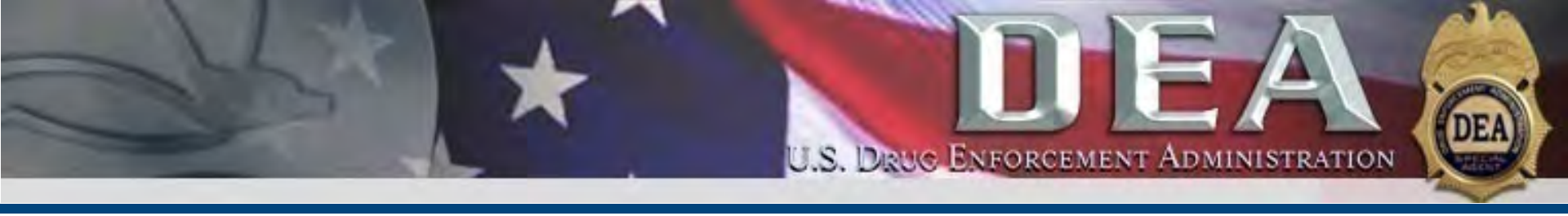


DEA Trends & Update

Little Rock Pharmacy Diversion Awareness Conference

June 12 & 13, 2016

The United States Department of Justice
Drug Enforcement Administration

Thomas W. Prevoznik,
Unit Chief Liaison
Liaison & Policy Section
Office of Diversion Control

Goals and Objectives

- Public Health Epidemic
- Impact on Society
- Drugs of Abuse
- Criminal Activity
- The Controlled Substances Act: Checks & Balances
- Legal obligations: DEA registrant
- The DEA Response
- Disposal
- Miscellaneous Pharmacy Topics

Public Health Epidemic

DRAWINGBOARD / SIGNE

Primum non nocere

Public Health Epidemic

2000-2014:

Unintentional drug overdose deaths in the US increased **137%**, which was a **200%** increase in overdose deaths involving opioids.

500,000 deaths due to prescription overdose

2014:

Over 47,000 drug-related overdose deaths

129 deaths every 24 hours
46 deaths by end of today's PDAC
1 death every 11.16 minutes

28,647 deaths involved opioids, including heroin
19,000 deaths involved prescription opioid

CDC National Center for Health Statistics/Morbidity and Morality Weekly Report (MMWR); January 1, 2016

Our Youth

ADDERALL XR
Chelsea Kennedy
ADDERALL XR 10 MG
Take one capsule
by mouth every
morning
LITHIUM CARB
ER300MG
CAUTIONS

Most Frequent Method of Obtaining a Pharmaceutical Controlled Substance for Non Medical Use

Friends and Family…For Free!!

Where else do our kids get their information from?

www.erowid.org

Where do kids get their information from?

www.bluelight.org

www.bluelight.ru/vb/

Google Bluelight

User Name | Password | Log in | Remember Me? | Help | Register

BLUELIGHT

HARM REDUCTION WORKSHOP with BLUELIGHT
PSYCHEDELICSCIENCE2013 APRIL 18TH REGISTER NOW
OAKLAND MARRIOTT CITY CENTER • CALIFORNIA

Home | Forum | What's New? | Wiki

The Front Page | Advanced Search

The Front Page

If this is your first visit, be sure to check out the FAQ.

You may have to register before you can post: click the register link above to proceed. To start viewing messages, select the forum that you want to visit from the selection below.

Features

Bluelight Wiki	Our own Wiki project
Blogs	Blogs from our members
Bluelight Mobile	Use Bluelight on the go!
Staff List	Contact our staff members
Twitter	Follow us on Twitter

Forums

Focus Forums
Drug FAQs
Ecstasy Discussion
Cannabis Discussion
Steroid Discussion
Psychedelic Drugs
Other Drugs

Drug Discussion
Drug Studies
Drugs in the Media
Basic Drug Discussion
Advanced Drug

Australia & Asia
Australian Drug Discussion
Australian Social & Events

Europe & Africa
European Drug Discussion
European Events

North America & South America
North & South American Social & Drug Discussion
North & South American Events

THE FRONT PAGE

A Letter to Bluelight and MAPS Forum members From Brad Burge (MAPS) and Sebastians_Ghost (BL)

by Sebastians_ghost Published on 05-04-2013 06:57

It is with great pride and enthusiasm that we announce today a major collaboration between Bluelight.ru and the Multidisciplinary Association for Psychedelic Studies.

Through the efforts of Brad Burge, MAPS' Director of Communications, Rick Doblin, MAPS' Founder and Executive Director, Sebastians_Ghost and The_Love_Bandit of Bluelight.ru, we will soon undertake an exciting partnership to reinvigorate the MAPS forum and increase opportunities for public education about psychedelic science and medicine. The existing plaintext email MAPS Forum will be migrating to Bluelight.ru, the world's leading drug information website. We're aiming to unveil the new MAPS Forums on Bluelight shortly before the Psychedelic Science 2013 symposium in mid-April.

In the coming weeks, the MAPS Forum will no longer be linked from maps.org. Instead, MAPS will provide a link to the new MAPS Forum hosted at Bluelight. MAPS will work closely with Bluelight to encourage public participation in our new "home" at Bluelight.ru as the migration of the MAPS Forum topics is completed.

...

start | Bluelight - The Front ...

Violence

Starting the year with a bang

Saranac Hale Spencer, The News Journal 12:36 a.m. EST January 4, 2016

18
3

(Photo: DELAWARE STATE POLICE)

A 26-year-old Lewes man threatened to detonate explosives he said were strapped to his body if a pharmacist at a Walgreens near Magnolia didn't give him prescription drugs, according to state police.

The man, Curtis Kuhn, didn't actually have explosives strapped to his body, according to police.

Kuhn went into the pharmacy at about 9:30 a.m. on Saturday and put a note on the counter demanding Percocet and Xanex – he told the pharmacist that he had explosives strapped to his body and he was being forced to commit the robbery by someone who was sitting in a car in the parking lot, according to police.

When officers arrived shortly after that, they took Kuhn into custody without incident and found that he had no explosives and there was no car fitting his description in the parking lot, according to police.

Kuhn was charged with first-degree attempted robbery, attempted theft of a controlled substance and two counts of terroristic threatening. He was arraigned and sent to Vaughn Correctional Center near Smyrna for lack of $27,000 secured bond and

Drugs of Abuse

Most commonly prescribed prescription medicine?

Hydrocodone/acetaminophen

Hydrocodone

- Hydrocodone / Acetaminophen (toxicity)

- Similarities:
  - Structurally related to codeine
  - Equal to morphine in producing opiate-like effects

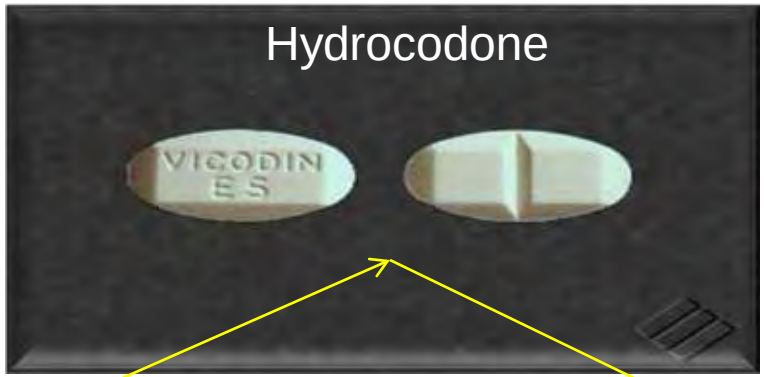
- Brand Names: Vicodin®, Lortab®, Lorcet®

- **October 6, 2014 moved to SCHEDULE II**

- "Cocktail" or "Trinity"
  - Hydrocodone
  - Soma ® / carisoprodol
  - Alprazolam / Xanax®

