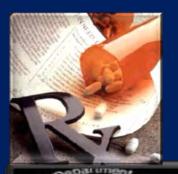


The Opioid Epidemic and the Practice of Medicine



Practitioner Diversion Awareness Conference Dover, Delaware June 3-4, 2019



James Arnold
Chief of Liaison
Diversion Control Division

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The following presentation was accompanied by an oral presentation on June 3-4, 2019, and does not purport to establish legal standards that are not contained in statutes, regulations, or other competent law. Statements contained in this presentation that are not embodied in the law are not binding on DEA. Summaries of statutory and regulatory provisions that are summarized in this presentation do not purport to state the full extent of the statutory and regulatory requirements of the cited statutes and regulations. I have no financial relationships to disclose.

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Objectives

To Introduce the DEA registered Practitioner with:

- Real Mission of the Diversion Control Division of the DEA
- Extent of the Opioid Epidemic in the U.S.
- History and Complexity of Drug Abuse in the U.S.
- Trends in Prescribing and Dispensing Patterns
- Nationwide Efforts to Combat the Problem

Questions To Discuss

At the completion of this block of instruction you will be able to answer the following questions:

- 1. What limits has Delaware placed on controlled substance prescriptions?
- 2. What are the top three most commonly prescribed controlled substances in the U.S.?

Questions To Discuss

- 3. According to the CDC approximately how many people died from drug overdoses in the year 2017?
- 4. Under Federal Law what is the primary responsibility of practitioners when it comes to issuing prescriptions for controlled substances?
- 5. According to IMS Data the total number of prescriptions being filled for oxycodone for the last three years has declined?



There Is Pain



There Is Legitimate Pain



There Is Dependence



There Is Addiction



There is Death as a Result of Addiction



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

^{1.} Rudd R, et al. MMWR Morb Mortal Wkly Rep. 2016 Jan 1;64:1378-82.

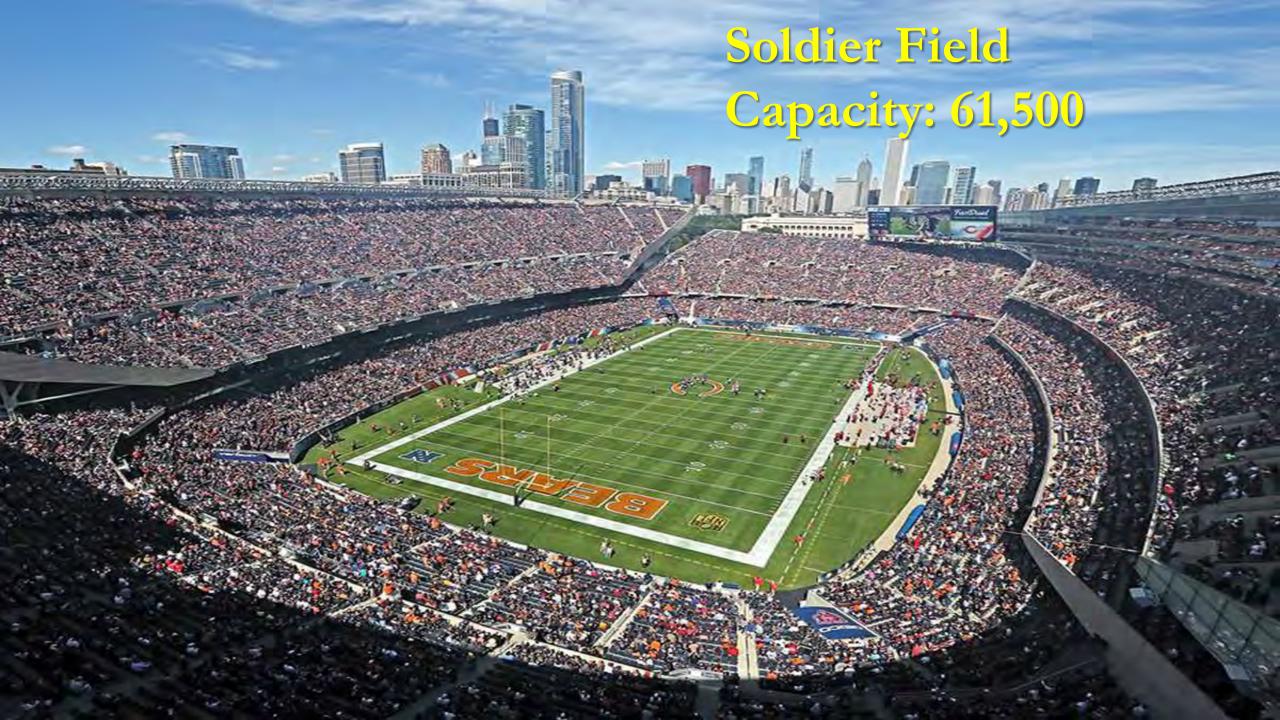
^{2.} CDC. https://www.cdc.gov/drugoverdose/data/analysis.html. Feb 2017. Accessed May 2017.



Public Health Epidemic

In 2017, there were 70,237 drug overdose deaths,

- ...one death every 7.5 minutes,
- ...approximately 192 per day,
- ...28,466 were due to fentanyl and other synthetic analogs, other than methadone.



Opioid Summaries by State



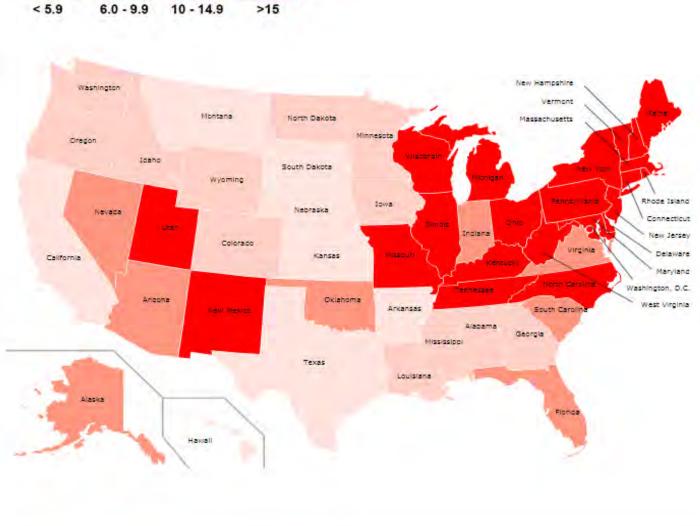




Revised February 2018

Opioid-Related Overdose Death Rates (per 100,000 people) 1





Pills laced with deadly opioid infiltrating drug market, DEA says

The Guardian

By Susan Zalkind

The illegal drugs look like known prescription painkillers and contain high amounts of fentanyl as law enforcement says problem is expected to escalate. Hundreds of thousands of counterfeit prescription pills laced with a deadly synthetic opioid have infiltrated the US drug market, according to the (DEA)...





Heroin Seizure

Pharmaceutical Oxycodone 30mg



Ten Most Commonly Prescribed Controlled Substances in the U.S.

- Hydrocodone
- Oxycodone
- Alprazolam
- Tramadol
- Dextroamphetamine

- Zolipem
- Clonazepam
- Lorazepam
- Codeine
- Buprenorphine



The Most Common Drugs Involved in Prescription Opioid Overdose Deaths

Hydrocodone

Oxycodone

Methadone



Unfortunately, The United States has a Long History **Drug Use** and **Abuse**



Morphine is Distilled from Opium for the First Time



The First Opium War Breaks Out as Britain Forces China to Sell Its India Grown Opium



The Hypodermic Syringe is Invented

The Inventor's Wife is the First to Die of an Injected Drug Overdose

1861-1865

Morphine Addiction

The Civil War

The "Soldier's Disease"



Bayer Chemist Invents diacetlymorphine,

Names It Heroin

Advent of the 20th Century Abuse Of Opium And Morphine A Significant Problem In The US But

There Was Widespread Distribution Of Medicinal Products Containing The New "Non-addictive" Alternative To Morphine - Heroin.







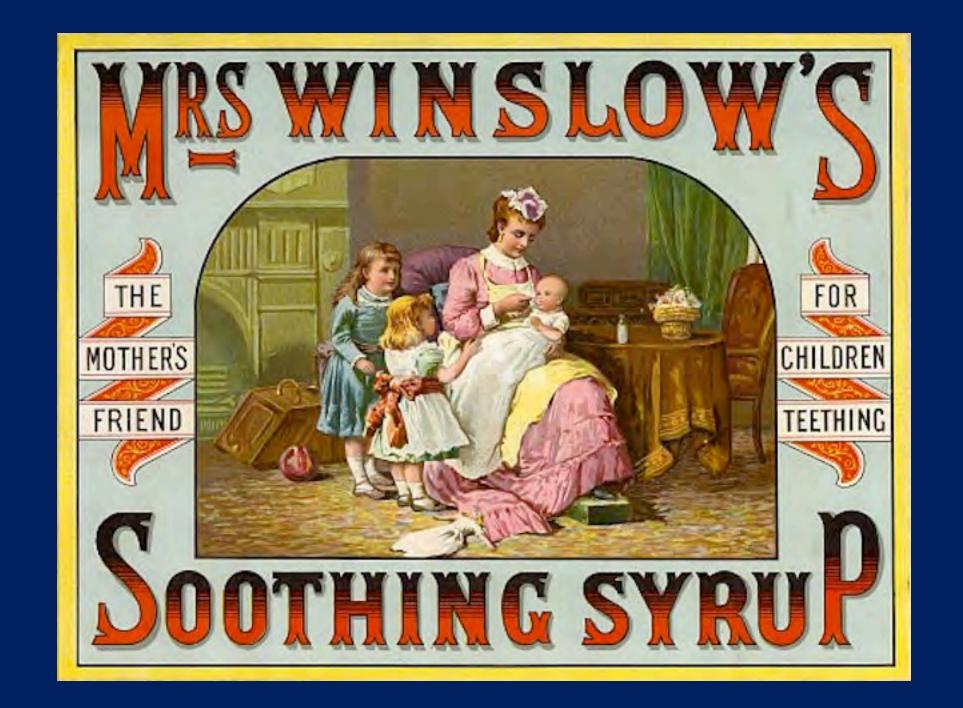


CATARRH, AND THROAT TROUBLES.

