

# Drug Enforcement Administration



## DEA Diversion Control Mission and Overview

*Michigan Practitioner Diversion Awareness Training*

November 9, 2018

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*DEA Diversion Program Manager*

Detroit Division

# Disclosure

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



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# Public Health Epidemic

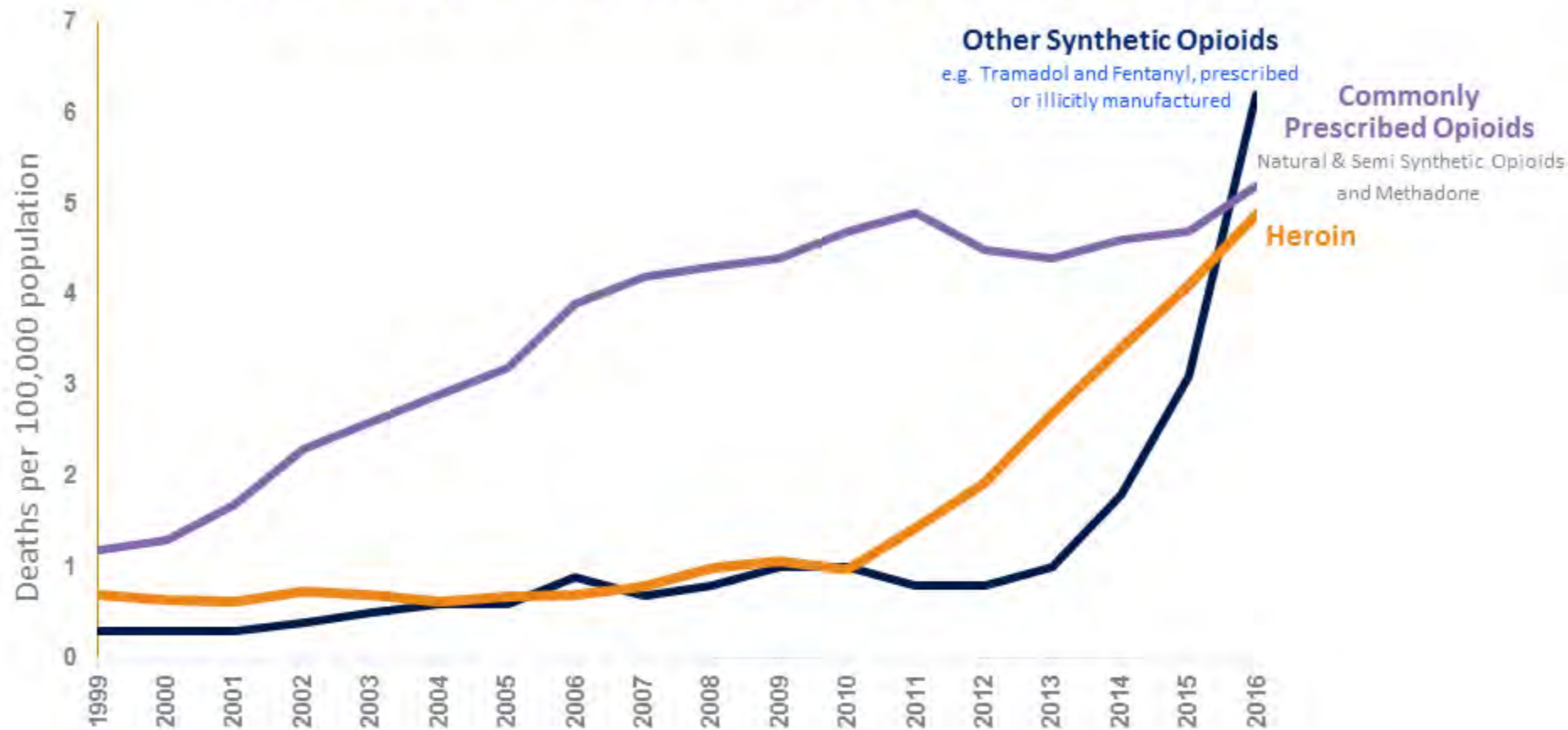
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# Public Health Epidemic

- 2016: 63,632 drug-related overdose deaths (estimated 72,000 in 2017)
  - Age-adjusted rate: 19.8 per 100,000
  - 42,249 (66.4%) involved an opioid
  - 116 opioid-related deaths per day
  - 2016 opioid overdose death rate 21% higher than 2015 rate
  - Adults aged 25-34, 35-44, and 45-54 experienced the highest rates of drug overdose deaths in 2016
- 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
- Estimated \$504 billion in economic costs

# 3 Waves of the Rise in Opioid Overdose Deaths



Wave 1: Rise in Prescription Opioid Overdose Deaths

Wave 2: Rise in Heroin Overdose Deaths

Wave 3: Rise in Synthetic Opioid Overdose Deaths

SOURCE: National Vital Statistics System Mortality File.