Street prices: $2 to $10+ per tablet depending on strength & region

The Trinity



Opiate

Muscle Relaxant

Benzodiazepine

Oxycodone

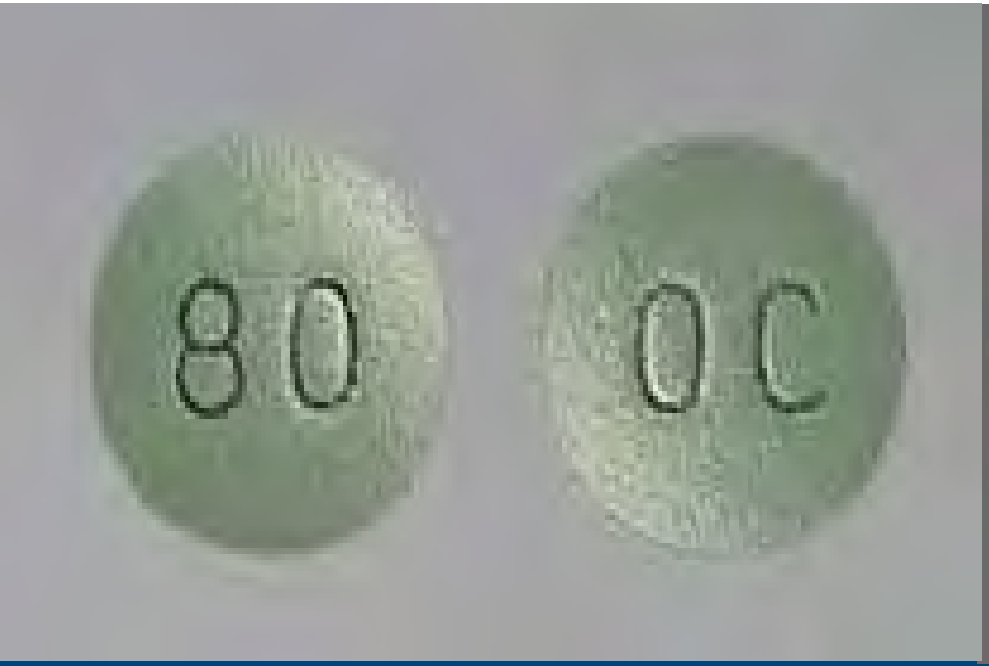
- OxyContin controlled release formulation of Schedule II oxycodone
  - The controlled release method of delivery allowed for a longer duration of drug action so it contained much larger doses of oxycodone
  - Abusers easily compromised the controlled release formulation by crushing the tablets for a powerful morphine-like high
  - 10, 15, 20, 30, 40, 60, 80mg available

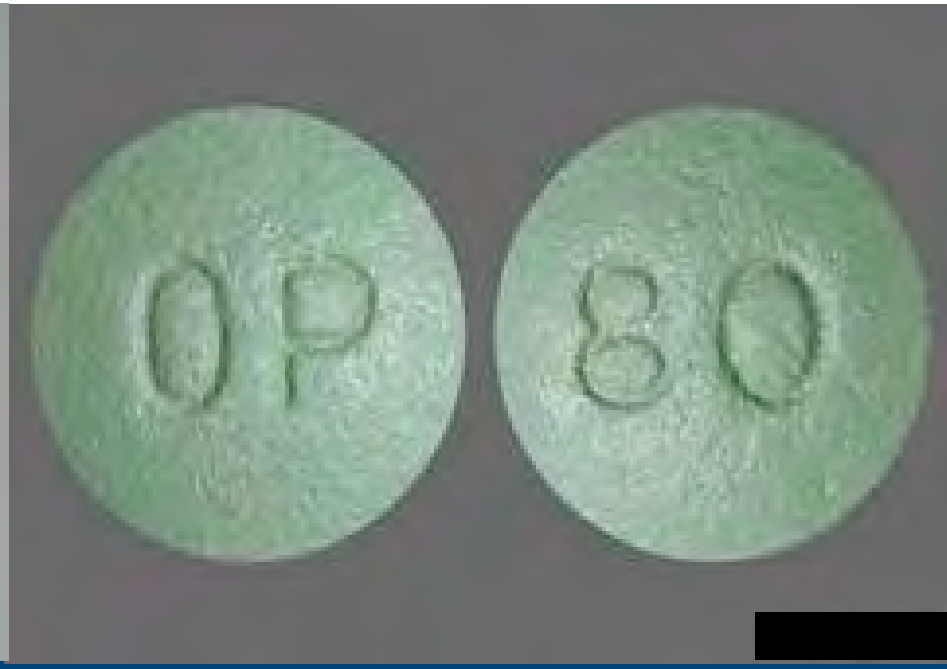
- Effects:
  - Similar to morphine in effects and potential for abuse/ dependence
  - Sold in “Cocktails” or the “Holy Trinity”
    - Oxycodone, Soma ® / Xanax®

- Street price: Approx. $80 per 80mg tablet

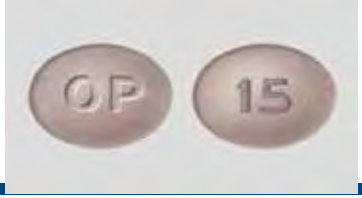
NOTE: New formulation introduced into the marketplace in 2010 that is more difficult to circumvent for insufflation (snorting) or injection. Does nothing to prevent oral abuse.

Oxycodone HCL CR (OxyContin®) Reformulation





New OxyContin® OP



08-27-2010, 01:11 AM #17

mz.mary420
Member

Join Date: May 2010
Location: down south
Posts: 6

well just got ours and they suck! when snorted the pill balls up in your nose and gets stuck, so i tried sucking on one and it did ok, but tastes nasty. No way you can shoot them as metioned in a previous post. havent tried smoking it yet, kinda in a hole money wise, it cost me over $700.00 to get my 80s filled and i probably wont even get half my money back

* if anyone has tried to smoke this new formulated shit, please post! thanks

Quote

08-27-2010, 06:09 AM #18

mephist00
Member

Join Date: Apr 2008
Location: NY
Age: 25
Posts: 628

ya my friend has tried to smoke the new ones... said its very harsh on the lungs and throat..

so far the only way ive been able to beat the time release, is use a hose clamp to grind it very fine, and snort it.. it doesnt gel up like you would think (doesnt gel up like the football shaped generic 40's do anyways) it just kinda turns snotty.. but if you can get it down fast it seems to work ok

_____

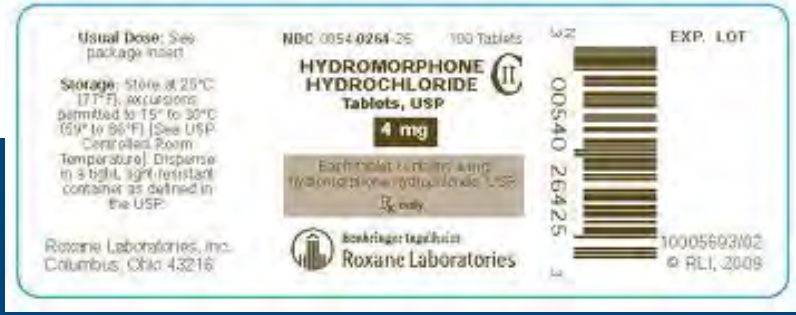
Quote:

Originally Posted by **stalk**
I've come to the conclusion it's because these psychedelic visions are simply vibrating on a higher, or different, spectrum of frequencies that normally the monkey does not perceive.

