



What's New From the DEA Diversion Control Division

Wednesday, April 14, 2021

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Handouts for today's presentations can be found at:

www.nabp.pharmacy/webinar

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What's New From the DEA Diversion Control Division

DIVERSION CONTROL DIVISION

LIAISON SECTION CHIEF CLAIRE BRENNAN

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Learning Objectives



At the conclusion of this webinar, participants will be able to:


1. Discuss the Opioid Crisis today
2. Identify some drugs of abuse and drug combinations
3. Name who needs to report suspicious orders
4. Locate DEA regulations and other DEA resources

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The Opioid Crisis Today

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Public Health Epidemic

- ☐ In 2014, there were 47,055 drug overdose deaths
- ☐ In 2015, there were 52,404 drug overdose deaths
- ☐ In 2016, there were 63,632 drug overdose deaths
- ☐ In 2017, there were 70,237 drug overdose deaths
- ☐ In 2018, there were 67,367 drug overdose deaths (first recorded decline)

Source: CDC

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CDC Drug Overdose Data 2018




- 4.1 % drop in drug overdose deaths
2017: 70,237
2018: 67,367
- 13.5% decline in prescription opioid deaths
2017: 14,495
2018: 12,552
- 10 % increase in deaths involving synthetic opioids (Fentanyl, etc)
- Opioids involved in 46,802 deaths (69.5% of drug overdoses)
- Prescription opioids involved in 32% of all opioid deaths
- Two out of three (67%) opioid-involved overdose deaths involve synthetic opioids

Source: CDC

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The Opioid Crisis Today

CDC Preliminary 2019 Data



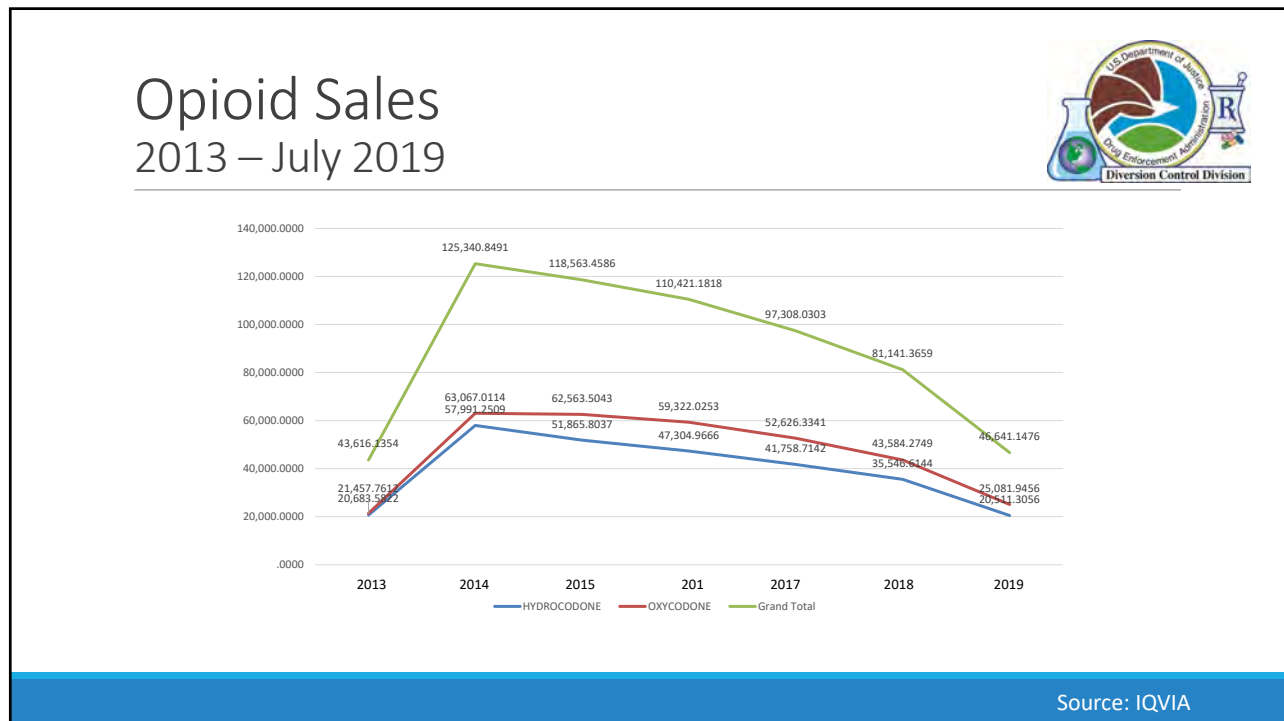
- 5% increase in drug overdose deaths
2018: 67,367
2019: 71,999
- 63,483 (79%) of drug overdose deaths attributed to opioids
↑ from 69% in 2018
- 37,137 (51%) deaths linked to synthetic opioids
↑ from 69% in 2018
- 12,068 (17%) deaths involved prescription opioids

