



# Pharmacy Diversion Awareness Conference

## **Pharmaceutical Diversion & Federal Health Care Programs**

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# Disclaimer: Christy Wells

I have no financial relationships to disclose.





# Learning Objectives

- Understand the mission of HHS/OIG
- Recognize that drug diversion and health care fraud involve both controlled and non-controlled medications
- Learn the common healthcare fraud/ drug diversion schemes and common methods how this is accomplished
- Describe the various drugs frequently found in drug diversion/healthcare fraud schemes





# Test Questions

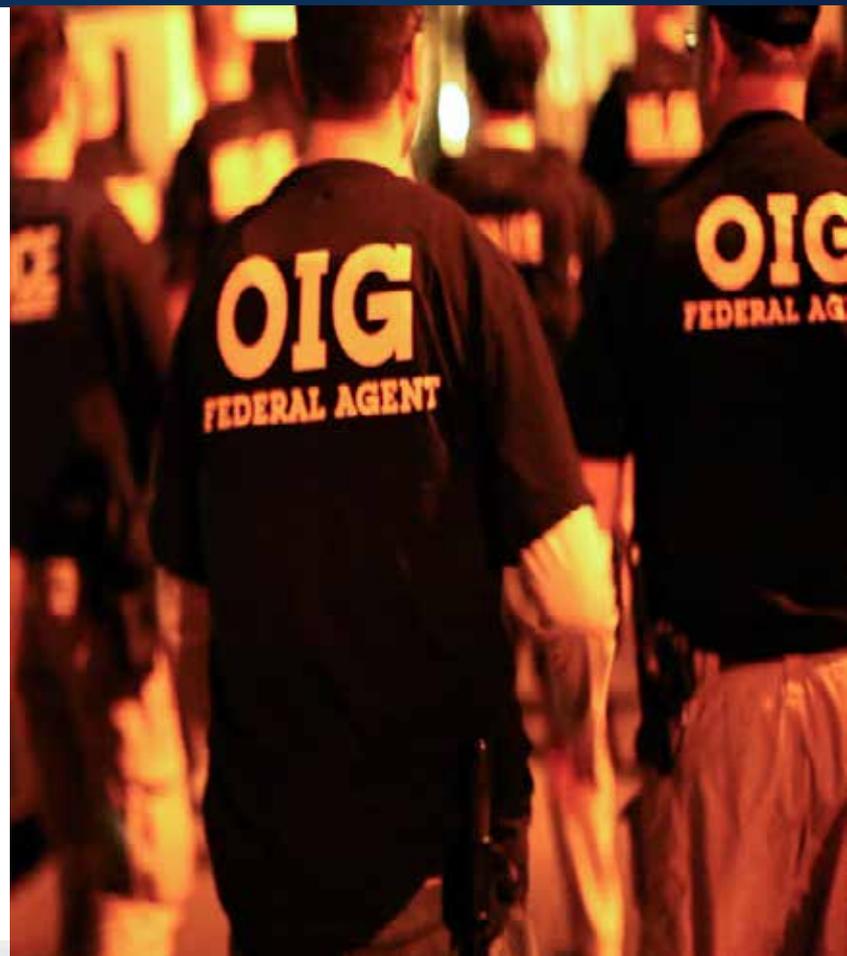
- Does HHS/OIG have oversight for controlled drugs, non-controlled drugs, or both?
- A pharmacist gives a local physician two tickets to next months playoff game in exchange for sending patients to her pharmacy. This is an illegal \_\_\_\_\_?\_\_\_\_\_.
- True or False? Diversion can occur of both controlled and non-controlled drugs.





