

DEA Diversion Control Mission and Overview

Michigan Practitioner Diversion Awareness Training

June 14, 2019

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Diversion Program Manager

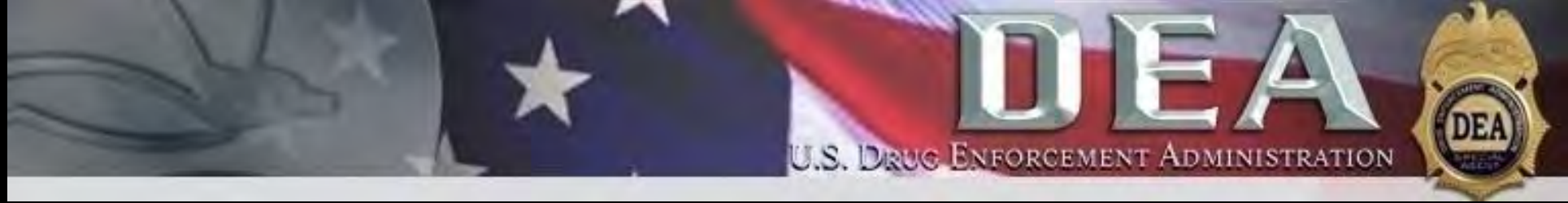
Detroit Field Division (Michigan/Ohio)

Disclosure

I do not have any relevant financial relationships with any commercial interests or any other conflicts of interests to disclose

Overview

- A Public Health Epidemic
- The Controlled Substances Act
- Diversion Control Program
- The Impact of Prescriptions
- Responsible Drug Disposal
- DEA Take Back Day



Public Health Epidemic

National Statistics: 2017

- 130 opioid-related deaths per day
- 12% increase in death rate from 2016
- Males aged 25-34 experienced the highest rate of drug overdose deaths in 2017
- Estimated \$504 billion in economic costs (2016)



Annual Drug-Related Deaths



Ford Field
Detroit, Michigan

Capacity: 65,000
2017 deaths: **70,237**

Annual Opioid-Related Deaths



Comerica Park
Detroit, Michigan

Capacity: 41,297
2017 deaths: **47,600**

National Statistics

- An estimated 21-29 percent of patients prescribed opioids for chronic pain misuse them
 - Between 8 and 12 percent develop an opioid use disorder
 - Approximately 4 to 6 percent who misuse prescriptions transition to heroin
 - About 80 percent of heroin users first misused prescription opioids



How Did We Get Here?



Heroin use is part of a larger substance abuse problem.

Nearly all people who used heroin also used at least one other drug.

Most used at least three other drugs.

Heroin is a highly addictive opioid drug with a high risk of overdose and **death** for users.

People who are addicted to...



ALCOHOL are 2x



MARIJUANA are 3x

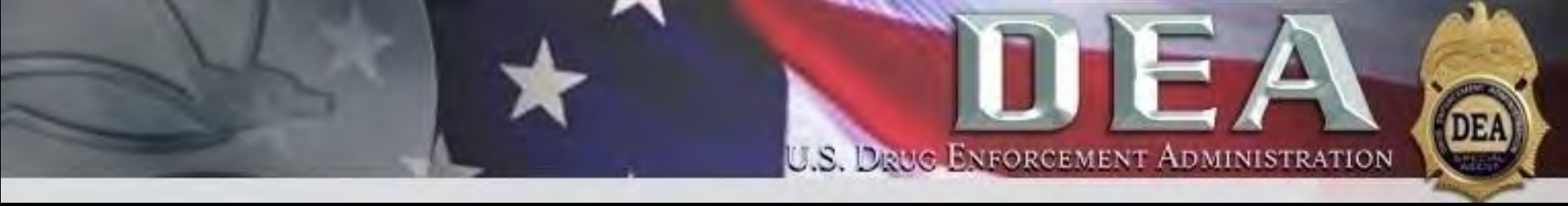


COCAINE are 15x



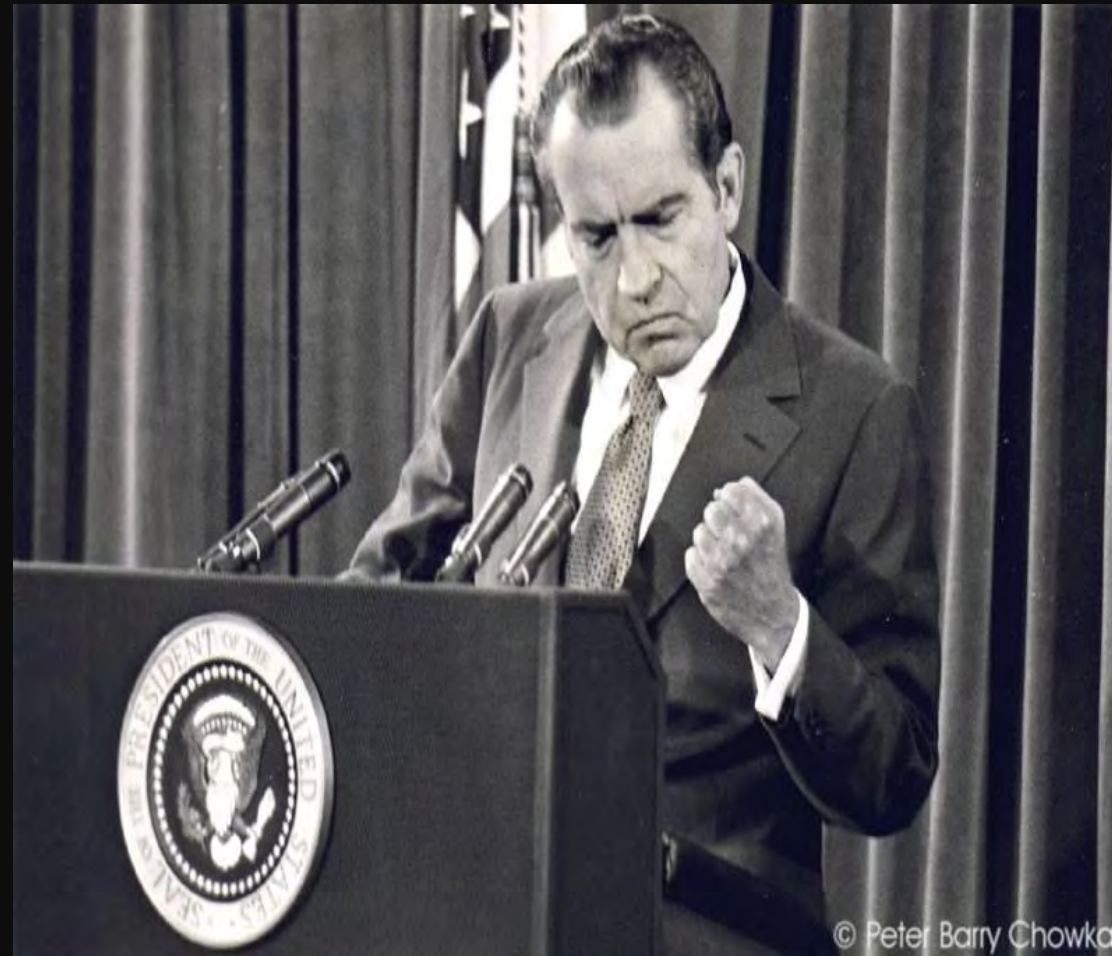
PRESCRIPTION OPIOID PAINKILLERS are 40x

...more likely to be addicted to heroin.