Source: CDC

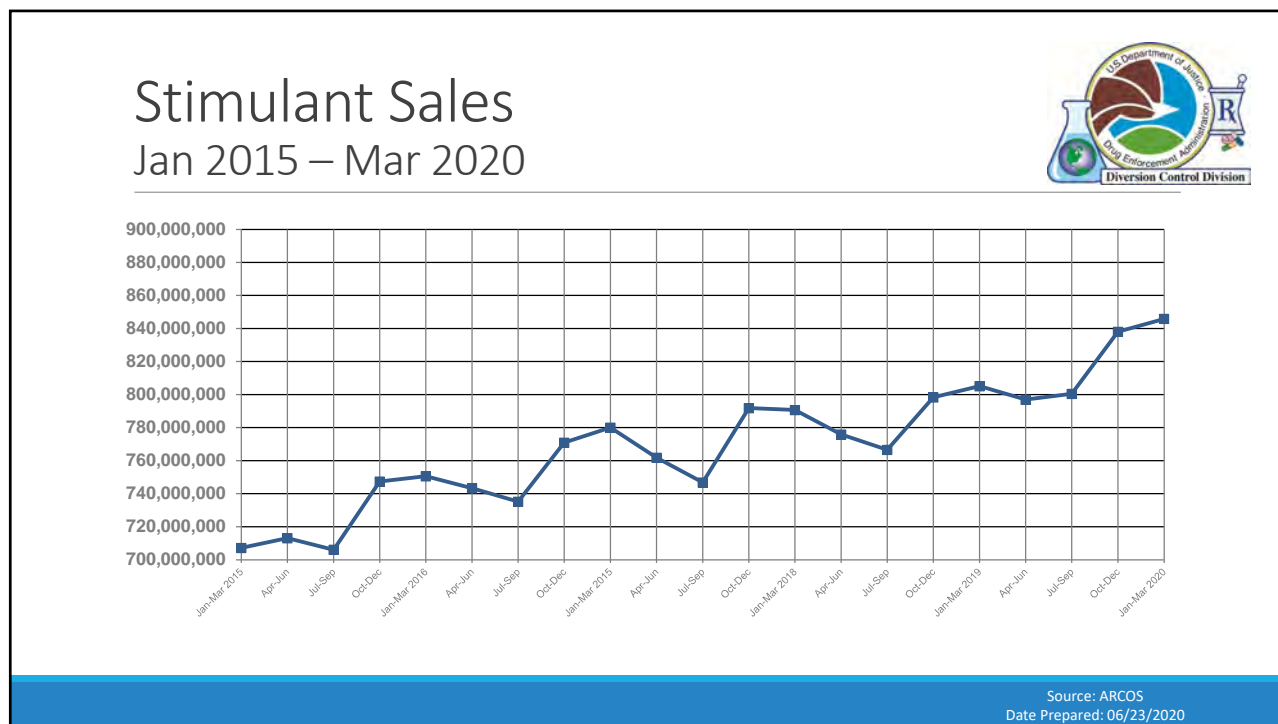
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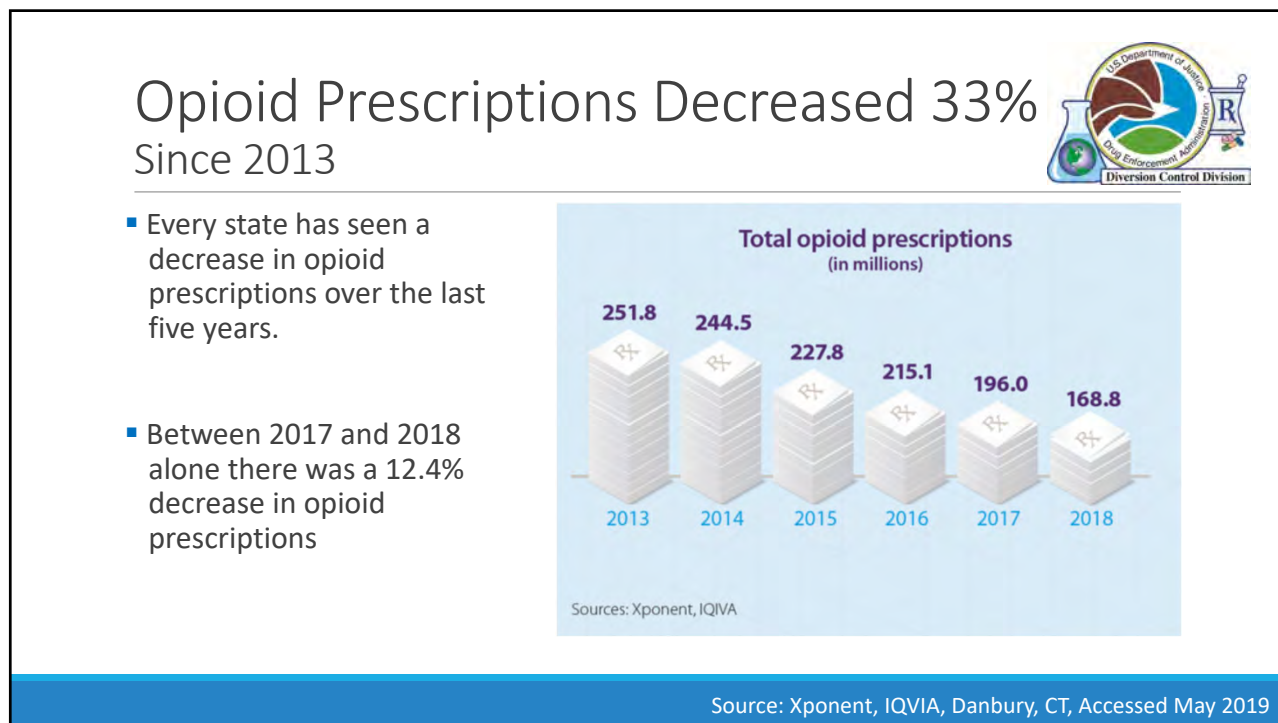
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