



What's New From The DEA Diversion Control Division

DIVERSION CONTROL DIVISION

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We have no financial relationship to disclose

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Objectives



1. Discuss the Overdose Crisis today
2. Understand DEA Guidance and Q&A's
3. How to find pending regs and hear about a new one
4. DEA's part in an important initiative



The Opioid (?) Crisis Today



CDC Provisional Overdose Data for 2020



Over 93,000 drug overdose deaths in the United States during 2020 – increase of 29.4% from the 72,151 deaths predicted in 2019

Synthetic opioids (primarily fentanyl)

Methamphetamine

Cocaine

Prescription pain medication

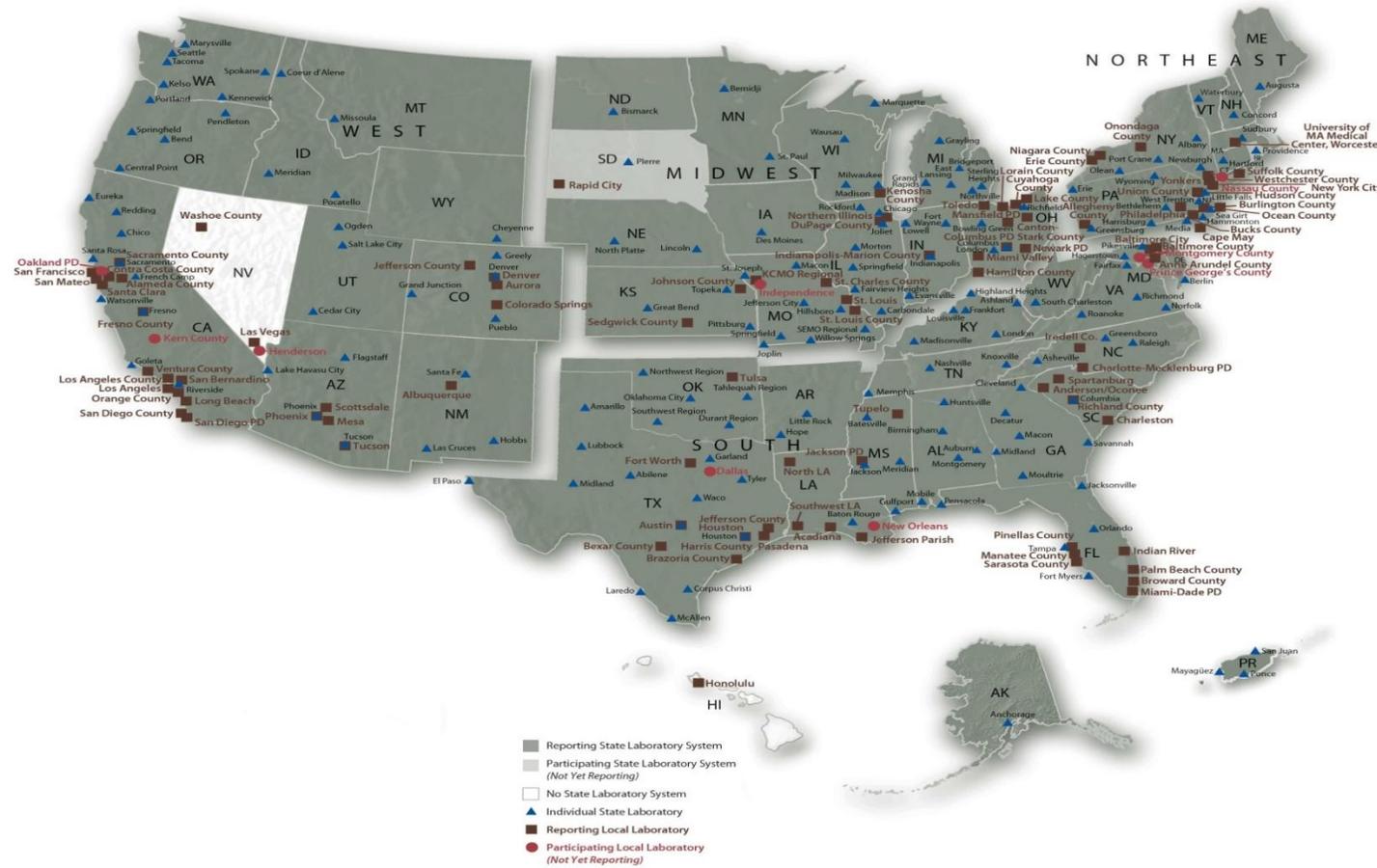


Provisional Drug Overdose Deaths

JUN 2019 *	14,856	12,148	2,863	33,164	14,894	14,583	
JUN 2020 *	14,480	12,966	3,195	48,006	19,215	20,318	