# HHS Office of Inspector General: Background

- **Mission:** Protect the integrity HHS programs as well as the health and welfare of program beneficiaries
- Fight fraud, waste, abuse in over 100 HHS programs
- Largest Inspector General's office in Federal Government
- Office of Investigations performs criminal, civil and administrative enforcement





# HHS Operating Divisions

- Centers for Medicare & Medicaid Services (CMS)
- Centers for Disease Control and Prevention (CDC)
- Indian Health Services (IHS)
- National Institutes of Health (NIH)
- Substance Abuse & Mental Health Services Admin (SAMHSA)
- Agency for Healthcare Research and Quality (AHRQ)
- Food and Drug Administration (FDA)
- Agency for Toxic Substances and Disease Registry (ATSDR)
- Administration for Children and Families (ACF)





# OIG Components



**Audit**



**Evaluate**



**Investigate**



**Counsel**





# Fighting Fraud is a Collaborative Effort

- Tactical Diversion Squads (with DEA)
- Strike Force Units (FBI on HEAT initiative)
- With state, local LE
- Support education of and provider community
- Inform policy makers (HHS, Congress, Private Payers)

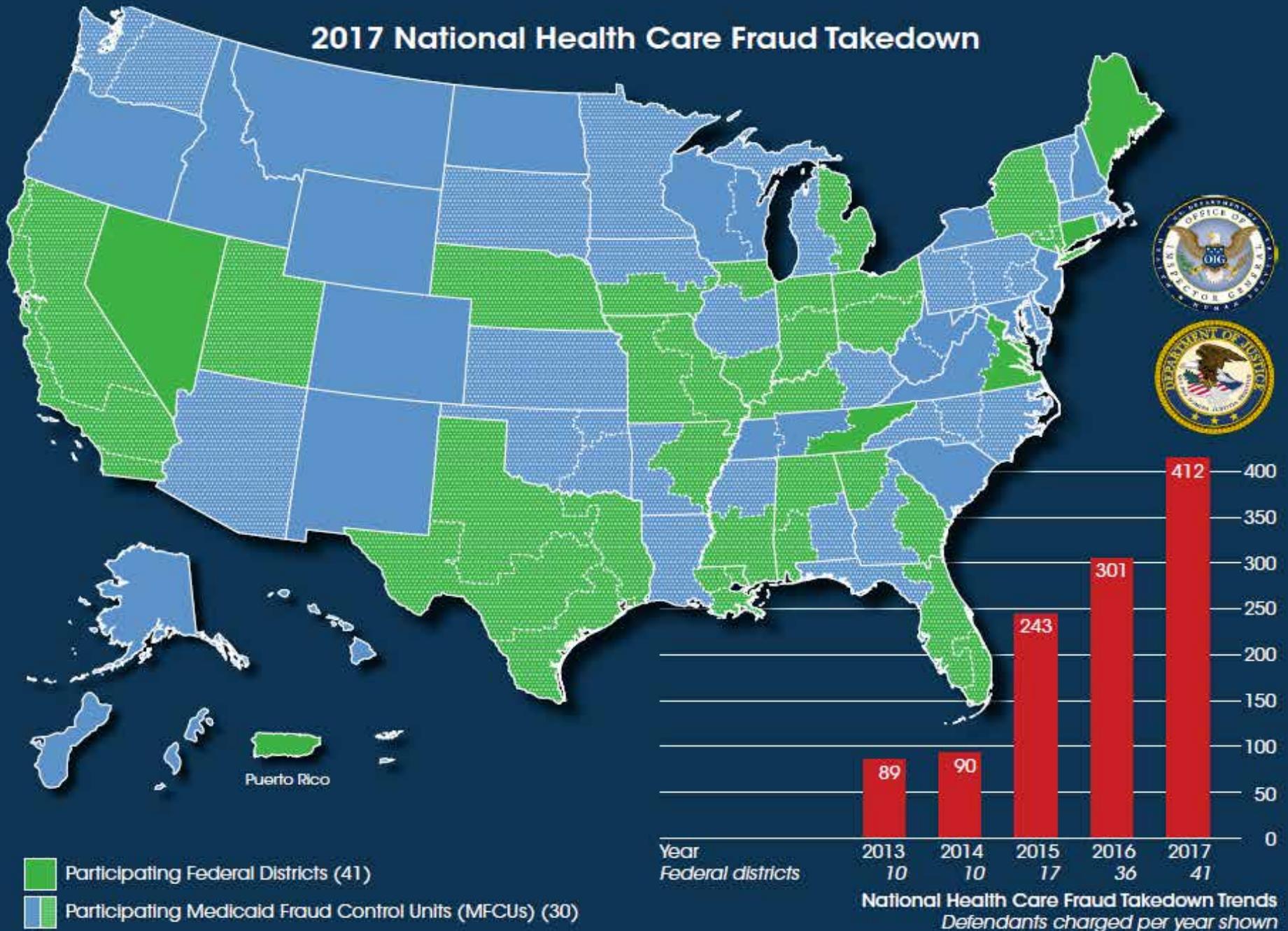




# Pharmaceutical Fraud: Top OIG Enforcement Priority



# 2017 National Health Care Fraud Takedown





# Recent OIG Drug Reports

- **Prescribers with Questionable Patterns in Medicare Part D**
  - 736 general care physicians identified
- **Retail Pharmacies with Questionable Part D Billing**
  - Over 2600 pharmacies identified
- **Medicare Inappropriately Paid for Drugs Ordered by Individuals Without Prescribing Authority**
  - Massage Therapists, Athletic Trainers, Home Repair Contractors, interpreters, dental hygienists, and transportation companies
- **Portfolio report on Part D & online portfolio of drug pricing and reimbursements**





# oig.hhs.gov

## Inappropriate Medicare Part D Payments for Schedule II Drugs Billed as Refills

### Executive Summary

#### WHY WE DID THIS STUDY

Schedule II drugs have the highest potential for abuse of any prescription drugs legally available in the United States. They include narcotics commonly used to relieve pain and stimulants. Federal law prohibits the refilling of prescriptions for them. In addition, Schedule II drugs cannot be dispensed without a prescription that contains the name, address, and signature of the prescriber.