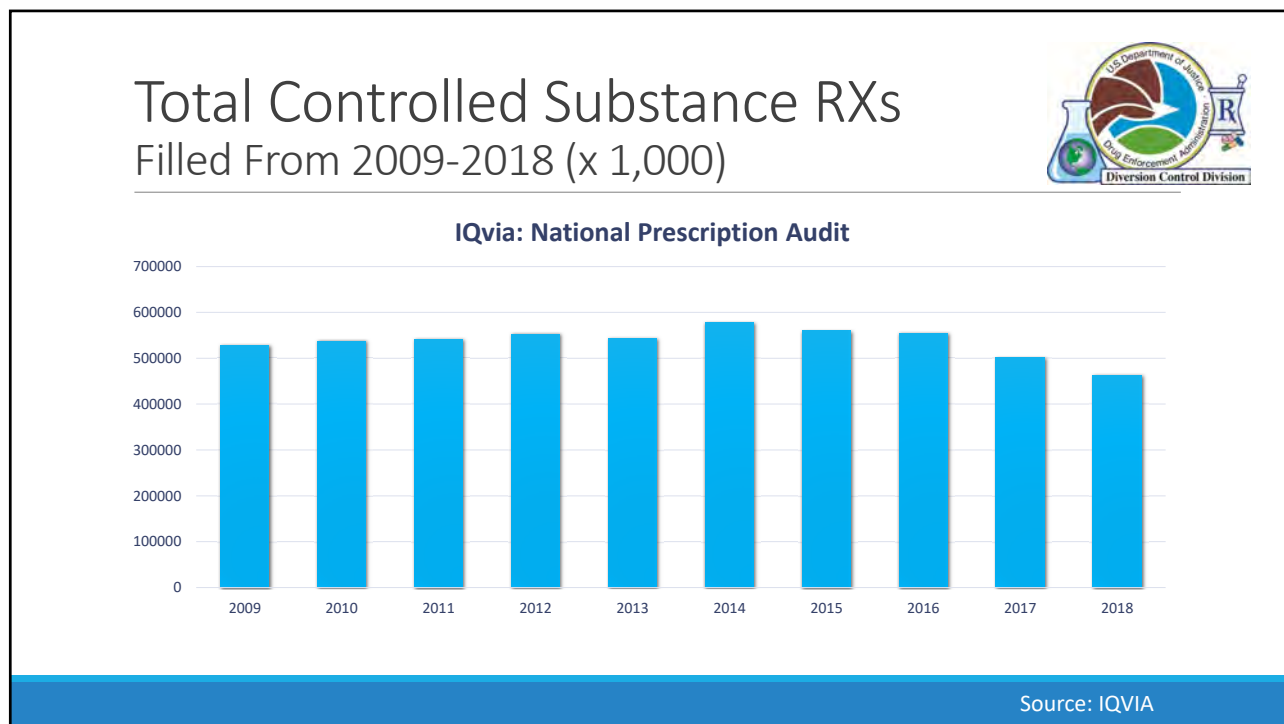
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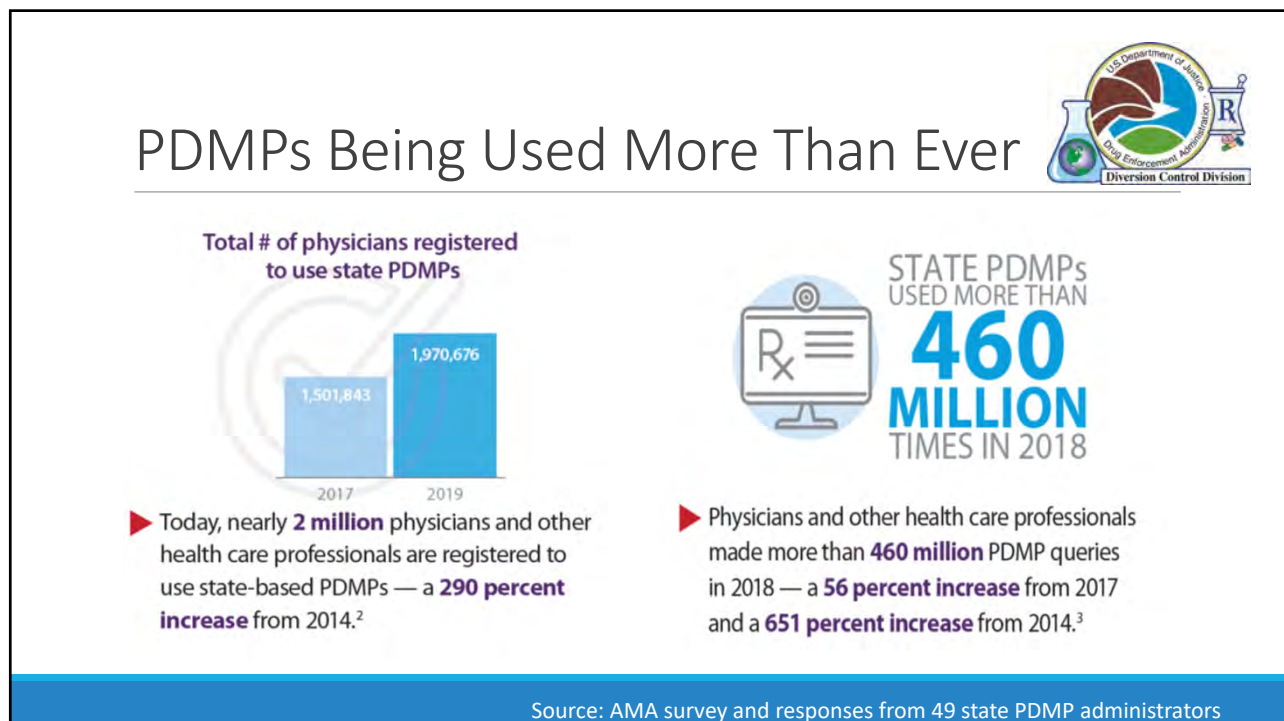
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The Opioid Crisis Today