Oxymorphone Extended Release
Opana ER® (Schedule II)

- **Opana ER® - (Schedule II)**
  - Treats constant, around the clock, moderate to severe pain
  - Becoming popular and is abused in similar fashion to oxycodone ; August 2010 (Los Angeles FD TDS)
  - Slang: Blues, Mrs. O, Octagons, Stop Signs, Panda Bears
  - Street: $10.00 – $80.00

Hydromorphone



Other Opiates of Interest

Trade Name: MS Contin
Controlled Ingredient: morphine sulfate, 100 mg

Trade Name: MS Contin
Controlled Ingredient: morphine sulfate, 15 mg

Trade Name: MS Contin
Controlled Ingredient: morphine sulfate, 30 mg

Trade Name: Oramorph SR
Controlled Ingredient: morphine sulfate, 30 mg

Trade Name: Oramorph SR
Controlled Ingredient: morphine sulfate, 100 mg

Trade Name: Oramorph SR
Controlled Ingredient: morphine sulfate, 60 mg

Trade Name: Dilaudid
Controlled Ingredient:
hydromorphone hydrochloride, 2 mg

Trade Name: Dilaudid
Controlled Ingredient:
hydromorphone hydrochloride, 4 mg

Fentanyl

Fentora®

- Fentanyl Patches
- Fentanyl Citrate dispensed in a berry flavored lollipop-type unit
- Fentanyl is 100 times more potent than morphine
- Intended to be used for chronic cancer pain & only for people who are tolerant to prescription opioid (narcotic) pain medicines
- Abused for its intense euphoric effects

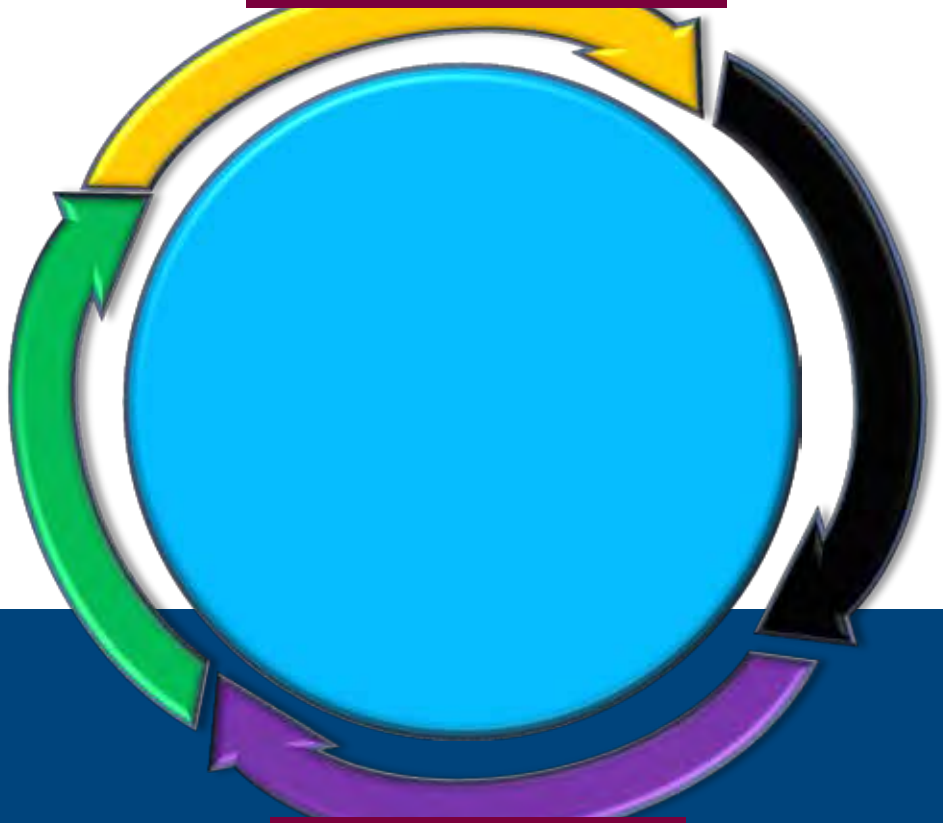
Methadone- 5mg &10mg

Methadone 40 mg

Prescription Opiates v. Heroin

Circle of Addiction & the Next Generation

Oxycodone Combinations
Percocet®
$7-$10/tab



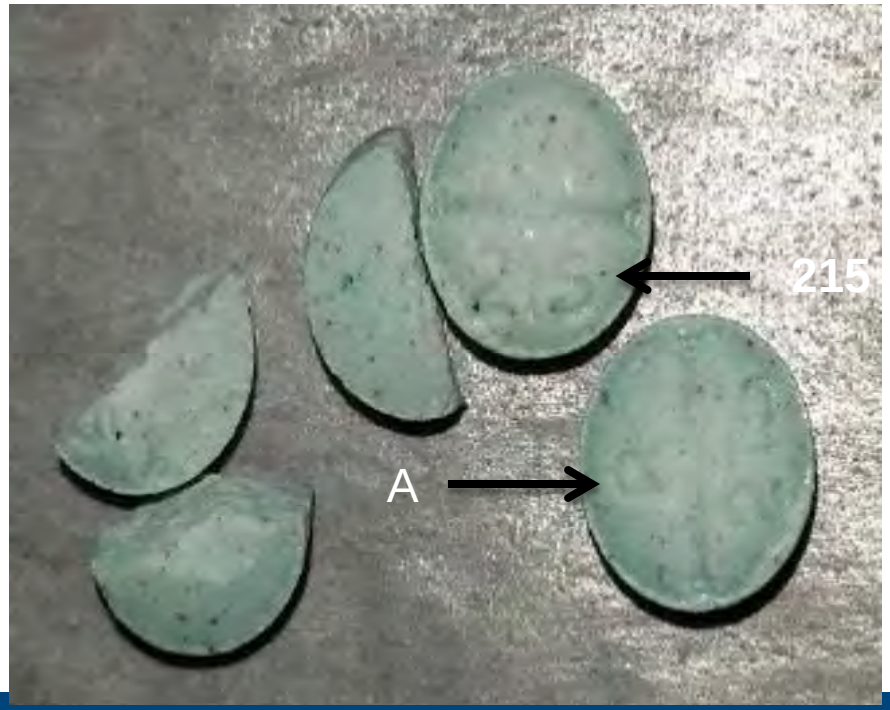
OxyContin®
$80/tab

Roxicodone®
Oxycodone IR 15mg, 30mg
$30-$40/tab

Hydrocodone
Lorcet®
$5-$7/tab

Heroin
$15/bag

U.S. Drug Enforcement Administration
Office of Diversion Control



Heroin Seizure

Pharmaceutical Oxycodone 30mg

Criminal Activity

Egregious Activity
(Not on the fringes)

United States V. Alvin Yee, M.D.

Dr. Alvin Yee

United States V. Alvin Yee, M.D.

Dr. Yee primarily met with his “patients” in Starbucks cafes throughout Orange County, California.

He would see up to a dozen patients each night between 7:00 and 11:00 p.m. and wrote these “patients” prescriptions, primarily for opiates, in exchange for cash.

Yee pled guilty to distributing millions of dollars in oxycodone, oxymorphone, hydrocodone, hydromorphone, Adderall® and alprazolam outside the course of professional practice and without a legitimate medical purpose.

United States V. Alvin Yee, M.D.

CURES Data (PMP)

During a one-year time period, Yee wrote prescriptions for a total of 876,222 dosage units of all medications combined.

52% of all prescriptions (458,056 dosage units) written by Yee were for oxycodone (92%-30mg) during the one-year period.

96% - oxycodone, hydrocodone, alprazolam, hydromorphone, and oxymorphone.

Almost half of Yee's patients were 25 and under.

United States V. Alvin Yee, M.D.