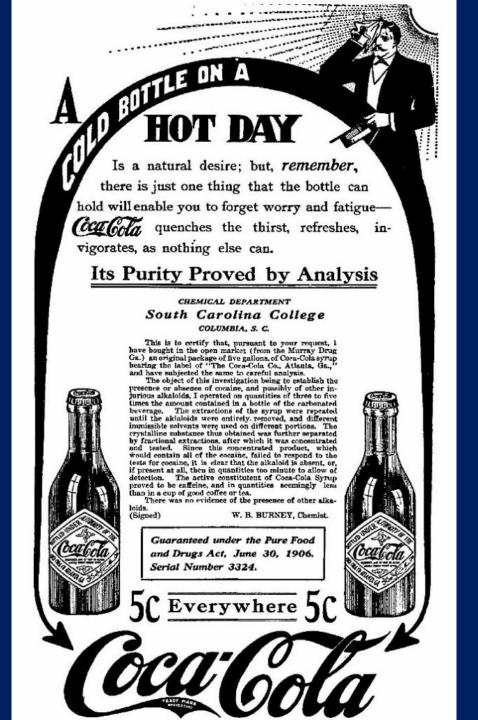
CURE NERVOUSNESS, HEADACHE, and SLEEPLESSNESS.

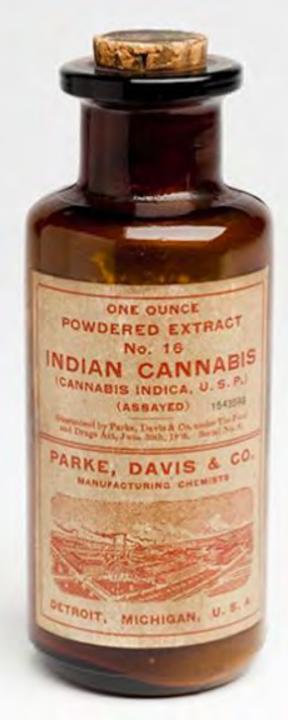
Price 50c. a box at Druggists or by mail. Send for Pamphlet. ALLEN COCAINE MFG. CO., 1254 Broadway, N. Y.

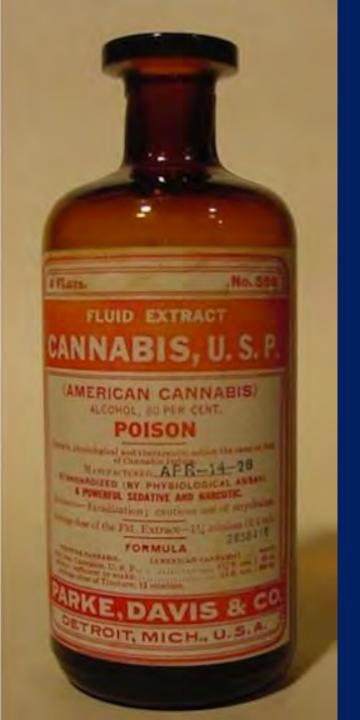














February 9, 1909

Congress Public Law 221

"An Act to Prohibit the Importation and Use of Opium for Other Than Medicinal Purposes"



U.S. Congress Passes Harrison Tax Act



Committee on the Problems of Drug Dependence is Formed

To Organize Research in Pursuit of the Holy Grail:

A Non-addictive Painkiller



Arthur Sackler Revolutionizes Drug Advertising With Campaign for the Antibiotic Terramycin



Arthur Sackler's campaign for Valium makes it the industry's first \$100 million drug



The New England Journal of Medicine publishes a letter to the editor that becomes known as "Porter and Jick"



ADDICTION RARE IN PATIENTS TREATED WITH NARCOTICS

Jane Porter
Hershel Jick, M.D.
Boston Drug Surveillance Program
Boston University Medical Center
New England Journal of Medicine.
January 1980

http://www.nejm.org/doi/pdf/10.1056/NEJM1980011030020221



ADDICTION RARE IN PATIENTS TREATED WITH NARCOTICS

"We conclude that despite widespread use of narcotic drugs in hospitals, the development of addiction is rare in medical patients with no history of addiction."

http://www.nejm.org/doi/pdf/10.1056/NEJM1980011030020221



Drs. Kathleen Foley and Russell Portenoy publish paper in the journal *Pain*, opening a debate about use of opiate painkillers for wider variety of pain



Dr. Mitchell Max President American Pain Society

"therapeutic use of opiate analgesics rarely results in addiction..."

OxyContin

FDA approved labeling

"iatrogenic addiction was "very rare" and that the delayed absorption of OxyContin reduced the abuse liability of the drug"



"Iatrogenic"

"an illness that is caused by medical examination or treatment."

https://en.oxforddictonaries.com/definition/iatrogenic



Purdue releases OxyContin, timedreleased oxycodone, marketed largely for chronic-pain patients



Dr. David Procter's clinic in South Shore, Kentucky, is presumed the nation's first pill mill



President of American Pain Society urges doctors to treat pain as a vital sign



October 2000

Department of Veterans Affairs

Pain: The Fifth Vital Sign Toolkit



October 31, 2000

106th U.S. Congress H.R. 3244

"Decade of Pain Control and Research."



Dr. Dennis O'Leary, President Joint Commission on Accreditation of Healthcare Organizations (The Joint Commission)

- standards for health care organizations to improve pain management.
- recommendation for systematic assessments and use of quantitative measures of pain



Dr. David Procter pleads guilty to drug trafficking and conspiracy and serves eleven years in federal prison



Purdue and three executives plead guilty to misdemeanor charges of false branding of OxyContin; fined \$634 million



Drug overdoses, mostly from opiates, surpass auto fatalities as leading cause of accidental death in the United States



Ohio passes House Bill 93, regulating pain clinics



The College on the Problems of Drug Dependence turns seventy-five without finding the Holy Grail of a nonaddictive painkiller



Intoxication: The Universal Drive for Mind Altering Substances

"Dr. Ron Siegel has suggested that throughout our entire history as a species, intoxication has functioned like the basic drives of hunger, thirst, or sex, sometimes overshadowing all other activities in life. Siegel further suggested "intoxication is the fourth drive".

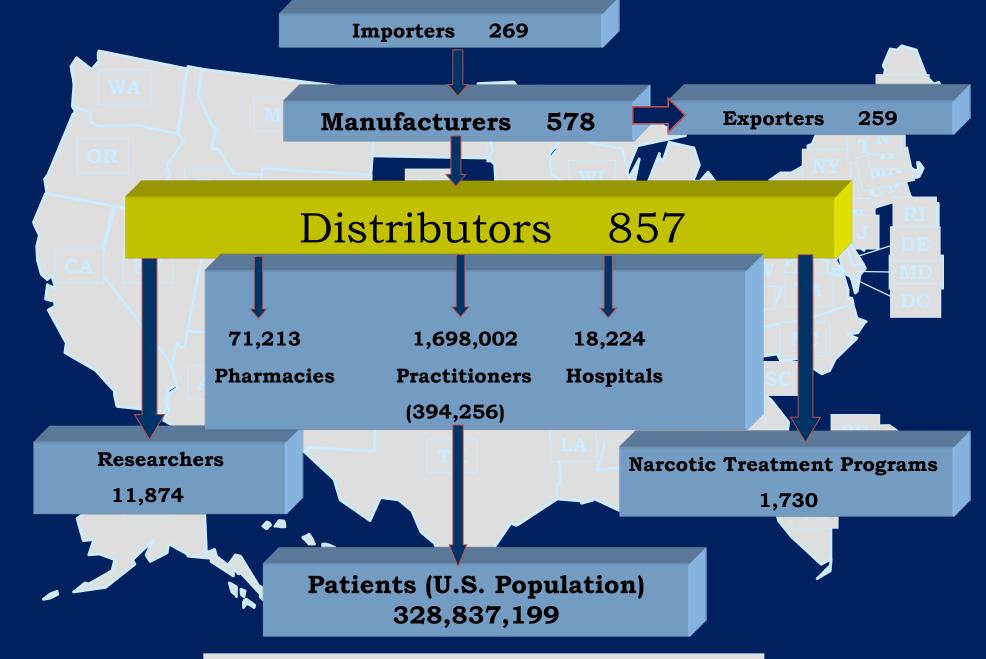
"Individual and group survival depends on the ability to understand and control this basic motivation to seek out and use intoxicants."



The Problem **Affects** Everyone



No one Is Un-Affected

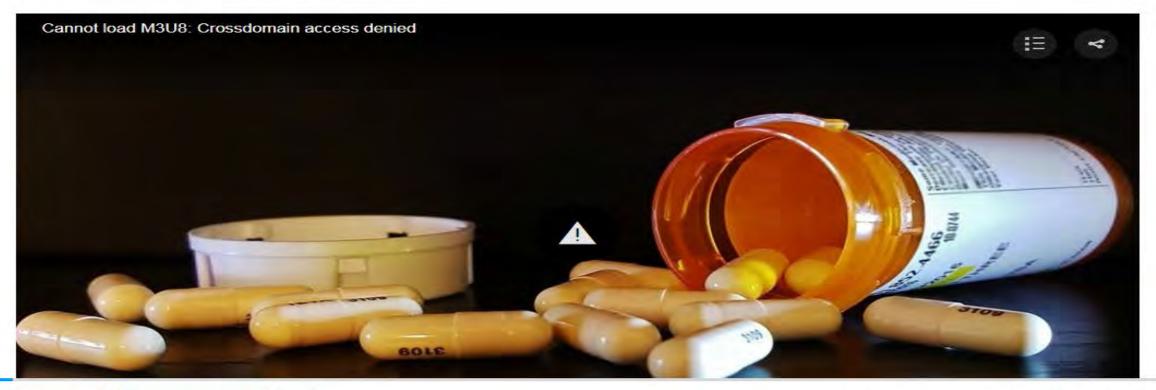




NEWS WEATHER CHIME IN SPORTS FEATURES STATION CIRCA FANZONE CONTESTS

Physician assistant among 2 charged in prescription drug case

by Bridget McClure | Friday, January 19th 2018







Trussville veterinarian arrested in fentanyl drug bust

Posted by: Tribune Staff Posted date: January 23, 2018

From The Trussville Tribune staff reports

ALABASTER — A Trussville veterinarian who lives in Alabaster was arrested as part of a drug bust involving a package of fentanyl by multiple law enforcement agencies Monday, according to a post by the Shelby County Drug Enforcement Task Force on social media.



David Wallace

Wallace worked part time at Trussville Animal Hospital, according to owner Dr. Kelly Baumann who opened the clinic in 1987.