Change	-2.6%	6.5%	11.0%	36.6%	25.3%	32.9%	

* Number of predicted deaths for the 12 months ending in June of the indicated year

NFLIS Data Collection



Most Frequently Identified Analyzed Drugs United States - 2019



- 1. Methamphetamine 27.47%**
- 2. Cannabis 18.58%**
- 3. Cocaine 13.74%**
- 4. Heroin 8.39%**
- 5. Fentanyl 6.50%**
- 6. Alprazolam 1.75%**
- 7. Oxycodone 1.48%**
- 8. Buprenorphine 1.35%**
- 9. Hydrocodone .84%**
- 10. Acetyl Fentanyl .80%**
- 11. Amphetamine .74%**
- 12. Tramadol .54%**

Most Frequently Identified Analyzed Drugs United States - Raw Data 2020*



1. Methamphetamine 32.88%
2. Cannabis/THC 16.29%
3. Cocaine 13.19%
4. Heroin 8.05%
5. Fentanyl 6.50%
6. Alprazolam 1.62%
7. Buprenorphine 1.42%
8. Oxycodone 1.41%
9. Hydrocodone .81%
10. ANPP .76%
11. Eutylone .75%
12. Amphetamine .75%

*Queried 6/25/2021. Due to pandemic, data may not follow previous trends.