#### HOW WE DID THIS STUDY

We based this study on an analysis of prescription drug event records. Sponsors submit these records to CMS for each drug dispensed to beneficiaries enrolled in their plans. Each record contains information about the pharmacy, prescriber, and drug. We analyzed all of the records for refills of Schedule II drugs that were billed in 2009.

#### WHAT WE FOUND

Medicare Part D inappropriately paid \$25 million for Schedule II drugs billed as refills in 2009. Sponsors should not have paid for any of these drugs because Federal law prohibits the refilling of Schedule II controlled substances. Some of these drugs may have been inaccurately billed. It is possible that some long-term-care pharmacies incorrectly billed these drugs as refills when they were partial fills. Partial fills occur when a pharmacist does not dispense all doses of the prescribed medication at one time. Several concerns exist, however, if partial fills are inaccurately billed as refills. Moreover, over 25,000 Schedule II refills had invalid prescribers. Lastly, three-quarters of Part D sponsors paid for Schedule II drugs billed as refills, indicating that many sponsors do not have adequate controls to prevent these refills.

#### WHAT WE RECOMMEND

#### Related Podcast

[Drug Diversion Overview](#)

Jennifer Trussell, Special Agent in Charge in the Office of Investigations, is interviewed by Roberta Baskin, Director of Media Communications.



#### Related Article

[Spotlight on Drug Diversion](#)



# 2015 Report: Questionable Billing and Geographic Hotspots in Medicare Part D

**Table 1: Number of Pharmacies with Questionable Billing by Measure, 2014**

Measure	National Average	Median	Threshold for Extremely High Amounts	Number of Pharmacies That Billed Extremely High Amounts*
Average number of prescriptions per beneficiary	23	21	62	403
Percentage of prescriptions that were for commonly abused opioids	6%	5%	17%	468
Average number of prescribers for commonly abused opioids per beneficiary who received opioids	2	2	4	216
Average number of types of drugs per beneficiary	6	6	12	314
Percentage of beneficiaries with an excessive supply of a drug	0.5%	0.4%	1.9%	332

\*The number of pharmacies with questionable billing—1,432 pharmacies—does not equal the sum of this column, because some pharmacies billed extremely high amounts for more than one measure.

Source: OIG analysis of Medicare Part D data, 2015.