"We're just shocked that this has happened," Baumann said.

Baumann said she had been contacted by the Alabama State Veterinarian Board of Examiners which is the agency that controls drugs and the records of their use. She said her staff was cooperating and helping investigators in any way possible.

"We are completely in the dark as to what's going

on," Baumann said. "We didn't even have that drug in the clinic. We've done a complete inventory here and nothing is missing."

Former Veterinary Technician Arrested For Illegally Prescribing Medications

Courtney Brown was prescribing medication for her deceased dog while employed as a veterinary technician in Georgia.

Amanda Carrozza
Published: June 06, 2018





A former veterinary technician from Savannah, Georgia has been arrested after it was discovered that she had been prescribing medication for her deceased dog.

The investigation began after the Chatham-Savannah Counter Narcotics Team received information suggesting that 33-year-old Courtney Brown was prescribing medication while employed as a technician at a local veterinary office. It has since been determined that Brown was regularly using her deceased dog's name to illegally prescribe Xanax, a scheduled IV controlled substance. All the fraudulent prescriptions were filled between 2017 and 2018.

Brown, who turned herself in on Monday, was charged with a felony for acquiring or obtaining a controlled substance by misrepresentation/fraud/forgery.

Earlier this year, another Georgia animal hospital employee was arrested after she allegedly stole 177 tramadol pills from the South Forsyth Animal Hospital in Forsyth County where she worked. Danielle Crescenzo, 22, was charged with felony drug distribution of controlled substances.

RELATED:

Second Suspect Charged For Running Fake Veterinary Clinic

Tweets by @VMDToday





Tamarac dentist arrested after cache of drugs found at Delray Beach home

Dr. Justin Devack faces drug-related charges

By Peter Burke - Local 10.com Managing Editor

Posted: 11:56 AM, September 28, 2018 Updated: 5:46 PM, September 28, 2018



DELRAY BEACH, Fla. - A Tamarac dentist was arrested Thursday on drug-related charges.

Dr. Justin Devack faces charges of trafficking in synthetic cannabinoids and possession of paraphernalia.





Feds bust massive pill mills that flooded NYC streets with painkillers

By Larry Celona, Priscilla DeGregory and Max Jaeger

October 11, 2018 | 12:35pm | Updated



Authorities search the home of one of the doctors involved in the oxycodone pills arrest.

Street, Francisco III

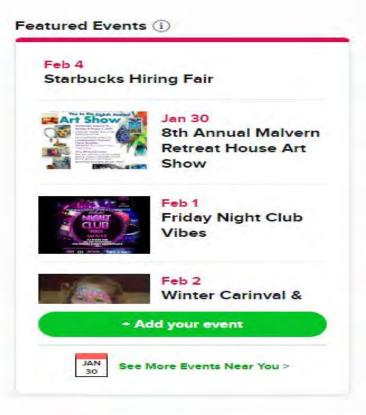
4 Montco Doctors Prescribed Opioids To Addicts, Drug Dealers: DA

Breaking: The doctors prescribed to both drug addicts and traffickers in exchange for money and, in some cases, sexual favors, the DA said.

By Justin Heinze, Patch Staff | Sep 12, 2018 12:36 pm ET | Updated Sep 13, 2018 5:12 pm ET

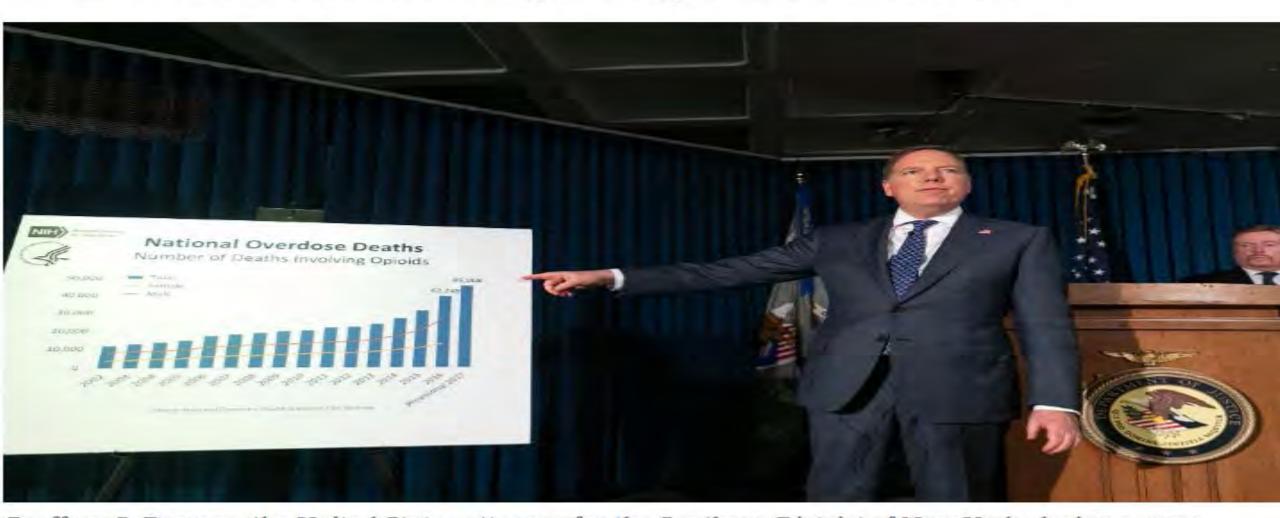






NORRISTOWN, PA — Four Montgomery County doctors have been arrested for illegally prescribing opioids to drug addicts and drug traffickers around the region, the District Attorney's Office announced on Wednesday morning. The prescriptions led to numerous overdose deaths, authorities said.

Prescriptions for Millions of Opioid Pills Lead to Charges Against 5 Doctors



Geoffrey S. Berman, the United States attorney for the Southern District of New York, during a news conference on Thursday in Manhattan. He announced that five doctors had been charged with

Nurse Arrested After Attempting to Steal Drugs From Savannah Hospital

The narcotics team quickly arrested the nurse before she could leave the building with drugs and stolen medical supplies.



Katie Malafronte December 10, 2018

Clarksville doctor facing federal charges for opioid distribution, healthcare fraud

Kara Apel, Forrest Sanders

⊙ Posted Dec 14, 2018 | ■ 0



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- » 19-year-old mother and newborn son both die after she delayed cancer treatment to save him
- » Loretta Lynn's grandson banned from Middle Tennessee school

Department of Justice



U.S. Attorney's Office

Central District of California

FOR IMMEDIATE RELEASE

Tuesday, December 18, 2018

O.C. Doctor Arrested on Federal Narcotics Charges that Allege Prescriptions to 'Patients' who Suffered Fatal Overdoses

SANTA ANA, California — Special Agents with the Drug Enforcement Administration this morning arrested an Orange County doctor on federal charges that allege he illegally distributed opioid and other powerful narcotics by writing prescriptions for "patients" without medical examinations and to at least five individuals who suffered overdose deaths. One man who allegedly obtained prescriptions from the doctor was involved in a car accident last month that killed a bicyclist who was a captain with the Costa Mesa Fire & Rescue Department.

Dzung Ahn Pham, 57, of Tustin, who owns Irvine Village Urgent Care, was arrested pursuant to a criminal complaint that charges him with two counts of illegally distributing oxycodone. The complaint alleges that Pham issued prescriptions for the controlled substance outside the usual course of professional practice and without a legitimate medical purpose.

The affidavit in support of the criminal complaint alleges that Pham was selling prescriptions to "patients" who were drug addicts and/or who were selling the drugs on the black market. A review of a state-maintained database shows that Pham issued "an extremely high amount" of prescriptions over a three-year period, and the types of drugs prescribed to certain patients would lead to "higher risks for addiction, overdose and overdose death," according to the affidavit. Investigators learned that a CVS pharmacy in Irvine stopped accepting prescriptions from Pham more than five years ago when the doctor could not justify the number of opioid pills he was prescribing to individual patients.

During two undercover operations this past summer that are discussed in the affidavit, a DEA agent quickly and easily obtained prescriptions for narcotics, including "a triple threat," also referred to as a "Holy Trinity, [which] is the combined use of an opioid (such as hydrocodone), a benzodiazepine (such as Valium), and carisoprodol (a muscle relaxer like Soma)." Pham allegedly steered the undercover agent to an Irvine pharmacy that filled many of his prescriptions.

The affidavit contains text messages in which "patients" seek prescriptions, sometimes asking for

Home / Press Releases / 2018 / 12 / 20 / Physician Assistant sentenced to 10 years in prison



Drug Enforcement Administration

San Francisco
Christopher Nielsen, Special Agent in
Charge
@DEASanFrancisco

C*

December 20, 2018

Contact: Casey Rettig

Phone Number: (415) 436-7900

FOR IMMEDIATE RELEASE

Physician Assistant sentenced to 10 years in prison

OAKLAND, Calif. – David Lague was sentenced to 10 years in prison, and ordered to pay a \$5,000 fine and for unlawfully distributing prescription drugs, announced United States Attorney Alex G. Tse, Drug Enforcement Administration Special Agent in Charge Chris Nielsen, and Health & Human Services, Office of Inspector General, Office of Investigations Special Agent in Charge Steven J. Ryan. The sentence was handed down by the Honorable Haywood S. Gilliam, Jr., U.S. District Judge.

On July 24, 2018, a jury found Lague guilty of 39 counts of unlawful distribution of controlled substances, after a two-week trial. During the trial, evidence showed that Lague intentionally prescribed drugs to five different patients, knowing that the prescriptions were outside the usual course of professional practice and without a legitimate medical purpose. The evidence showed that, on two occasions, a patient asked Lague to double his prescriptions for powerful opioids so that the patient could sell the drugs. Lague not only doubled the prescriptions, he also discussed with the patient how to do it in a way to avoid scrutiny by pharmacies or law enforcement. Lague admitted at trial that he wrote false medical records of those visits in order to cover up what he was doing. The evidence at trial also showed that Lague falsified records as to other patients as well, detailing exams that never took place and indicating that he had reviewed lab work that he never reviewed. An expert who reviewed four of Lague's patient files found that his handling of those patients was an extreme departure from the standard of care. Further, the evidence at trial showed that, among physicians who prescribed opioids to 50 or more MediCare patients, Lague was the highest prescriber of opioids in California in 2015 and 2016.