DEA Launches Public Safety Alert – September 27, 2021

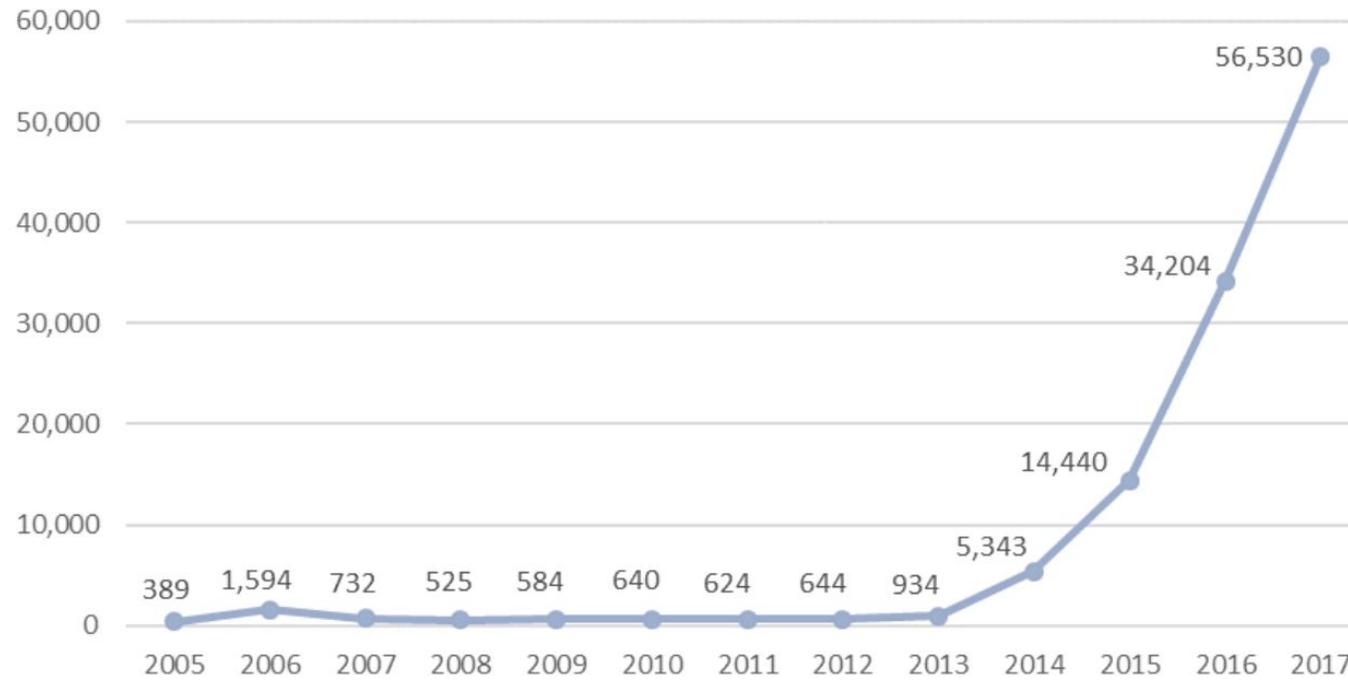


DRUG ENFORCEMENT ADMINISTRATION

Threat of Illicit Fentanyl



Figure 2. Forensic Laboratory Reports of Fentanyl, 2005 – 2017



Source: DEA

Counterfeit Pills Containing Fentanyl

DEA Seizures



Why Counterfeit Pills? Profit Margin



One Kilogram Fentanyl

- Costs approximately \$3500-\$4200

1,000,000
1mg doses

- Sold for \$10/pill
- \$10 Million Profit

666,666
1.5 mg doses

- Sold for \$10/pill
- \$6.6 Million Profit

Counterfeit Pills Containing Methamphetamine

DEA Seizure





Questions sent to DEA

????????????????

Executive Order 13891

November 1, 2019



- Requires DEA to obtain permission from the Department of Justice (DOJ) and the Office of Management and Budget (OMB) prior to publishing any public guidance document
- Prior to this Executive Order (EO) DEA could publish guidance documents on their own
- DOJ put this into rules, so even though EO rescinded, process still in effect for DEA

What is the Guidance process?



- Question comes into policy section
- Response sent to regulatory drafting and policy support section
- Sent to DEA's Chief Counsel
- If deemed guidance, sent to OLP and OMB
- Once approved, posted as guidance on DOJ and DEA Diversion websites

<https://www.deaiversion.usdoj.gov/Resources.html>

Significant guidance documents

Drug Enforcement Administration

www.DEADiversion.usdoj.gov



Guidance Document Portal *

Executive Order 13891 requires agencies to put their guidance documents on easily searchable websites so individuals are able to access them, and Department of Justice policy prohibits using guidance as a substitute for regulation. Guidance may not be used to impose new requirements on persons outside the Executive Branch except as expressly authorized by law or expressly incorporated into a contract, grant, or cooperative agreement. See JM 1-19.000.

* Just beginning of the portal page...

What is the Q&A process?



- Question comes into policy section, deemed to be Q&A
- Routine question converted to Q&A based on frequency asked
- Response sent to regulatory drafting and policy support section
- Sent to attorney section
- Once approved, posted as guidance on Diversion website

<https://www.deaiversion.usdoj.gov/Resources.html>

Questions & Answers

Drug Enforcement Administration

www.DEADiversion.usdoj.gov



Questions & Answers*

Administering and Dispensing

Question: Can a physician transport controlled substances and administer at the patient's home residence (the so-called "black bag exception")?

