

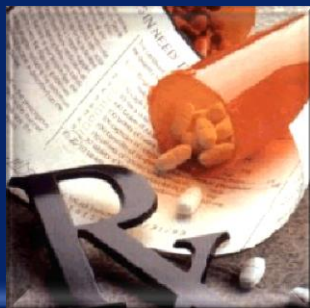


The United States Department of Justice

Drug Enforcement Administration



Federal Law, Regulations, and Dispensing Controlled Substances



American Dental Association
April 25, 2018



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Liaison and Policy Section
Diversion Control Division

LEGAL DISCLAIMER

The following presentation was accompanied by an oral presentation on **April 25, 2018**, 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.**



Goals and Objectives

- Recognizing the extent of the epidemic and the controlled substances most commonly abused
- Understanding the Closed System of Distribution enforced by the DEA
- The importance of inventories, records, reports, and inspections
- Recognizing and preventing common methods of diversion
- Introduction to Resources available to Practitioners



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

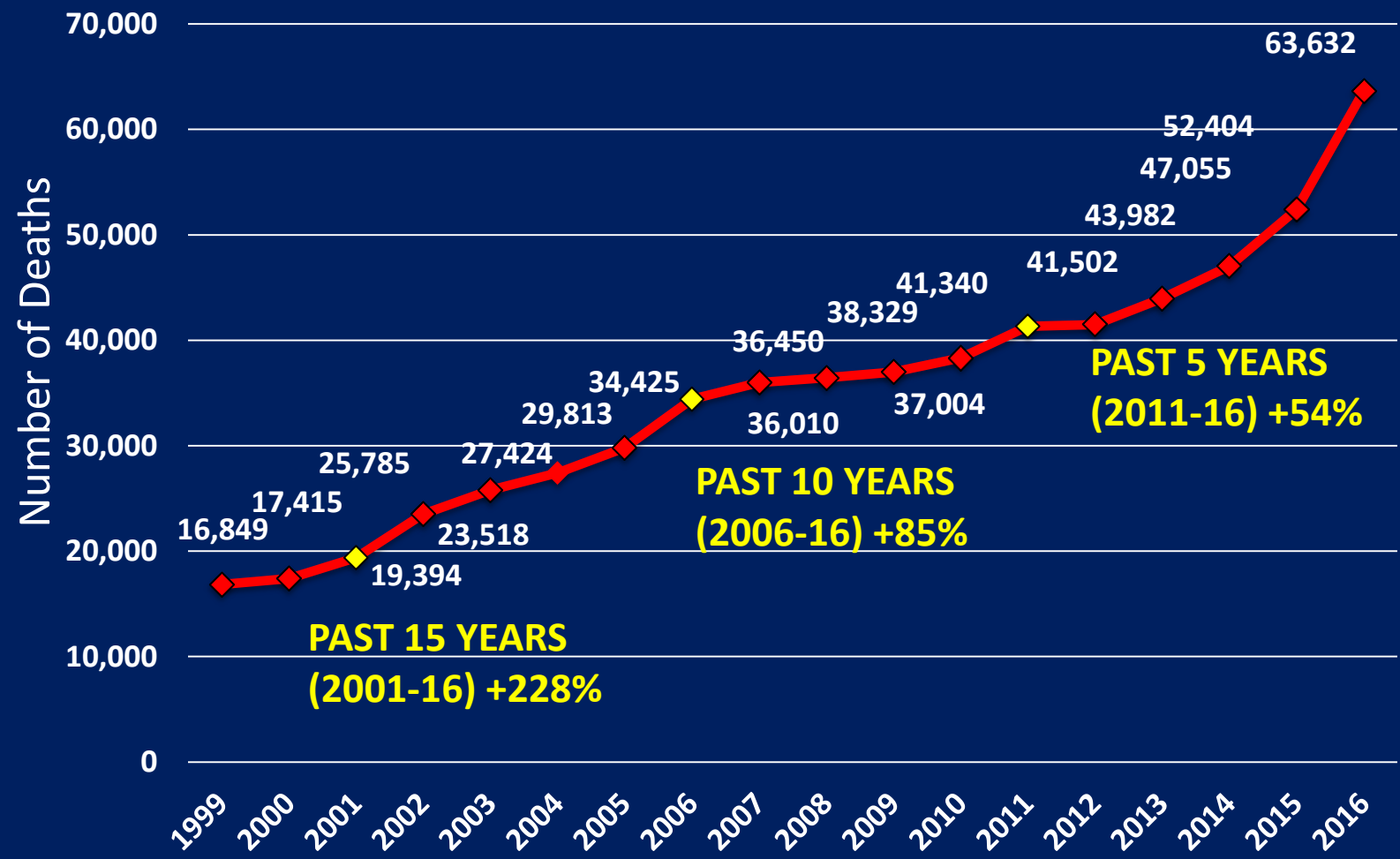
Soldier Field

Capacity: 61,500





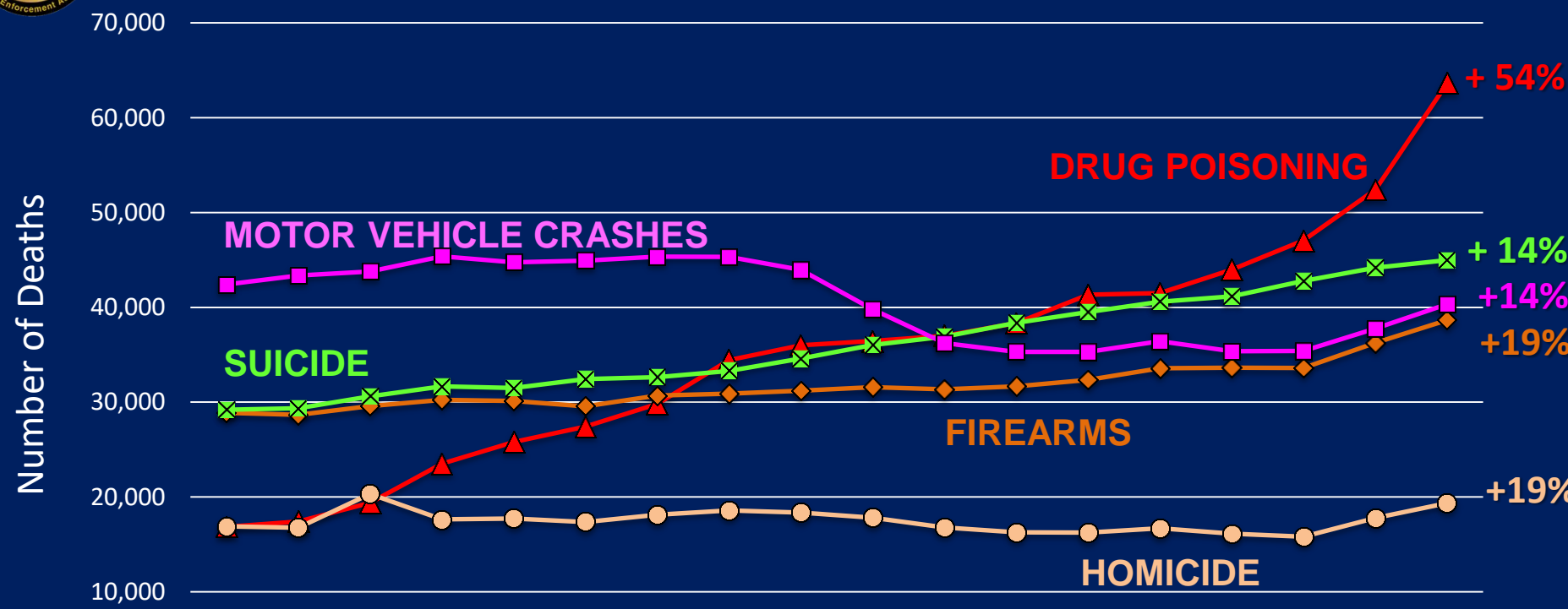
Drug Poisoning Deaths, 1999-2016