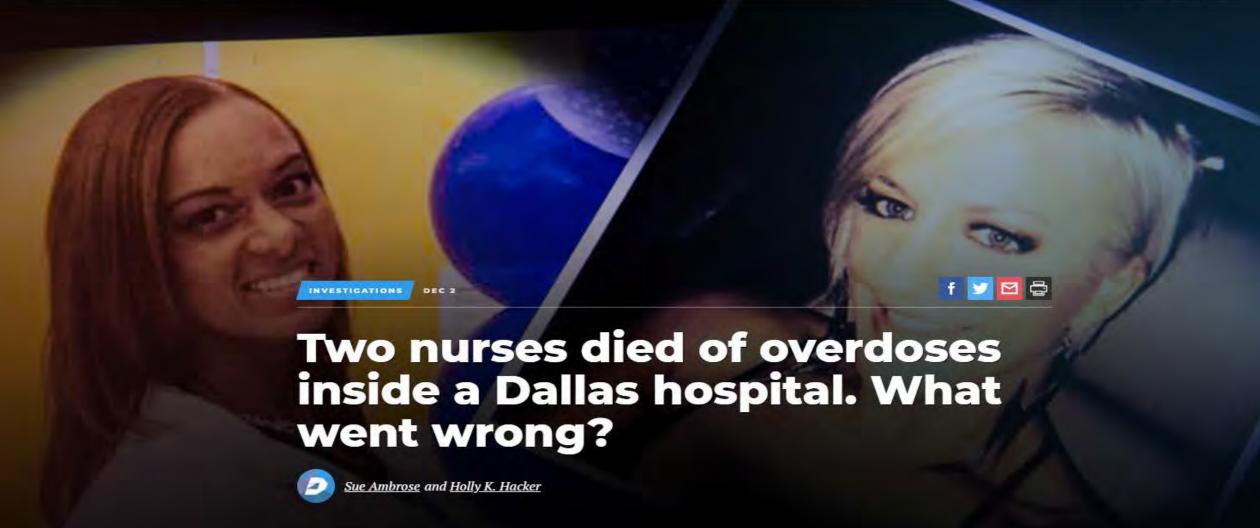






ELECTIONS 2020 TEXAS LEGISLATURE





https://www.dallasnews.com/news/investigations/2018/12/02/two-nurses-died-overdoses-inside-dallas-hospitalwent-wrong

Health & Fitness

Northridge Nurse Arrested In Massive Prescription Drug Sting

Federal authorities arrested Southland doctors and clinic workers accused of black market opioid sales linked to at least one death.

By California News Wire Services, News Partner | Feb 22, 2019 1:14 am ET



Share







An opioid crackdown in the Los Angeles area has led to the arrest of four doctors and other medical professionals. ((AP Photo/Jae C. Hong))

Firefighters, cop, pizzeria owner among 7 arrested in Jersey Shore drug fraud ring with ties to James Kauffman

by Amy S. Rosenberg, Updated: March 15, 2019



COLT SHAW / THE PRESS OF ATLANTIC CITY VIA AP

Seven people, including three firefighters, a police officer, and an owner of Tony's Baltimore Grill in Atlantic City, were arrested Friday and charged in a \$50 million prescription-drug health-benefits scheme that has already snagged dozens of public employees and pharmaceutical representatives at the New Jersey Shore.

The arrests followed the unsealing of a 50-count federal indictment charging William Hickman, 42, of Northfield; his wife, Sara, 42; Ventnor Police Officer Thomas Schallus, 42; brothers and Margate Firefighters John, 37, and Thomas Sher, 46; Camden Firefighter Christopher Broccoli, 47, of West Deptford; and Brian Pugh, 41, of Absecon, identified in the indictment as a businessman.

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Pikeville doctor arrested on federal drug charges

POSTED BY SHANNON DESKINS ON APRIL 17, 2019 IN BREAKING, LATEST NEWS



PIKEVILLE, Ky. – A Pikeville doctor and one other were arrested Wednesday morning by US Marshals on federal drug charges. 47 year old Scott Akers and 32 year old Serissa Collier, aka Serissa Stamper were lodged in the Pike County Detention Center, each facing seven counts of unlawfully distributing quantities of hydrocodone, oxycodone and fentanyl between

August of 2016 and May of 2018. A federal grand jury indicted the pair on April 11th. According to documents filed in federal court, Akers owned and operated a pain management clinic in Pikeville where Collier was employed. However, Akers closed the clinic in 2016 and allegedly began dispensing prescriptions for pain medication from Akers' residence where Collier resided from time to time.

EKB News is continuing to gather the details on the case and will post a more complete story later today.

In multistate crackdown, doctors charged with exchanging drugs for sex, writing prescriptions for Facebook friends

By ASSOCIATED PRESS / APRIL 17, 2019



Brian Benczkowski of the Department of Justice speaks beside members of Appalachian Regional Prescription Opioid Strike Force during a news conference Wednesday in Cincinnati.



INCINNATI — Federal authorities said Wednesday they have charged 60 people, including 31 doctors, for their roles in illegally prescribing and distributing millions of pills containing opioids and other dangerous drugs.

Nearly 60 Doctors, Other Medical Workers Charged In Federal Opioid Sting

April 17, 2019 CARRIE JOHNSON

Federal prosecutors are charging 60 doctors, pharmacists, medical professionals and others in connection with alleged opioid pushing and health care fraud, the Justice Department said Wednesday.

The cases involve more than 350,000 prescriptions for controlled substances and more than 32 million pills — the equivalent of a dose of opioids for "every man, woman and child," across Ohio, Kentucky, Tennessee, Alabama and West Virginia, said Assistant Attorney General Brian Benczkowski.



What's Trending?

Some Good News?

Opioid addiction is plateauing. But the crisis isn't over.

Vox

By Dylan Scott

New data from the Blue Cross Blue Shield Association suggests opioid addiction rates are finally plateauing.

The big finding from the BCBSA data, which compiles medical claims information from the various Blue Cross affiliates across the United States: Diagnoses of opioid use disorder (addiction, in other words) declined from 2016 to 2017, from 6.2 per 1,000 patients to 5.9.

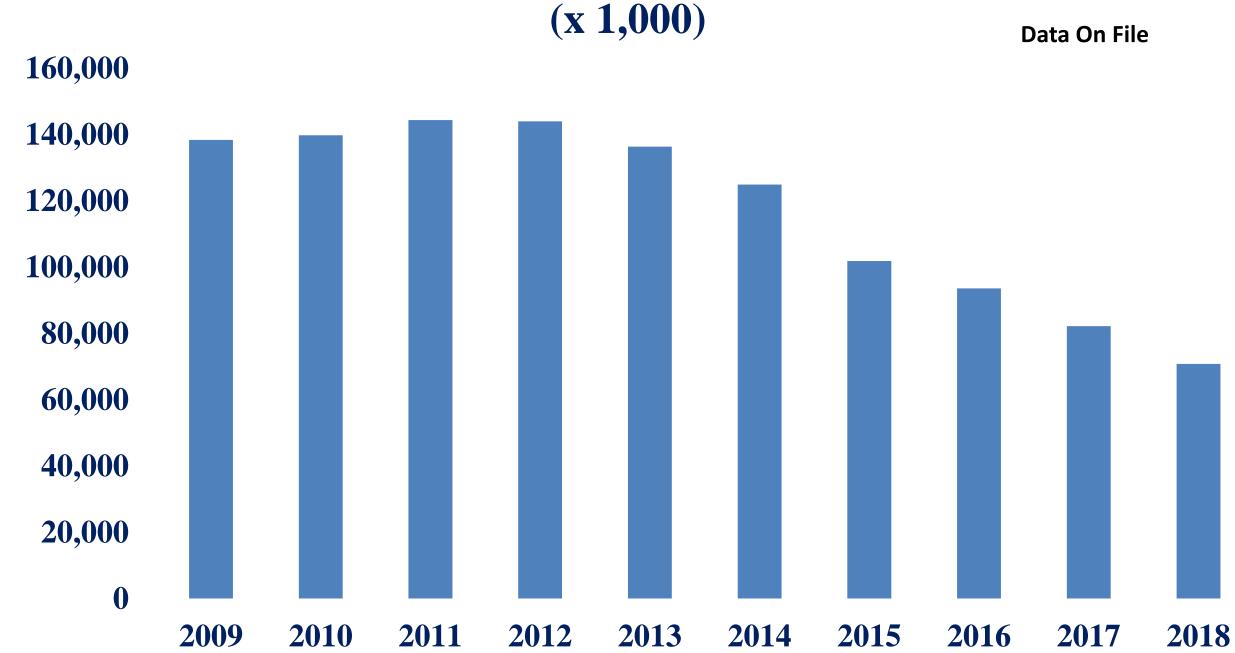
It was the first decline BCBSA had measured in eight years



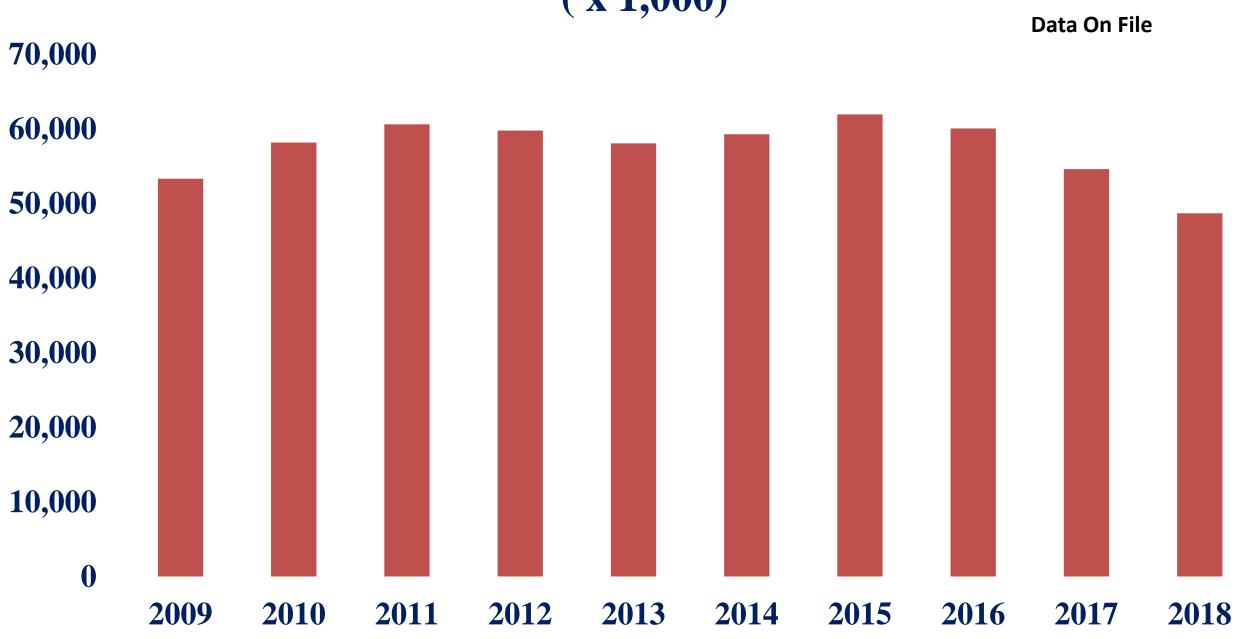
U.S. Health Chief Says Overdose Deaths Are Starting to 'Plateau' But 'We Are So Far From the End'

- TIME Health
- (WASHINGTON) The number of U.S. drug overdose deaths has begun to level off after years of relentless increases driven by the opioid epidemic, health secretary Alex Azar said Tuesday, cautioning it's too soon to declare victory.
- "We are so far from the end of the epidemic, but we are perhaps, at the end of the beginning," Azar said in prepared remarks for a health care event sponsored by the Milken Institute think tank.