# 2017 OIG Report: Opioids in Medicare Part D: Concerns about Extreme Use and Questionable Prescribing

## Key Takeaways:

- ✓ *One in three Medicare Part D beneficiaries received a prescription opioid in 2016*
- ✓ *About 500,000 beneficiaries received high amounts of opioids*
- ✓ *Almost 90,000 beneficiaries are at serious risk; some received extreme amounts of opioids, while others appeared to be doctor shopping*
- ✓ *About 400 prescribers had questionable opioid prescribing patterns for beneficiaries at serious risk*

In 2016, Medicare Part D covered 44 million beneficiaries  
**14.4 million received opioids**



**HALF A MILLION**  
Part D beneficiaries received  
**HIGH AMOUNTS**  
of opioids in 2016.

These beneficiaries received an average daily dose of opioids, equivalent to taking more than:

**12 VICODIN  
TABLETS**



Vicodin 10mg

**OR**

**16 PERCOCET  
TABLETS**



Percocet 5mg

**These dosages far exceed the amounts CDC recommends avoiding.**



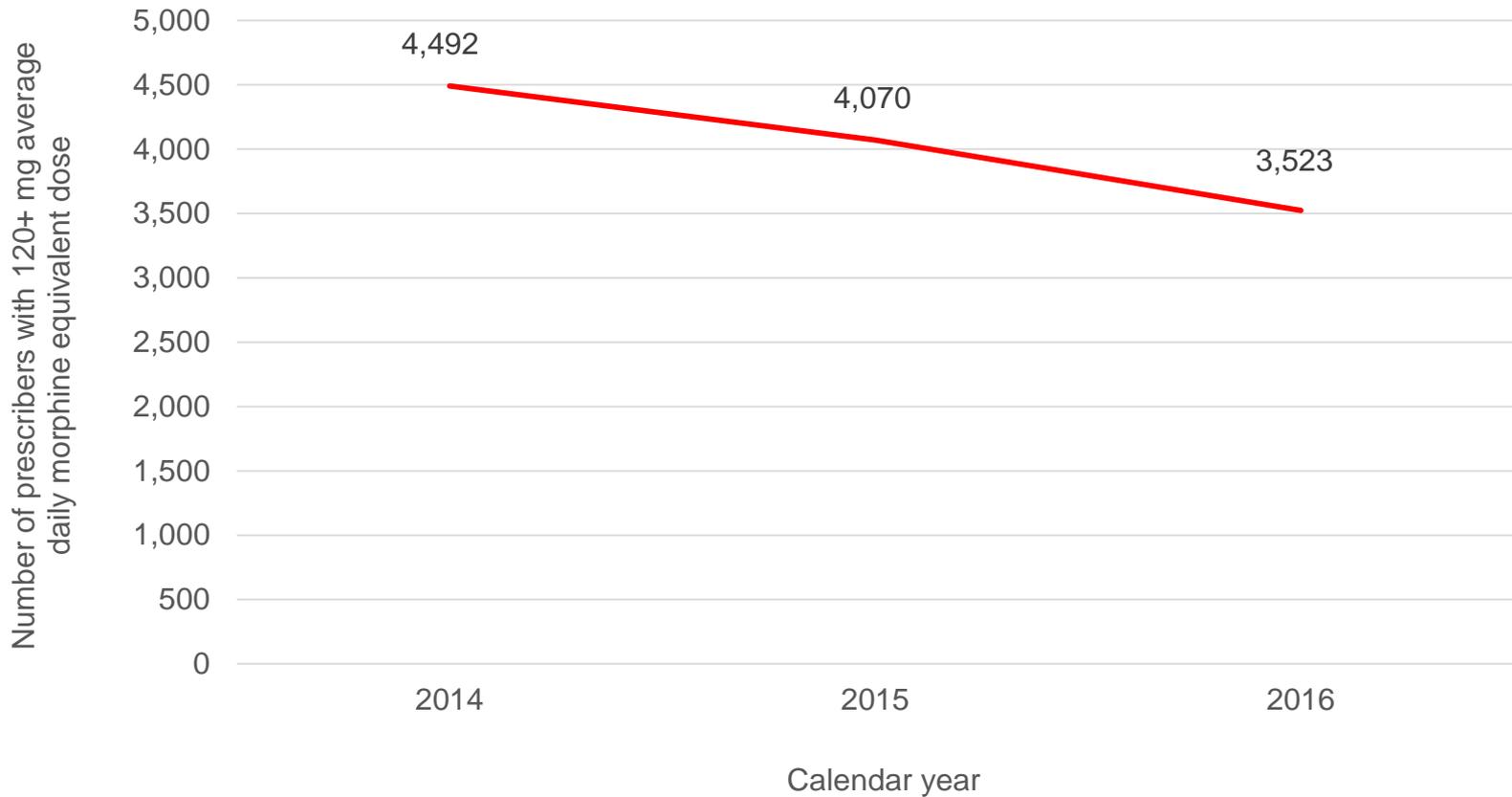
Source: OIG analysis of Medicare Part D data, 2017  
U.S. Department of Health and Human Services  
Office of Inspector General