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.



Causes of Injury Death 1999-2016



	1999	2000	2001	2002	2003	2004	2005	2006	2007	2008	2009	2010	2011	2012	2013	2014	2015	2016
Drug Poisoning	16,849	17,415	19,394	23,518	25,785	27,424	29,813	34,425	36,010	36,450	37,004	38,329	41,340	41,502	43,982	47,055	52,404	63,632
Firearms	28,874	28,663	29,573	30,242	30,136	29,569	30,694	30,896	31,224	31,593	31,347	31,672	32,351	33,563	33,636	33,599	36,252	38,658
Suicide	29,199	29,350	30,622	31,655	31,484	32,439	32,637	33,300	34,598	36,035	36,909	38,364	39,518	40,600	41,149	42,773	44,193	44,965
Homicide	16,889	16,765	20,308	17,638	17,732	17,357	18,124	18,573	18,361	17,826	16,799	16,259	16,238	16,688	16,121	15,809	17,793	19,362
MV Crashes	42,401	43,354	43,788	45,380	44,757	44,933	45,343	45,316	43,945	39,790	36,216	35,332	35,303	36,415	35,369	35,398	37,757	40,327

NOTE: Suicide and homicide include deaths by drug poisoning or firearms

Source: Centers for Disease Control and Prevention, National Center for Health Statistics. *Multiple 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.