Total Prescriptions Dispensed: Hydrocodone 2009-2018 (x 1.000)



Total Prescriptions Dispensed: Oxycodone 2009-2018 (x 1,000)



Total Prescriptions Dispensed: Methadone 2009-2018 (x 1,000)

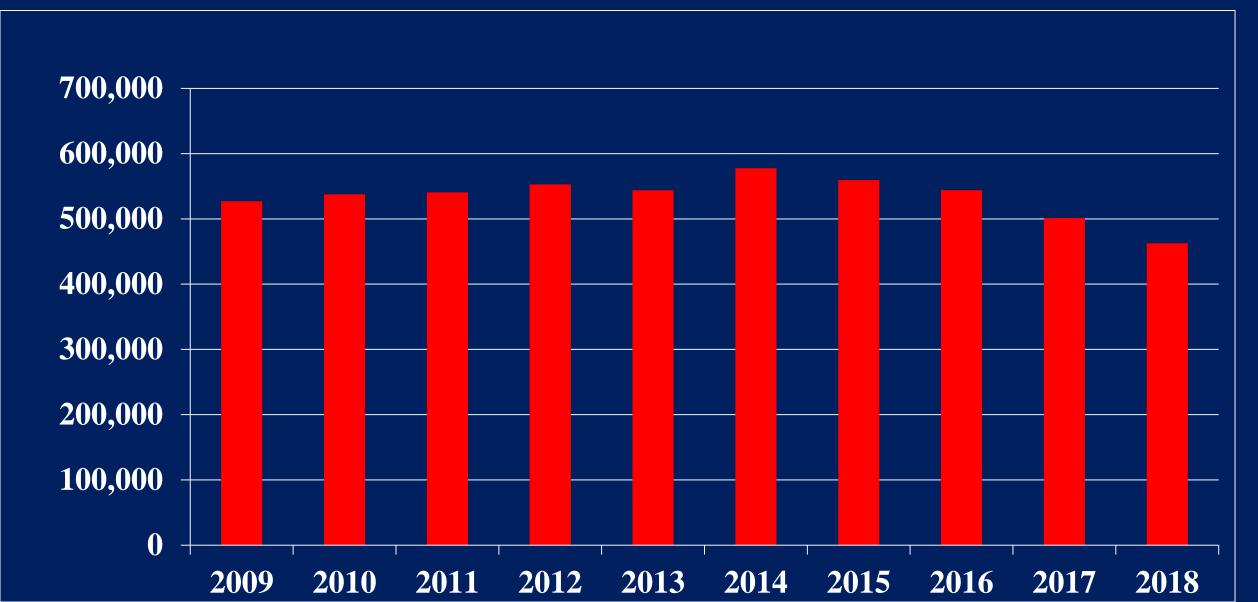




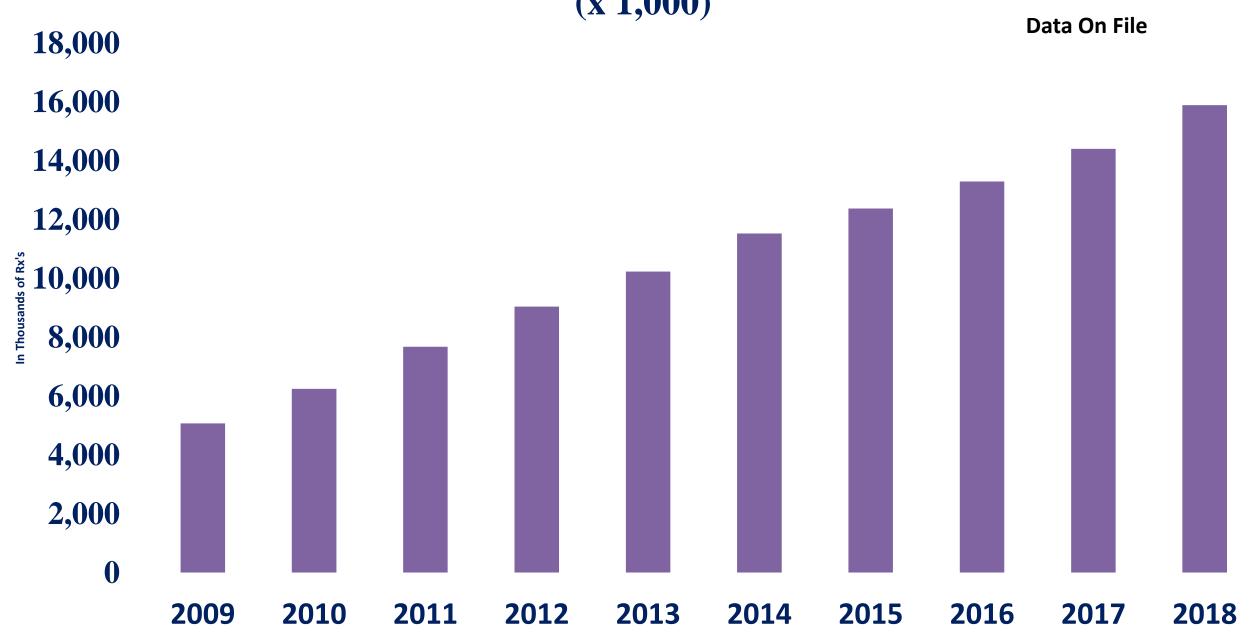
Total Controlled Substance RX's Filled 2009-2018

(x 1,000)

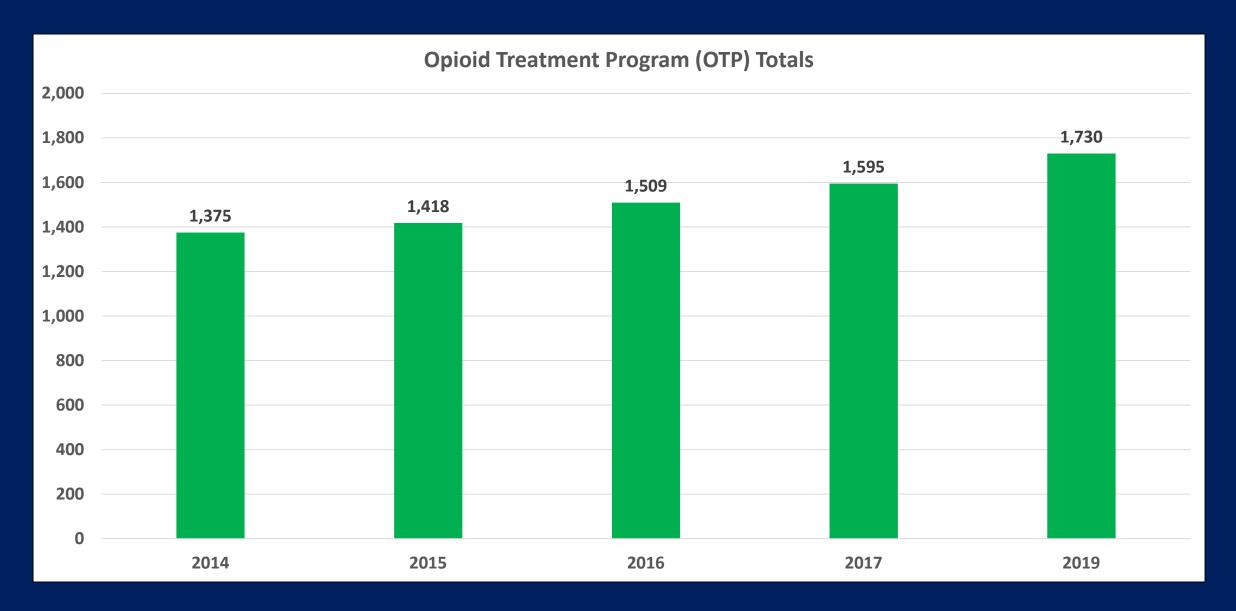
Data On File



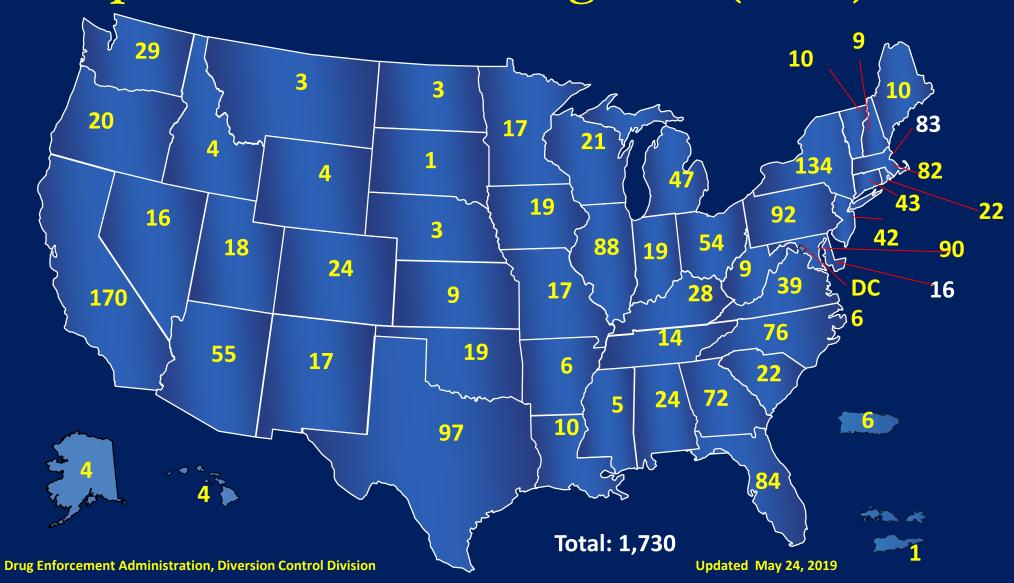
Total Prescriptions Dispensed Buprenorphine 2009-2018 (x 1,000)