CDC Provisional Data for 2020



Over 81,000 drug overdose deaths in the 12 months ending in May 2020 – highest number ever recorded in a 12-month period

While overdose deaths were already increasing in the months preceding COVID-19, the latest numbers suggest an acceleration of overdose deaths during the pandemic



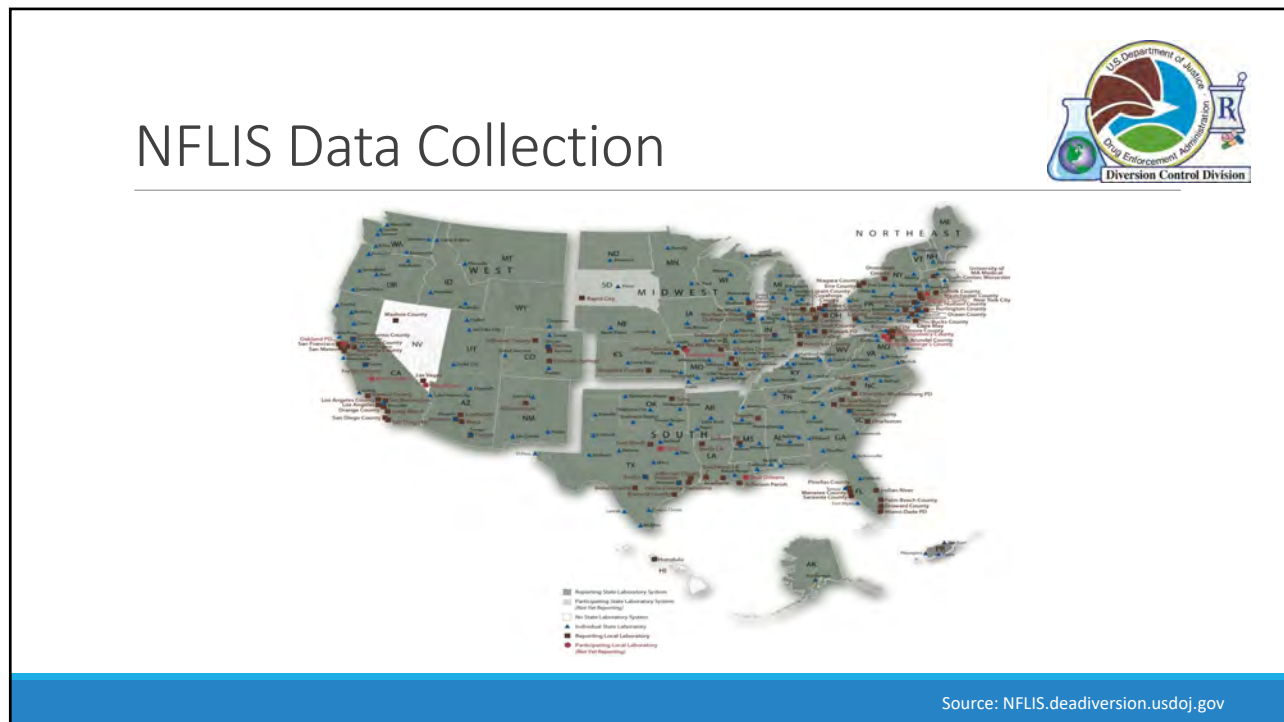
Source: CDC

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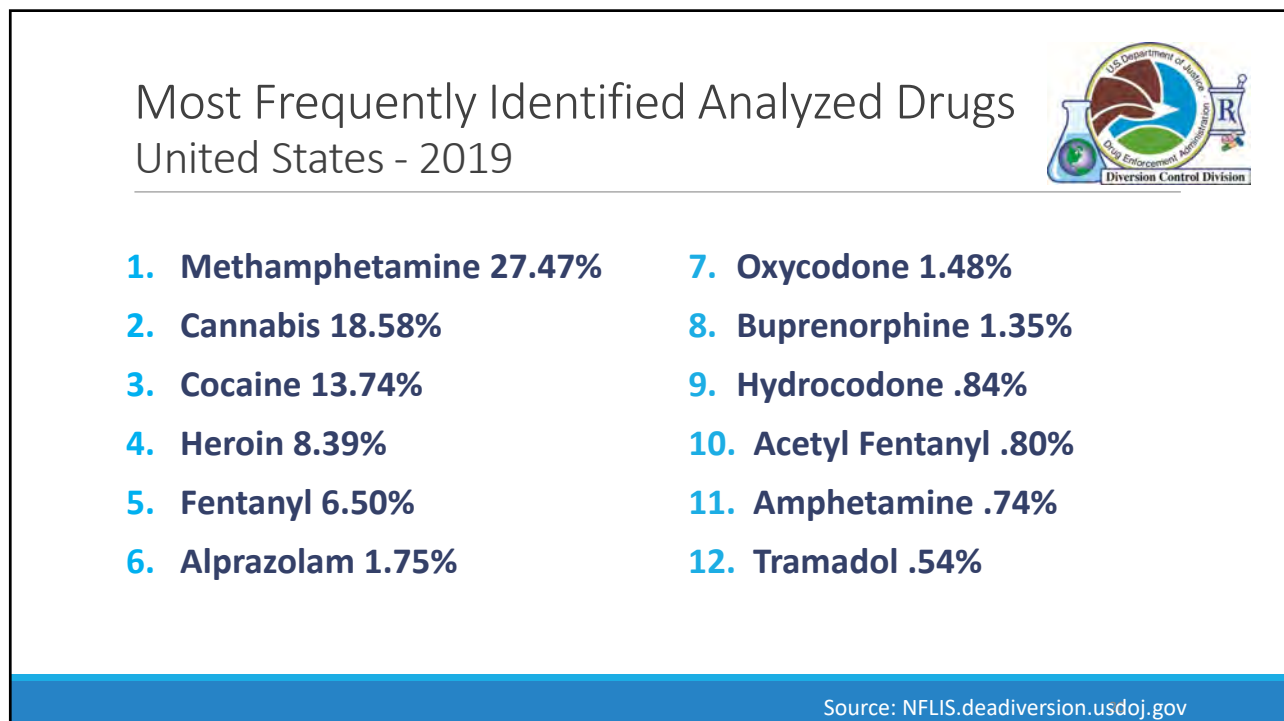
Drugs of Abuse




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Drug Combinations

Street Name	Drug Combinations	Effects
Holy Trinity	Opioid, Benzodiazepine, Carisoprodol	Heroin-like, Euphoric high
Stimulant Trinity	Opioid, Benzodiazepine, Stimulant	Heroin-like, Euphoric high
Gaba Trinity	Opioid, Benzodiazepine, Gabapentin	Euphoric high
Zolpidem Trinity	Opioid, Benzodiazepine, Zolpidem	Downer, Depressant
Speedball	Opioid and Stimulant	Combination of Heroin & Cocaine *more intense/long lasting high

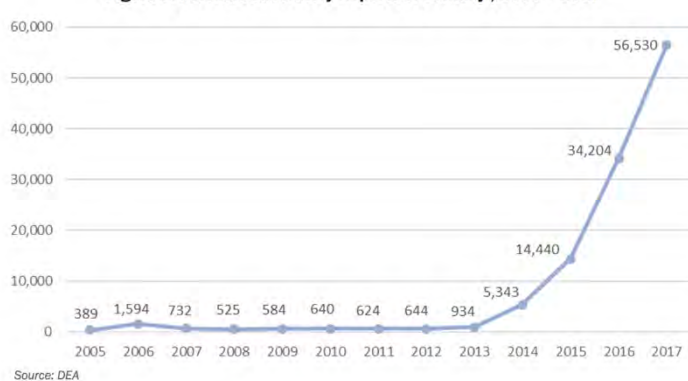
Source: DEA Targeting and Special Project Unit (DOIT)