# How Did We Get Here

1990s

- Pain as “the 5<sup>th</sup> vital sign”



1996

- OxyContin marketed
- Medical boards curtailed restrictions on laws governing the prescribing of opioids for the treatment of chronic non cancer pain

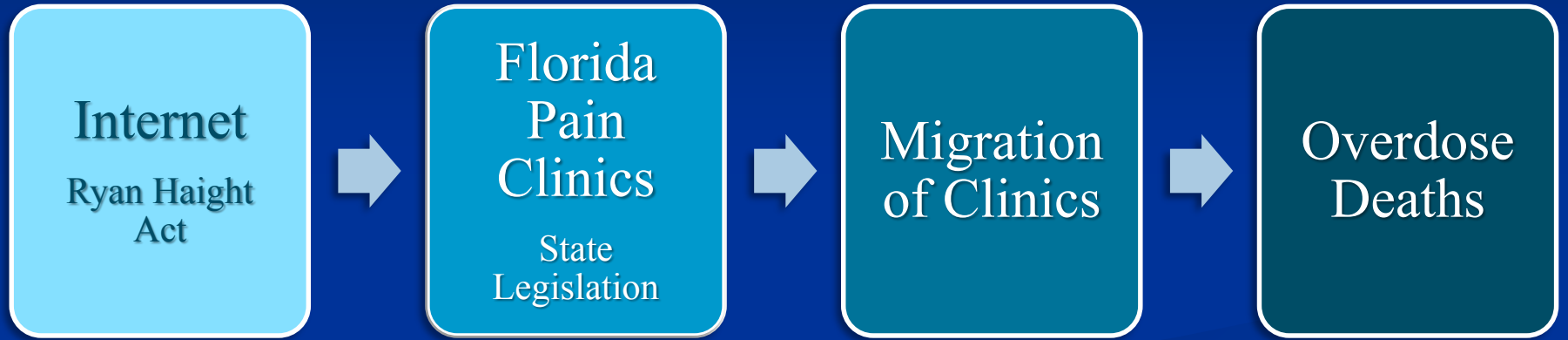


2000

- JCAHO Pain Management Standards “right to pain relief”
- Opioids considered highly effective and safe, with no focus on adverse effects or addiction potential
- “...no disciplinary action will be taken against a practitioner based solely on the quantity and/or frequency of opioids prescribed.”



# How Did We Get Here





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# The Controlled Substances Act: Accountability & Compliance

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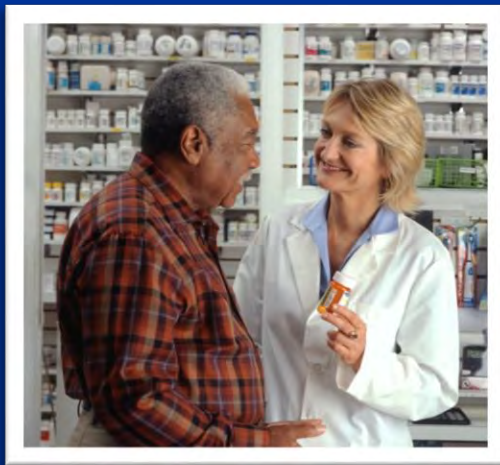