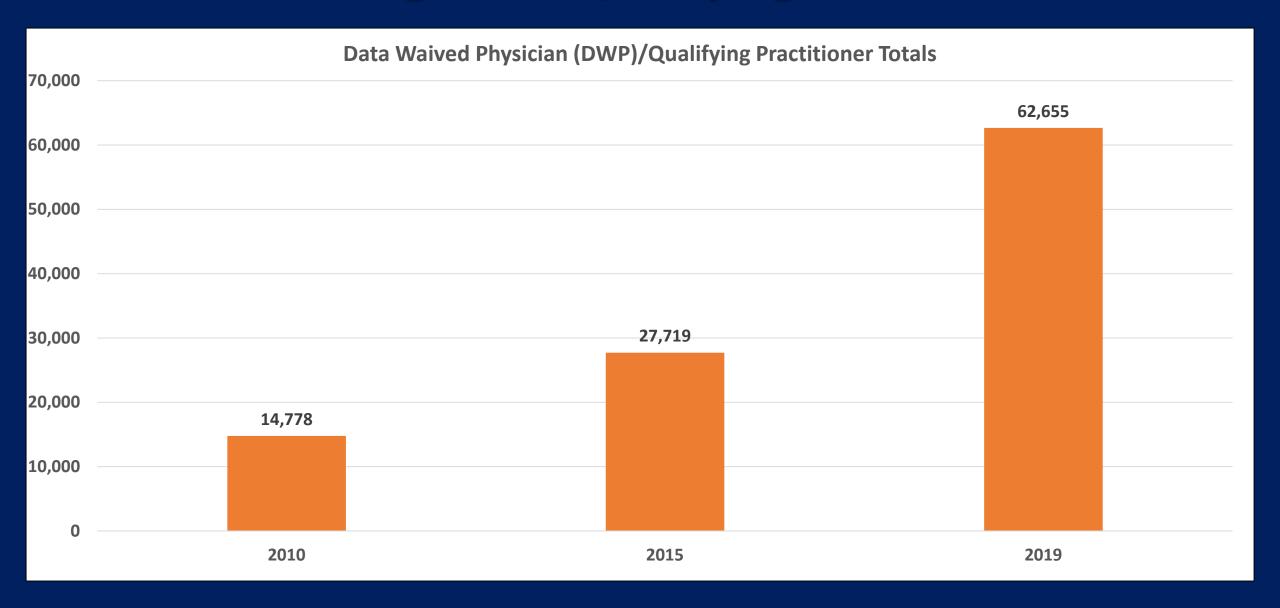
Opioid Treatment Programs (OTPs)



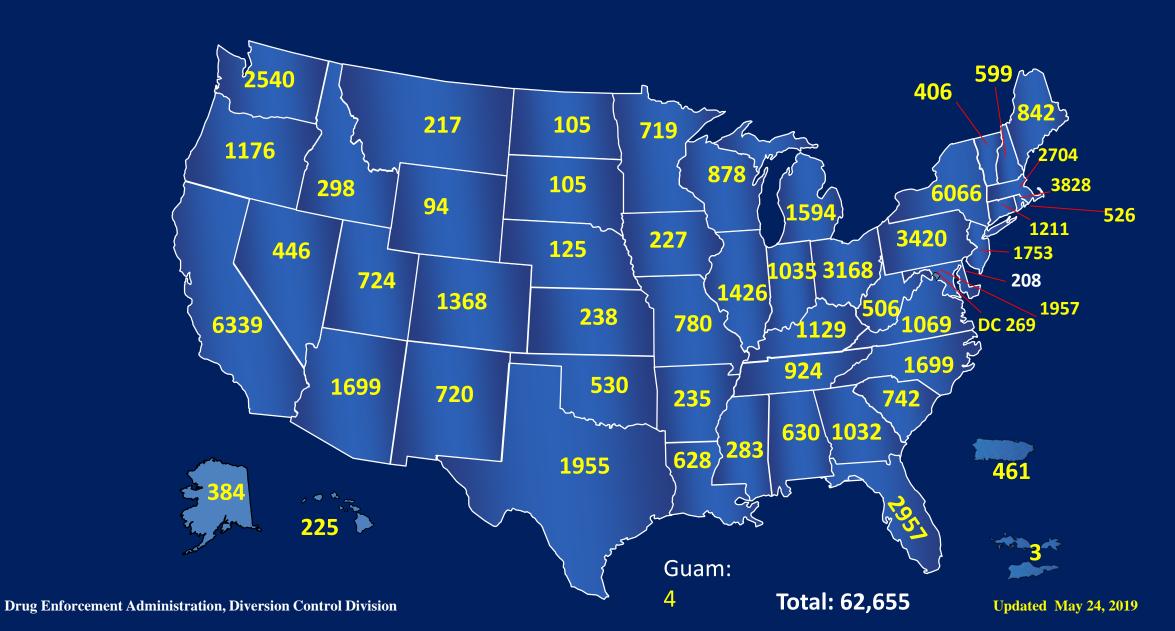
DEA Registered Opioid Treatment Programs (OTP)



DEA Registered Qualifying Practitioners



DEA Registered Qualifying Practitioners





Qualifying Practitioners (US)

• Practitioner DW-30	35,240
• Practitioner DW-100	9,734
• Practitioner DW-275	5,007
• Nurse Practitioner DW-30	8,423
• Physician Assistant DW-30	2,218
• Nurse Practitioner DW-100	1,580
• Physician Assistant DW-100	417



Qualifying Practitioners (DE)

• Practitioner DW-30	98
• Practitioner DW-100	27
• Practitioner DW-275	25
• Nurse Practitioner DW-30	43
• Physician Assistant DW-30	2
• Nurse Practitioner DW-100	7
• Physician Assistant DW-100	5

Nationwide Efforts to Combat the Problem



States

Practitioners

Hospitals

Treatment Providers

Medical Schools

Pharmacies



Alaska 7 Day Supply (initial prescription)

Arizona 7 Day Supply (initial prescription)

7 Day Supply (for minors)

California Currently no special restrictions on Schedule 2

Connecticut 7 Day Supply (initial prescription)

7 Day Supply (for minors)

Delaware 7 Day Supply (adult or minor), acute episode



District of Columbia 7 Day Supply

(emergency situation)

Florida 3 Day Limit/Acute Pain

7 Day Supply/Medically Necessary

Hawaii 30 Day Supply

Illinois 30 Day Supply: CII (Some exceptions)

Indiana 7 Day Supply (initial prescription)

7 Day Supply (for minors)



Kansas 30 Day Supply

(Substances to treat obesity)

Kentucky 3 Day Supply (acute pain) with

exceptions: e.g. Chronic Pain, Cancer

Pain, End of Life, Hospice, Narcotic

Drug Treatment, Major Surgery.

Louisiana 10 Day Supply: CII-III

(Prescribers not licensed in Louisiana)

Maine 30 Day Supply (chronic pain)

7 Day Supply (acute pain)



Massachusetts 7 Day Supply (unless more is indicated)

7 Day Supply (all opioids for minors)

Massachusetts 30 Day Supply: CII-III

60 Day Supply (Dextroamphetemine)

Missouri 30 Day Supply: CII

90 Day (If medical reason given)

Nevada 14 Day Supply

New Hampshire 34 Day Supply: CII

60 Day Supply (ADD/ADHD)



New Jersey First prescription: 5 Day Supply

New York 30 Day Supply

7 Day Supply (initial prescription)

North Carolina 5 Day Supply (acute pain)

Ohio 7 Day Supply for Adults (Initial)

5 Day Supply for Minors (Initial)

Oklahoma 7 Day Supply for Acute Pain (Initial)

Oregon 7 Day Supply (initial prescription)

7 Day Supply (for minors)



Pennsylvania 7 Day Supply (for minors/consent)

7 Day Supply (emergency department;

urgent care centers; observation status in

hospitals) with some exceptions.

Rhode Island 20 Doses for opioids (initial

prescription)

No more than 30 morphine

MME/day

South Carolina 31 Day Supply

(Except Transdermal patches)

90 Day Supply: CIII-V



Tennessee 30 Day Supply of Opioids and

Benzodiazepines

Texas 90 Day Supply (multiple

prescriptions)

Utah 30 Day Supply: CII

Vermont 90 Day Supply

72 MME (first prescription for

minors)

350 MME – 7 Day limit (acute pain,

first prescription)



Virginia Limitations on Number of Days

7 Day Supply (acute pain)

14 Day Supply (surgical procedures)

(Some exceptions)

Washington 7 Day Supply (initial prescription)

3 Day Supply (dentist)

West Virginia 4 Day Supply ER (Initial Script Adults)

3 Day Supply ER (Children)

7 Day Supply Private Practice

3 Day Supply Dentists/Optometrists



- 33 States Have Enacted Legislation with Some Type of Limit, Guidance, or Requirement Related to Opioid Prescribing
- Seven Day Supply in the Most Common'
- Most States Exempt Treatment for Cancer, Palliative Care, Medication Assisted Treatment
- Exceptions for the Professional Judgement of the Provider/Documented
- Check the Prescription Drug Monitoring Program (PDMP)



CVS Pharmacy Policy: 2/01/18

- Acute Pain (Opioid Naïve Patients: No Opioid Script within the Past Year)
- 7-Day Supply
- Opioid Prescriptions
- Requirement to Counsel Patients:
 - -Risks Of Addiction
 - -Secure Storage Of Medications In The Home
 - -Proper Disposal of Medications

Walmart giving away solution to dispose of unused prescription pills January 26, 2018



Narcan available at more than 8,000 Walgreens locations nationwide

- CBS News, By Peter Martinez: October 27, 2017
- Walgreens (WBA) is now stocking Narcan at all of its more than 8,000 locations nationwide, the company announced Thursday. The nasal spray, which is an FDA-approved form of naloxone, can reverse the effects of an opioid overdose.
- The drug store chain said the move was "part of its comprehensive national plan to combat drug abuse" and help the communities it serves.

