



The Opioid Epidemic and the Practice of Medicine

Practitioner Diversion Awareness Conference
Nashville, Tennessee
November 18-19, 2018



The United States Department of Justice
Drug Enforcement Administration

James Arnold
Chief of Liaison
Diversion Control Division



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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 Tennessee placed on Schedule 2 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 2016?**
- 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



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 legitimate medical purpose by an individual practitioner acting in the usual course of his professional practice.



Public Health Epidemic

In 2014, there were **47,055** drug overdose deaths,

...one death every **11.16** minutes,

...approximately **128** per day,

...**19,000** were due to prescription opioid pain relievers

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 2015, there were **52,404** drug overdose deaths,

...one death every **10.06** minutes,

...approximately **143** per day,

...**22,598** were due to prescription opioid pain relievers



Public Health Epidemic

In 2016, there were **63,632** drug overdose deaths,

...one death every **8.28** minutes,

...approximately **174** per day,

...**42,249** were due to opioids



Public Health Epidemic

Preliminary reported numbers 2017

over **72,000** drug overdose deaths,

...one death every **7** minutes,

...approximately **197** per day,

...**30,000** were due to fentanyl and
other synthetic analogs

Soldier Field

Capacity: 61,500



Mountaineer Field Capacity: 60,000





Drug Poisoning Deaths, 1999-2016



Source: Centers for Disease Control and Prevention, National Center for Health Statistics. *Underlying Cause of Death 1999-2016* on CDC WONDER Online Database, released 2017. Data on drug poisoning deaths were extracted by ONDCP from <http://wonder.cdc.gov/mcd-icd10.html> on December 21, 2017.



Heroin Seizure



Pharmaceutical Oxycodone 30mg



U.S. Drug Enforcement Administration

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

- Hydrocodone
- Oxycodone
- Alprazolam
- Tramadol
- Zolpidem
- Clonazepam
- Lorazepam
- Dextroamphetamine
- Codeine
- Methylphenidate



The Most Common Drugs Involved in Prescription Opioid Overdose Deaths

Hydrocodone

Oxycodone

Methadone



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



1804

Morphine is Distilled from Opium for the First Time

Sam Quinones, 2015, *Dream Land: The Tale of America's Opiate Epidemic*



1839

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

Sam Quinones, 2015, Dream Land: The Tale of America's Opiate Epidemic



1853

**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”



1898

**Bayer Chemist Invents
diacetylmorphine,**

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.**









**POPULAR
FRENCH TONIC WINE**

*Fortifies and Refreshes Body & Brain
Restores Health and Vitality*

St. Louis

© 1911 J. H. P. Co. St. Louis, Mo.

This advertisement features a woman in a vibrant yellow dress with a floral corsage, holding a wine glass. The background is a mix of blue and white. The word 'MARIAN' is partially visible in large red letters at the top. The text 'POPULAR FRENCH TONIC WINE' is prominently displayed in blue, with a smaller italicized line of text below it. A signature 'St. Louis' is visible on the left side.

HALL'S COGNAC WINE

THE ELIXIR

This advertisement features a woman in a yellow dress with a black and gold patterned cape and a large floral headpiece. The background is a solid red color. The text 'HALL'S COGNAC WINE' is written in large, stylized silver letters at the top. Below the woman, the words 'THE ELIXIR' are written in large, bold black letters.



For HAY FEVER,
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.



COCAINE TOOTHACHE DROPS

Instantaneous Cure!

PRICE 15 CENTS.

Prepared by the

LLOYD MANUFACTURING CO.

219 HUDSON AVE., ALBANY, N. Y.

For sale by all Druggists.

(Registered March 1885.)

See other side. ¹⁹

MRS WINSLOW'S



THE

MOTHER'S

FRIEND

FOR

CHILDREN

TEETHING

SOOTHING SYRUP

The "Allenburys" Throat Pastilles

No. 56.

Menthol, Eucalyptus and Cocaine

$\frac{7}{10}$ Menthol, 1 min. Eucalyptus Oil, $\frac{1}{20}$ gr. Cocaine.

*A Pastille may be taken every four or six hours,
if required.*

Manufactured by

Allen & Hanburys Ltd.

LONDON

TRADE MARK

For Body and Brain

Since 30 Years all Eminent Physicians recommend

VIN MARIANI

Over 7,000
written in-
dorsements
from prominent
Physicians in
Europe and
America

Nourishes
Fortifies
Refreshes
Strengthens the
Entire System

Most popularly
used Tonic-
Stimulant in
Hospitals, Pub-
lic & Religious
Institutions
Everywhere

The most Agreeable, Effective and Lasting Tonic

Ask for Vin Mariani
at Druggists and
Fancy Grocers

EVERY Test, strictly
on its Own Merits,
proves its Excep-
tional Reputation

To avoid disappoint-
ments accept no sub-
stitutions

Free Offer! We will mail, gratis,
75 Portraits, Sketches,
Biographical Notes and
Autographs of Celebrities, testifying to excellence
of "Vin Mariani"

Paris: 41 Boulevard Haussmann
London: 239 Oxford Street

Mariani & Co.
52 W. 15th St., New York



**A COLD BOTTLE ON A
HOT DAY**



Is a natural desire; but, *remember*, there is just one thing that the bottle can hold will enable you to forget worry and fatigue—*Coca-Cola* quenches the thirst, refreshes, invigorates, as nothing else can.

Its Purity Proved by Analysis

CHEMICAL DEPARTMENT
South Carolina College
COLUMBIA, S. C.

This is to certify that, pursuant to your request, I have bought in the open market (from the Murray Drug Co.) an original package of five gallons, of Coca-Cola syrup bearing the label of "The Coca-Cola Co., Atlanta, Ga.," and have subjected the same to careful analysis.

The object of this investigation being to establish the presence or absence of cocaine, and possibly of other injurious alkaloids, I operated on quantities of three to five times the amount contained in a bottle of the carbonated beverage. The extractions of the syrup were repeated until the alkaloids were entirely removed, and different immiscible solvents were used on different portions. The crystalline substance thus obtained was further separated by fractional extractions, after which it was concentrated and tested. Since this concentrated product, which would contain all of the cocaine, failed to respond to the tests for cocaine, it is clear that the alkaloid is absent, or, if present at all, then in quantities too minute to allow of detection. The active constituent of Coca-Cola Syrup proved to be caffeine, and in quantities seemingly less than in a cup of good coffee or tea.