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Threat of Illicit Fentanyl

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



Year	Reports
2005	389
2006	1,594
2007	732
2008	525
2009	584
2010	640
2011	624
2012	644
2013	934
2014	5,343
2015	14,440
2016	34,204
2017	56,530

Source: DEA

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Counterfeit Pills Containing Fentanyl DEA Seizures



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Why Counterfeit Pills? Profit Margin



One Kilogram
Fentanyl

- Costs approximately \$3,500-\$4,200

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

Source: DEA

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Counterfeit Pills Containing Methamphetamine

DEA Seizure



Source: DEA

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Counterfeit Pills Containing Methamphetamine

DEA Seizure



- 5000 pills seized with marking 3/0 on one side and 974 on the other side
- Sold for \$7-8 per pill

Source: DEA

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Xylazine Non-Controlled Substance



- Non-opioid, prescription veterinary sedative and muscle relaxant (not all-inclusive use by veterinarians)
- Not intended for human consumption
- [LiveScience.com](https://www.livescience.com) study in Philadelphia found Xylazine involved in nearly 1/3 (31%) of fatal opioid drug overdoses in 2019*
- Often found mixed with heroin or fentanyl
- Between 2010 and 2015, Xylazine was only detected in 2% of deaths

* Data from Philadelphia Medical Examiner's Office

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Xylazine Non-Controlled Substance



- Often found as an adulterant in illicit substances
- NFLIS received 816 reports of xylazine from items submitted to participating laboratories in 2020
- 84% contained at least one other identified drug
- Fentanyl was present in 96% of items containing xylazine and at least one other drug

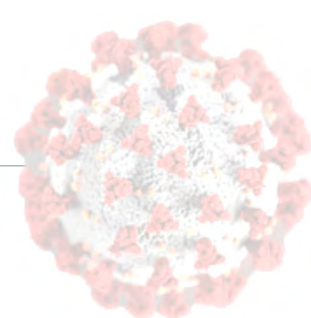
Source: NFLIS [DEADiversion.usdoj.gov](https://deadiversion.usdoj.gov)

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Responding to the Opioid Epidemic



DURING A GLOBAL PANDEMIC



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Executive Order 13891

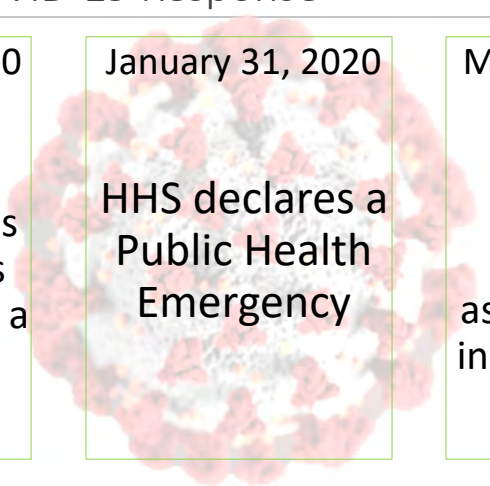

November 1, 2019



- 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, DEA could publish guidance documents on its own.

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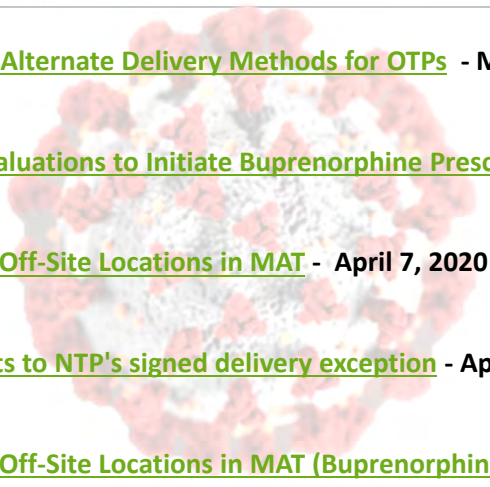

Drug Enforcement Administration Timeline of COVID-19 Response



January 27, 2020 Secretary of Health and Human Services (HHS) declares the coronavirus a public health threat	January 31, 2020 HHS declares a Public Health Emergency	March 15 – April 20 DEA issues 24 emergency guidance documents to assist practitioners in the treatment of patients
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Medication-Assisted Treatment Guidance During COVID 19



- [Exemption Allowing Alternate Delivery Methods for OTPs](#) - March 16, 2020
- [Use of Telephone Evaluations to Initiate Buprenorphine Prescribing](#) - March 31, 2020
- [Use of Unregistered Off-Site Locations in MAT](#) - April 7, 2020
- [Distributor shipments to NTP's signed delivery exception](#) - April 11, 2020
- [Use of Unregistered Off-Site Locations in MAT \(Buprenorphine\)](#) - April 28, 2020

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Drug Enforcement Administration Guidance During COVID-19



- Suspicious Orders & Due Diligence
- Prescriptions
- Registration
- Quota
- National Drug Supply
- Electronic Prescribing of Controlled Substances
- Telemedicine
- Records and Reports


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Reporting Requirement



Attention, this is **required**

Suspicious Orders Reporting



Source: SUPPORT Act & DEA

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Reporting Requirement



The Substance Use-Disorder Prevention that Promotes Opioid Recovery and Treatment for Patients and Communities (SUPPORT) Act (Public Law 115-271 – Oct. 24, 2018)

- Requires that **ALL** DEA registrants that **distribute** controlled substances report suspicious orders to DEA

Source: SUPPORT Act & DEA

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Reporting Requirement



October 23, 2019, DEA launched the Suspicious Orders Report System (SORS)

- To be used by DEA registrants who distribute controlled substances to other DEA registrants
- Reporting a suspicious order to the centralized database constitutes compliance with the reporting requirement under 21 USC 832(a)(3)

Source: SUPPORT Act & DEA

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Reporting Requirement



The SUPPORT Act states the term “suspicious order” may include, but is not limited to: an order of a controlled substance of unusual size; an order of a controlled substance deviating substantially from a normal pattern; and an order of controlled substances of unusual frequency as per 21 USC 802(57) and 21 CFR 1301.74(b)

Source: SUPPORT Act & DEA

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Reporting Requirement



Pharmacies need to register on the website in order to report to SORS:

1. Go to [ARCOS Online Reporting System](#) and click on "**SORS Registration (for Non-ARCOS Reporters)**" hyperlink.
2. After completing the initial registration, a confirmation e-mail will be sent to the e-mail address provided.
3. Once DEA approves the registration, another e-mail will be sent with a temporary password.
4. Go to [ARCOS Online Reporting System](#) and type in your username and the temporary password. The system will require you to change the temporary password.
5. Upon successfully changing the password, the account will be fully registered to report to the SORS Online system.