MEDICAL OFFICE
Various Locations, Orange County, California

The Controlled Substances Act: Checks & Balances

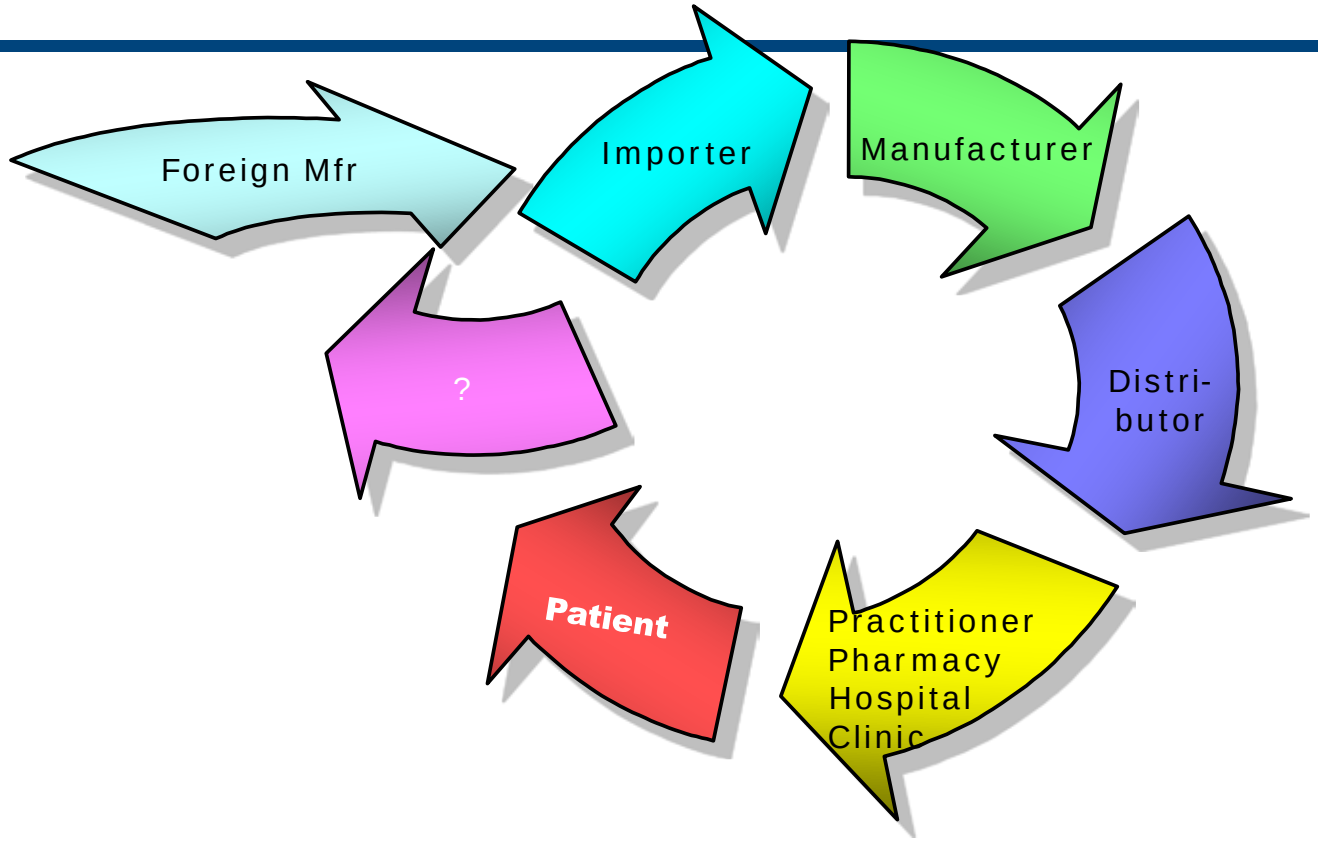
Mission

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

while …

ensuring an adequate and uninterrupted supply of controlled substances to meet legitimate medical, commercial, and scientific needs.

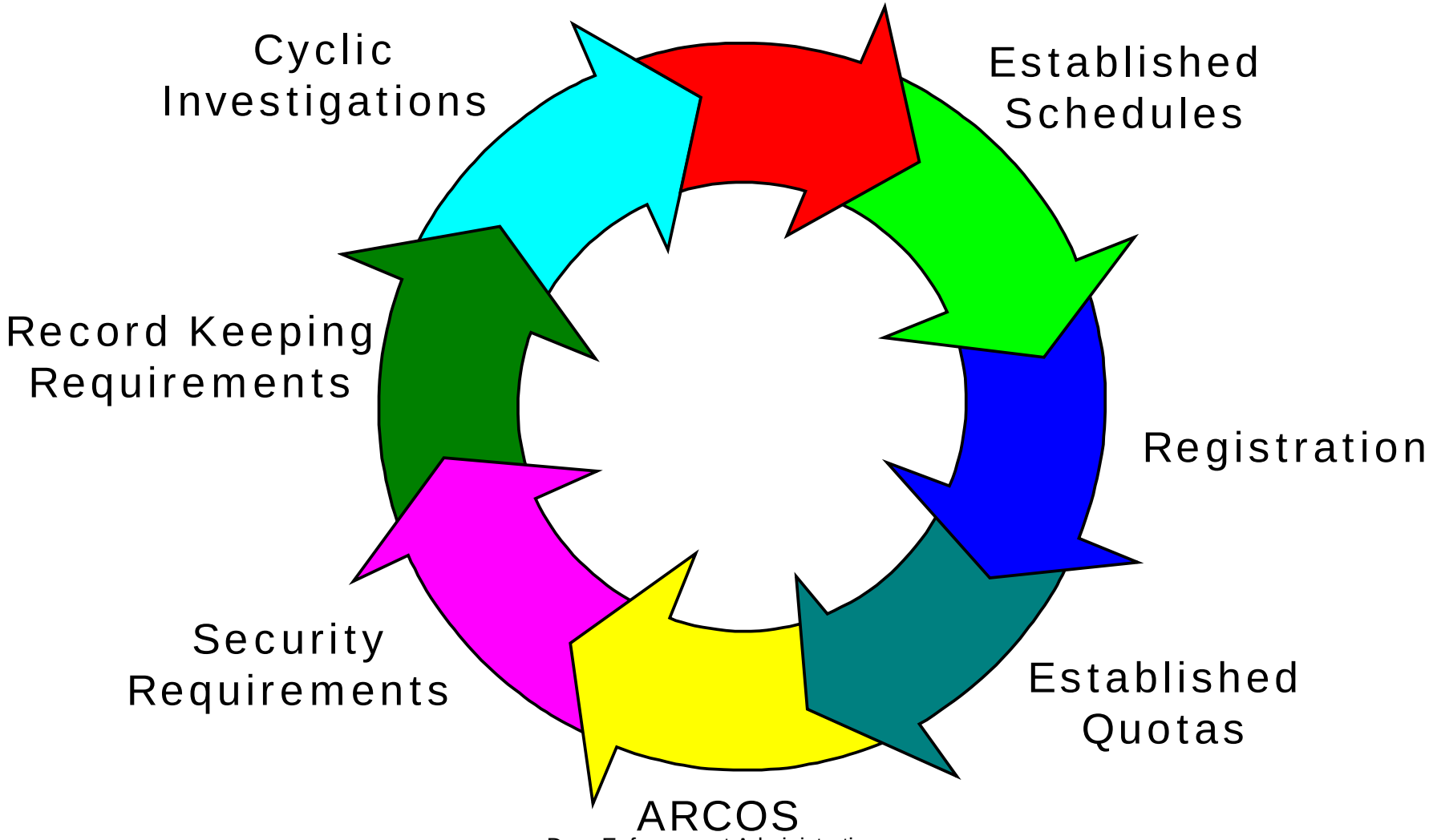
Closed System of Distribution



1,638,232 **(06/09/2016)**

- **Practitioners: 1,233,795**
- **Retail Pharmacies: 73,665**
- **Hospital/Clinics: 16,951**

Closed System of Distribution



Closed System of Distribution

The DEA is responsible for:

- **the <u>oversight</u> of the system**
- **the <u>integrity</u> of the system**
- **the <u>protection</u> of the public health and safety**

Legal Obligations: DEA Registrant

Effective Controls

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

- In order to determine whether a registrant has provided effective controls against diversion, the Administrator shall use the security requirements set forth in §§ 1301.72-1301.76 as standards for the physical security controls and operating procedures necessary to prevent diversion.