**Learn More**  
<https://oig.hhs.gov/opioidsbrief>





# Prescribers with 120+ mg average daily morphine equivalent dose





# 2017 OIG Report Cont.

Exhibit 2: Most Common Opioids in Part D, by Number of Prescriptions, 2016



**Tramadol**  
14.8 million



**Hydrocodone-Acetaminophen\***  
5 mg 11.3 million  
10 mg 11.2 million  
7.5 mg 5.7 million



**Oxycodone-Acetaminophen\***  
5 mg 5.0 million

\* Tablets also contain 325 mg of acetaminophen.  
Source: OIG analysis of Medicare Part D data, 2017.

Exhibit 3: Average Daily MED



**Level to Avoid, per CDC\***  
 $\geq 90$  mg



**High Amount**  
 $> 120$  mg  
for 3 months



**Extreme Amount**  
 $> 240$  mg  
for 12 months

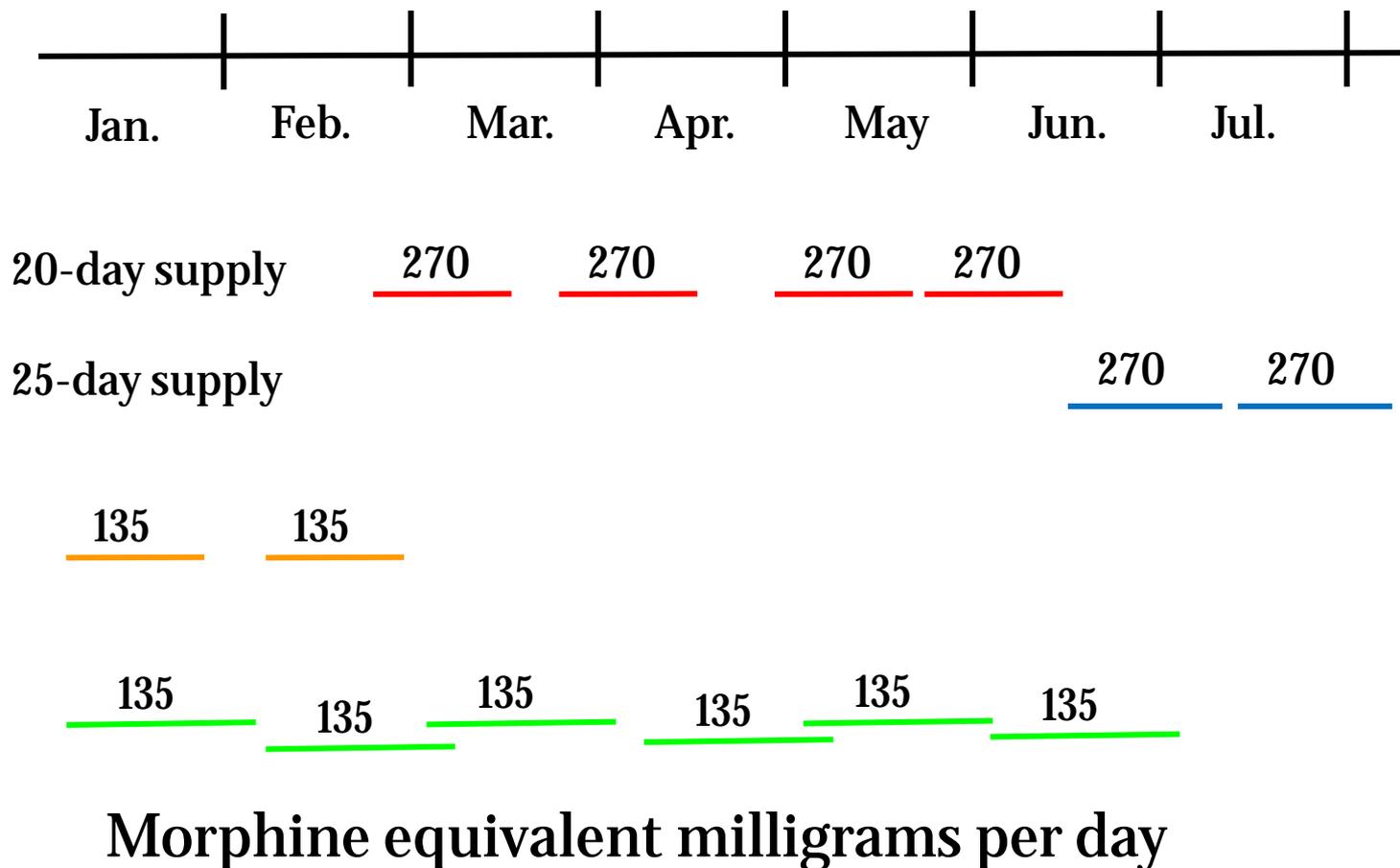
\* CDC Guidelines for Prescribing Opioids for Chronic Pain, March 2016.