There was no evidence of the presence of other alkaloids.
(Signed)

W. B. BURNEY, Chemist.



Guaranteed under the Pure Food
and Drugs Act, June 30, 1906.
Serial Number 3324.

5c Everywhere 5c

Coca-Cola





February 9, 1909

Congress

Public Law 221

**“An Act to Prohibit the
Importation and Use of Opium
for Other Than Medicinal
Purposes”**



1914

**U.S. Congress Passes Harrison
Tax Act**

Sam Quinones, 2015, *Dream Land: The Tale of America's Opiate Epidemic*



1928

**Committee on the Problems of
Drug Dependence is Formed**

**To Organize Research in Pursuit
of the Holy Grail:
A Non-addictive Painkiller**

Sam Quinones, 2015, *Dream Land: The Tale of America's Opiate Epidemic*



1951

**Arthur Sackler Revolutionizes
Drug Advertising
With Campaign for the
Antibiotic Terramycin**

Sam Quinones, 2015, Dream Land: The Tale of America's Opiate Epidemic



1960

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



1980

***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/NEJM](http://www.nejm.org/doi/pdf/10.1056/NEJM1980011030020221)

M1980011030020221



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.”



1986

**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**



1996

**Purdue releases OxyContin,
timed-released oxycodone,
marketed largely for
chronic-pain patients**



1996

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



1996

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



2002

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



2007

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



2008

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



2011

**Ohio passes House Bill 93,
regulating pain clinics**



2013

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

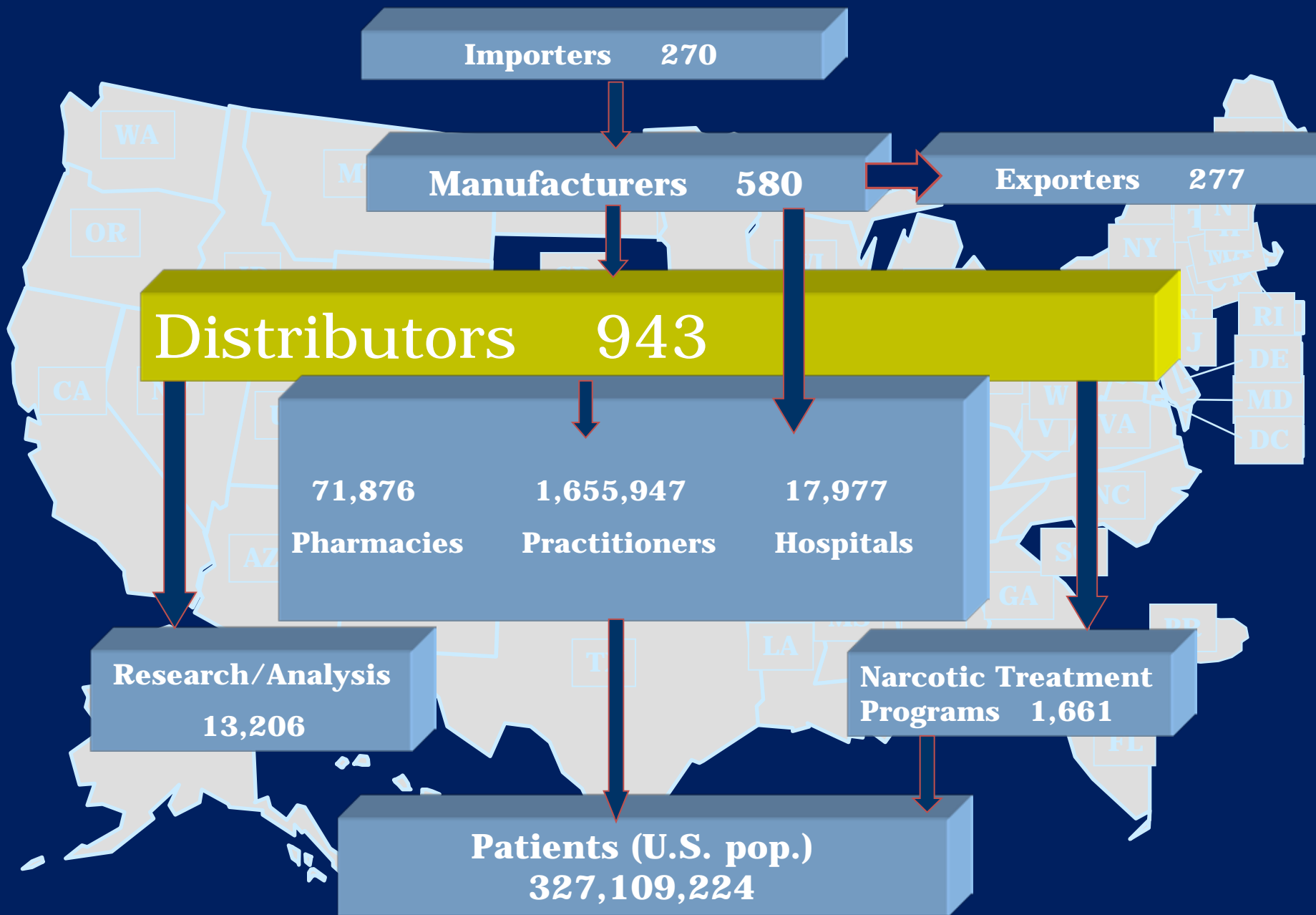
Sam Quinones, 2015, *Dream Land: The Tale of America's Opiate Epidemic*



The Problem Affects Everyone



**No one
Is
Un-Affected**



DEA Registrants as of July 31, 2018: 1,763,068



Livonia doctor, 7 others charged in \$18M prescription drug scheme

January 9, 2018

<http://www.fox2detroit.com/news/local-news/livonia-doctor-7-others-charged-in-18m-prescription-drug-scheme>

“Great Falls pharmacy manager charged with stealing drugs”

January 12, 2018

Seaborn Larson, Great Falls Tribune,
<https://www.greatfallstribune.com/story/news/crime/2018/01/12/great-falls-pharmacy-manager-charged-stealing-drugs/1029290001/>

“Police: Maryland officer arrested after he stole opioids from a bedridden citizen”

February 2, 2018

Brad Bell, WJLA News, <http://wjla.com/news/local/md-police-officer-arrested-sources-say-he-was-allegedly-stealing-opioids-from-citizens>

“Ex-dentist pleads guilty to illegally prescribing drugs”