21 CFR § 1301.71(a)

Suspicious Orders

Non-practitioners of controlled substances

"The registrant shall design and operate a system to disclose to the registrant suspicious orders of controlled substances…Suspicious orders include orders of unusual size, orders deviating substantially from a normal pattern, and orders of unusual frequency."

21 CFR § 1301.74(b)

Prescriptions

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.

21 CFR § 1306.04(a)

United States v Moore 423 US 122 (1975)

CDC Guidelines for Prescribing Opioids for Chronic Pain

- Clinical Reminders:
  - Opioids are not first-line or routine therapy for chronic pain
  - Establish and measure goals for pain and function
  - Discuss benefits and risks and availability of nonopioid therapies with patient

Source: CDC Morbidity & Mortality Weekly Report **CDC Guideline for Prescribing Opioids for Chronic Pain — United States, 2016, March 15, 2016** www.cdc.gov/drugoverdose/prescribing/guideline.html

CDC Guidelines for Prescribing Opioids for Chronic Pain

- Use immediate-release opioids when starting
- Start low and go slow
- When opioids are needed for acute pain, prescribe no more than needed
- Do not prescribe ER/LA opioids for acute pain
- Follow-up and re-evaluate risk of harm; reduce dose or taper and discontinue if needed

Source: CDC Morbidity & Mortality Weekly Report **CDC Guideline for Prescribing Opioids for Chronic Pain — United States, 2016, March 15, 2016** www.cdc.gov/drugoverdose/prescribing/guideline.html

CDC Guidelines for Prescribing Opioids for Chronic Pain

- Evaluate risk factors for opioid-related harms
- Check PDMP for higher dosages and prescriptions from other providers
- Use urine drug testing to identify prescribed substances and undisclosed use
- Avoid concurrent benzodiazepine and opioid prescribing
- Arrange treatment for opioid use disorder if needed

Source: CDC Morbidity & Mortality Weekly Report **CDC Guideline for Prescribing Opioids for Chronic Pain — United States, 2016, March 15, 2016** www.cdc.gov/drugoverdose/prescribing/guideline.html

Corresponding Responsibility by Pharmacist

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 CFR § 1306.04(a)

Corresponding Responsibility by Pharmacist

- A pharmacist, by law, has a corresponding responsibility to ensure that prescriptions are legitimate.
- When a prescription is presented by a patient or demanded to be filled for a patient by a doctor's office, a pharmacist is not obligated to fill the prescription!!!

The Last Line of Defense

Potential Red Flags

Many customers receiving the same combination of prescriptions; cocktail

Many customers receiving the same strength of controlled substances; no individualized dosing: multiple prescriptions for the strongest dose

Many customers paying cash for their prescriptions

Early refills

Many customers with the same diagnosis codes written on their prescriptions;

Individuals driving long distances to visit physicians and/or to fill prescriptions;

Potential Red Flags continued

Customers coming into the pharmacy in groups, each with the same prescriptions issued by the same physician; and

Customers with prescriptions for controlled substances written by physicians not associated with pain management (i.e., pediatricians, gynecologists, ophthalmologists, etc.).

Overwhelming proportion of prescriptions filled by pharmacy are controlled substances

Pharmacist did not reach out to other pharmacists to determine why they were not filling a particular doctor's prescription

Verification of legitimacy not satisfied by a call to the doctors office

Red Flag?

What happens next?

You attempt to resolve…

www.nabp.net

NABP
NATIONAL ASSOCIATION OF BOARDS OF PHARMACY
GO
HOME
ABOUT
PROGRAMS
PUBLICATIONS
NEWS
MEETINGS
CONTACT
QUESTIONS? CHAT IS AVAILABLE
Meet the NABP Executive Committee
2015-2016 Executive Committee
Do You Know What a Doctor Shopper Looks Like?
redflag
Red Flags for Pharmacists
Verified Pharmacy Program
CPE Monitor
Safe Online Pharmacies
NEWSROOM HEADLINES

Resolution is comprised of many factors

- Verification of a valid practitioner DEA number ! It is not, **however**, the end of the pharmacist's duty. Invalid DEA number = Invalid RX
- Resolution cannot be based solely on patient ID and prescriber verification.
- You must use your professional judgment, training and experience…we all make mistakes
- Knowledge and history with the patient
- Circumstances of prescription presentation
- Experience with the prescribing practitioner
- It does not require a call to the practitioner for every CS RX
- This is not an all-inclusive list…

Who do I call to report a practitioner?

- State Board of Pharmacy, Medicine, Nursing, Dental
- State, County, Local Police
- DEA local office and Tactical Diversion Squad
- Health Department
- HHS OIG if Medicare, Medicaid fraud

The DEA Response

360 Degree Strategy

Community Partnerships

- DEA recognizes we cannot arrest our way out of the drug problem – our goal is lasting success in the communities we serve.
- Education and Prevention are key elements for a true 360 Strategy.
- Law enforcement operations provide an opportunity for community empowerment and a jumping off point for education and prevention efforts.

DEA Registrant Initiatives

Distributor Initiative

Educate and inform distributors/manufacturers of their due diligence responsibilities under the CSA by discussing their Suspicious Order Monitoring System, reviewing their ARCOS data for sales and purchases of Schedules II and III controlled substances, and discussing national trends involving the abuse of prescription controlled substances