# Diversion Control Division Mission

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.**

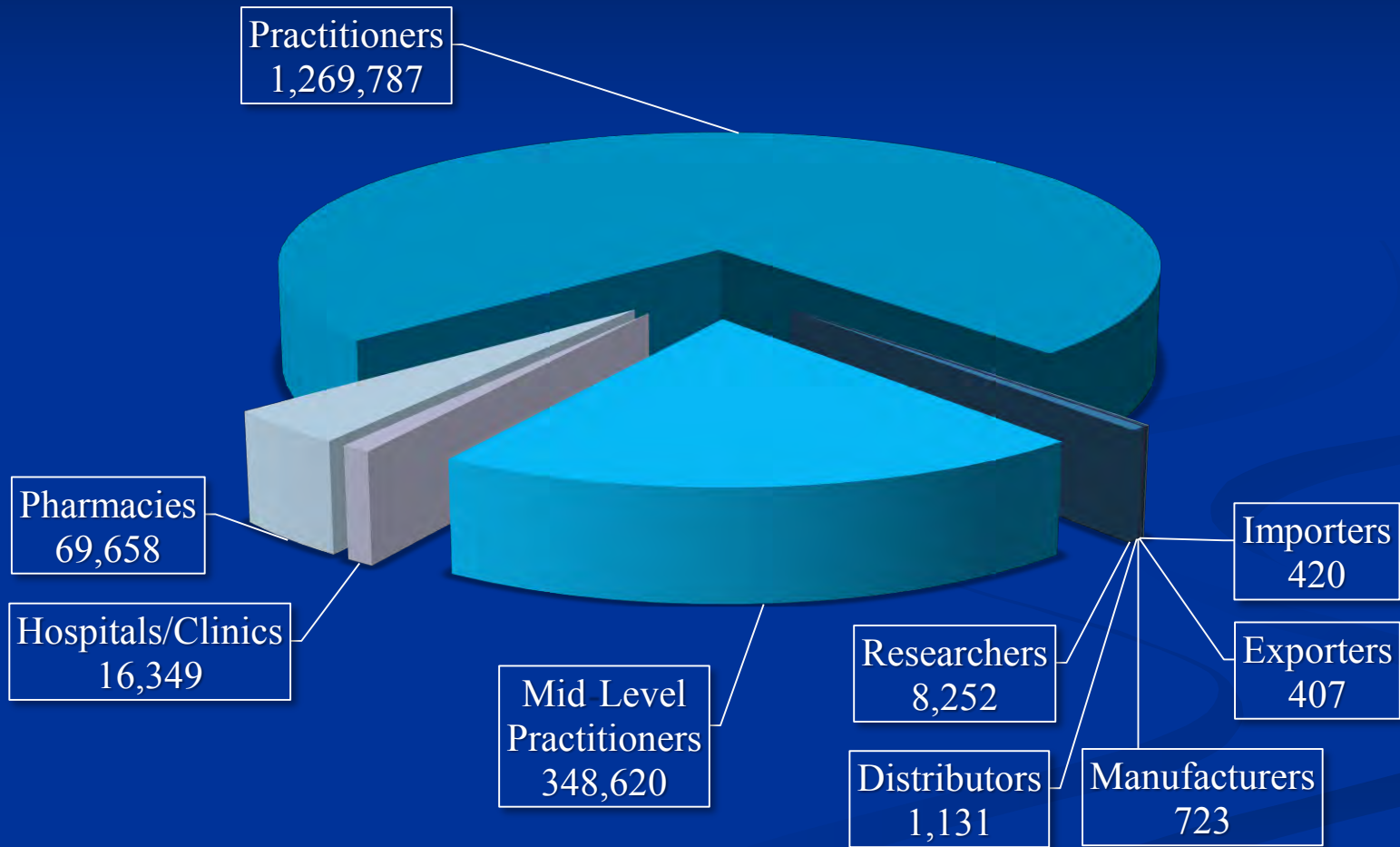
On a single day that December, **a nurse and doctor both overdosed on stolen pain medication** in different areas of the sprawling University of Michigan Health System.

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.

# Active Registrants

## 1,722,526\* total (nationwide)



\*Chart totals represent some, not all, DEA registrants



# Michigan Registrant Population

(52,927 registrants\*)

■ Manufacturers:	17
■ Distributors:	24
■ Practitioners:	37,913
■ NPs/PAs:	10,845
■ Pharmacies:	2,577
■ Opioid Treatment Programs:	43
■ DATA-Waived Practitioners:	1,240*
	*2.5%