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



On Average **(From 2009-2016)**

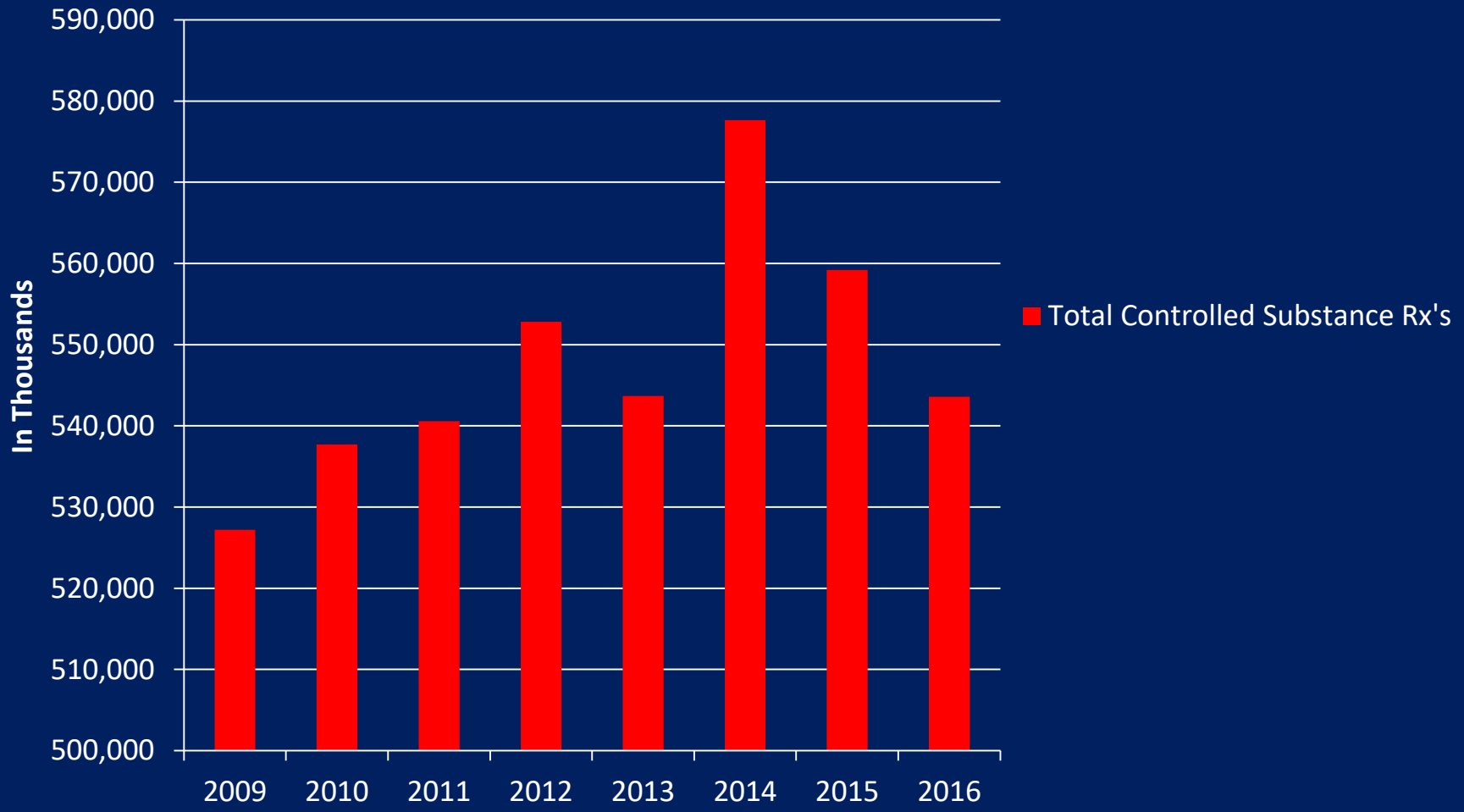
**What % of All Prescriptions
Filled By A Pharmacy Involve
Controlled Substances?**