Source: DEA

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Reporting Requirement



The SUPPORT Act requires reporting the suspicious order to both the local DEA field office as well as the DEA Administrator.

HOWEVER, if a DEA registrant files through the DEA electronic SORS portal, that comports with the reporting component as stated above.

Source: DEA

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Scam Alert



Source: DEA

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Scam Alert



- Phone call came into the pharmacy. Caller identified himself as being with the board. Told the pharmacist that this was a “sensitive or confidential” matter, and they needed to go somewhere private and call back on cell phone. Gave a phone number.
- Stated that illegal prescriptions with the pharmacist license (NPI) were found in an abandoned car. 45.6g of CII, 1,500 units of CIII, and 500 units of CIV. 16 accounts have been used to wire over 5.4 million/2.3 million, and all have been seized. 15 days ago, received complaint from FBI.
- They knew his/her license number and other personnel data (so much is online now).

Source: DEA

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Scam Alert



- Stated that “Federal parties say to suspend license”– he/she cannot practice until receive permission from Board by mail.
- Set up a conference call with “FBI Agent”; was told the case had been forwarded to DOJ and the “protocol of privacy act” must be followed thoroughly.
- During conference call, the “Agents” claim to have the appropriate documents and will forward him/her the DOJ papers to read. Will fax the documents to a UPS store (because it is a privacy issue, they don’t want to send it to the pharmacy).

Source: DEA

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Scam Alert



- Another conference call is set up with “Board and FBI”; they tell pharmacist that they need to give DOJ assurance that the privacy act will be followed.
- This is done by a “global transfer” to the US Ambassador. Due to COVID, it all has to remain distant, and due to the “privacy act,” it has to go through an international bank.
- This was an international wire transfer of \$9,500 from the pharmacist’s bank to a bank in Poland.
- There were numerous phone calls/texts and threats made against the pharmacist.

Source: DEA

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Scam Alert



- When the pharmacist did begin to question, he/she was threatened not only with job but with taking other assets (they had the pharmacist’s home address).

Important note

Licensures, addresses, children’s names, colleges they attend – these can be found on social media and professional and government websites. (These scam artists took the time to dig out the information on the pharmacist). Names of federal and state officials also available.

Source: DEA

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Scam Alert



What to do –

DEA Imposter? [ReportFraud.ftc.gov](https://www.ftc.gov/identity-theft/identity-theft-fraud-report)

Internet Crime Complaint? [ic3.gov](https://www.ic3.gov)

Can always call local DEA Diversion Group

Source: DEA

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DEA Resources

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

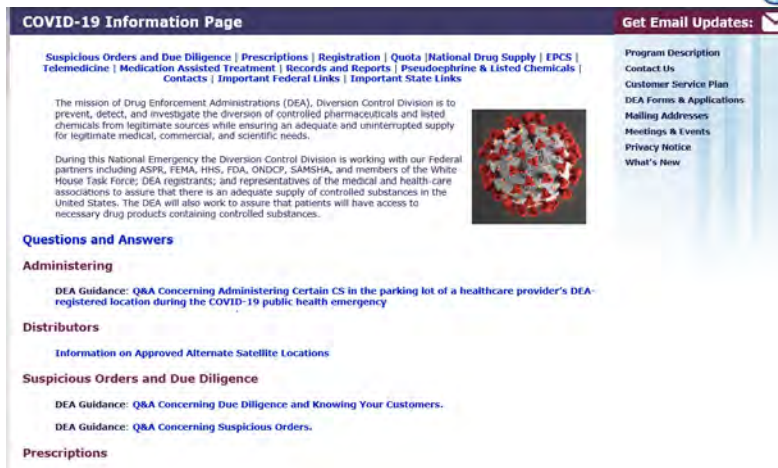
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Drug Enforcement Administration www.DEADiversion.usdoj.gov



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What's New

Final Rule: Placement of cyclopentyl fentanyl, isobutyl fentanyl, para-chloroisobutyl fentanyl, para-methoxybutyl fentanyl, and valeryl fentanyl in Schedule I (November 25, 2020)
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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)

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Questions & Answers



Meetings & Events



Quick Links

- ARCOS (Automation of Reports & Consolidated Orders System)
- Cases Against Doctors
- Chemical Control Program
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- CSOS (Controlled Substances Ordering System)
- EPCS (Electronic Prescriptions for Controlled Substances)
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EMERGENCY DISASTER RELIEF



Search for Year Round Pharmaceutical Disposal Locations



DEA NATIONAL TAKEBACK

National Prescription Drug Take Back Day




Report Illicit Pharmaceutical Activities RX ABUSE ONLINE

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- Drug and Chemical Information
- E-commerce Initiatives
- Federal Agencies & Related Links
- Federal Register Notices



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Code of Federal Regulations Reports Required by 21 CFR