# Example: Prescriber with 120+ mg avg daily morphine equivalent dose

One patient's prescriptions



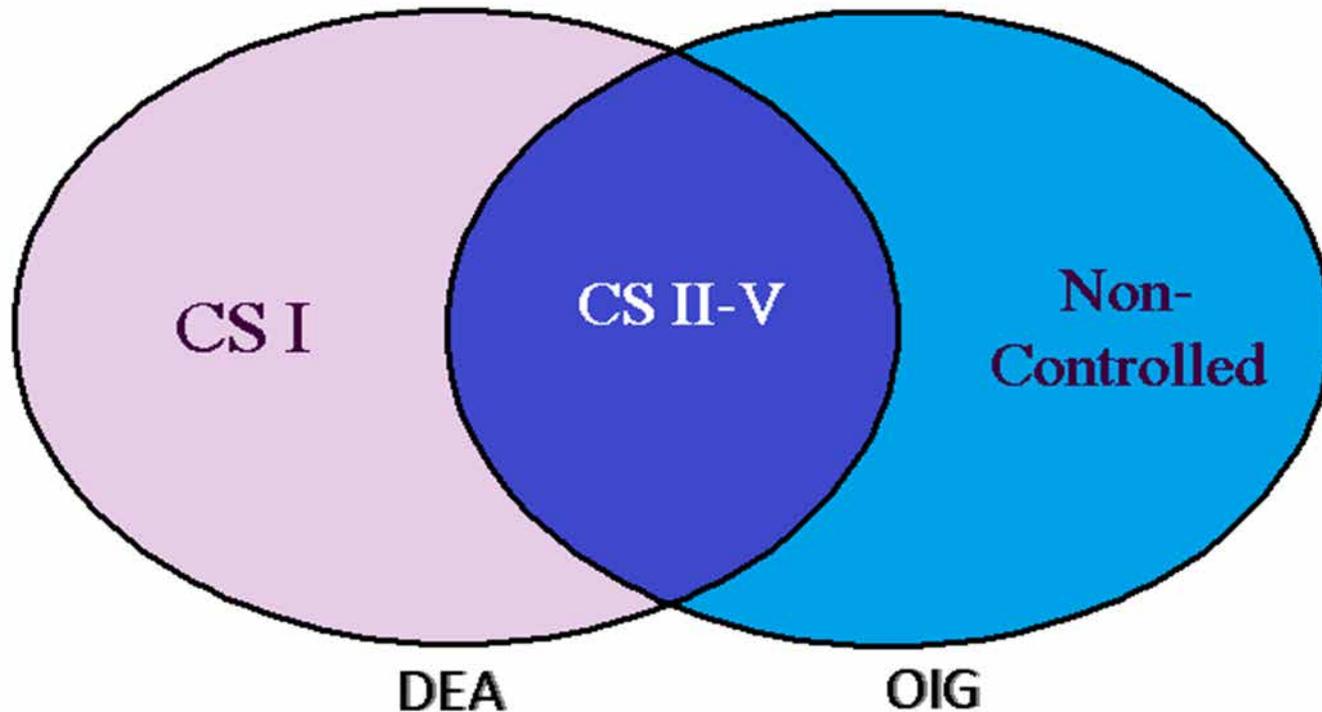


# Different Drug Jurisdictions

- **DEA:** Controlled substance laws and regulations of the United States
- **HHS/OIG:** Fraud and Diversion affecting Federal health care programs and their beneficiaries
  - Medicare, Medicaid, TRICARE
  - Controlled and Non-Controlled Substances