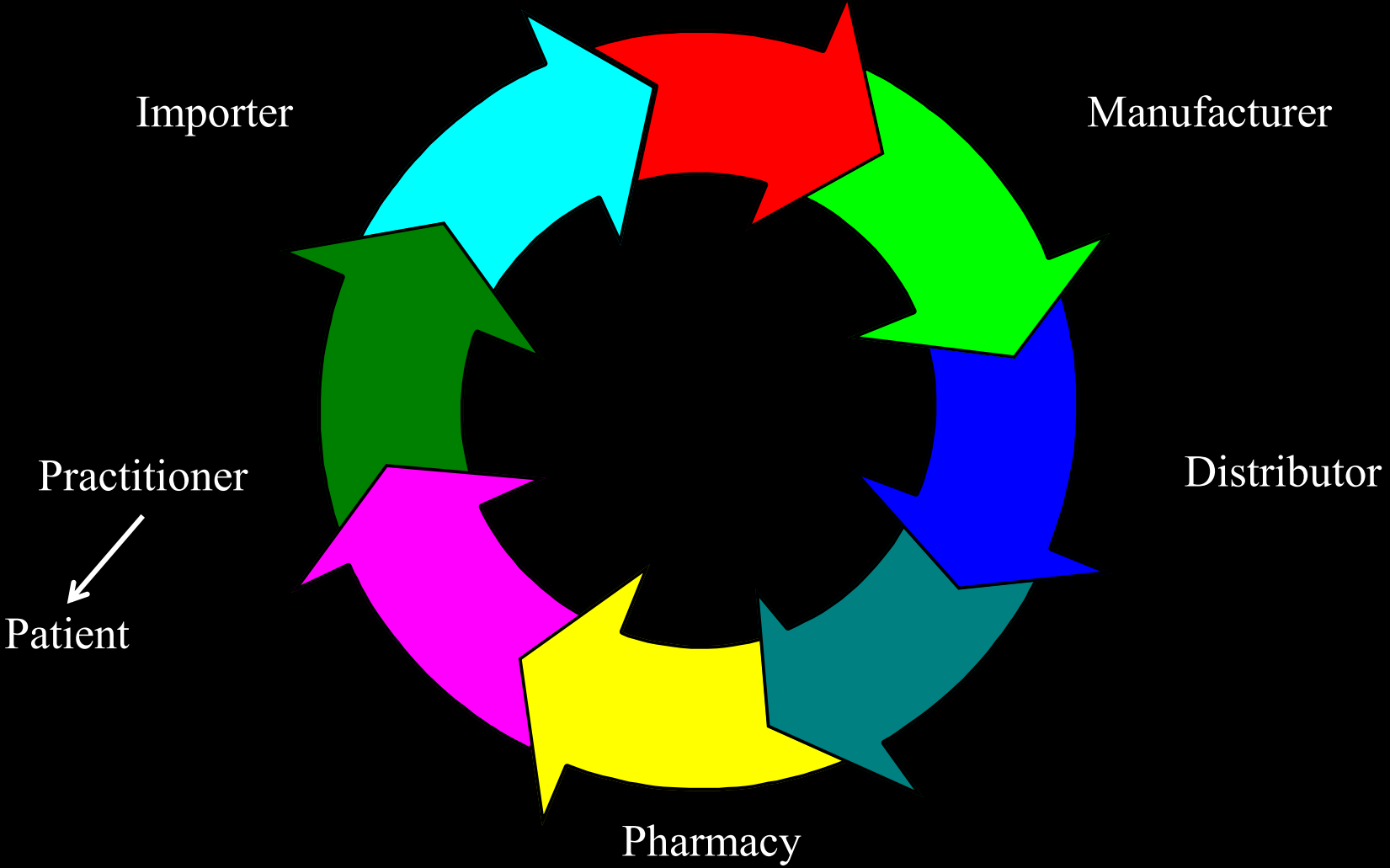


The Controlled Substances Act of 1970

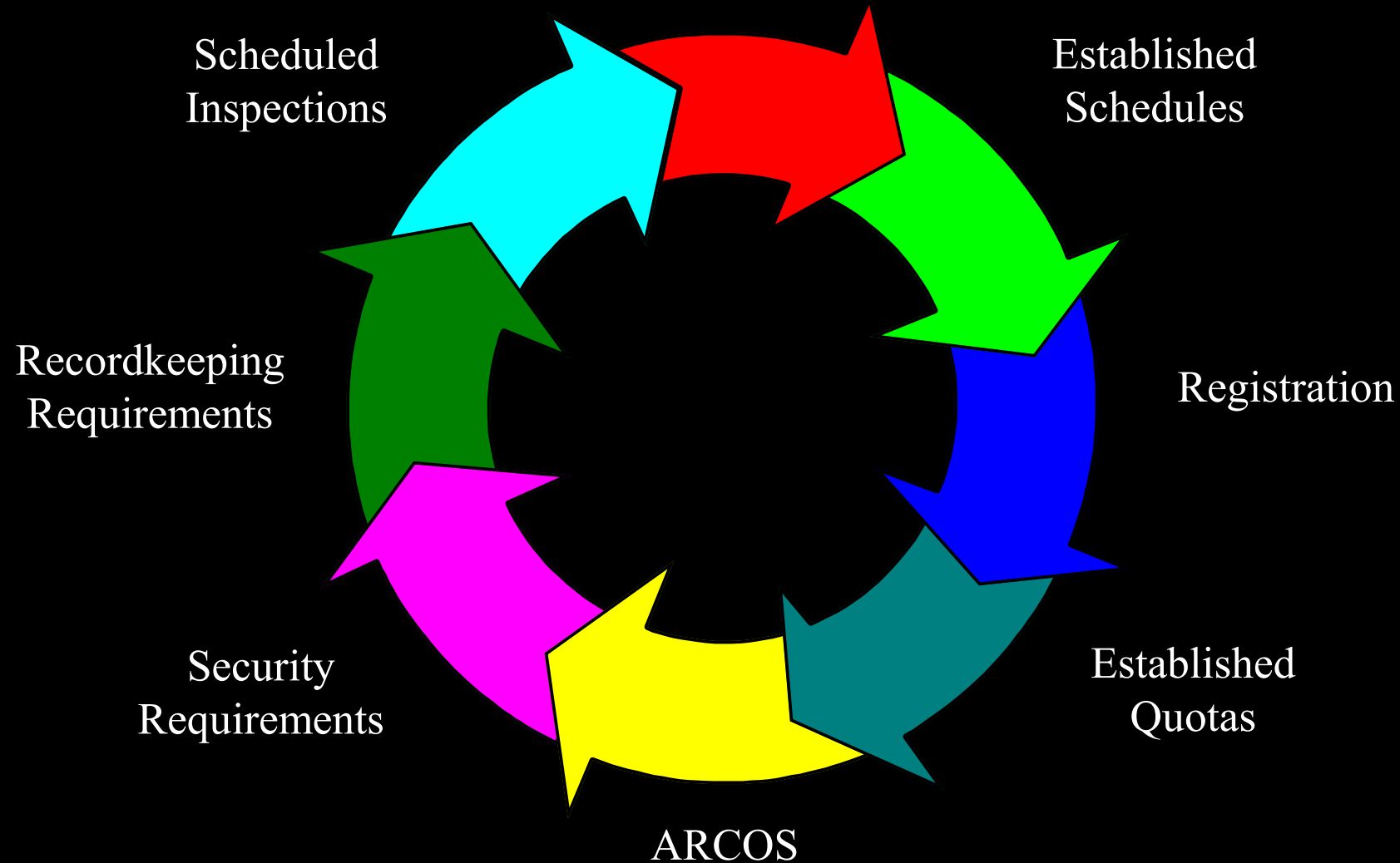
Uniform Controlled Substances Act of 1970 (CSA)