February 5, 2018

Fox 61, <http://fox61.com/2018/02/05/ex-dentist-pleads-guilty-to-illegally-prescribing-drugs/>

“More than a dozen people arrested in Bloomington drug investigation”

February 6, 2018

Fox59 News, <http://fox59.com/2018/02/06/more-than-a-dozen-people-arrested-in-bloomington-drug-investigation/>

**“Doctor prescribed needless pills
and bilked Medicare, feds say”**

February 12, 2018

Paula McMahon, Sun Sentinel, <http://www.sun-sentinel.com/local/broward/fl-reg-doctor-arrested-fraud-pain-pills-20180212-story.html>

“Las Vegas doctor charged with unlawful distribution of opioid, health care fraud”

February 14, 2018

Brenda Yahm, Fox 5 Vegas, <http://www.fox5vegas.com/story/37505788/las-vegas-doctor-charged-with-unlawful-distribution-of-opioid-health-care-fraud>

“Nurse arrested for forging opioid prescriptions”

February 18, 2018

Jesse Leavenworth, EMS1, <https://www.ems1.com/opioids/articles/375512048-Nurse-arrested-for-forging-opioid-prescriptions/>

“Federal agents raid doctor's office and suspected 'pill mill'”

February 27, 2018

Lee Zurik, Megan Luther, and Andy Miller, WTXL News,
http://www.wtxl.com/news/federal-agents-raid-doctor-s-office-and-suspected-pill-mill/article_0e8a0064-1bf3-11e8-b409-cb776b750102.html

**“Doctor accused of trading
prescription drugs for sex; 44
arrested in massive bust”**

March 1, 2018

Mark Winne, WSBTV, <http://www.wsbtv.com/news/local/doctor-accused-of-trading-prescription-drugs-for-sex-44-arrested-in-massive-bust/709268909>

Philadelphia doctors charged in \$5M prescription drug bust



By [Dann Cuellar](#)

Thursday, May 12, 2016

SOUTH PHILADELPHIA (WPVI) --

According to a federal indictment, three doctors illegally sold over \$5 million worth of prescription drugs out of their now-defunct Philadelphia clinic on South Broad Street.

Two Mobile Pain Doctors Arrested On Drug And Fraud Charges

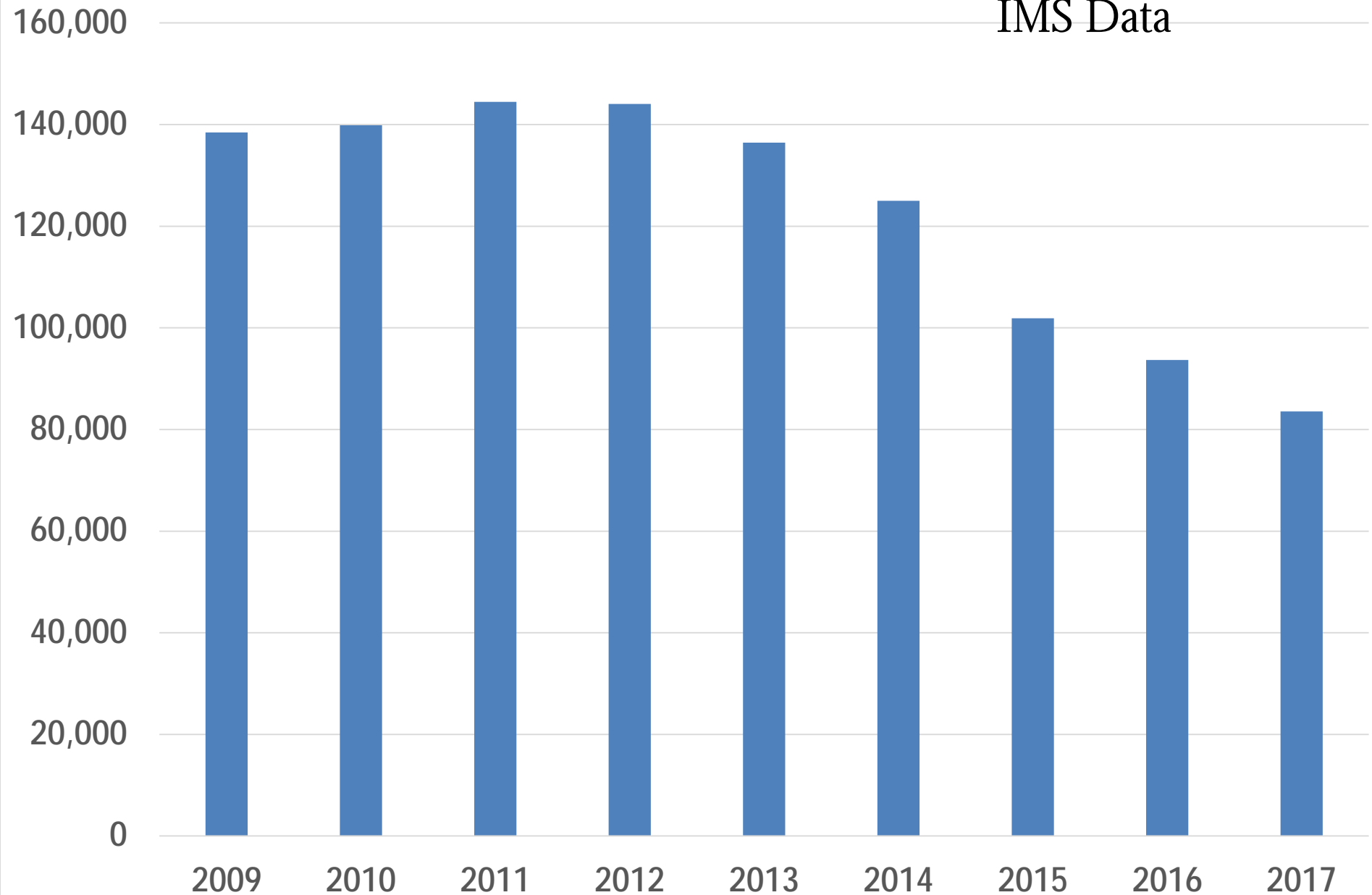
Wednesday, May 20, 2015

United States Attorney Kenyen R. Brown of the Southern District of Alabama, along with FBI-Mobile Special Agent in Charge Robert Lasky, and DEA-Mobile Special Agent in Charge Keith Brown, New Orleans Field Division, announce the arrests of Dr. John Patrick Couch and Dr. Xiulu Ruan.