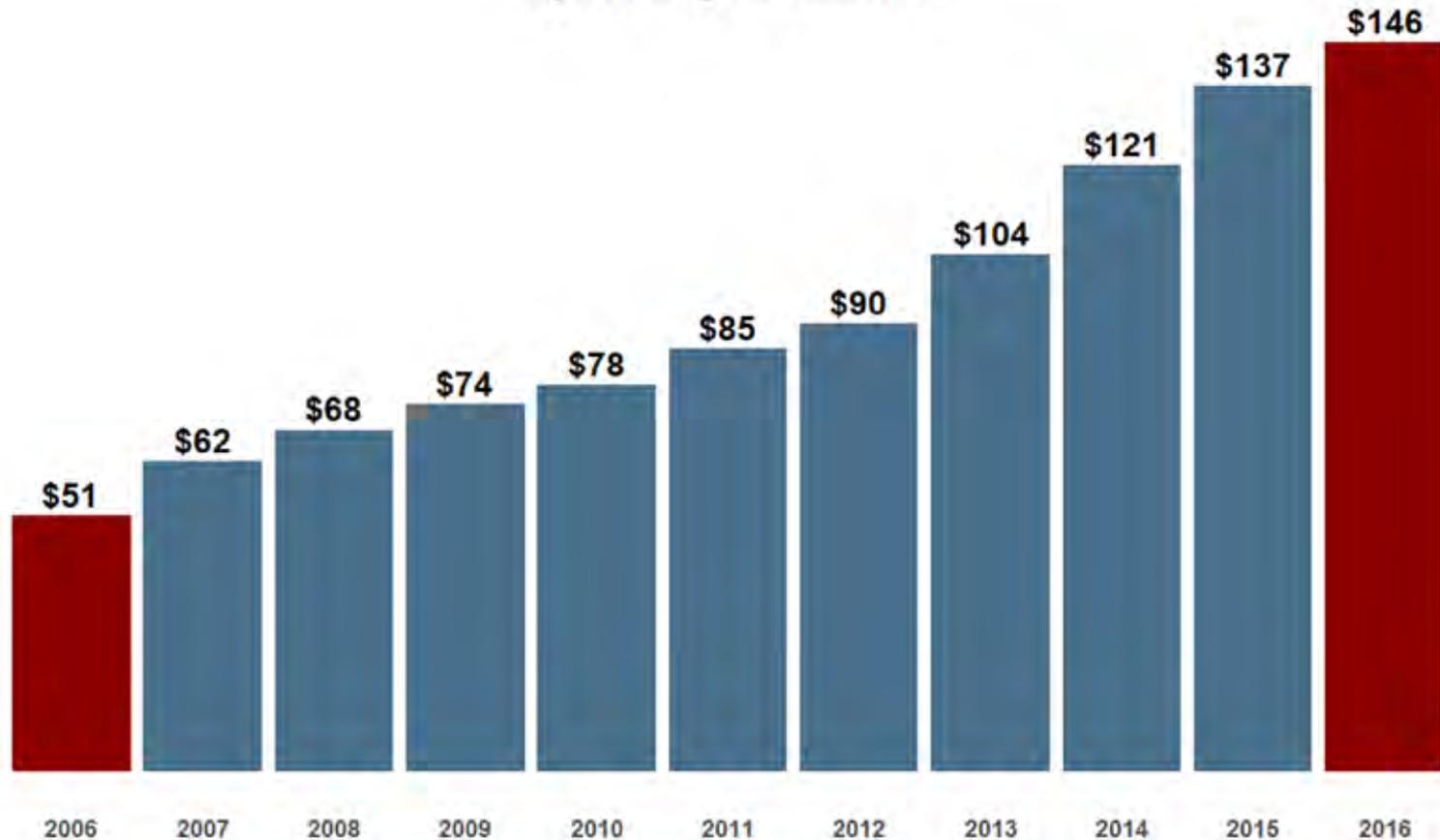


# DEA & HHS/OIG Authority



# Spending for Part D Drugs 2006-2016

Spending in Billions





# Why Divert Non-Controlled?

- **Controlled Drugs:**
  - Diverted for recreational use
  - \$100+B in societal costs
- **Non-Controlled Drugs:**
  - High reimbursement – financial crime. Not dispensed, just billed.
    - 94% Medicare Part D spending
  - Perceived lower risk
  - Mixed into street cocktails with opioids = POTENTIATORS





# Potentiators

- Drug recipes that aggregate drugs that in combination enhance the euphoria
- May be another controlled drug but often are non-controlled drugs (OIG purview)
- Pushes patients over edge to respiratory arrest/death
- Hundreds of potentiators in thousands of combinations
- Large financial exposure to Medicare program





# Trends in Abuse Methodologies

- Finding vascular beds to absorb drugs and avoid liver “first pass” effect
- Cold Water Extraction techniques
- Parachuting
- Plugging
- Insufflation (snorting)
- Vaporization/inhalation
- Alkalinization (Adderall)
- Transvaginal absorption (e.g. prometh/codeine)





# Drug Blogs

- [Erowid.org](http://Erowid.org)
- [Bluelight.org](http://Bluelight.org)
- [Drugs-Forum.com](http://Drugs-Forum.com)
- [Opiphile.org](http://Opiphile.org)





# Erowid.org

## Erowid Experience Vaults

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### Help Erowid win a 2013 Health Award!

...by rating us in Great Nonprofit's "Health Nonprofits 2013" campaign.  
Spread the word that Erowid improves health. [Write a Review]

**Knocked Out!!!**  
Percocet, Fioricet, Elavil & Lyrica  