Reports Required by 21 CFR

- Registrant Record of Controlled Substances Destroyed - DEA Form 41**
 - Destruction of Controlled Substances
- Chemical Import/Export Declarations**
 - DEA Form 486
 - DEA Form 486a
- Import/Export Permit Applications and Declarations**
 - DEA Form 161 - Application for Permit to Export Controlled Substances
 - DEA Form 161R - Application for Permit to Export Controlled Substances for Subsequent Reexport
 - DEA Form 236 - Controlled Substances Import/Export Declaration
 - DEA Form 357 - Application for Permit to Import Controlled Substances for Domestic and/or Scientific Purposes
 - DEA Form 453 - Notification of Domestic Transactions Involving Listed Chemicals (Coming Soon)
- Quota Applications**
 - DEA Form 189 - Application for Individual Manufacturing Quota for a Basic Class of Controlled Substance
 - DEA Form 250 - Application for Procurement Quota for Controlled Substance
 - DEA Form 488 - Application for Import Quota for Ephedrine, Pseudoephedrine, Phenylpropanolamine
- Reports for Regulated Machines - DEA Form 452**
 - DEA Form 452 - Import, Export, or Domestic Transactions of Tisbiting and Encapsulating Machines
- Theft/Loss Reporting**
 - DEA Form 106 - Report of Theft or Loss of Controlled Substances
 - DEA Form 107 - Report of Theft or Loss of Listed Chemicals
 - Theft/Loss Reports for 2014-2018

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NFLIS

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Questions & Answers

Significant Guidance Documents

Synthetic Drugs

Title 21 Code of Federal Regulations

Title 21 USC Codified CSA

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Code of Federal Regulations Part 1300 – END

Title 21 Code of Federal Regulations, PART 1300-END

This online version is updated according to the Electronic Code of Federal Regulations (e-CFR)

PART 1300 - DEFINITIONS

PART 1301 - REGISTRATION OF MANUFACTURERS, DISTRIBUTORS, AND DISPENSERS OF CONTROLLED SUBSTANCES

PART 1302 - LABELING AND PACKAGING REQUIREMENTS FOR CONTROLLED SUBSTANCES

PART 1303 - QUOTAS

PART 1304 - RECORDS AND REPORTS OF REGISTRANTS

PART 1305 - ORDER FORMS

PART 1306 - PRESCRIPTIONS

PART 1307 - MISCELLANEOUS

PART 1308 - SCHEDULES OF CONTROLLED SUBSTANCES

PART 1309 - REGISTRATION OF MANUFACTURERS, DISTRIBUTORS, IMPORTERS AND EXPORTERS OF LIST I CHEMICALS

PART 1310 - RECORDS AND REPORTS OF LISTED CHEMICALS AND CERTAIN MACHINES; IMPORTATION AND EXPORTATION OF CERTAIN MACHINES

PART 1311 - REQUIREMENTS FOR ELECTRONIC ORDERS AND PRESCRIPTIONS

PART 1312 - IMPORTATION AND EXPORTATION OF CONTROLLED SUBSTANCES

PART 1313 - IMPORTATION AND EXPORTATION OF PRECURSORS AND ESSENTIAL CHEMICALS


PART 1314 - RETAIL SALE OF SCHEDULED LISTED CHEMICAL PRODUCTS

PART 1315 - IMPORTATION AND PRODUCTION QUOTAS FOR EPHEDRINE, PSEUDOEPHEDRINE, AND PHENYLPROPRANOLAMINE

PART 1316 - ADMINISTRATIVE FUNCTIONS, PRACTICES, AND PROCEDURES

PART 1317 - DISPOSAL

PART 1321 - DEA MAILING ADDRESSES

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DEA NATIONAL TAKEBACK

National Prescription Drug Take Back Day

Report Illicit Pharmaceutical Activities

RX ABUSE ONLINE



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National Prescription Drug Drop Box Locations





U.S. DEPARTMENT OF JUSTICE ★ DRUG ENFORCEMENT ADMINISTRATION

DIVERSION CONTROL DIVISION

Controlled Substance Public Disposal Locations - Search Utility

Zip Code:

22202

City:

State:

Select State

Search Radius:

5 miles

10 miles

20 miles

50 miles

Search



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National Prescription Drug Drop Box Locations



U.S. DEPARTMENT OF JUSTICE ★ DRUG ENFORCEMENT ADMINISTRATION						
DIVERSION CONTROL DIVISION						
Controlled Substance Public Disposal Locations - Search Utility						
Public Controlled Substance Disposal Locations:						
Bus Name	Addr. 1	Addr. 2	City, State Zip	Dist.	Map	
NEIGHBORHOOD PHARMACY OF DEL RAY	2204 MT. VERNON AVE		ALEXANDRIA, VA 22301	2 miles	Map	
Kaiser Permanente NW DC-Pharmacy	2301 M STREET NW	SUITE 200	WASHINGTON, DC 20037	4 miles	Map	
WALGREEN CO	1217 22ND ST. NW		WASHINGTON, DC 20037	4 miles	Map	
DISTRICT OF COLUMBIA CVS PHARMACY, L.L.C.	6-7 DUPONT CIRCLE NW		WASHINGTON, DC 20036	4 miles	Map	
WALGREEN CO.	1155 F STREET NW		WASHINGTON, DC 20004	4 miles	Map	
WALGREEN CO.	801 7TH ST NW		WASHINGTON, DC 20001	4 miles	Map	
MEDSTAR PHARMACY STORE #10	MEDSTAR PHARMACY AT GEORGETOWN UNIV HOSPITAL	3800 RESERVOIR RD NW PASQUERILLA	WASHINGTON, DC 20007	5 miles	Map	
USN BRANCH HEALTH CLINIC, WASHINGTON NAVY YARD	915 N ST SE		WASHINGTON, DC 20374	4 miles	Map	
SKYLINE PHARMACY & CLINIC	5100 LEESBURG PIKE	STE 101	ALEXANDRIA, VA 22302	5 miles	Map	
VIRGINIA CVS PHARMACY, L.L.C.	3133 LEE HIGHWAY		ARLINGTON, VA 22201	4 miles	Map	
Kaiser Permanente CAPITOL HILL PHARMACY		700 2ND STREET NE SUITE L18	WASHINGTON, DC 20002	5 miles	Map	
INOVA ALEXANDRIA HOSPITAL	C/O PHARMACY	4320 SEMINARY RD	ALEXANDRIA, VA 22304	5 miles	Map	
VIRGINIA HOSPITAL CENTER OUTPATIENT PHARMACY	1701 NORTH GEORGE MASON DRIVE		ARLINGTON, VA 22205	6 miles	Map	
WALGREEN CO.	111 MICHIGAN AVE NW STE 1107		WASHINGTON, DC 20010	7 miles	Map	