The CSA's Closed System of Distribution



Maintaining the CSA's Closed System of Distribution





Closed System of Distribution

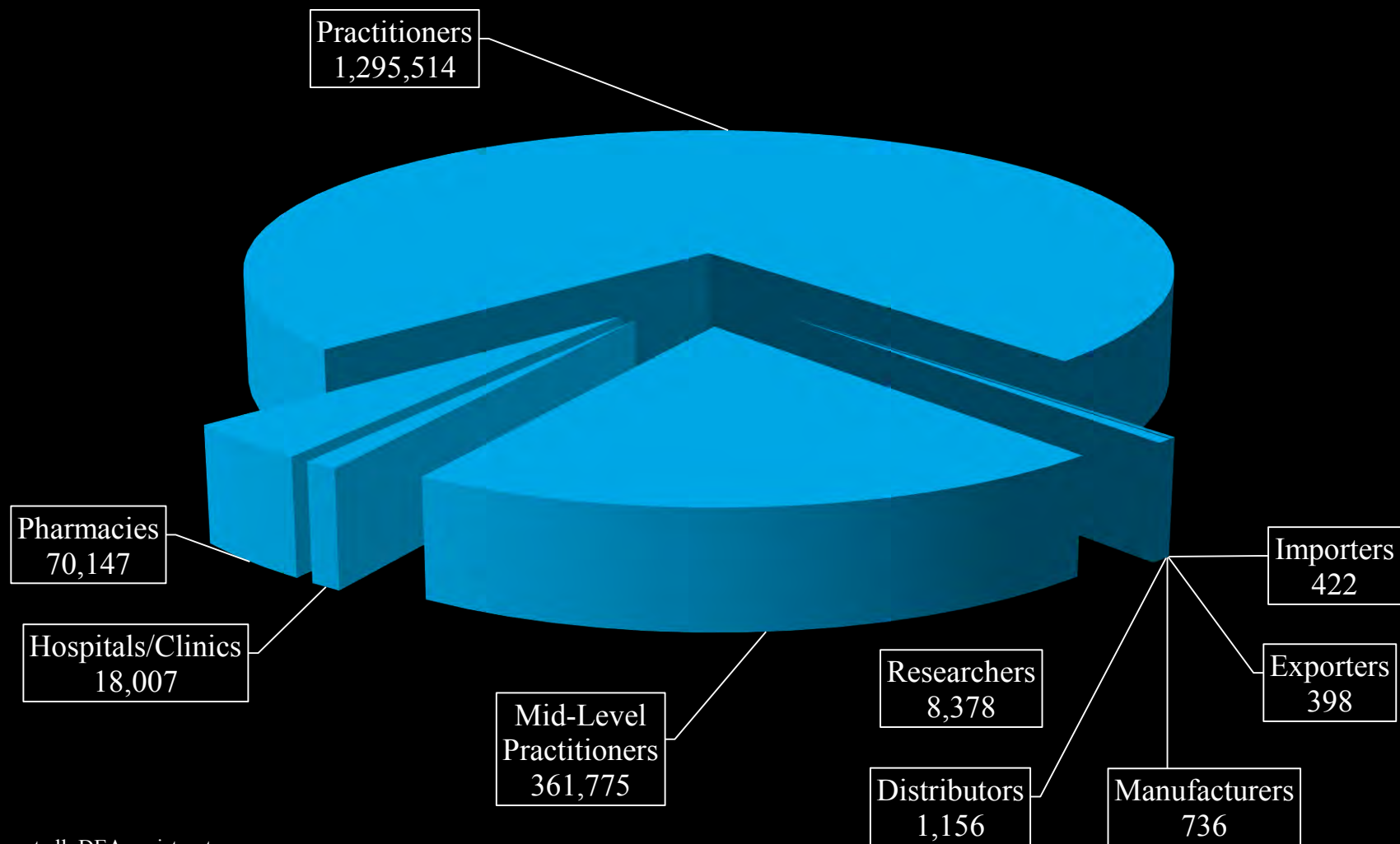
The DEA is responsible for:

- The *oversight* of the system
- The *integrity* of the system
- The *protection* of the public health and safety

DEA does *NOT* regulate the practice of medicine

Active Registrants

1,797,258* total (nationwide)



*Chart totals represent some, not all, DEA registrants

*Source: RICS
Date Prepared: 06/03/2019

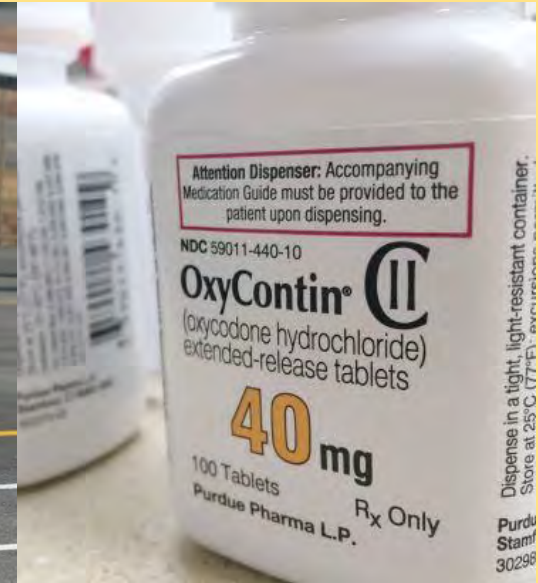
Michigan Registrant Population

(53,680 registrants*)

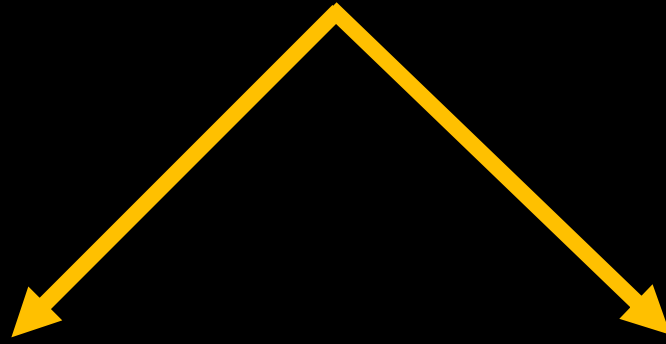
■ Manufacturers:	19
■ Distributors:	23
■ Practitioners:	38,372
■ NPs/PAs:	11,209
■ Pharmacies:	2,537
■ Opioid Treatment Programs:	45
■ DATA-Waived Practitioners:	1,566*
	*2.9%

*not all registrants are represented by the listed categories

Enforcing the CSA...