13.10 %



Total Controlled Substance Rx's

Total Controlled Substance Rx's 2009-2016

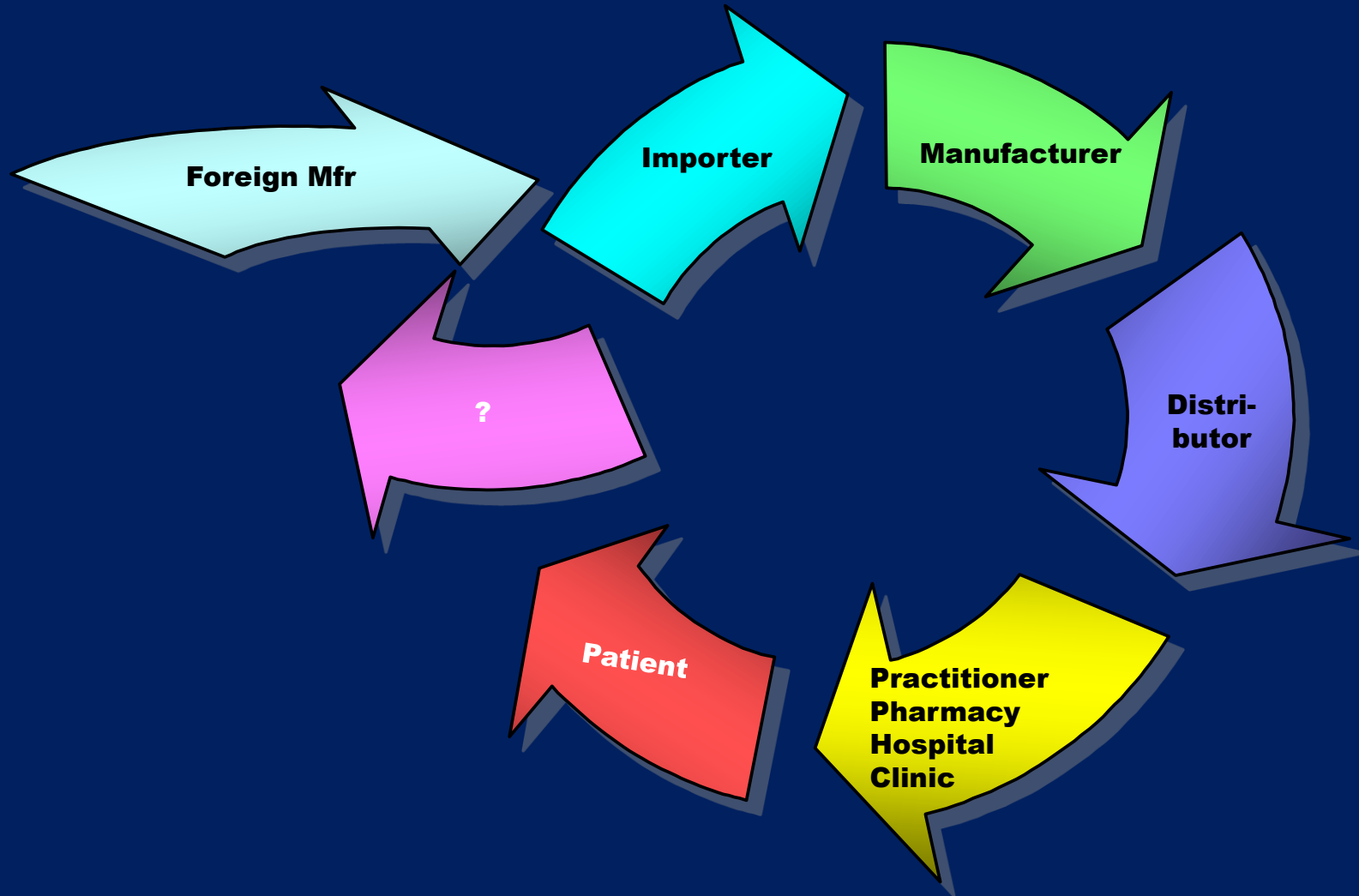




“Controlled Substances Act”

- In 1973 it created a system of controls for the **legitimate** manufacture, distribution, import, export, dispensing, and prescribing of controlled substances for **legitimate** medical, commercial, scientific, and research needs.

Closed System of Distribution

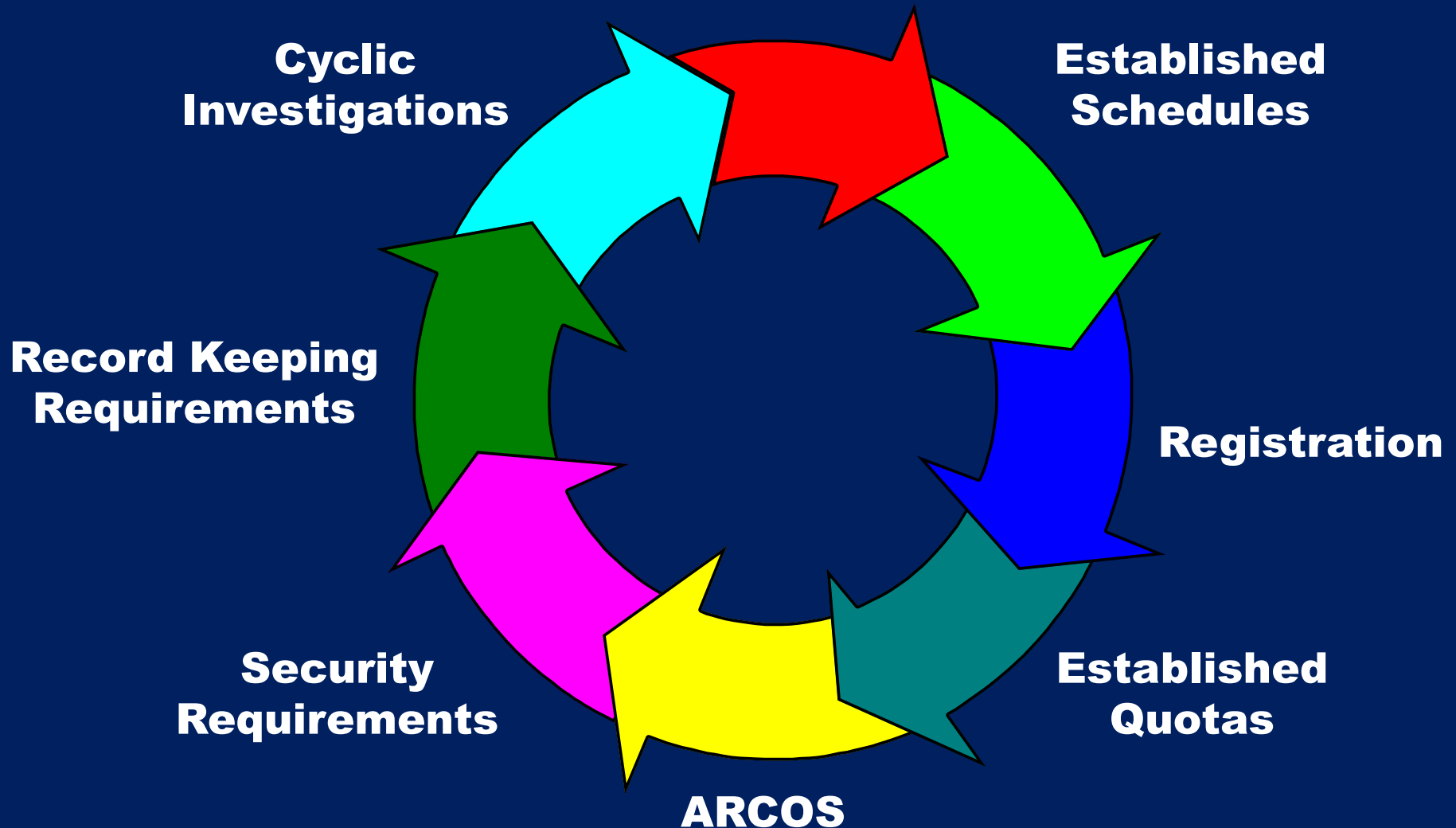




Closed System

- DEA is responsible for
 - the oversight of the system
 - the integrity of the system,
 - the protection of the public health and safety.