Answer: Yes, with a limit. DEA will permit a physician who is registered with DEA to dispense controlled substances at a particular location in a state to travel to other unregistered locations in the *same state* to dispense controlled substances on an "as-needed and random basis," so long as the physician does not maintain a principal place of professional practice at any of those unregistered locations. See *Jeffery J. Becker, D.D.S.*, 77 FR 72387, 72388 (Dec. 05, 2012); see also [21 U.S.C. 822\(e\)\(1\)](#), [21 CFR 1301.12\(b\)\(3\)](#). If a physician intends to dispense controlled substances from a particular location several times a week or month, he must first file a separate registration for the location. See *Moore Clinical Trials, L.L.C.*, 79 FR 40145-02, 40155 (July 11, 2014) citing *United States v. Clinical Leasing Serv., Inc.*, 930 F.2d 394, 395 (5th Cir. 1991). Registrants should keep themselves apprised of state and local laws otherwise consistent with DEA regulations regarding the dispensing of controlled substances in a patient's home residence. **EO-DEA212, DEA-DC-047, October 8, 2020**

*1st question in Q&A



DEA Regulations

Regulations in Progress



Reginfo.gov

(Office of Information and Regulatory Affairs
Office of Management and Budget)

Agency Rule List – Spring 2021 (Published fall and spring)

Agency, Agenda Stage of Rulemaking, Title

Effective July 28, 2021



Narcotic Treatment Programs with Mobile Components

Summary



Narcotic Treatment Programs (NTPs) are permitted to operate mobile components as a coincident activity under the program's current DEA registration – a separate registration not needed

Getting Started



Narcotic Treatment Programs (NTPs) must:

Notify the local DEA office of its intent to do so, in writing

Visit from Diversion Investigators from local office

Receive written approval from the local DEA office prior to operating a mobile component

Vehicles



Must be “vehicle propelled under its own motive power and lawfully used on public streets, roads, or highways with more than three wheels in contact with the ground. This term **does not** include a trailer”

Vehicles



Must have valid county/city and state information (e.g., VIN, registration, etc.) on file at the NTP's registered location

Security



Must have an installed safe – less than 750 pounds, bolted to floor or wall

Must have an alarm system that alerts a security company, 24-hour control station operated by the registrant, or local or state law enforcement when there is an unauthorized entry attempt

Security



Safe must provide the same protection as required for safes at the registered NTP

Security



The storage area for controlled substances must not be accessible from outside the vehicle and only accessible to minimum number of authorized employees

Adequate observation must be provided when maintenance personnel, business guests, or visitors pass through storage area

Security



Personnel must maintain control over all controlled substances when transferring them between the registered location and the vehicle, while en route, and while dispensing

Patients must be required to wait in an area that is physically separated from the controlled substances storage and dispensing areas
- If can't separate, patients must wait outside

Security



Mobile component must be returned to the registered location at end of day and all controlled substances must be removed from the vehicle and secured within the NTP

Parked at the registered location or at secure, fenced-in area (after DEA office has been notified of fenced-in area)

Exception

Mobile components are required to return to the registered location at the end of each day...

21 CFR 1301.72(e)(2) provides NTPs may apply for an exception pursuant to 21 CFR 1307.03, which allows for any person to apply for an exception to any provision of DEA regulations



Exception

Exceptions will be reviewed on a case-by-case basis, and must be approved by the Assistant Administrator of the Diversion Control Division

Applicant needs to demonstrate exceptional circumstances that warrant an exception to the daily return requirement

If granted, the NTP will be required to enter into a MOU with DEA





DEA Initiative

Opioid Rapid Response Program



DEA has joined this federal effort to reduce opioid overdose deaths

Program is coordinated by:

- The Office of the Assistant Secretary for Health (OASH)
- US Centers for Disease Control and Prevention (CDC)
- The Office of the Inspector General within the US Department of Health and Human Services (HHS OIG)

Opioid Rapid Response Program

ORRP supports all 50 US states and the District of Columbia

Why: Sometimes federal law enforcement actions result in sudden loss of a provider's ability to prescribe or dispense controlled substances, including opioids or medication assisted treatment/medication