DEA



Diversion Control Program

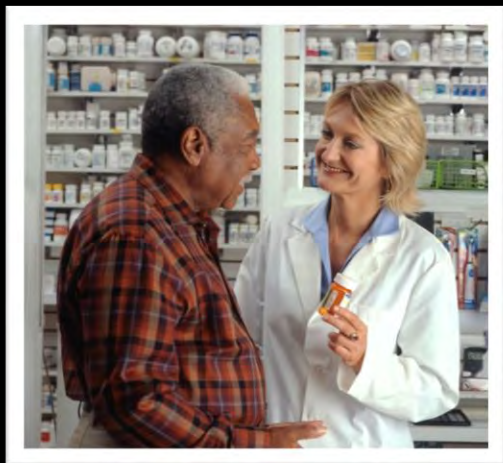


Enforcement



Diversion Control Division Mission

To prevent, detect, and investigate the diversion of controlled substances from legitimate sources



while



ensuring an adequate and uninterrupted supply for legitimate medical and scientific purposes

Diversion Control Division

Target:
DIVERSION



Goal:
COMPLIANCE

Compliance: Life or Death Issue

UM Health System pays record \$4.3 million settlement in drug diversion case

The DEA began its investigation after two tragic incidents occurred in December 2013 involving two UMHS employees - a nurse and an anesthesiology resident.

On a single day that December, a nurse and doctor both overdosed on stolen pain medication in different areas of the sprawling University of Michigan Health System.

Both were found in hospital bathrooms with drugs meant for patients injected into their own bodies.

The DEA concluded that UMHS' deficient record keeping negatively impacted UMHS' ability to guard against the theft and diversion of controlled substances.



Inspection Authority

- Notice of Inspection DEA Form 82
- Administrative Inspection Warrant
- Search Warrant



Potential Consequences





DEA Actions

- Administrative actions
- Civil litigation
- Criminal prosecutions





Administrative Actions

Letter of Admonition (LOA)

Memorandum of Agreement (MOA)

Order to Show Cause (OTSC)

Immediate
Suspension
Order (ISO)

Argue case in
front of Admin
Law Judge





Civil Penalties USC 842

- Registrant has refused or negligently failed to make, keep or furnish any information required to be kept
- As of 8/1/2016: Each violation can be assessed up to \$14,502 or \$62,500 per instance
- No intent necessary





Criminal Penalties USC 843

- Distributes a Schedule 2 w/o Order Form
- Obtain a CS by fraud, misrepresentation, forgery, deception, or subterfuge
- Furnish false or fraudulent or omit material information from a required record



Criminal Penalties

Title 21 US Code 841:



Sentencing is based on marijuana equivalents

Prescription Requirements



In order to be legal, a prescription must be issued:

- By a registered practitioner;
- For a legitimate medical purpose;
- In the usual course of professional practice.



Pharmacist's corresponding responsibility:

- Corresponding responsibility rests with the pharmacist who fills the prescription.

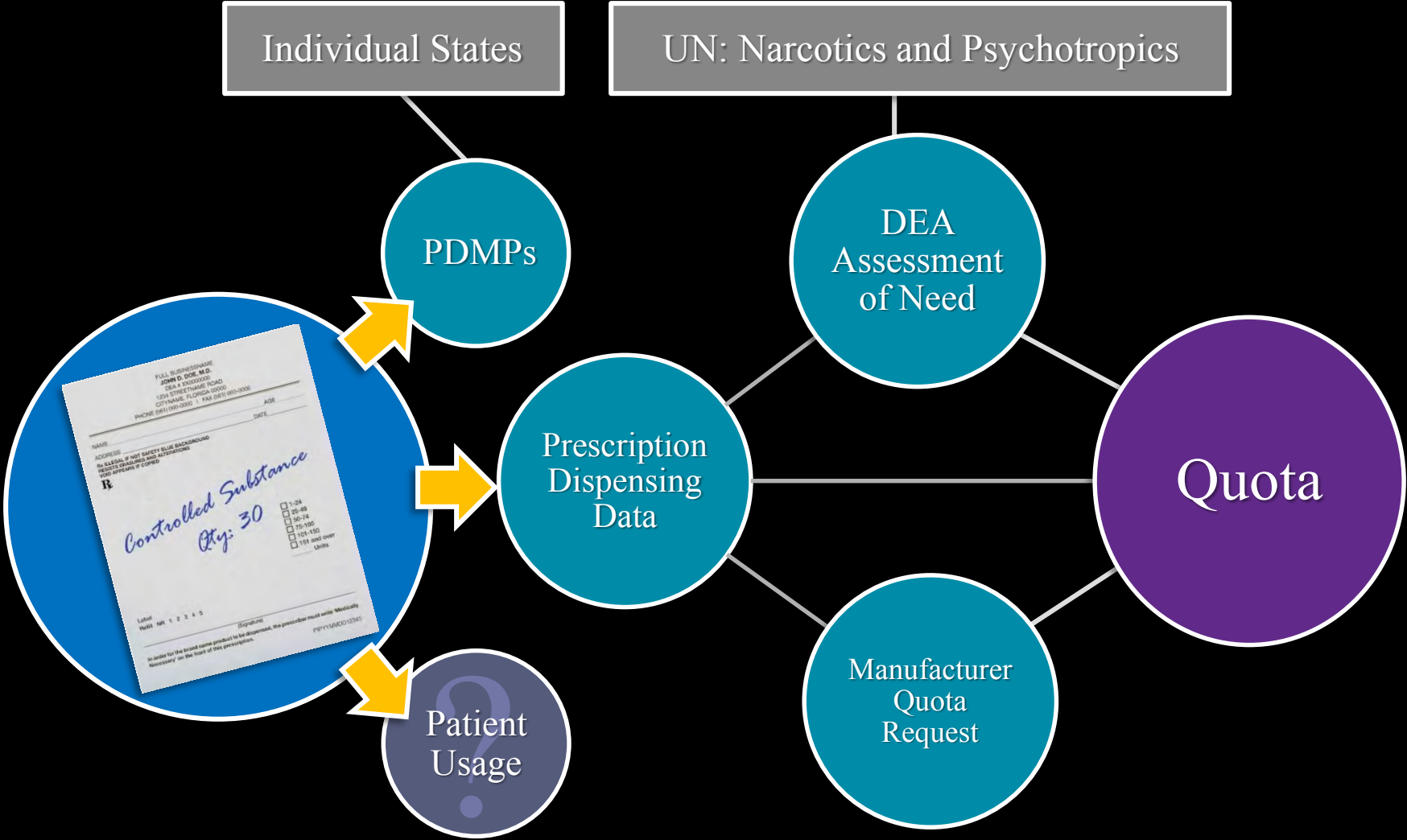
21 C.F.R. § 1306.04(a)