Briefings to **95** firms with **305** registrations

DEA Registrant Initiatives

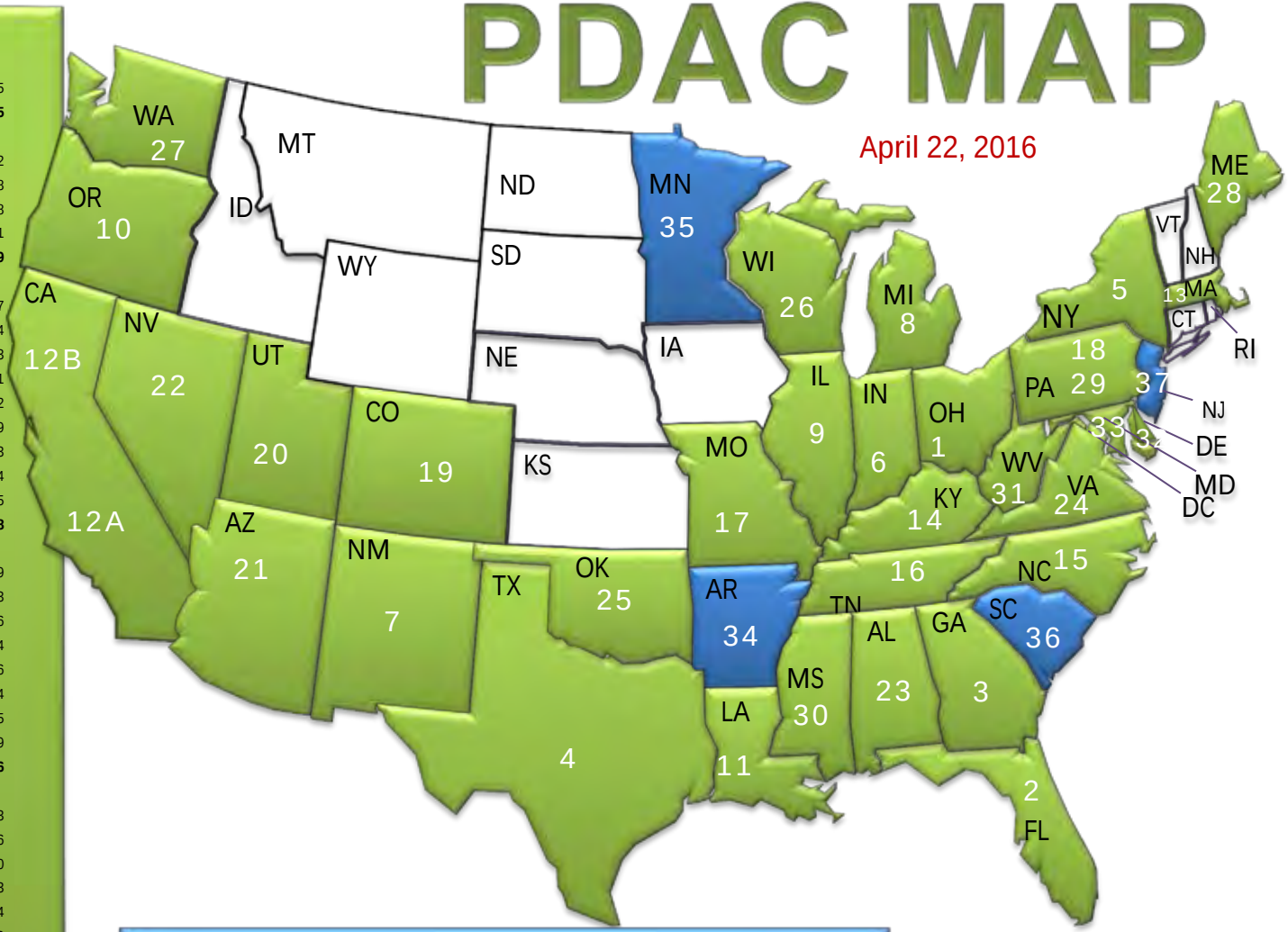
Pharmacy Diversion Awareness Conference

This conference is designed to educate pharmacists, pharmacy technicians, and pharmacy loss prevention personnel on ways to address and respond to potential diversion activity

PDAC MAP

April 22, 2016

Completed PDACs	Attendance
FY-2011	
1-Cincinnati, OH 9/17-18/11	75
FY-2011 Total Attendance	**75**
FY-2012	
2-WPB, FL 3/17-18/12	1,192
3-Atlanta, GA 6/2-3/12	328
4-Houston, TX 9/8-9/12	518
5-Long Island, NY 9/15-16/12	391
FY-2012 Total Attendance	**2,429**
FY-2013	
6-Indianapolis, IN 12/8-9/12	137
7-Albuquerque, NM 3/2-3/13	284
8-Detroit, MI 5/4-5/13	643
9-Chicago, IL 6/22-23/13	321
10-Portland, OR 7/13-14/13	242
11-Baton Rouge, LA 8/3-4/13	259
12A-San Diego, CA 8/16-17/13	353
12B-San Jose, CA 8/18-19/13	434
13-Boston, MA 9/21-22/13	275
FY-2013 Total Attendance	**2,948**
FY-2014	
14-Louisville, KY 11/16-17/13	149
15-Charlotte, NC 2/8-9/14	513
16-Knoxville,TN 3/22-23/14	246
17-St. Louis, MO 4/5-6/14	224
18-Philadelphia,PA 7/12-13/14	276
19-Denver, CO 8/2-3/14	174
20-SLC, UT 8/23-24/14	355
21-Phoenix, AZ 9/13-14/14	259
FY-2014 Total Attendance	**2,196**
FY-2015	
22-Las Vegas, NV 2/7-8/15	193
23-Birmingham, AL 3/28-29/15	296
24-Norfolk, VA 5/30-31/15	410
25-Oklahoma City 6/27-28/15	253
26-Milwaukee, WI 7/25-26/15	114
27-Seattle, WA 8/8-8/9/15	210
28-Portland, ME 9/12-9/13/15	94
FY-2015 Total Attendance	**1,570**
FY-2016	
29-Pittsburgh, PA 12/10-11/15	196
30-Jackson, MS 1/9-10/16	185
31-Charleston, WV 2/27-28/16	245
32-Wilmington, DE 3/19-20/16	111
33-Towson, MD 4/17-4/18/16	442
Total Attendance To Date	**10,397**



Proposed FY-2016 PDACs

34-Little Rock, Arkansas - June 12 & 13, 2016
35-Minneapolis/St. Paul, Minnesota - July 9 & 10, 2016
36-Charleston, South Carolina - August 2016
37-New Brunswick, New Jersey - September 2016

32 STATES 68 PDAC CONFERENCES

Completed PDACs
Proposed PDACs

DEA Registrant Initiatives

- The Federation of State Medical Boards (FSMB) promotes excellence in medical practice, licensure, and regulation on behalf of 70 state medical and osteopathic Boards across the country in their protection of the public

- DEA and FSMB are currently working on developing strategies to work more effectively and jointly on indiscriminate prescriber investigations in order to facilitate the administrative process to take action against those that are a threat to the public health and welfare quickly, and at the same time not jeopardize a criminal investigation

DEA Registrant Initiatives

"Stakeholders' Challenges and Red Flag Warning Signs Related to Prescribing and Dispensing Controlled Substances"

- Represents the medical, pharmacist, and supply chain spectrum highlighting the challenges and "red flag" warning signs related to prescribing and dispensing controlled substance prescriptions

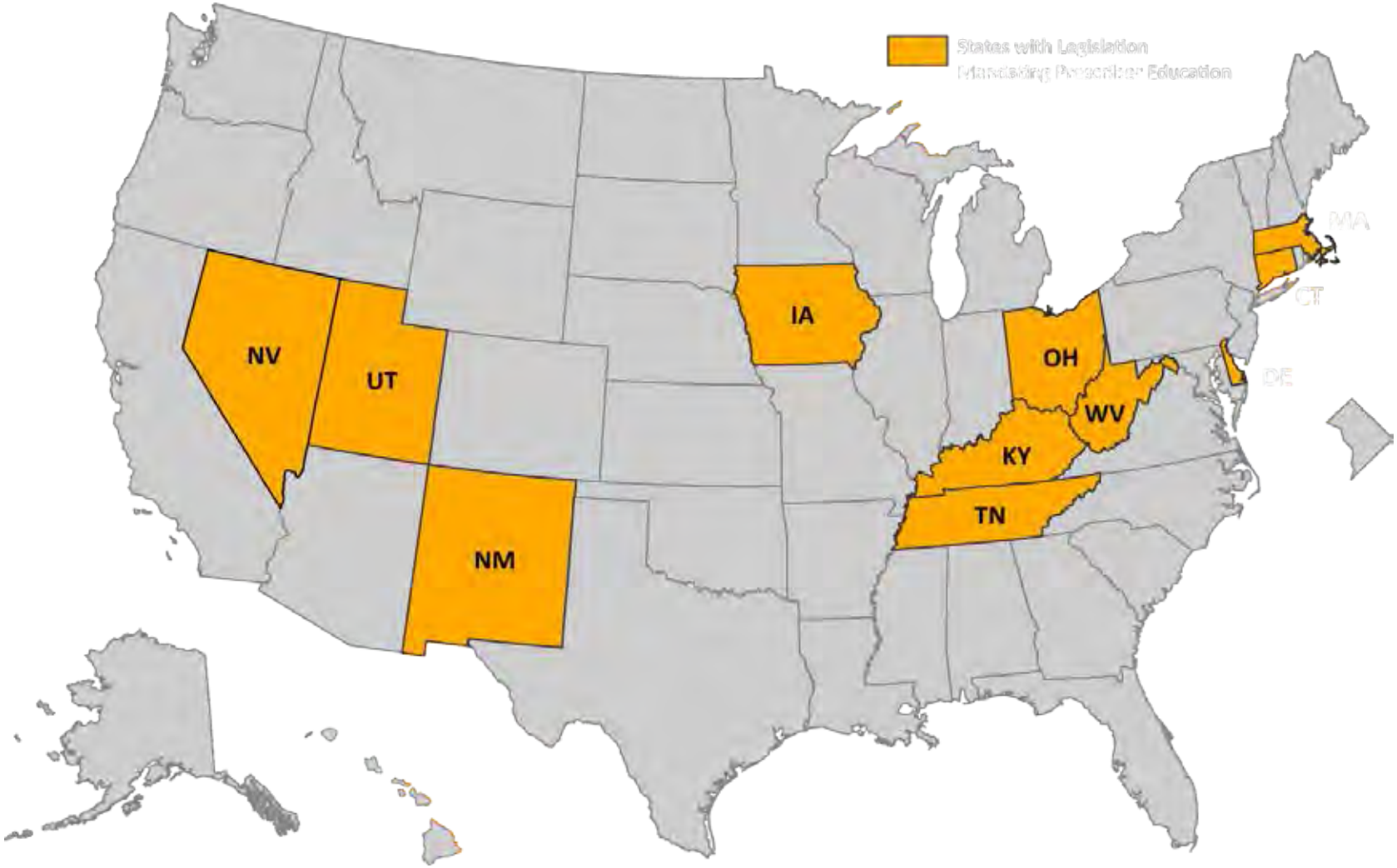
- The goal was to provide health care practitioners with an understanding of their shared responsibility to ensure that all controlled substances are prescribed and dispensed for a legitimate medical purpose, as well as to provide guidance on which red flag warning signs warrant further scrutiny