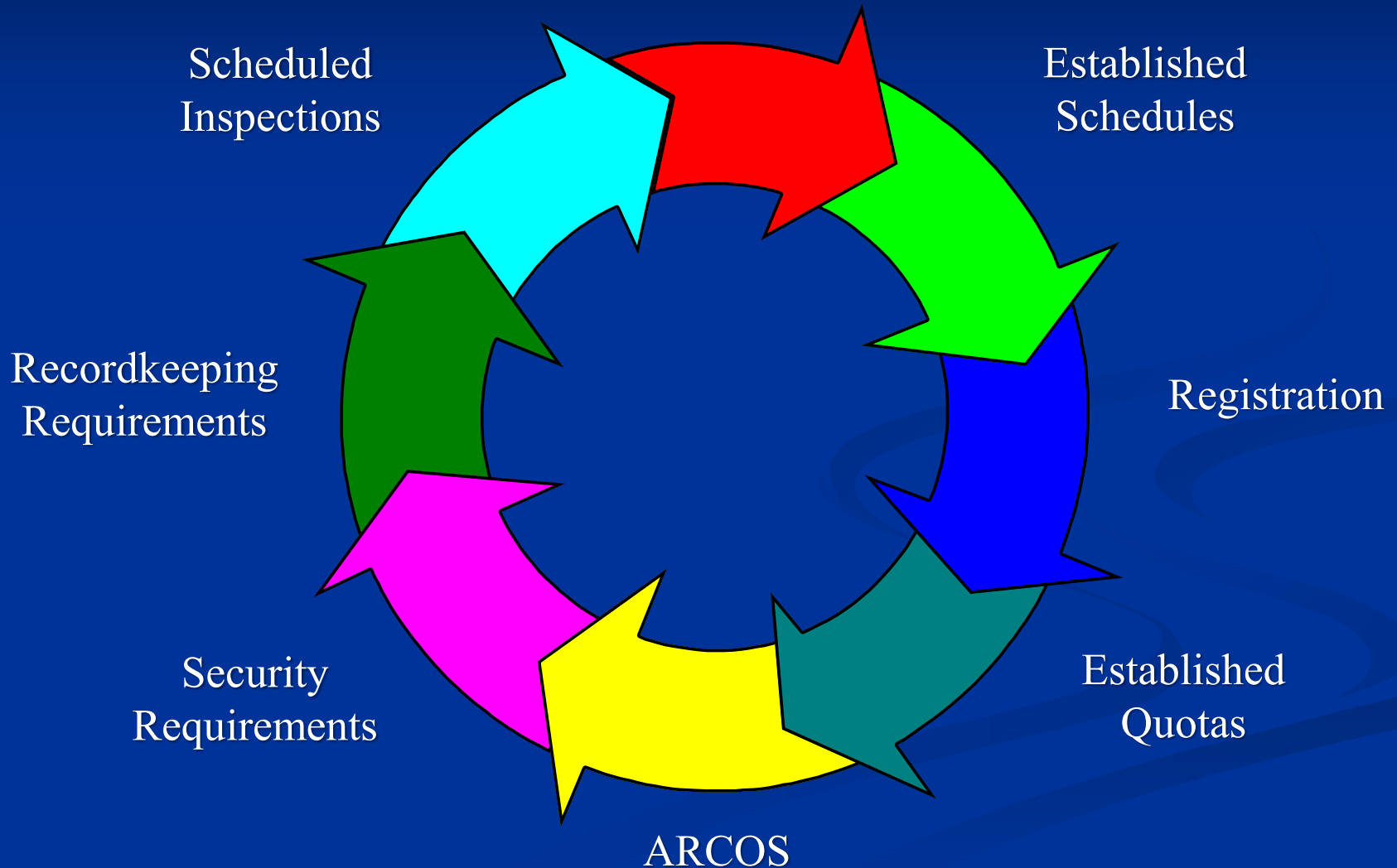
\*not all registrants are represented by the listed categories