What's Trending

Total Prescriptions Filled : Hydrocodone 2009-2017 (x 1,000)

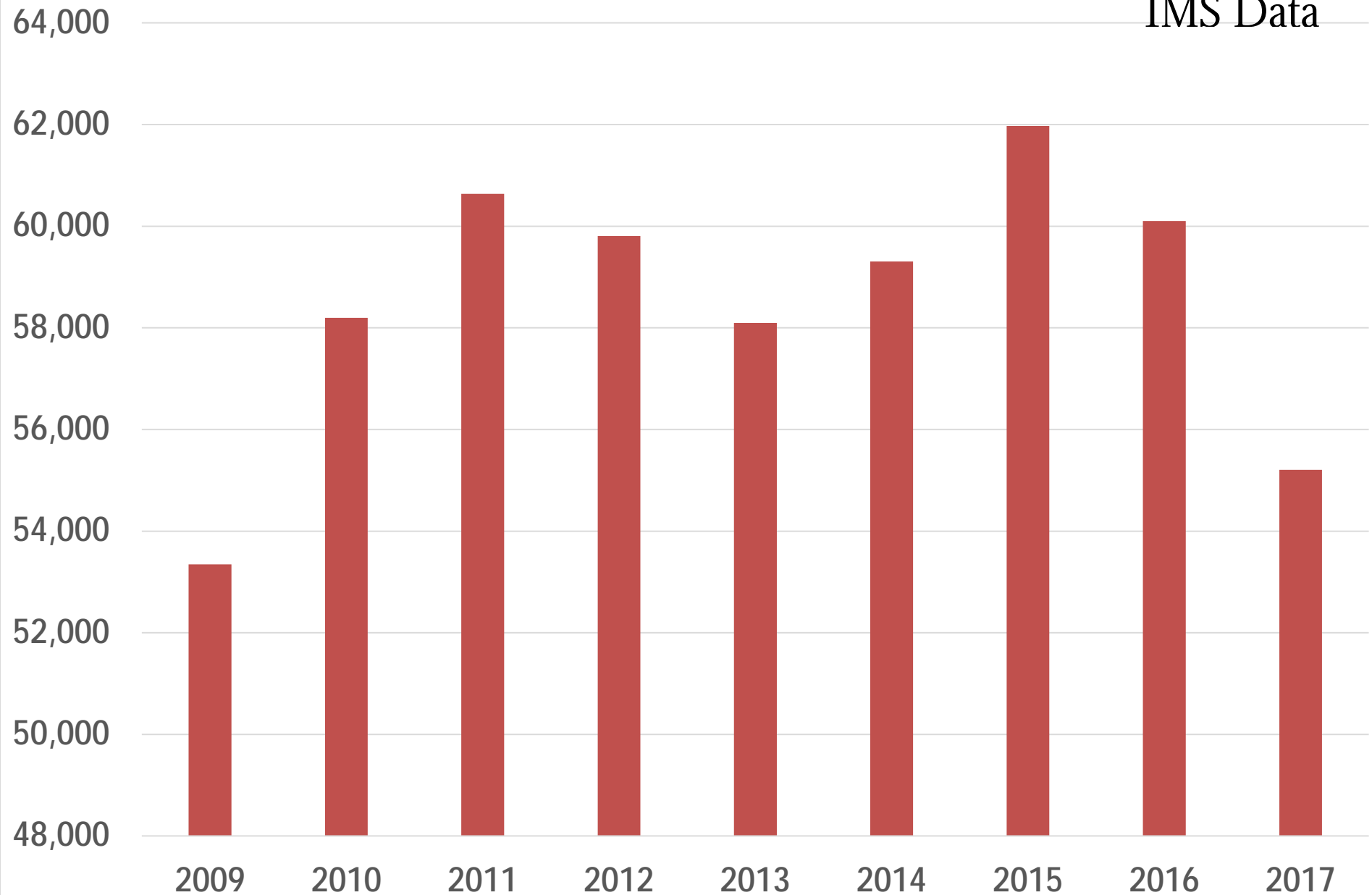
IMS Data



Total Prescriptions Filled: Oxycodone 2009-2017

(x 1,000)

IMS Data



Total Prescriptions Filled: Methadone 2009-2017

(x 1,000)