- NABP along with 10 national associations and 6 major pharmaceutical firms were the coalition of stakeholders of this document.

Scheduled Investigations

- Increase in the number of DEA registrants that are required to be investigated to ensure compliance with the Controlled Substances Act and its implementing regulations
- Increase in the frequency of the regulatory investigations
- Verification investigations of customers and suppliers

Since 2011, Eleven States have Passed Legislation Mandating Prescriber Education



Maine

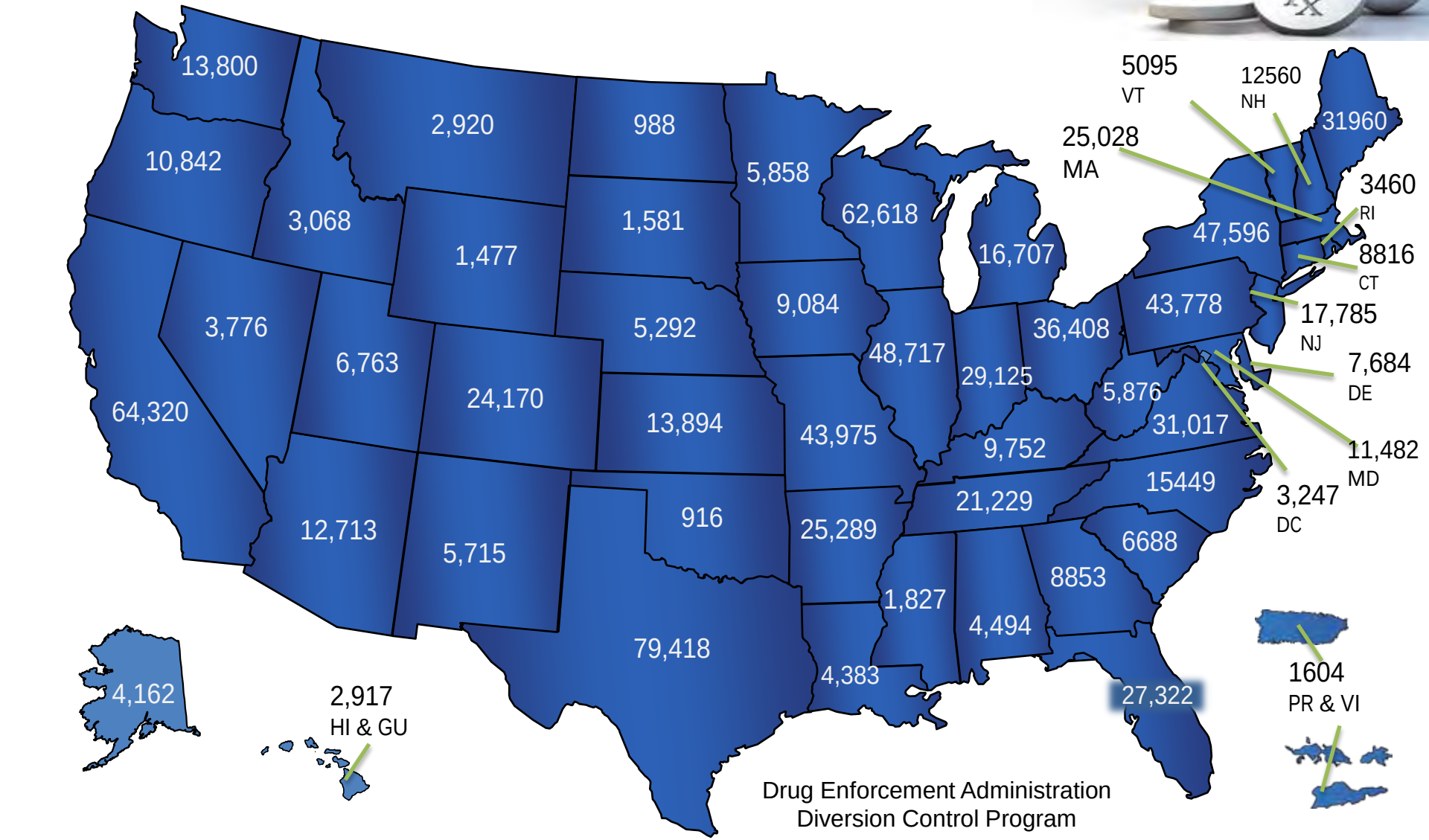
- Second State to Mandate Electronic Prescribing
- Prescribers are required to undergo addiction training every 2 years
- Set cap on daily strength for opioid prescribing:
  - Acute pain – 7 days
  - Chronic pain – 30 days
- To begin January 2017

National Take Back Initiative
April 30, 2016

10:00 AM – 2:00 PM

11th National Take Back Day: April 30, 2016

Total Weight Collected (pounds): 893,498 (447 Tons)



Secure and Responsible Drug Disposal Act of 2010

U.S. Drug Enforcement Administration
Office of Diversion Control

Ultimate User

Ultimate user means as "a person who has lawfully obtained, and who possesses, a controlled substance for his own use or for the use of a member of his household or for an animal owned by him or a member of his household."

21 USC § 802(27)

Ultimate user methods of destruction prior to Disposal rule:

- ü Disposal in Trash (ONDCP method); or
- ü Flushing (FDA opioids and select CSs)
- ü National Take-back Event (DEA)
- ü Transfer to Law Enforcement
- ü (Police Station Receptacles or local Take-back events)
- ü DEA

Secure and Responsible Drug Disposal Act of 2010

- CSA amended to provide ultimate users and LTCF with additional methods to dispose of unused, unwanted or expired controlled substance medication in a secure, safe and responsible manner

  21 USC § 822(f) & (g)

- Participation is voluntary

  21 USC § 822(g)(2)

- Registrants authorized to collect:
  - Manufacturers
  - Distributors
  - Reverse Distributors
  - Narcotic Treatment Programs
  - Hospitals/clinics with an on-site pharmacy
  - Retail Pharmacies

  21 CFR § 1317.40

Authorized collectors, as registrants, are readily familiar with the security procedures and other requirements to handle controlled substances.