Prescription Requirements

- DEA does not define nor regulate medical practice standards
- There are no federal laws or regulations that put limits on the quantity of controlled substances that may be prescribed
- Some states or insurance providers may limit the quantities of controlled substances prescribed or dispensed

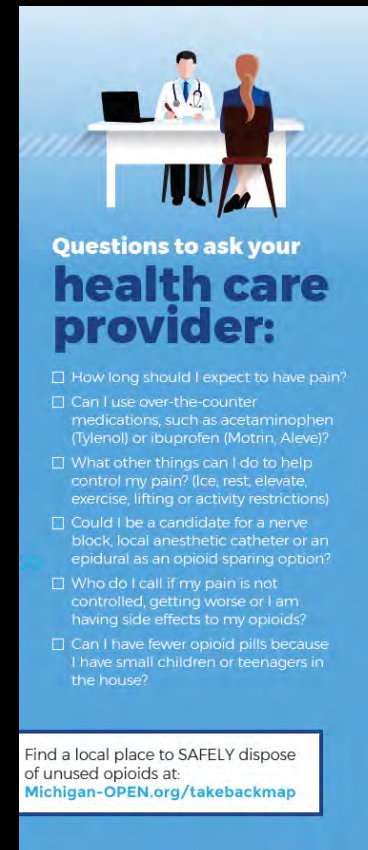


Impact of a Prescription



Research: Opioid Prescribing

- Michigan Opioid Prescribing Engagement Network (OPEN)
 - Online at Michigan-OPEN.org and opioidprescribing.info
 - Printable resources for providers and patients



Issuing Multiple Prescriptions

- A practitioner may provide individual patients with multiple prescriptions for the same Schedule II controlled substance, to be filled sequentially
- The combined effect of these multiple prescriptions is to allow the patient to receive, over time, up to a 90-day supply of that controlled substance

FULL BUSINESSNAME
JOHN D. DOE, M.D.
DEA # A00000000
1234 STREETNAME ROAD
CITYNAME, FLORIDA 00000
PHONE (000) 000-0000 | FAX (000) 000-0000

NAME _____ AGE _____
DATE _____

ADDRESS _____
IN ALLEGAL IF NOT SAFETY BLUE BACKGROUND
RESULTS EXAMINED AND ALTERATIONS
NOTED PLEASE IF COPIED

R

Controlled Substance
Qty: 10

1-24
 25-49
 50-74
 75-100
 101-150
 151 and over
Units _____

Label _____
Rule 1 2 3 4 5 _____

Signature _____
In order for the brand name product to be dispensed, the prescriber must write "Medically Necessary" on the front of this prescription. PPT12UMD012345

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CARA: Partial Fills



Section 702 amended 21 U.S.C. 829

- A prescription for a controlled substance in Schedule II may be partially filled if:
 - It is not prohibited by state law;
 - The prescription is written and filled in accordance with federal and state law and regulations
 - The partial fill is requested by the patient, or the practitioner that wrote the prescription; and
 - The total quantity dispensed in all partial fillings does not exceed the total quantity prescribed

CARA: Partial Fills

- Remaining portions of a partially filled prescription for a controlled substance in Schedule II:
 - May be filled; and
 - Shall be filled not later than 30 days after the date on which the prescription is written



Cause and Effect

Reducing the prescribing of controlled substances to legitimate patients

Pharmacists Blame Patient Fears on DEA

DEA Inflicts Harm on Chronic Pain Patients

'The other opioid crisis': Doctors weaning patients off much-needed painkillers

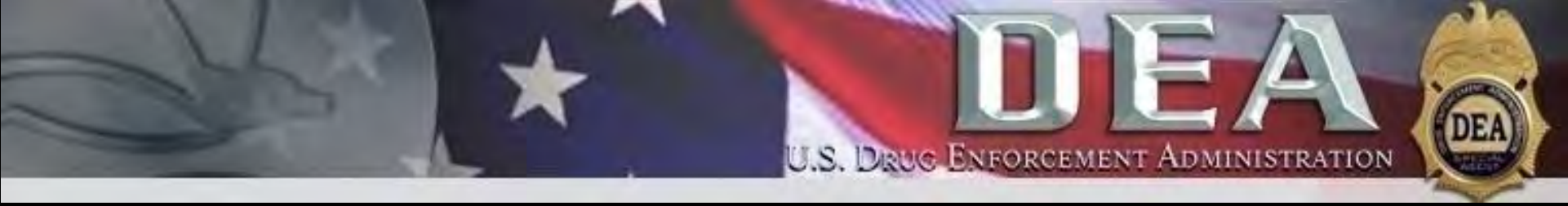
One local pharmacist told WESH 2 the DEA instructed him not to fill certain drug combinations.

"The DEA is saying, 'No, we don't want you filling this,' so who am I to go against the DEA?" said pharmacist Dele Obaitan.

Suffering and abandoned: Chronic pain patients cut off in the opioid era

The War On Doctors: How The DEA is Scaring Doctors from Prescribing Pain Medications

Chronic pain patients suffering because some doctors too fearful to prescribe opioids