Opioid Rapid Response Program



ORRP leverages relationships across federal, state, and local agencies

ORRP facilitates timely communication, care coordination, risk reduction, and other overdose prevention interventions

Works closely with law enforcement to ensure sensitive information remains confidential and the integrity of an investigation is not compromised

Opioid Rapid Response Program



Importance of PDMP information and reporting



DEA Resources

[DEADIVERSION.USDOJ.GOV](https://deadiversion.usdoj.gov)

Drug Enforcement Administration

www.DEADiversion.usdoj.gov

A screenshot of the DEA Diversion Control Division website. The header includes the U.S. Department of Justice logo and the text "U.S. DEPARTMENT OF JUSTICE ★ DRUG ENFORCEMENT ADMINISTRATION" and "DIVERSION CONTROL DIVISION". A search bar is on the right. A red banner in the center contains the text:

[COVID-19 Information Page](#)
[Civil Unrest/Looting Registration Guidance](#)
[Registration Fee Increase](#)

 Below the banner is a navigation menu with tabs for HOME, REGISTRATION, REPORTING, RESOURCES, and ABOUT US. The REGISTRATION tab is active. On the left, under "Registration Support", there is a list of links: "Call: 1-800-882-9539 (8:30 am-5:50 pm ET)", "Email: DEA.Registration.Help@usdoj.gov", "Contact Local Registration Specialist", "Renewal Applications", "New Applications", "Check the Status of My Application", "Registrant Validation Toolset", "Request Copy of DEA Certificate", "Request Copy of Last Application/Receipt", "Make Changes to My DEA Registration", "Order Form Request (DEA Form 222)", "Registration for Disposal of Controlled Substances", and "Search for Year Round Pharmaceutical Disposal Locations". On the right, there is a featured article titled "DEA Supports the Use of Medication Assisted Treatment (MAT) for Opioid Use Disorder" with a background image of a pill bottle labeled "OXYCODON 5/325 TAB M" and "TAKE 1 TABLET BY MOUTH EVERY 4 HOURS AS NEEDED".

DEA Diversion Resources

www.DEADiversion.usdoj.gov



What's New

Get Email Updates:

Final Rule: Placement of cyclopentyl fentanyl, isobutyryl fentanyl, para-chloroisobutyryl fentanyl, para-methoxybutyryl fentanyl, and valeryl fentanyl in Schedule I (November 25, 2020)

Johnson Matthey Pharmaceutical Materials Inc. (November 23, 2020)

Lewis Leavitt III, M.D.; Decision and Order (November 19, 2020)

Suntree Pharmacy and Suntree Medical Equipment, LLC; Decision and Order (PDF) (November 19, 2020)

ECO Apothecary, LLC; Decision and Order (November 19, 2020)

Monica Ferguson, F.N.P., R.N.; Decision and Order (November 19, 2020)

Jeffrey M. Wolk, M.D.; Decision and Order (November 19, 2020)

Julie I. Dee, M.D.; Decision and Order (November 19, 2020)

Verne A. Schwager, M.D.; Decision and Order (November 19, 2020)

In The News

Pharmacy Pays \$250,000 to Resolve Controlled Substances Act Violations (November 17, 2020)

Valley Stream man arrested for allegedly using doctor's prescription pad to acquire thousands of opioid pills (November 13, 2020)

Burke County men indicted for operation of illegal pill factory (November 09, 2020)

DEA and partners collect a record amount of unwanted medications during National Prescription Drug Take Back Day (October 30, 2020)



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)
- TLR (Theft/Loss Reporting Online)
- Theft/Loss Reports for 2014-2018
- Find Your Local Diversion Field Office
- Mailing Addresses for Topics Related to Title 21 CFR
- Medical Missions
- Submit a Tip to DEA



DETA
DIVERSION

Questions?

Thank You

Website: DEADiversion.usdoj.gov

Email: ODLP@usdoj.gov