IMS Data

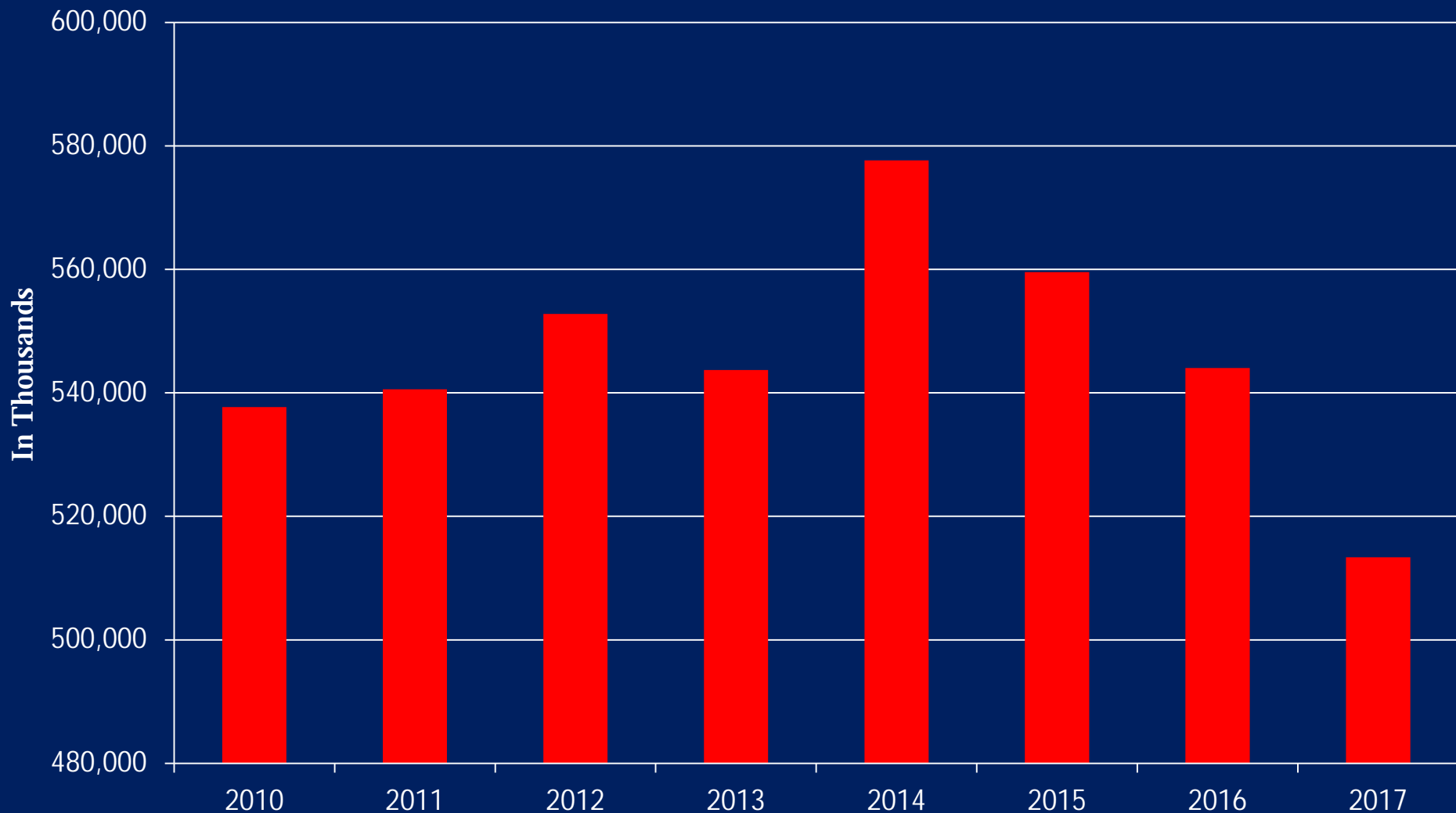




Total Controlled Substance Rx's Filled

IMS Data

Total Controlled Substance Rx's 2009-2017 (In Thousands)