Closed System of Distribution





21 U.S.C. § 822 (a)(2)

- Persons Required to Register:
- “Every person who dispenses ...
any Controlled Substance ...”



21 U.S.C. § 827

All DEA Registrants Must:

- Make and Keep Inventories
- Make and Keep Records
- Make and Keep Reports
- Provide Effective Controls to Prevent Diversion



21 U.S.C. § 827

**Inventories, Records, And Reports Must
Be:**

- In a Form as Required By
Regulation**
- Readily Retrievable**
- Complete and Accurate**
- Kept for Two Years**



Mission

The mission of the Office of Diversion Control 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.



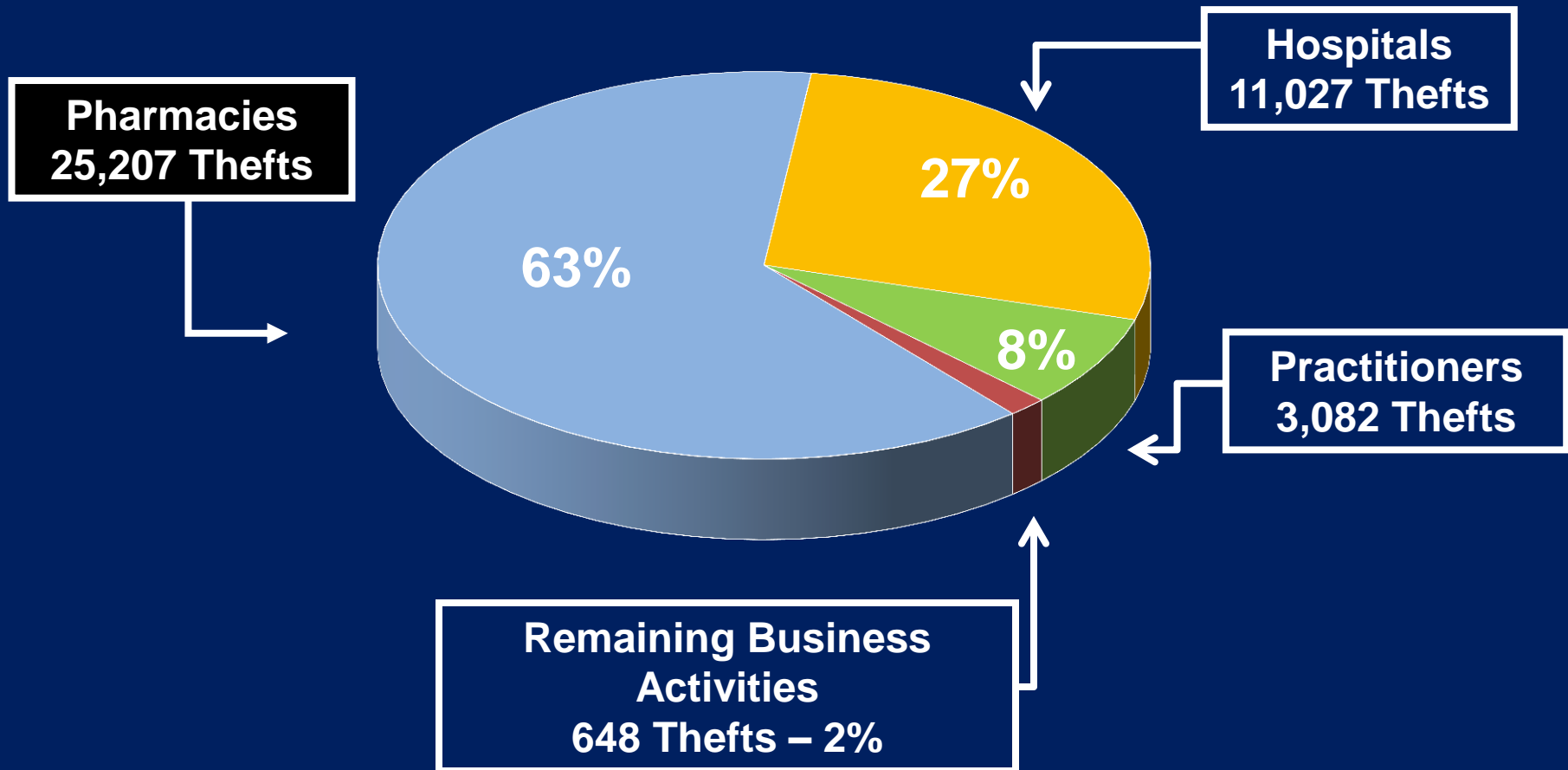
What is “Diversion”?

The movement of legitimate controlled substances and chemicals into other than legitimate medical, scientific, research, or industrial channels. It can happen anytime, anyplace.