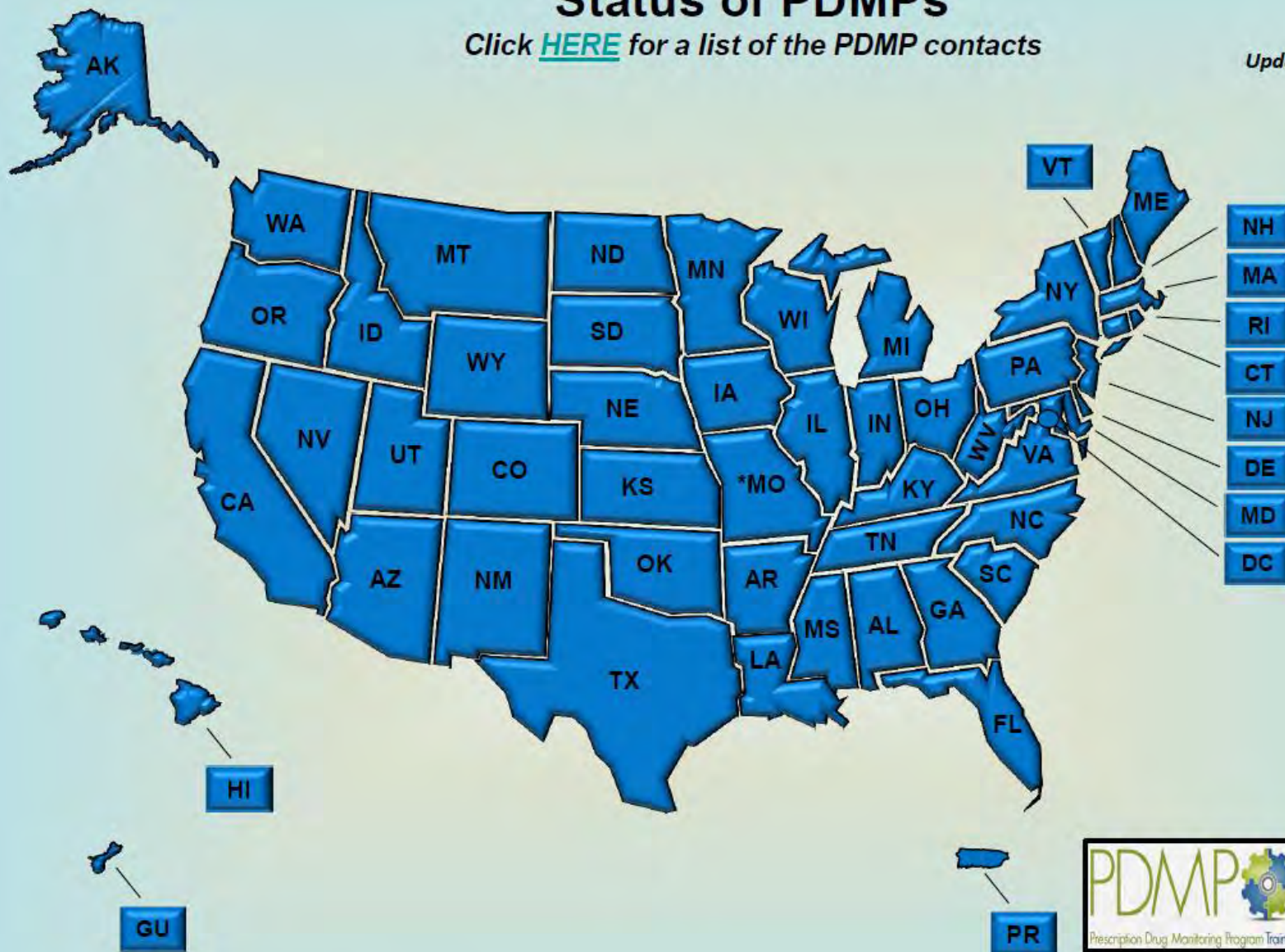


Prescription Drug Monitoring Programs

Status of PDMPs

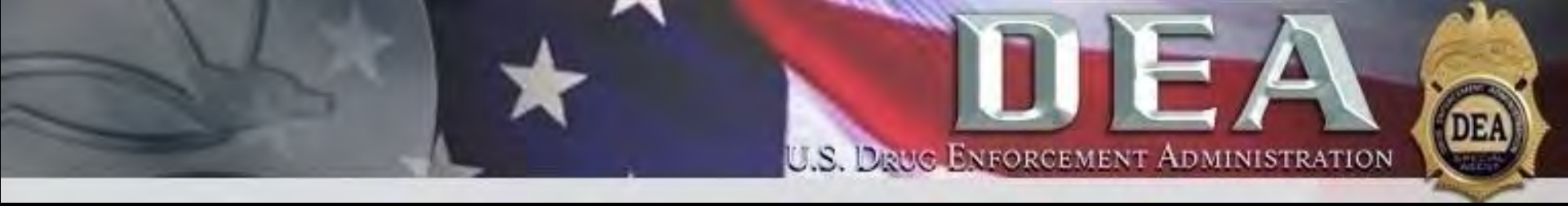
Click [HERE](#) for a list of the PDMP contacts

Updated August 2018



* Missouri does not have a state-wide PDMP

PDMP TTAC
Prescription Drug Monitoring Program Training and Technical Assistance Center