\*Source: RICS  
Date Prepared: 10/2/2018





# 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**

# How Does DEA Combat Diversion?



# 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

Individual States

UN: Narcotics and Psychotropics

PDMPs

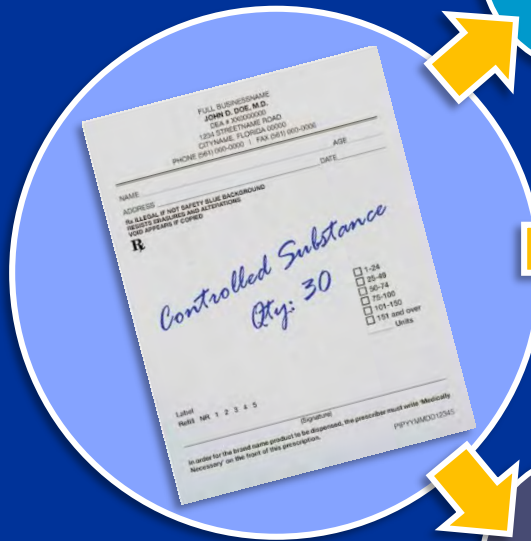
DEA  
Assessment  
of Need

Prescription  
Dispensing  
Data

Quota

Manufacturer  
Quota  
Request

Patient  
Usage





# Research: Opioid Prescribing

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

**4**  
evidence-based  
**reasons**  
for changing the way  
you prescribe opioids

**OPEN**  
OPIOID PRESCRIBING ENGAGEMENT NETWORK

Talking to your  
doctor about  
**pain  
control**

**OPEN**  
OPIOID PRESCRIBING ENGAGEMENT NETWORK

**Questions to ask your  
health care  
provider:**

- How long should I expect to have pain?
- Can I use over-the-counter medications, such as acetaminophen (Tylenol) or ibuprofen (Motrin, Aleve)?
- What other things can I do to help control my pain? (Ice, rest, elevate, exercise, lifting or activity restrictions)
- Could I be a candidate for a nerve block, local anesthetic catheter or an epidural as an opioid sparing option?
- Who do I call if my pain is not controlled, getting worse or I am having side effects to my opioids?
- Can I have fewer opioid pills because I have small children or teenagers in the house?

Find a local place to SAFELY dispose of unused opioids at:  
[Michigan-OPEN.org/takebackmap](http://Michigan-OPEN.org/takebackmap)

Do you know  
the facts about  
**opioid pain  
medications?**

**OPEN**  
OPIOID PRESCRIBING ENGAGEMENT NETWORK

# 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.  
1234 STREETNAME ROAD,  
CITYNAME, FLORIDA 07000  
PHONE (888) 000-0000 | FAX (888) 000-0000

NAME \_\_\_\_\_ AGE \_\_\_\_\_  
DATE \_\_\_\_\_

ADDRESS \_\_\_\_\_  
IN ALABAMA, IF NOT SAFETY BLUE BACKGROUND  
RESULTS EXAMINED AND ALTERATIONS  
NOTED APPEAR IF COPIED

**R**

*Controlled Substance*  
*Qty: 10*

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

Label \_\_\_\_\_  
Puff 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. PPT1234567890

FULL BUSINESSNAME  
JOHN D. DOE, M.D.  
1234 STREETNAME ROAD,  
CITYNAME, FLORIDA 07000  
PHONE (888) 000-0000 | FAX (888) 000-0000

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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

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

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.

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



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# Drug Addiction Treatment Act of 2000