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

Vox

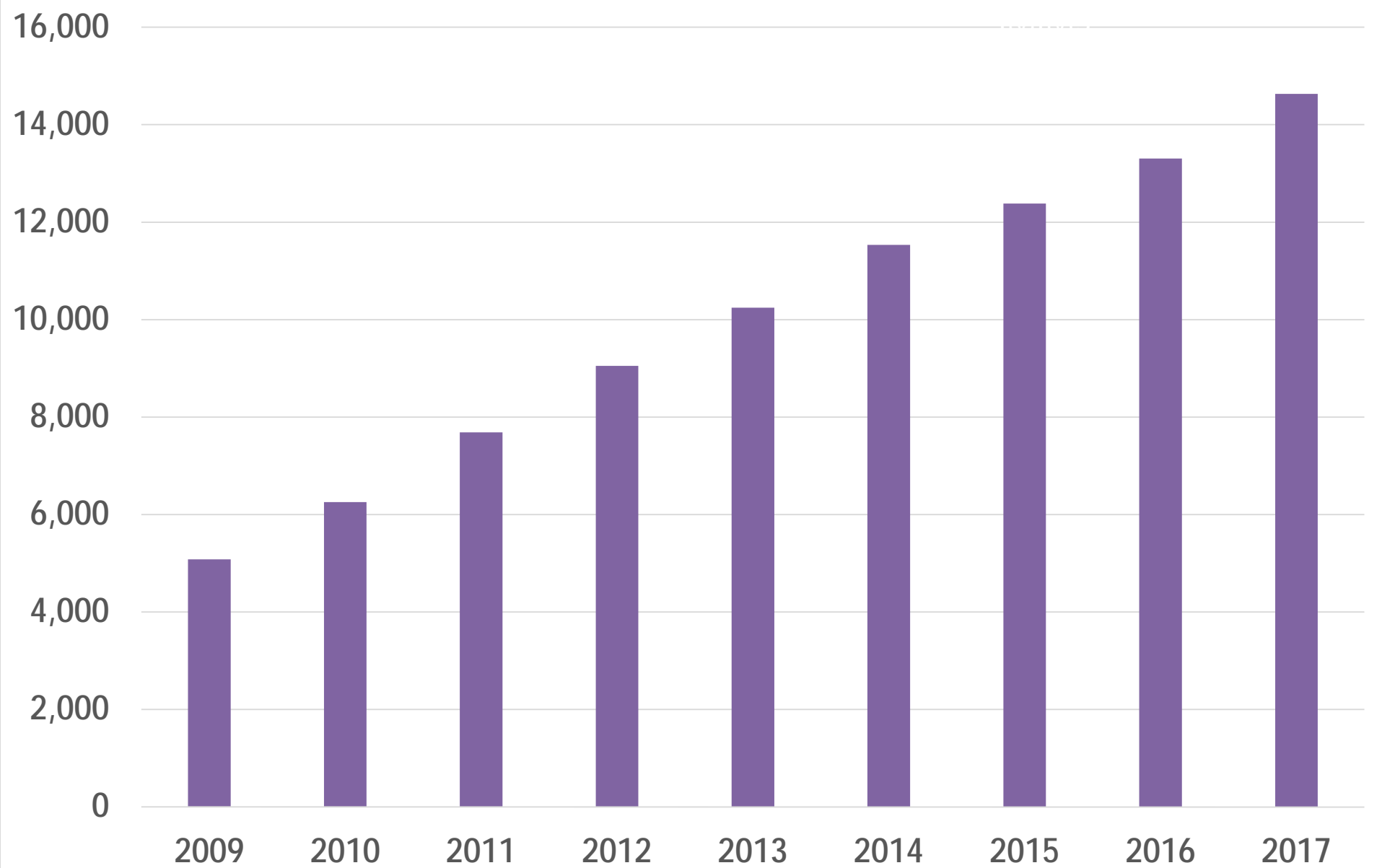
By Dylan Scott

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

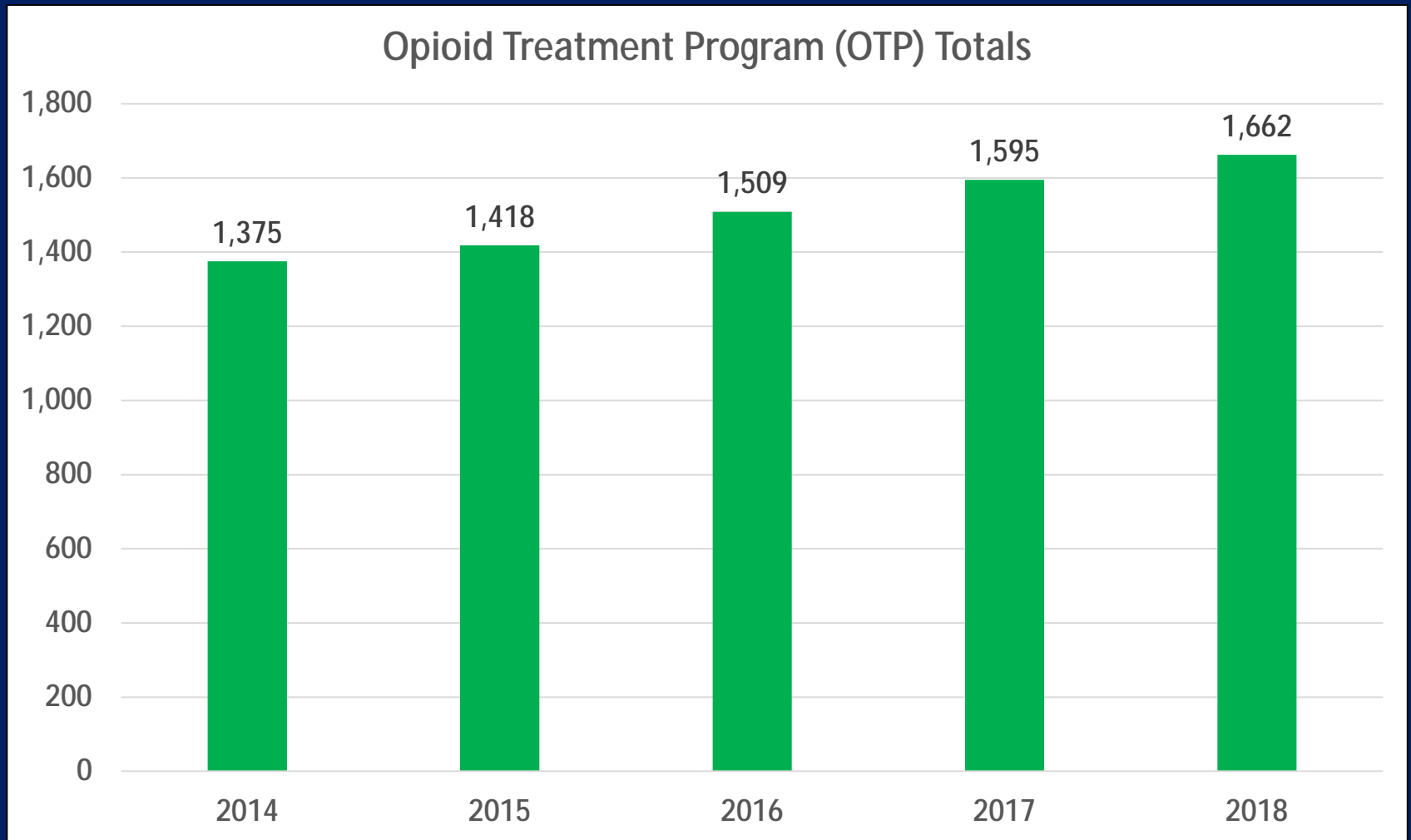
The big finding from the BCBSA data, which compiles medical claims information from the various Blue Cross affiliates across the United States: Diagnoses of opioid use disorder (addiction, in other words) declined from 2016 to 2017, from 6.2 per 1,000 patients to 5.9.

Total Prescriptions Filled: Buprenorphine 2009-2017

(x 1,000)