Nationwide Reported Thefts

(Armed Robbery, Employee Pilferage and Night Break-In Only)

January 1, 2009 – December 31, 2016



Source: DTL



Inventories

- **Initial Inventory**
- **Biennial Inventory**
- **Newly Controlled Drugs**



Initial Inventory

- Inventory of all Stocks of CS
- On The Date: First Engage in the Dispensing of Controlled Substances
- Should Be Labeled “Initial Inventory”
- Nothing on Hand: Record “0”
- 21 CFR 1304.11 (b)



Biennial Inventory

- After the Initial Inventory
- New Inventory Every Two Years
- On Any Date Which is Within Two Years of The Previous Inventory Date
- Should Be Labeled “Biennial Inventory”
- Nothing on Hand: Record “0”
- 21 CFR 1304.11 (c)



Newly Controlled Substances

- For Any Newly Controlled Substances
- Inventory of all stocks on hand
- On The Effective Date of The Rule
- 21 CFR 1304.11 (d)



Records: General Requirements

- Maintain on a Current Basis...
- Complete and Accurate Record of Each Substance...Manufactured, Imported, Exported, Received, Sold, Delivered, or Otherwise Disposed of
- 21 CFR 1304.21 (a)



Records: General Requirements

- Schedule I & II:
- Inventories and Records Shall Be Maintained Separately from All Other Records
- 21 CFR 1304.04 (f)(1);(h)(1)



Records: General Requirements

- Schedules III, IV, & V
- Separate from All Other Records or
“Readily Retrievable”
 - Separated Out from all other Records
in a Reasonable Time Period.

21 CFR 1304.04 (f)(2); (g); (h)(2)



Records: General Requirements

- Separate Records.. For Each Registered Location.
- 21 CFR 1304.21 (b)



Records: Dispensing

- Name of CS, Form, Quantity, Strength
- Number of Units or Volume of Finished Form Dispensed
- Name, Address of the Person to Whom It Was Dispensed.
- Date of Dispensing



Records: Dispensing

- Written or Typewritten Name or Initials of the Individual Who Dispensed or Administered the Substance on Behalf of the Dispenser
- Amount Disposed of in Any Other Manner
- 21 CFR 1304.22 (c)



Dates for Records

- Dates Must be the Actual Date of **Transfer** (Received, Imported, Exported, Distributed, or Otherwise Transferred ...)
- 21 CFR 1304.21 (d)



DEA Form 222

DEA's Official Order Form (DEA Form 222) is Required to be used for Each Transfer of a Controlled Substance in Schedules I & II



21 CFR 1301.76 (b)

- The registrant shall notify the Field Division Office of the Administration in his area of any theft or significant loss of any controlled substances within one business day of discovery.



21 CFR 1301.76 (b)

- The registrant shall also complete, and submit DEA Form 106...
- “Significant Loss” is also defined here.
- Reporting is On-Line or DEA Form 106.



Theft/Loss of CS

- Theft Should also be Reported to Local Police with Jurisdiction where the Theft Occurred.
- Also Reported to Any State Agency Which May Also Require Such Reports



21 CFR 1304.04

**Must Keep
Inventories, Records, and Reports
for **Two** Years**



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 or her professional practice.



21 C.F.R. § 1306.04(a)

The responsibility for the proper prescribing and dispensing of controlled substances is upon the prescribing practitioner, but a corresponding responsibility rests with the pharmacist who fills the prescription .



21 C.F.R. § 1306.04(a)

An order purporting to be a prescription issued not in the usual course of professional treatment ... is not a prescription...

The pharmacist is not required to fill a controlled substance prescription



Prescriptions

- **§1306.03 Persons entitled to issue prescriptions.**
- (a) A prescription for a controlled substance may be issued only by an individual practitioner who is:
 - (1) authorized to prescribe controlled substances by the jurisdiction in which he is licensed to practice his profession and
 - (2) either registered or exempted from registration pursuant to Secs. 1301.22 (c) and 1301.23 of this chapter.



Prescriptions

- (b) A prescription issued by an individual practitioner may be communicated to a pharmacist by an employee or agent of the individual practitioner.



Prescriptions

- (f) A prescription may be prepared by the secretary or agent for the signature of a practitioner, but the prescribing practitioner is responsible in case the prescription does not conform in all essential respects to the law and regulations.



Prescriptions

- §1306.05 Manner of issuance of prescriptions.
- (a) All prescriptions for controlled substances shall be dated as of, and signed on, the day when issued and shall bear the full name and address of the patient, the drug name, strength, dosage form, quantity prescribed, directions for use, and the name, address and registration number of the practitioner.



Prescriptions

- (d) A practitioner may sign a paper prescription in the same manner as he would sign a check or legal document (e.g., J.H. Smith or John H. Smith). Where an oral order is not permitted, paper prescriptions shall be written with ink or indelible pencil, typewriter, or printed on a computer printer and shall be **manually signed** by the practitioner.



Prescriptions

- (e) Electronic prescriptions shall be created and signed using an application that meets the requirements of 21 C.F.R. part 1311.



Points of Diversion

- **Nurses**
- **Physicians**
- **Physician Assistants**
- **Dental Assistants**
- **Office Managers**
- **Cashiers**
- **General Maintenance Personnel**



Points of Diversion

- **Fraudulent “Call-In”
Prescriptions**
- **Forged Prescriptions**
- **Employee Theft**
- **Armed Robbery**
- **Burglary**



Effective Controls

21 C.F.R. § 1301.71(a)

“All applicants and registrants shall provide effective controls and procedures to guard against theft and diversion of controlled substances.”



