surrounding the “three day rule”

What can be done in correctional facilities?
Manuals

Pharmacists Manual
Narcotic Treatment Best Practice Guidelines
DATA Waiver Manual (new)
Practitioner’s Manual
Mid Level Practitioner’s Manual (new)
Researcher’s Manual (new)
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
Marihuana is a Schedule I Controlled Substance Under Federal Law.
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 22, 2019, DEA has approved a total of 812 researchers nationwide to perform research with Schedule I controlled substances.

• Approximately 592 of those researchers are conducting research with marijuana, marijuana extracts, and/or THC.
What’s New?
Substance Use-Disorder Prevention that Promotes
Opioid Recovery and Treatment for
Patients and Communities Act

or

the SUPPORT for Patients and Communities Act
Section 3204:

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

The DEA has not yet addressed this in regulation.
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
Section 3222:

Disposal of Controlled Substances of a Hospice Patient by Employees of a Qualified Hospice Program

The DEA has not addressed this in regulation.
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. The controlled substance is not needed due to a change care plan
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

The DEA has until the end of the month to publish in the Federal Register.
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.
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
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