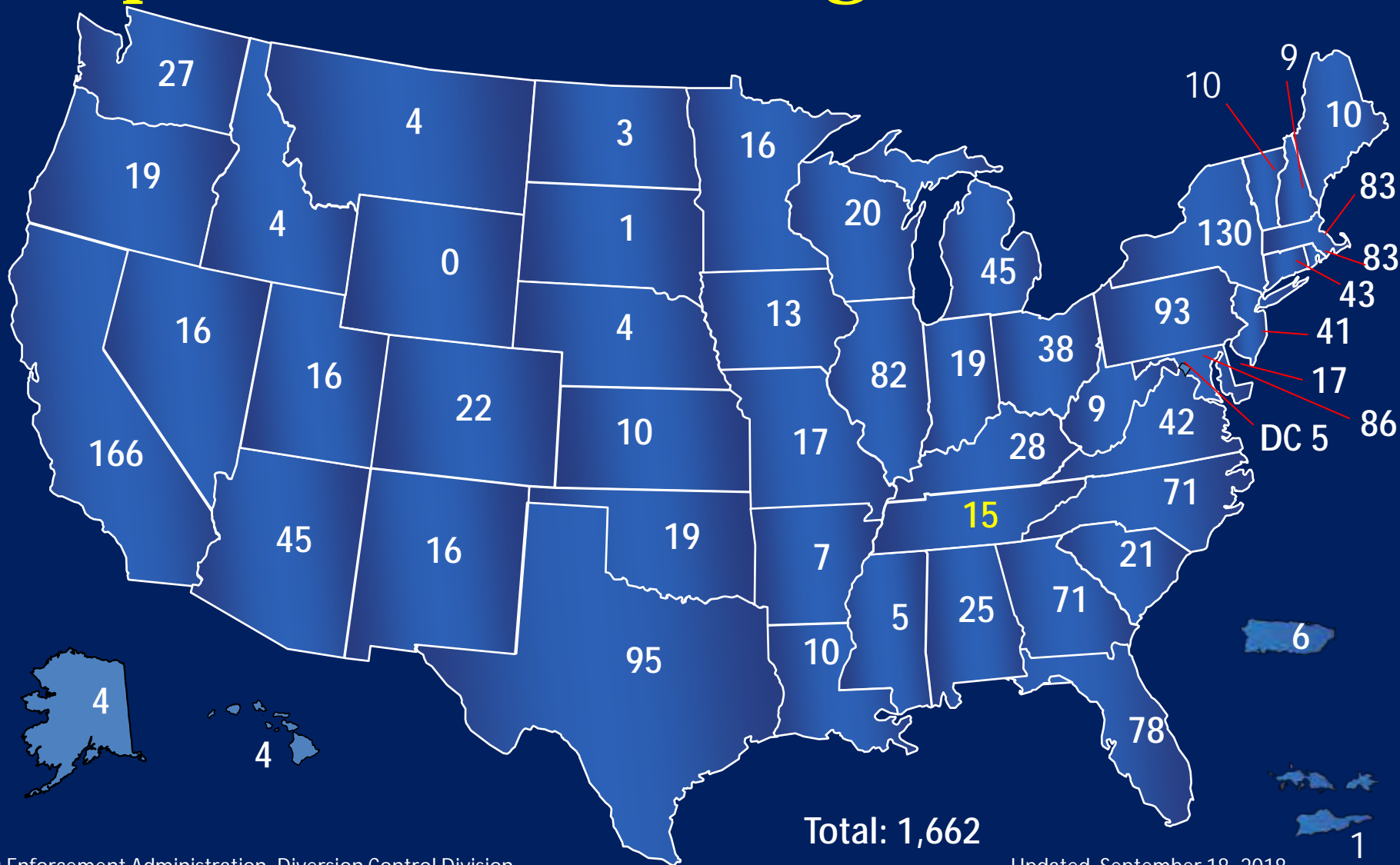


Opioid Treatment Programs (OTPs)



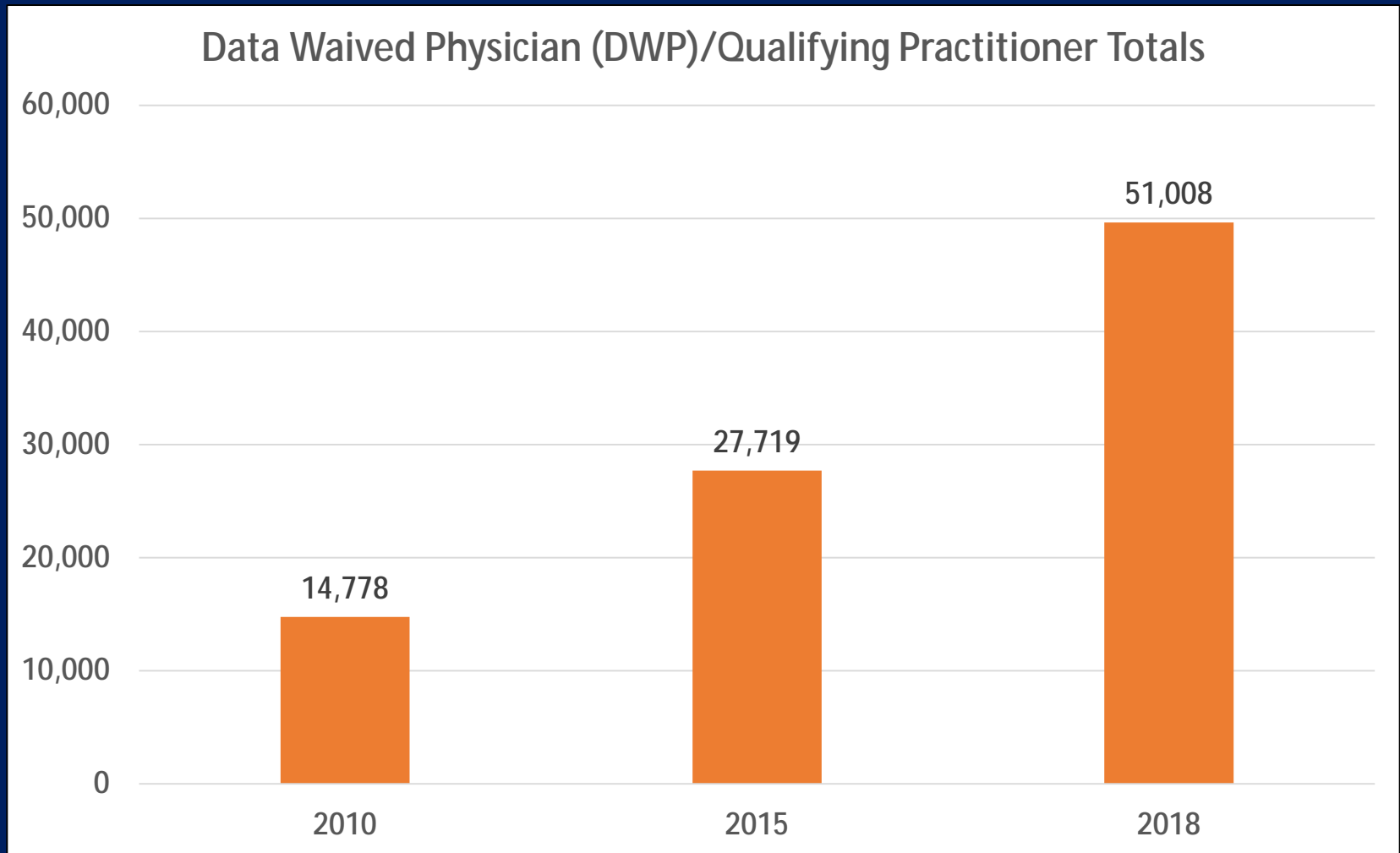
***As of September 18, 2018: DEA Data**

DEA Registered Opioid Treatment Programs (OTP)



Total: 1,662

DEA Registered Qualifying Practitioners



*As of September 18, 2018 (NPs and PAs as of 01/01/2017)

DEA Registered Qualifying Practitioners





Qualifying Practitioners (US)

- **Practitioner DW-30** **29,621**
- **Practitioner DW-100** **9,389**
- **Practitioner DW-275** **4,539**

- **Nurse Practitioner DW-30** **5,917**
- **Physician Assistant DW-30** **1,542**



Qualifying Practitioners (TN)

- **Practitioner DW-30** **382**
- **Practitioner DW-100** **262**
- **Practitioner DW-275** **218**

- **Nurse Practitioner DW-30** **3**
- **Physician Assistant DW-30** **0**

**Nationwide Efforts
to
Combat
the Problem**



States

Practitioners

Hospitals

Treatment Providers

Medical Schools

Pharmacies



States with Limits CII

Alaska 7 Day Supply (initial prescription)

Arizona 7 Day Supply (initial prescription)
7 Day Supply (for minors)

Connecticut 7 Day Supply (initial prescription)
7 Day Supply (for minors)

Delaware Up to 100 dosage units or a
31 day supply, whatever is greater



States with Limits CII

- 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 under certain conditions)
- Indiana 7 Day Supply (initial prescription)
7 Day Supply (for minors)