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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.M.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)

DEA Forms & Applications

Publications & Manuals

Questions & Answers

Meetings & Events

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



**EMERGENCY
DISASTER
RELIEF**



Search for Year Round Pharmaceutical Disposal Locations




**DEA NATIONAL
TAKEBACK**
National Prescription Drug Take Back Day




Report Illicit Pharmaceutical Activities
**RX ABUSE
ONLINE**

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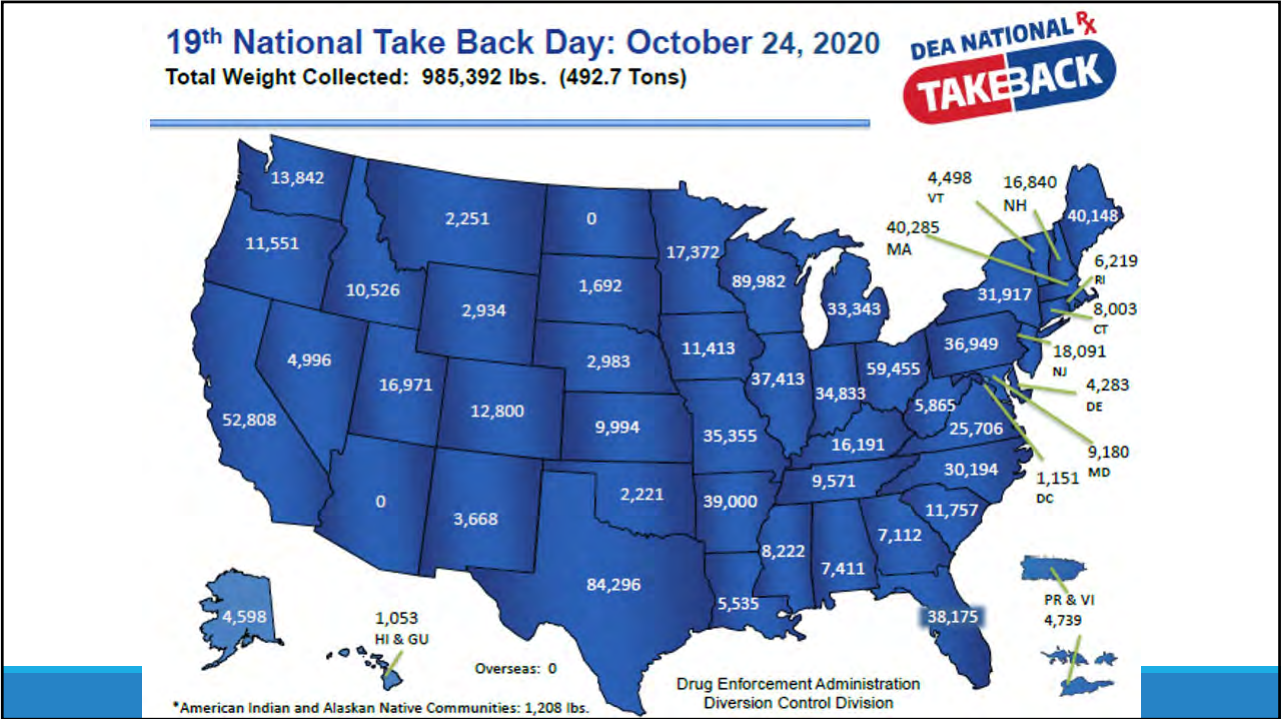
National Prescription Drug Take Back Day



- ☐ Free, anonymous way to safely dispose of unused, unwanted and expired prescription medications
- ☐ Began in 2010
- ☐ 19 successful National Prescription Take Back Days
- ☐ Held twice a year – typically on the last Saturday in April and October



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Secure Your Meds Campaign

Securely store your meds
until it's time to take back

**FIND
RESOURCES**

TakeBackDay.DEA.gov

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Post Test Question #1

True or False:

Buprenorphine and methylphenidate are two of the Top 5 drugs Sold Nationwide (January 2019-June 2020).

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Post Test Question #1

True

Buprenorphine and methylphenidate are two of the Top 5 drugs Sold Nationwide (January 2019-June 2020)

62

Post Test Question #2

True or False:

Gaba Trinity is the street name for one of the trinity combinations of drugs.

63

Post Test Question #2

True

Gaba Trinity is the street name for one of the trinity combinations of drugs.

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Post Test Question #3

True or False:

Every pharmacy has to report to the Suspicious Orders Report System.

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Post Test Question #3

False

Only a pharmacy that *distributes* to another DEA registrant has to report to the Suspicious Orders Report System.

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Thank You

Website: DEADiversion.usdoj.gov

Email: ODLP@usdoj.gov

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Q&A

Please use the chat tool on your screen to submit questions to the presenter.

Please change the "To" field in the chat box to "All panelists and attendees" so that everyone can see your question or comment.

Our host will read the questions out loud in the order they are received.

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Submit Your CPE Claim

1. Claim your CPE credit by signing in to NABP's submission site:
<https://nabp.pharmacy/claimcpe> (case-sensitive)
2. Select the webinar from the Live Meetings and Conferences section
3. Enter the session code provided at the end of the webinar
4. Complete the course and speaker evaluations
5. Select the appropriate credit (pharmacist or pharmacy technician)
6. Enter your NABP e-Profile ID and date of birth and certify that the information is correct
7. Click the claim button

Claims must be submitted by noon on June 13, 2021



NABP® and NABP Foundation® are accredited by the Accreditation Council for Pharmacy Accreditation (ACPE) as providers of continuing pharmacy education (CPE). ACPE provider number: 0205.

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ACPE Universal Activity Numbers and CPE Information

1 contact hour (0.1 CEU)
0205-0000-21-023-L03-P
0205-0000-21-023-L03-T

Claims must be submitted by noon on June 13, 2021

<https://nabp.pharmacy/claimcpe>



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Questions about submitting your claim? Please contact Prof-Affairs@nabp.pharmacy.

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