Knowing the Risks of Opioid Prescription Pain Medications (Rite Aid)

Opioid prescription pain medications are a type of medicine used to relieve pain. Some of the common names include oxycodone and acetaminophen (Percocet®); oxycodone, (OxyContin®); and hydrocodone and acetaminophen (Vicodin®).

These medications...

- Cause your brain to block the feeling of pain; they **do not** treat the underlying cause of pain.
- Are very addictive, **especially** if they are not used correctly.
- *Increase your chances of accidental overdose, coma, and death* if taken with prescription medications, including anti-anxiety and sedating medications, and alcohol.

Effective non-opioid options are available for relieving short-term pain, including ibuprofen (Advil®, Motrin®), acetaminophen (Tylenol®), physical therapy, chiropractic, acupuncture, and cognitive behavioral therapy. Talk with your pharmacist or healthcare provider to learn more.

Protect yourself - and your loved ones - with Naloxone (Rite Aid)

What is Naloxone?

• Naloxone is a lifesaving, rescue medication that can be used in an emergency to reverse the effects of an accidental opioid overdose.

Why should I get Naloxone?

- Any prescription opioid medication has the potential risk for unintended consequences such as slowed breathing and accidental overdose.
- Guidelines recommend naloxone if you take high doses of opioids, certain interacting medications or have medical condition(s) that increase your risk.
- Having naloxone at home can not only protect yourself, but loved ones that may ingest the opioid by accident an emergency can occur after just one dose.
- Similar to a fire extinguisher in your home, **naloxone** is important to have "just in case" of an emergency or accident *it is always better to take appropriate precautions and be safe!*



Walmart Will Implement New Opioid Prescription Limits By End Of Summer



"Tylenol, Motrin just as effective in treating pain in ER patients as opioids"

November 7, 2017

Lindsey Tanner, November 7, 2017, The Denver Post, https://www.denverpost.com/2017/11/07/tylenol-motrin-effective-treating-pain-er-patients-as-opioids/

Reducing opioids not associated with lower patient satisfaction scores, study finds Science Daily

A Kaiser Permanente study of nearly 2,500 patients who used high doses of opioids for at least six months showed that reducing their opioid use did not lower their satisfaction with care. The study, "Satisfaction With Care After Reducing Opioids for Chronic Pain," was published today in The American Journal of Managed Care.

"Physicians are often concerned they will receive lower satisfaction scores if they reduce opioids for patients who are accustomed to high opioid doses to manage chronic pain," said the study's lead author, Adam L. Sharp, MD, MS, of Kaiser Permanente Southern California Department of Research & Evaluation. "This study showed that following current recommendations and reducing opioids for chronic pain did not result in lower satisfaction scores."

Could DNA help doctors predict opioid addiction? MDDI

By Kristopher Sturgis

New research out of Bentley University aims to explore the genetic links between human DNA and opioid addiction. The new study could help doctors identify patients susceptible to opioid dependence and choose different treatment methods.

The research project aims to help better inform doctors on how likely a patient is to become addicted to opioids before ever prescribing opioid drugs. The new data could also be used to predict how patients addicted to opioids will respond to certain treatments.

FDA approves the first non-opioid treatment for management of opioid withdrawal symptoms in adults

Encouraging more widespread innovation and development of safe and effective treatments for opioid use disorder remains top agency priority

Most doctors are ill-equipped to deal with the opioid epidemic. Few medical schools teach addiction. Jan Hoffman, The New York Times

Comprehensive addiction training is rare in American medical education. A report by the National Center on Addiction and Substance Abuse at Columbia University called out "the failure of the medical profession at every level — in medical school, residency training, continuing education and in practice" to adequately address addiction.

September 27, 2018

The Heal Initiative

The NIH HEAL Initiative will bolster research across NIH to:

•Improve Treatments for Opioid Misuse and Addiction

Develop New Treatments for Addiction, Overdose Prevention and Reversal

Enhance Treatments for Infants with Neonatal Abstinence Syndrome/Neonatal Opioid Withdrawal Syndrome

Optimize Effective Treatments for Opioid Addiction

Enhance Pain Management

Understanding Biological Underpinnings of Chronic Pain

Accelerate the Discovery and Pre-Clinical Development of Non-Addictive Treatments for Pain

Advance New Non-Addictive Treatments for Pain through the Clinical Pipeline

Guidelines for the Chronic Use of Opioid Analgesics

Federation of State Medical Boards

April 2017

CDC

• New project to estimate best practice opioid prescribing in the United States.

• Using large health insurance claims data, CDC will estimate current opioid prescribing rates in the US for various conditions and procedures. Using clinical guidelines and related research, CDC will estimate what the prescribing rates would be for these conditions and procedures if best practices were followed.

Study: Dental painkillers may put young people at risk of opioid addiction

The Washington Post
By Ronnie Cohen

Dentists who prescribe opioid painkillers to teenagers and young adults after pulling their wisdom teeth may be putting their patients at risk of addiction, a new study finds.

The study, published in JAMA Internal Medicine Monday, shines a light on the largely overlooked role dental prescriptions play in an epidemic of addiction that has swept the United States, leading to a record 70,237 drug overdose deaths in 2017.

"Given the gravity of the opioid epidemic, the degree of persistent use and abuse we observed in adolescents and young adults, especially females, is alarming," said researcher Alan Schroeder, a pediatrician and professor at Stanford University School of Medicine. "Our findings should trigger heightened scrutiny over the frequency of prescribing dental opioids."

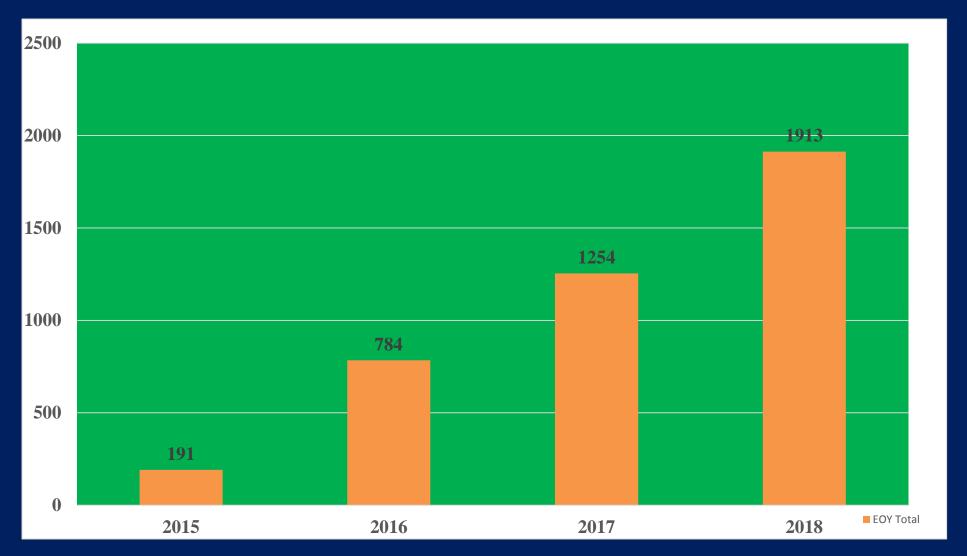
Adolescents and young adults often are introduced to highly addictive opioid painkillers when they have their third molars pulled. Millions of Americans undergo the procedure every year, and dentists routinely prescribe opioids to the vast majority. Only recently have dentists — the most frequent prescribers of opioids for youths between the ages of 10 and 19 in 2009 — started to reconsider the use of narcotics in managing post-surgical pain.



DEA Initiatives



Diversion Control Division: Outreach Activities FY 2015 - FY 2018



^{*}As of September 30, 2018

Dear DEA-Registered Practitioner - February 2018

CDC's Recommendations for the Prescribing of Opioid Pain Medications

Dear DEA-Registered Practitioner:

In March, 2016, the Centers for Disease Control and Prevention (CDC) published its "CDC Guideline for Prescribing Opioids for Chronic Pain" to provide recommendations for the prescribing of opioid pain medication for patients 18 and older in primary care settings. Recommendations focus on the use of opioids in treating chronic pain (pain lasting longer than 3 months or past the time of normal tissue healing) outside of active cancer treatment, palliative care, and end-of-life care.

CDC's Guideline is part of a comprehensive approach to addressing the opioid overdose epidemic and is one step toward a more systematic approach to the prescribing of opioids, while ensuring that patients with chronic pain receive safer and effective pain management. According to the CDC, The Guideline's twelve recommendations, published in August 2017, are based on three key principles:

- 1. Non-opioid therapy is preferred for chronic pain outside of active cancer, palliative, and end-of-life care. Opioids should only be used when their benefits are expected to outweigh their substantial risks.
- When opioids are used, the lowest possible effective dosage should be prescribed to reduce risks of opioid use disorder and overdose. Clinicians should start low and go slow.
- 3. Providers should always exercise caution when prescribing opioids and monitor all patients closely. Clinicians should minimize risk to patients—whether checking the state prescription drug monitoring program, or having an 'off-ramp' plan to taper.

You are receiving this email as part of DEA's effort to improve its communication with its more than 1.7 million registrants while simultaneously improving the dissemination of the CDC Guidelines to those authorized to prescribe opioids.

A copy of CDC's publication entitled, "Guideline for Prescribing Opioids for Chronic Pain: Recommendations" may be found at: https://www.cdc.gov/drugoverdose/pdf/Guidelines_Factsheet-a.pdf.

Additionally, an Interactive Training Webinar for providers who prescribe opioids may be found at: https://www.cdc.gov/drugoverdose/training/index.html.



More than

11 million people
abused prescription
opioids in 2016.

Opioid Addiction Resources - March 16, 2018

Opioid Addiction Resources



Resources for DEA Registered Practitioners for Patients Who May Be Dependent and/or Addicted To Opioids

According to the U.S. Centers for Disease Control and Prevention (CDC) there were 63,632 drug overdose deaths in the United States in 2016; 174 deaths per day; one death every 8.28 minutes; 42,249 (66.4%) of those

deaths were due to opioids. More deaths than those as a result of firearms, homicide, suicide, and motor vehicle crashes.