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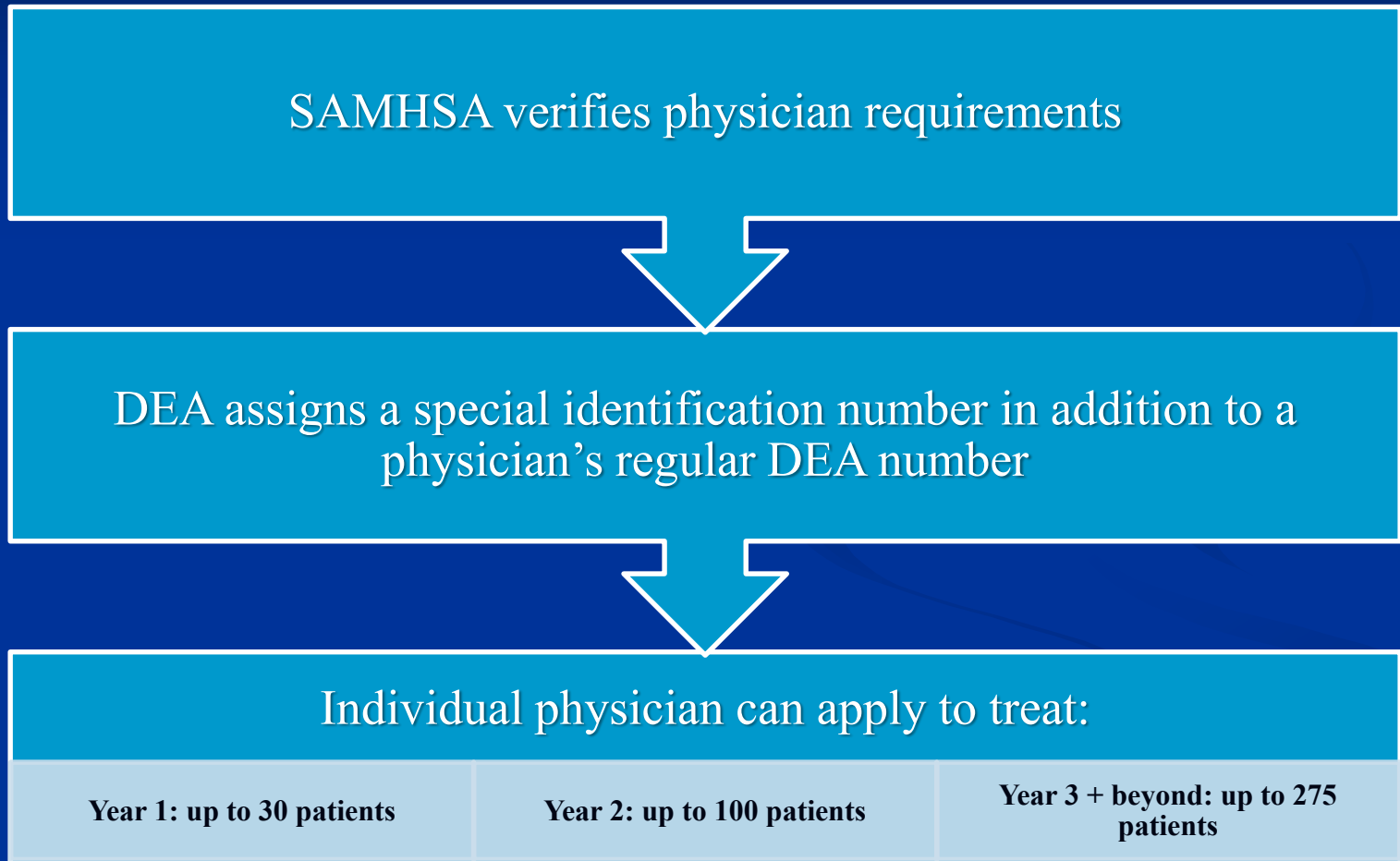




# DATA Waivers

- Approximately **2.5%** 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





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# Secure and Responsible Drug Disposal Act of 2010

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# 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](https://apps.deadiversion.usdoj.gov/pubdispsearch)

# Resources for Drug Disposal

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





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# Prescription Drug Monitoring Programs (PDMPs)

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# PDMP Successes

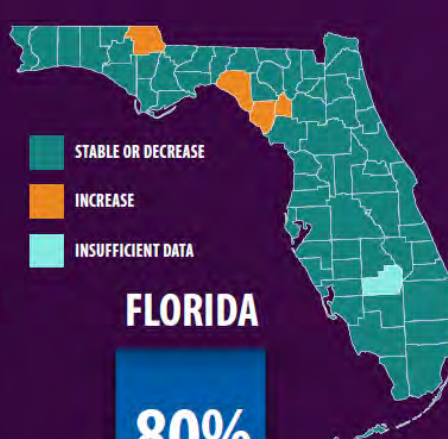
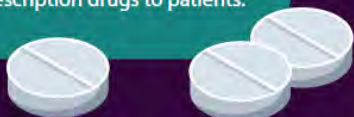
## STATE SUCCESSSES: Decreases in Opioid Prescribing

Average Morphine Milligram Equivalents (MME)\* per person decreased in most counties in Florida, Ohio, and Kentucky from 2010 to 2015.



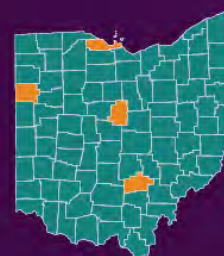
These states have **regulated pain clinics** and set requirements for their state's PDMP.

PDMP, Prescription Drug Monitoring Program, is a state-run electronic database used to track the prescribing and dispensing of controlled prescription drugs to patients.



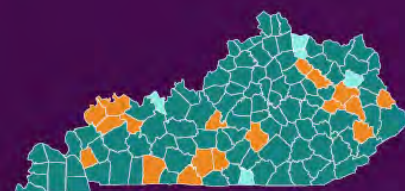
**FLORIDA**

**80%**  
of counties  
DECREASED



**OHIO**

**85%**  
of counties  
DECREASED



**KENTUCKY**

**62%**  
of counties  
DECREASED

\* MME is a way to calculate the amount of opioids, accounting for differences in opioid drug type and strength.

[www.cdc.gov/vitalsigns/opioids](http://www.cdc.gov/vitalsigns/opioids)