Effective Controls

21 C.F.R. § 1301.75 (b):

Controlled substances listed in Schedules II, III, IV, and V shall be stored in a securely locked, substantially constructed cabinet.



Preventative Measures

- **Pre-Employment Screening**
 - **Background Checks**
 - **Drug Screening**
- **Updated Background Checks
(Every 3-5 Years)**
- **Random Drug Screening**



Preventative Measures

- **SOP's for Handling CS**
- **Limited Access to CS**
- **Limited Access to Alarms, Keys, and Pass Codes**
- **Limited Access to Dispensing Areas**
- **Physical Security (Cameras, PB's)**



Preventative Measures

- Cameras in areas where CS are being dispensed
- **Complete and Accurate Dispensing Records**
- **Periodic Physical Inventories**
- Medications to be Administered by Authorized Personnel Only as Expressly Authorized by an Individual Practitioner



Preventative Measures

- **Do not create a work environment that condones self use**
- **Be aware of what pharmaceuticals or combination of pharmaceuticals are being sought**
- **Know how to contact your local DEA office**

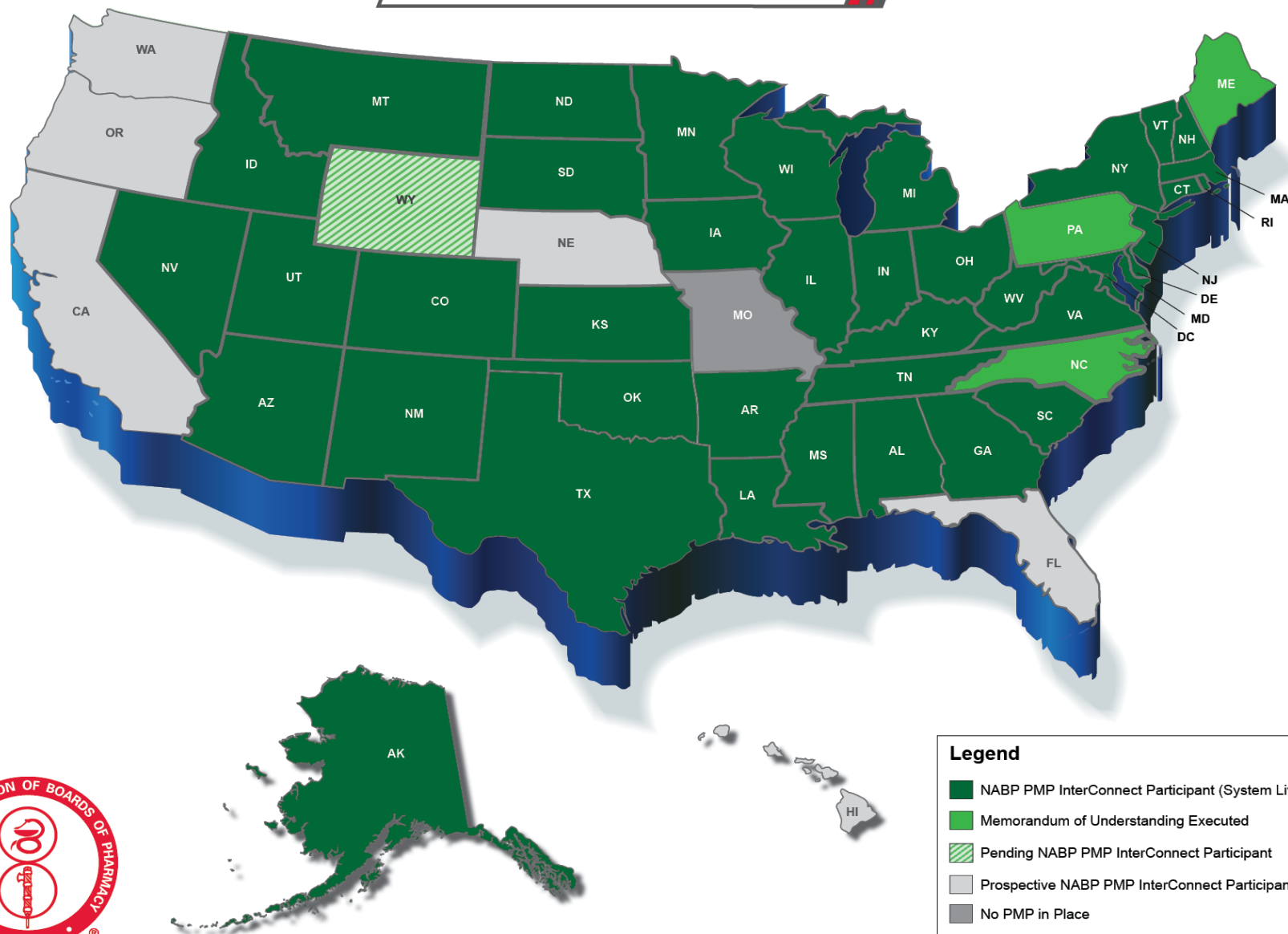


Preventative Measures

All DEA Registered Practitioners
should

secure their prescription pads when
not in use

PMP INTERCONNECT®



Legend

- NABP PMP InterConnect Participant (System Live)
- Memorandum of Understanding Executed
- Pending NABP PMP InterConnect Participant
- Prospective NABP PMP InterConnect Participant
- No PMP in Place





Take-Back of Medications

Once a CS has been Dispensed to the Ultimate User it becomes the Legal Property of the Patient.