Secure and Responsible Drug Disposal Act of 2010

- Disposal rule eliminated existing 21 CFR § 1307.12 & 1307.21

- New part 1317 contains the requirements on:
  - disposal procedures;
    - registrant inventory
    - collected substances
  - collection of pharmaceutical controlled substances from ultimate users;
  - return and recall; and
  - destruction of controlled substances

Law Enforcement

- Law Enforcement may continue to conduct take-back events.
- Any person may partner with Law Enforcement.
- Law Enforcement shall maintain control and custody of collected substances until secure transfer, storage, or destruction has occurred.
- Authorized collection receptacles and inner liners “should” be used.

21 CFR § 1317.35 and 1317.65

Collection

Collection

Collection means to receive a controlled substance for the purpose of destruction from an:

- Ultimate user,
- Person lawfully entitled to dispose of an ultimate user decedent's property, or
- LTCF on behalf of an ultimate user who resides or has resided at the facility.

21 USC § 822(g)(3) & (4) and 21 CFR § 1300.01(b)

Design of Collection Receptacles

- Securely fastened to a permanent structure.
- Securely locked, substantially constructed container with permanent outer container and removable inner liner.
- Outer container must have small opening that allows for contents to be added, but does not allow for removal of contents.
- Outer container must display a sign stating only Schedule II-V and non- controlled substances are acceptable substances.
- Schedule I controlled substances are not permitted to be collected

21 CFR § 1317.75(e)

Collection Receptacle Inner Liner

- ü Waterproof, tamper-evident, and tear-resistant.
- ü Removable and sealable upon removal without emptying or touching contents.
- ü Contents shall not be viewable from the outside when sealed (i.e., can't be transparent).
- ü Size shall be clearly marked on the outside of the liner (e.g., 5-gallon, 10-gallon, etc.).
- ü Outside of liner shall have permanent, unique ID number.

21 CFR § 1317.60(a)

Collection Receptacles

- Ultimate users *shall* put the substances directly into the collection receptacle.
- Controlled and non-controlled substances may be comingled.
- Collected substances shall not be counted, sorted, inventoried, or otherwise individually handled.
- Registrants **shall not dispose of stock or inventory** in collection receptacles.

21 CFR § 1317.75(b) and (c)

Collection Receptacle Location

- Registered location – immediate proximity of designated area where controlled substances are stored and at which an employee is present.
  - LTCF – located in secure area regularly monitored by LTCF employees.
  - Hospital/clinic – located in an area regularly monitored by employees---not in proximity of where emergency or urgent care is provided.
  - NTP – located in a room that does not contain any other controlled substances and is securely locked with controlled access.

21 CFR § 1317.75(d)

Mail-Back Program

Requirements of mail-back program

- Only lawfully possessed schedules II-V controlled substances may be collected
- Controlled and non-controlled substances may be collected together
- **Must have method of on-site destruction**

21 CFR § 1317.70 (b)

DEA Registrant who sells mail-back packages for another registrant is **NOT** required to modify registration as a collector

Registrant Disposal

Registrant Disposal - Inventory

Practitioner & Non-Practitioner may **dispose of inventory**

- Prompt on-site destruction
- Prompt delivery to **reverse distributor** by common or contract carrier or **reverse distributor pick-up**
- Return and recall : Prompt delivery by common or contract carrier or pick-up at the registered location

Practitioner may also request assistance from the SAC

Non-Practitioner may also transport by its own means

21 CFR § 1317.05(a) and (b)

DEA Form 41

- Form 41 shall be used to record the **destruction of all controlled substances, including controlled substances acquired from collectors.**
  - The Form 41 shall include the names and signatures of the two employees who witnessed the destruction.
  - Exceptions for DEA Form 41:
    - Destruction of a controlled substance dispensed by a practitioner for immediate administration at the practitioner's registered location, when the substance is not fully exhausted (i.e. wastage) shall be properly recorded in accordance with § 1304.22(c), and such record **need not** be maintained on a Form 41
    - Transfers by registrant to a reverse distributor must be recorded in accordance with § 1304.22(c), and such record **need not** be maintained on a Form 41

21 CFR § 1304.21(e)

Abandoned Controlled Substances

- Circumstances when there is no authorized person to dispose of controlled substances
  - School
  - Summer camp
  - Hospital

- Return to ultimate user is not feasible

- Options
  - Contact law enforcement or DEA
  - Destroy on-site

79 FR 53546 (Disposal Final Rule)

Pharmaceutical Wastage

Pharmaceutical Wastage

Not subject to **21 CFR Part 1317**

- Destruction does not have to be "non-retrievable"
- DEA Form 41 must not be utilized

§ Dispensing must be recorded as a record

21 CFR § 1304.22(c)

§ Clarification memorandum on DEA website at www.deaDiversion.usdoj.gov

Miscellaneous Pharmacy Topics

Changes to a Schedule II Prescription

Pharmacist may change:

- Patient's address upon verification
- Dosage form, drug strength, drug quantity, directions for use, or issue date only after consultation with and agreement of the prescribing practitioner.
  - Consultation should be noted on the prescription
  - Must be in compliance with state law/regulation/policy

Pharmacy may <u>not</u> make changes:

- Patient's name
- Controlled substance prescribed (except for generic substitution permitted by state law), or
- Prescriber's signature

Multiple Prescriptions Schedule II Controlled Substances

- Individual practitioner may issue multiple prescriptions which authorizes patient to receive 90-day supply of C-II
  - § Each separate prescription is for legitimate medical purpose issued by practitioner acting in usual court of professional practice
  - § Written instructions on each prescription indicating earliest date it can be filled
  - § Doesn't cause undue risk of diversion by patient
  - § Compliance with all other elements of CSA and state laws

21 CFR § 1306.12(b)

Faxed Prescription vs. EPCS

- True electronic prescriptions are transmitted as **electronic data files** to the pharmacy, whose application imports the data file into its database.

- A system that allows the prescriber to “sign” his/her name does **NOT** conform to EPCS regulations.

- A facsimile with a written signature is **NOT** an electronic Rx.

21 CFR § 1306.05(d)

Hospice & LTCF Prescriptions

Schedule II narcotic substances may be transmitted by the practitioner or the practitioner's agent to the dispensing pharmacy by facsimile

- § Practitioner (or agent) must note it is hospice patient
- § Facsimile serves as original written prescription

21 CFR § 1306.11(f), (g) & 1306.13(b)

Schedule III-V prescription

- – Written prescription signed by a practitioner, or
- – Facsimile of a written, signed prescription transmitted by the practitioner (or agent) to the pharmacy, or
- – Oral prescription made by an individual practitioner and promptly reduced to writing by the pharmacist

Distribution by Pharmacy to Practitioner

- Practitioner registered to dispense may distribute a quantity of such substance to another practitioner for general dispensing
  - Purchaser must be registered with DEA
  - Schedule III-V - records by purchaser and receiver must conform to 21 CFR § 1304.22(c)
  - Schedule I or II - an order form must be used and must conform to 21 CFR § 1305
  - Total number of controlled substances dispensed cannot exceed 5% of total controlled substances dispensed

21 CFR § 1307.11(a)(1)

Repackaging by Pharmacy

- Practitioner can prepare, compound, package, or label in the course of his professional practice
  21 CFR § 1300.01(b)

- Pharmacy can NOT repackage drugs (ie 100 ct bottle packaged in smaller size bottles) and sell the drugs in the form of a distribution <u>to any DEA Registrant – including practitioner office</u>.

- Violation of DEA and FDA regulations

Questions?

Thomas.W.Prevoznik@usdoj.gov

U.S. Drug Enforcement Administration
Office of Diversion Control