States with Limits CII

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)



States with Limits CII

Massachusetts	7 Day Supply (unless more in indicated) 7 Day Supply (all opioids for minors)
Massachusetts	30 Day Supply: CII-III 60 Day Supply (Dextroamphetamine)
Missouri	30 Day Supply: CII 90 Day (If medical reason given)
New Hampshire	34 Day Supply: CII 60 Day Supply (ADD/ADHD)



States with Limits CII

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 5 Day Supply (for minors)
Oregon	7 Day Supply (initial prescription) 7 Day Supply (for minors)



States with Limits CII

Pennsylvania 7 Day Supply (for minors)
7 Day Supply
(emergency department
and urgent care centers)

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



States with Limits CII

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)



States with Limits CII

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



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



Gene Myers, Staff Writer, @myersgene

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



Vanessa Romo, May 8, 2018



Non-opioid medication outperforms opioids for chronic pain, study shows

The Washington Times

By Laura Kelly

Journal of the American Medical Association,
March 6, 2018

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.¹⁹⁷

**“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/>

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



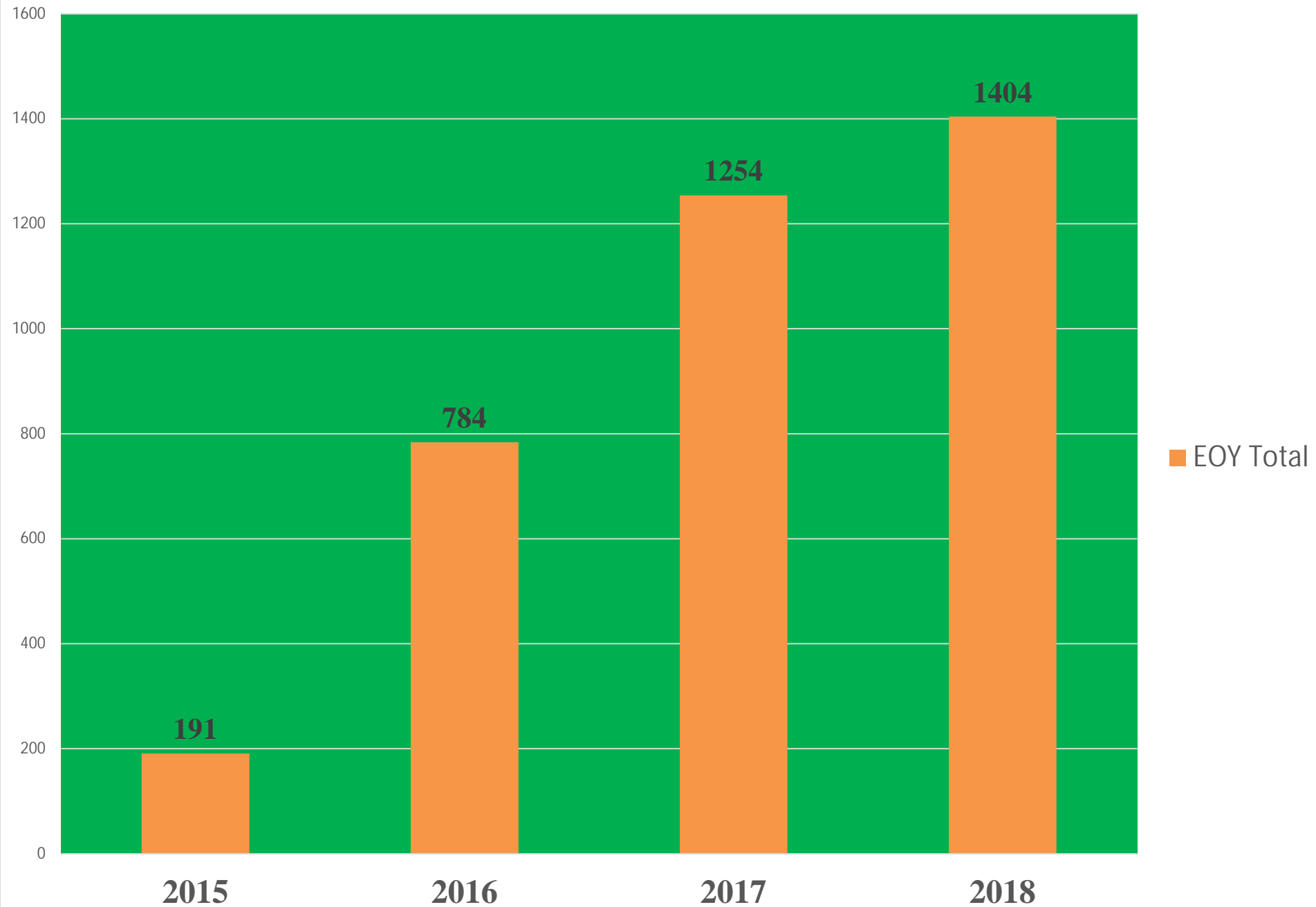
CDC

- 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.



DEA Initiatives

HQ and Field Outreach Totals FY2015-June 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.
2. 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



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.

Safe Prescribing Saves Lives

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

**GET SMART
ABOUT DRUGS**

A DEA RESOURCE FOR PARENTS, EDUCATORS & CAREGIVERS

www.getsmartaboutdrugs.gov

800-662-HELP (4357)

NATIONAL HELPLINE



www.samhsa.gov/treatment




Prescription opioids can be **addictive** and **dangerous**.

It only takes a little to lose a lot.

www.cdc.gov/RxAwareness

Developed by CDC



EMPOWERING PROVIDERS. IMPROVING CARE.

GUIDELINE FOR PRESCRIBING OPIOIDS FOR CHRONIC PAIN

www.cdc.gov



Do You or a Family Member Need Help with Drugs?

1-800-662-HELP (4357)



SAMHSA
Substance Abuse and Mental Health
Services Administration





A Final Note



Solutions to the Problem

Prevention/Detection

Education

Treatment

Enforcement

Post Questions

1. What basic limit has Tennessee placed on Schedule 2 controlled substance prescriptions?
 - A. 60 Days
 - B. 90 Days
 - C. 30 Days

Post Questions

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.

Post Questions

3. According to the CDC approximately how many people died from drug overdoses in the year 2016?

A. 52,404

B. 47,055

C. 63,632

Post Questions

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

Post Questions

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





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