It cannot be re-distributed unless otherwise permitted for by Federal Law/DEA Disposal Regulations.



The Medicine Cabinet and Pharmaceutical Controlled Substances



Many Patients Share Prescribed Controlled Substances

University of Pennsylvania Dental School Study:

- ***More than half of the narcotics prescribed for wisdom teeth removal go unused...findings suggest that more than 100 million pills prescribed go unused... leaving the door open for possible misuse or abuse.**



National Take Back Initiative

NTBI XV

Saturday

April 28, 2018



Drug Disposal

21 C.F.R. § 1317.05(a)(b)

Inventory

VS

(Pharmaceutical Waste)



Resources for Patients

www.drugdropbox.org

www.disposemymeds.org

www.sharpsinc.com/locations

www.fda.gov (Search: Disposal)

www.epa.gov (Search: Disposal)



Partial Fills

Comprehensive Addiction and Recovery Act of 2016 (P.L. 114-198)

Effective: July 22, 2016

- Additional Options for Patient/Practitioner**
- Patient does not have to take the Full Amount of Prescribed Quantity**
- 30 days to Take All if So Desired.**



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

30-Day Notice (Extension): Report of Theft or Loss of Controlled Substance; DEA Form 106 (July 18, 2017)

30-Day Notice (Extension): Self-Certification, Training, and Logbooks for Regulated Sellers and Mail-Order Distributors of Scheduled Listed Chemical Products; DEA Form 597 (July 18, 2017)

30-Day Notice (Extension): Registrant Record of Controlled Substances Destroyed; DEA Form 41 (July 18, 2017)

Final Rule: Designation of Alpha-Phenylacetoacetonitrile (APAAAN) as a List I Chemical (July 14, 2017)

Temporary Scheduling Order: Temporary Placement of Acryl Fentanyl Into Schedule I (July 14, 2017)

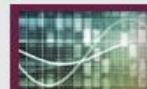
Proposed Rule: Removal of Naldemedine From Control (July 12, 2017)



DEA Forms & Applications



Questions & Answers



Publications & Manuals



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 \(Electronic Prescriptions for Controlled Substances\)](#)

[DEA Form 106: Report Theft or Loss of Controlled Substances](#)

[Drug Theft/Loss Reports for 2014-2016](#)

[Find Your Local DEA Office](#)

[Mailing Addresses for Topics Related to Title 21 CFR](#)

[Medical Missions](#)

[Submit a Tip to DEA](#)

In The News

Safeway Pharmacies Pay \$3 Million to Resolve Allegations Chain Failed to Timely Report Drug Diversion (July 18, 2017)

Northern California Doctor Indicted (July 13, 2017)

National Health Care Fraud Takedown: Charges Against Over 412 Individuals Responsible for \$1.3 Billion in Fraud (July 13, 2017)

13.5 Million Lethal Doses of Fentanyl: California Man Indicted in DEA-Kansas Highway Patrol Investigation (July 06, 2017)



EMERGENCY DISASTER

www.deadiversion.usdoj.gov/consumer_alert.htm

National Prescription Drug

TAKE BACK DAY

Turn in your unused or
expired medication
for safe disposal

October 28, 2017



Report Illicit Pharmaceutical Activities

RX ABUSE ONLINE





Resources

www.DEADiversion.usdoj.gov

www.dea.gov

www.operationprevention.com

“Chasing the Dragon”



www.cdc.gov

**“Guideline for Prescribing Opioids
for Chronic Pain”**

**“Checklist for Prescribing Opioids
for Chronic Pain”**

**[https://www.cdc.gov/drugoverdose/
prescribing/trainings.html](https://www.cdc.gov/drugoverdose/prescribing/trainings.html)**



Contact Information

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Thank You





Providers Clinical Support System (PCSS) Training

PCSS is a collaborative effort led by the American Academy of Addiction Psychiatry (AAAP) in partnership with the: Addiction Technology Transfer Center (ATTC); American Academy of Family Physicians (AAFP); American Academy of Neurology (AAN); American Academy of Pain Medicine (AAPM); American Academy of Pediatrics (AAP); American College of Emergency Physicians (ACEP); American College of Physicians (ACP); American Dental Association (ADA); American Medical Association (AMA); American Osteopathic Academy of Addiction Medicine (AOAAM); American Psychiatric Association (APA); American Psychiatric Nurses Association (APNA); American Society of Addiction Medicine (ASAM); American Society for Pain Management Nursing (ASPMN); Association for Medical Education and Research in Substance Abuse (AMERSA); International Nurses Society on Addictions (IntNSA); National Association of Community Health Centers (NACHC); National Association of Drug Court Professionals (NADCP), and the Southeast Consortium for Substance Abuse Training (SECSAT).

For more information visit: <https://pcssNOW.org/>

For questions, email: pcss@aaap.org

Visit us on Twitter: @PCSSProjects

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Webinar Evaluations (Post and 30-Day)

Each PCSS partner organization is asked to distribute a post and 30-day evaluation to participants for their completion.

Participants in today's webinar will be emailed the link to complete their evaluations.

Thank you for your feedback!



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