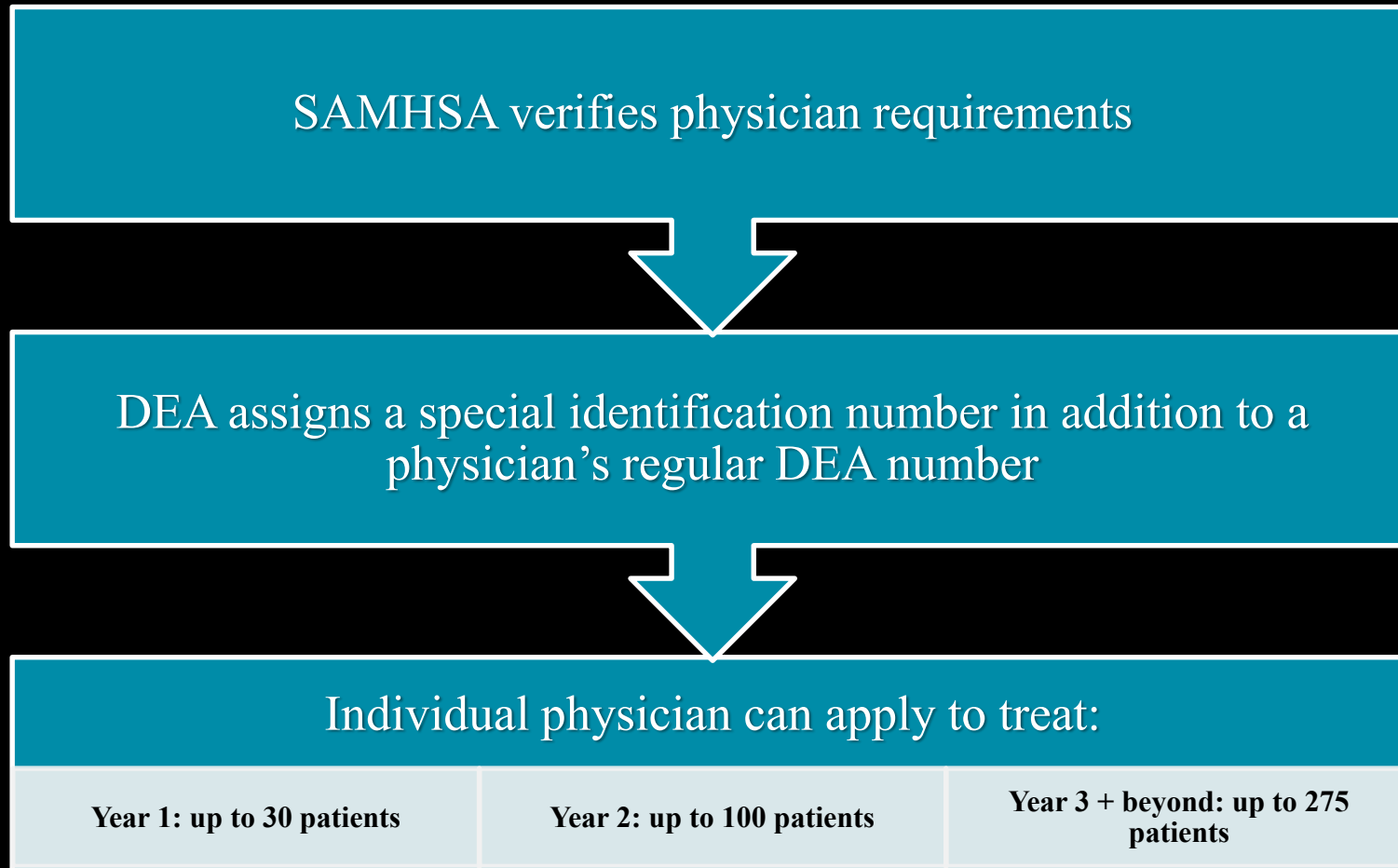
Drug Addiction Treatment Act of 2000

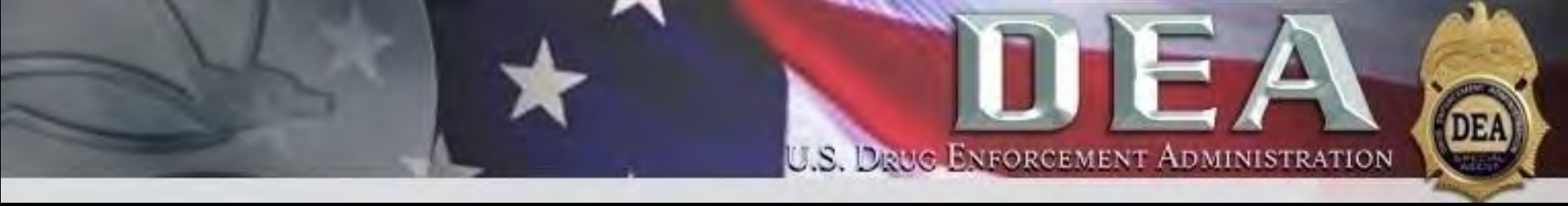
DATA Waivers

- Approximately **2.9%** of Michigan practitioners are DATA-waived
- Learn more about buprenorphine and how to qualify for a DATA waiver at:
 - <https://www.samhsa.gov/medication-assisted-treatment/buprenorphine-waiver-management/qualify-for-physician-waiver>



Obtaining a DATA Waiver





Secure and Responsible Drug Disposal Act of 2010

Patient's Controlled Substances

- A physician **cannot** take back controlled substances that have been administered, prescribed, or dispensed to the “ultimate user
- It is **not authorized** by Federal Laws and Regulations
- Do not put **yourself or your practice** in harm's way by ignoring this



Patient Education



Monitor

- Note how many pills are in your home
- Keep track of refills
- Control drugs prescribed to teens
- **NEVER** share



Secure

- Protect prescriptions like valuables
- Secure medication in a place only you know about



Dispose

- Properly dispose of unused or expired medicine
- **Practitioners: NEVER take back patient drugs**

Collection Receptacle Locations



Pharmacies



Long-Term Care Facilities



Hospitals/clinics



Opioid Treatment Programs



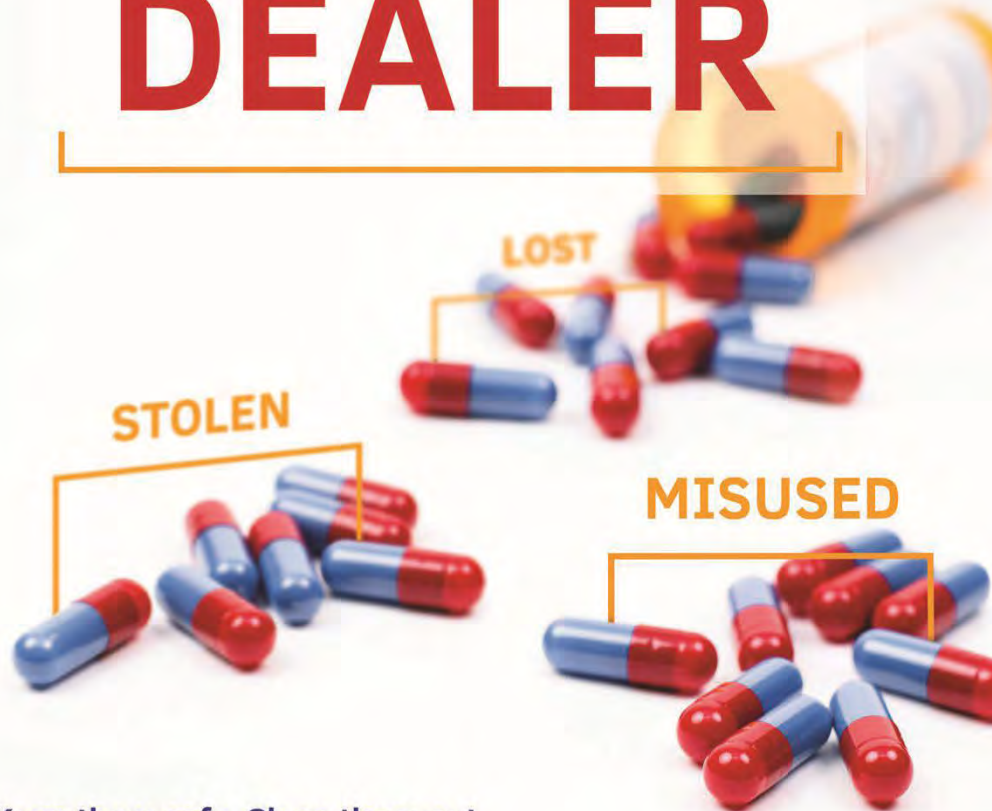
Police Departments

Search for a disposal location online at: apps.deadiversion.usdoj.gov/pubdispsearch

Resources for Drug Disposal

- **DEA Diversion website:** www.deadiversion.usdoj.gov
(click “Drug Disposal Information,” then “Search for an Authorized Collector Location”)
- **Rx Drug Drop Box:** www.rxdrugdropbox.org
- **Dispose My Meds:** www.disposemymeds.org
- **U.S. Food and Drug Administration:** www.fda.gov
(search “disposal”)

DON'T BE THE DEALER



Keep them safe. Clean them out.
Take them back.