Practitioners are in a unique position to help combat the current opioid epidemic in this country. Please take time to understand and recognize the signs of this disease in your patients. If you or anyone in your office suspects that a patient may have a problem with opioid dependence, please provide your patients with the below listed information so they, or someone in their family, can get the help that they may need.

Practitioners may also wish to talk with their patients who are currently taking opioids for a legitimate medical issue about the benefits of naloxone (e.g. Narcan®, Evzio®) in the case of an overdose situation which may involve themselves or anyone in their family. These types of products can rapidly reverse the effects of an opioid overdose and are the standard treatment for these types of situations. Information on naloxone products can be found at www.fda.gov.

The Substance Abuse and Mental Health Services Administration (SAMHSA) has a National Helpline, **1-800-662-HELP (4357)**, for those with a possible opioid use disorder. The Helpline is a confidential, free, 24-hour-a-day, 365-day-a-year, information service, in English and Spanish, for individuals and family members facing mental and/or substance use disorders. This service provides referrals to local treatment facilities, support groups, and community-based organizations. Callers can also order free publications and other information here.

To find an authorized Opioid Treatment Program dispensing methadone or buprenorphine to treat opioid dependency in your state visit:

Use of Telemedicine While Providing MAT - May 15, 2018

The Use of Telemedicine While Providing Medication Assisted Treatment (MAT)



Under the Ryan Haight Act of 2008, where controlled substances are prescribed by means of the Internet, the general requirement is that the prescribing Practitioner must have conducted at least one in-person medical evaluation of the patient. U.S.C. § 829(e). However, the Act provides an exception to this requirement. 21 U.S.C. § 829 (e)(3)(A). Specifically, a DEA-registered Practitioner acting within the United States, is **exempt** from the requirement of an in-person medical evaluation as a prerequisite to prescribing or otherwise dispensing controlled substances by

means of the Internet, **if** the Practitioner is engaged in the practice of telemedicine and is acting in accordance with the requirements of 21 U.S.C. § 802(54).

Under 21 U.S.C. § 802(54)(A),(B), for **most** (DEA-registered) Practitioners in the United States, **including** Qualifying Practitioners and Qualifying Other Practitioners ("Medication Assisted Treatment Providers") who are using FDA approved Schedule III-V controlled substances to treat opioid addiction, the term "practice of telemedicine" means the practice of medicine in accordance with applicable Federal and State laws, by a practitioner (other than a pharmacist) who is at a location remote from the patient, and is communicating with the patient, or health care professional who is treating the patient, using a telecommunications system referred to in section 1395m(m) of Title 42 (42 C.F.R. § 410.78(a)(3)), which practice is being conducted:

A. while the patient is being treated by, and physically located in, a DEA-registered hospital or clinic registered under 21 U.S.C. § 823(f) of this title; and by a practitioner

- -who is acting in the usual course of professional practice;
- -who is acting in accordance with applicable State law; and
- -is registered under 21 U.S.C. § 823(f) with the DEA in the State in which the patient is located.

OR

B. while the patient is being treated by, and in the physical presence of, a DEA-registered practitioner

- -who is acting in the usual course of professional practice;
- -who is acting in accordance with applicable State law; and
- -is registered under 21 U.S.C. § 823(f) with the DEA in the State in which the patient is located.

Use of Mobile Devices in the Issuance of EPCS - August 16, 2018

Use of Mobile Devices in the Issuance of EPCS



The DEA is issuing the following statement regarding the use of mobile devices for issuing electronic prescriptions for controlled substances (EPCS) due to confusion surrounding this issue.

At this time, the DEA does not preclude the use of a mobile device, for the issuance of an electronic prescription for a controlled substance, **if** the encryption used on the device

meets security requirements set out in Federal Information Processing Standards (FIPS 140-2). The DEA will allow the use of a mobile device as a hard token, that is separate from the computer or device running the EPCS application, **if** that device meets FIPS 140-2 Security Level 1 or higher. The device used to create the prescription cannot be the same device that serves as the hard token in the two-factor authentication.

A practitioner who uses a mobile or other electronic device for EPCS, and who does not wish to carry a hard token on a separate device, must use biometrics, and a password or a challenge question. See 21 C.F.R. §§ 1311.115 and 1311.116.

A practitioner may issue an electronic prescription for a Schedule II, III, IV, or V controlled substance when all of the requirements under 21 C.F.R. Part 1311 (Subpart C) are met.

Please note that while this document reflects DEA's interpretation of the relevant provisions of the Controlled Substances Act (CSA) and DEA regulations, to the extent it goes beyond merely reiterating the text of law or regulations, it does not have the force of law and is not legally binding on registrants.

For more information contact DEA Policy & Liaison Section at ODLP@usdoj.gov.

April 10, 2019

Continuing Education available through the FDA-approved Opioid Analgesic Risk Evaluation and Mitigation Strategy (REMS)

Opioid analgesics, such as hydrocodone, oxycodone, and morphine, are powerful pain-reducing medications that have both benefits as well as potentially serious risks. The FDA has determined that a Risk Evaluation and Mitigation Strategy (REMS) is necessary for all opioid analgesics intended for outpatient use to ensure that the benefits of these drugs continue to outweigh the risks. The Opioid Analgesics REMS, approved on September 18, 2018, is one strategy among multiple national and state efforts to reduce the adverse outcomes of addiction, unintentional overdose, and death resulting from inappropriate prescribing, abuse, and misuse of opioid analgesics.

The REMS program requires that training be made available to all health care providers (HCPs) who are involved in the management of patients with pain, including nurses and pharmacists. To meet this requirement, drug companies with approved opioid analgesics are providing unrestricted grants to accredited continuing education (CE) providers for the development of accredited CE programs for HCPs based on the with Pain.

Although training is not mandatory for HCPs to prescribe or dispense opioid analgesics, the FDA believes that all HCPs involved in the management of patients with pain should be educated about the fundamentals of acute and chronic pain management and the risks and safe use of opioids so that when they write or dispense a prescription for an opioid analgesic, or monitor patients receiving these medications, they can help ensure the proper product is selected for the patient and used with appropriate clinical oversight.

HCPs are strongly encouraged to use the <u>Patient Counseling Guide</u> to discuss the safe use, serious risks, and proper storage and disposal of opioid analgesics with patients and/or their caregivers every time these medicines are prescribed. HCPs are also strongly encouraged to emphasize to patients and their caregivers the importance of reading the Medication Guide every time it is provided by their pharmacist, and to consider other tools to improve patient, household, and community safety such as a patient-provider agreement.

Accredited CE programs available under the Opioid Analgesic REMS are offered for free or for a nominal fee and can be found at the following website: https://search.opioidanalgesicrems.com/Guest/Guest/AgeExternal.aspx



DEA RX Drug Take Back - Saturday, October 27, 2018

DEA National RX Drug Take Back Day



DEATakeBack.com

On Saturday, October 27, 2018, from 10:00am to 2:00pm, the Drug Enforcement Administration (DEA) will hold its 16th National Prescription Drug Take Back Day. Held on the last Saturday of April and October of every year, this national event addresses a crucial public safety and public health issue. Since its introduction to the public on September 25, 2010, the DEA has collected and incinerated over **4,982 tons** of unwanted, unused, and

potentially dangerous medications.

According to the 2016 National Survey on Drug Use and Health **6.2 million Americans misused controlled prescription drugs**. Unfortunately, a majority of misused prescription drugs are obtained from family, friends, and relatives from their kitchen, bedroom or medicine cabinet.

The DEA's National Take Back Day is an opportunity for Americans to help prevent drug addiction and overdose deaths and to raise awareness about the dangers of opioid misuse.

The DEA is asking for your help in getting the word out. As a DEA-registered doctor, dentist, nurse practitioner, physician's assistant, veterinarian and/or state authorized dispensing pharmacist, you are perfectly situated to help DEA spread the word about this important initiative. You can help by providing patients with information on how to locate a safe, convenient and anonymous collection location on October 27th.

For more information please visit <u>DEAtakeback.com</u>. We have also created a "<u>Partnership Toolbox</u>" where you will find posters and pamphlets, in both English and Spanish, that you can print and place in your waiting rooms. This site may also be used to <u>identify a collection location</u> in close proximity to your office.

Please help DEA in its effort to help keep unused prescription drugs out of the wrong hands. The DEA thanks you for your support!

Safe Prescribing Saves Lives

Use the resources below to learn more about DEA, SAMHSA, and CDC working together to help you prescribe with confidence



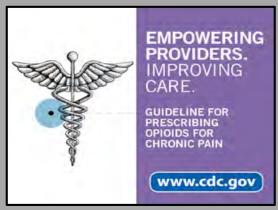
A DEA RESOURCE FOR PARENTS, EDUCATORS & CAREGIVERS

www.getsmartaboutdrugs.gov

NATIONALHELP (4357)

www.samhsa.gov/treatment











Do You or a Family Member Need Help with Drugs?

1-800-662-HELP (4357)









A Final Note



Mission

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.



21 C.F.R. § 1306.04 (a)

A prescription for a controlled substance to be effective must be issued for a <u>legitimate</u> medical purpose by an individual practitioner acting in the usual course of his <u>professional practice</u>.



Solutions to the Problem

Prevention/Detection

Education

Treatment

Enforcement

- 1. What are some basic limits Delaware has placed on first time controlled substance prescriptions for an acute episode?
 - A. 5 Day Supply for Minors
 - B. 15 Days (ER and Urgent Care)
 - C. No Special Restriction
 - D. 7 Day Supply for Acute Episode (Initial)

2. What are the top three most commonly prescribed controlled substances in the U.S.?

- A. Hydrocodone
- B. Methadone
- C. Oxycodone
- D. Alprazolam
- E.Tramadol
- F. A,C, & D.

3. According to the CDC approximately how many people died from drug overdoses in the year 2017?

A. 47, 055

B. 52,404

C. 63,632

D. 70,237

- 4. Under Federal Law what is the primary responsibility of practitioners when it comes to issuing prescriptions for controlled substances?
 - A. A prescription must be issued for a legitimate medical need.
 - B. A prescription must issued in the usual course of professional practice.
 - C. A&B

5. According to IMS Data the total number of prescriptions being filled for oxycodone for the last three years has declined?

A. Yes

B. No



Thank You