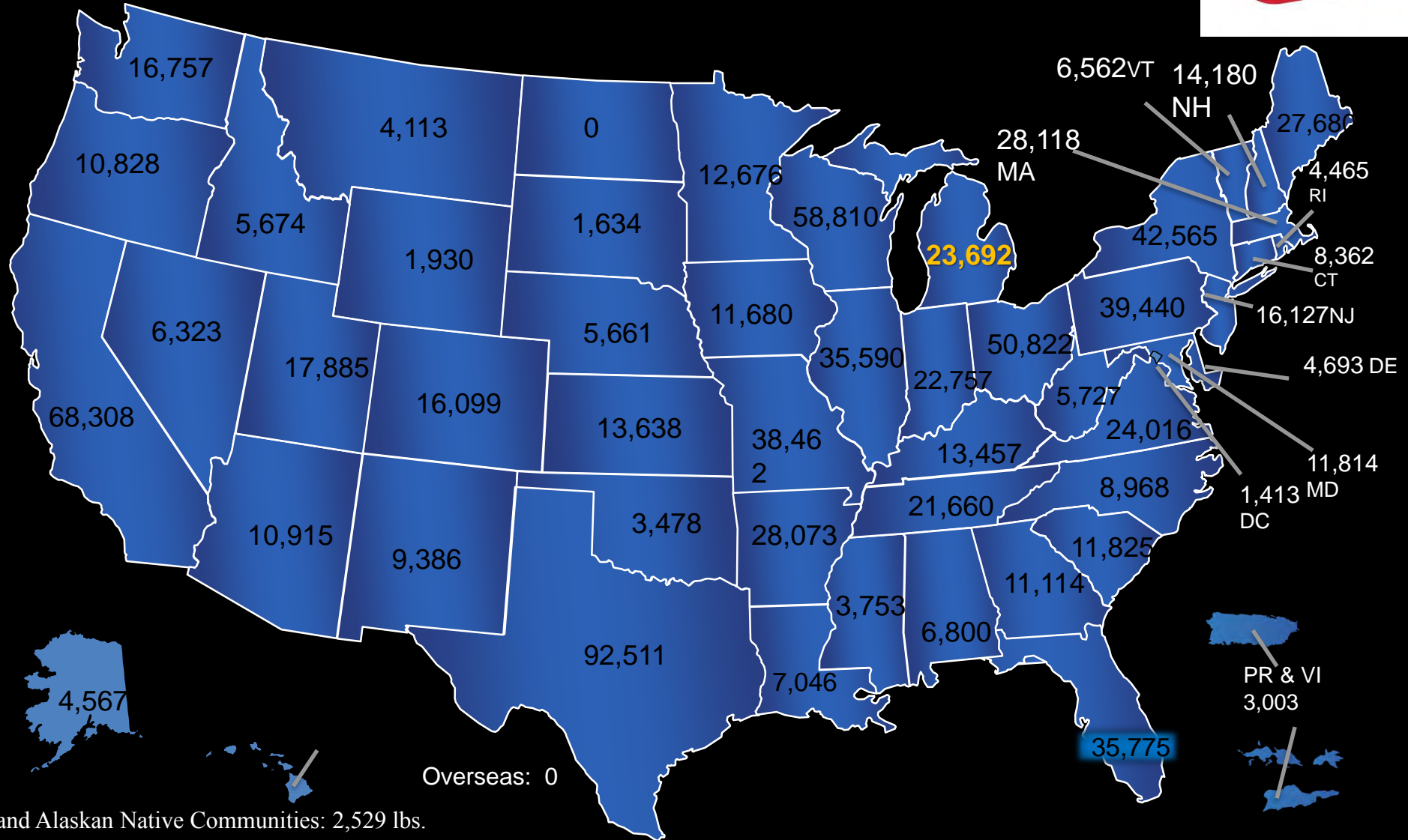
Visit DEATakeBack.com for a collection site near you.

DEA National Take Back Initiative

Visit www.dea.gov for
downloadable posters, pamphlets,
and more information

17th National Take Back Day: April 27, 2019

Total Weight Collected: 937,443 lbs. (468.72 Tons)



*American Indian and Alaskan Native Communities: 2,529 lbs.

For Additional
Information

The screenshot shows the homepage of the U.S. Department of Justice Drug Enforcement Administration Diversion Control Division. The header includes the agency name and a search bar. The main navigation menu has five categories: HOME, REGISTRATION, REPORTING, RESOURCES, and ABOUT US. The primary content area features a large banner for 'Report Illicit Pharmaceutical Activities' with a sub-headline 'RX Abuse Online Reporting' and an image of spilled pills. To the right, a 'Registration Support' section lists contact information and various services like 'New Applications' and 'Registration Changes'. Below the banner, there are four smaller boxes: 'What's New' with a list of recent updates, 'Get Email Updates' with an envelope icon, 'DEA Forms & Applications', 'Publications & Manuals', 'Questions & Answers', and 'Meetings & Events'. A 'Quick Links' section at the bottom right provides shortcuts to systems like ARCOS, CSOS, and EPCS.

U.S. DEPARTMENT OF JUSTICE ★ DRUG ENFORCEMENT ADMINISTRATION
DIVERSION CONTROL DIVISION

Search

HOME REGISTRATION REPORTING RESOURCES ABOUT US

Report Illicit Pharmaceutical Activities
RX Abuse Online Reporting

Registration Support
Call: 1-800-882-9539 (8:30 am-5:50 pm ET)
Email: DEA.Registration.Help@usdoj.gov
Locate Field Registration Specialists

New Applications
Renewal Applications
Registration Changes (Address, Drug Code, Name, Schedule)
CMEA (Combat Meth Epidemic Act)
Registration for Disposal of Controlled Substances
Duplicate Certificate Request
Duplicate Receipt of Registration
Order Forms (DEA 222)
Registration Validation
Search for an Authorized Collector Location

What's New Get Email Updates:

Siemens Healthcare Diagnostics Inc. (March 21, 2019)
Fisher Clinical Services, Inc. (March 21, 2019)
Joel A. Smithers, D.O.; **Decision and Order** (March 18, 2019)
William A. Sanpablo, M.D.; **Decision and Order** (March 18, 2019)
Sharp (Bethlehem), LLC (March 18, 2019)
Importer of Controlled Substances Registration (March 6, 2019)
Bulk Manufacturer of Controlled Substances Registration (March 6, 2019)
Patheon Pharmaceuticals, Inc. (March 6, 2019)
S&B Pharma Inc. (March 6, 2019)
Siegfried USA, LLC (March 1, 2019)
Meridian Medical Technologies (March 1, 2019)

In The News

Southern Ohio man sentenced for possessing carfentanil (March 27, 2019)
South Bay doctor pleads guilty to unlawfully distributing hydrocodone and health care fraud (March 26, 2019)
J-CODE announces 61 arrests in its second coordinated law enforcement operation targeting opioid trafficking on the Darknet (March 26, 2019)
Spokane dentist pleads guilty to distributing opioids (March 25, 2019)

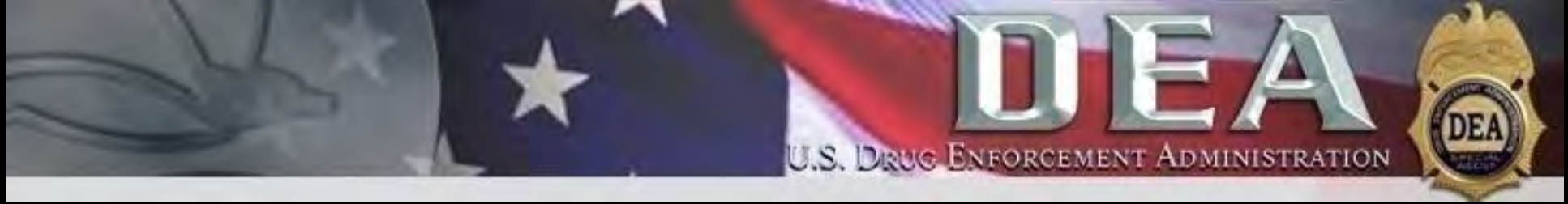
DEA Forms & Applications **Publications & Manuals**
Questions & Answers **Meetings & Events**

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 2014-2016
Find Your Local DEA Office
Mailing Addresses for Topics Related to Title 21 CFR
Medical Missions

www.DEAdiversion.usdoj.gov

or

www.dea.gov



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