by webguy15

Citation: webguy15, "Knocked Out!!! experience with Percocet, Fioricet, Elavil & Lyrica (ID 77361)" Erowid.org, Mar 21, 2010, erowid.org/exp/77361

DOSE:	300 mg	oral	Pharms - Pregabalin	(pill / tablet)
	200 mg	oral	Pharms - Amitriptyline	(pill / tablet)
	10 mg	oral	Pharms - Oxycodone	(pill / tablet)
	1 tablet	oral	Acetaminophen	(pill / tablet)

BODY WEIGHT:	160 lb
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1945-- I just took 300mg lyrica, 200mg elavil, 10mg percocet, and 1 fioricet. I also have one of those power energy shots that im thinking of taking when i get really tired. Looking back at all of that typed out makes me think that it may not have been my best idea ever, but i guess im just going to have to see where this takes me...

1950-- Already bored of waiting for the effects to kick in, i guess that i will just go smoke a bowl (marijuana) while i wait.

2000-- Starting to feel a little warm in the face and lightheaded... a little bit of tingling. Its pretty faint and not easy to describe, but it is noticeable. I have been reading some of the other experiences and i just want to mention this incase something crazy happens and i die or something, i love you mom and am so proud of my two brothers that i cant even describe it.

2011-- I find myself feeling really tingly and also really warm and fuzzy. Im spacing out alot and forgetting to keep typing. Im normally a really quick typist but im finding it really really hard to focus on it at all, its now 2018 and i am still typing...

2033-- My thinking and even my movement seems really slow and sluggish, like things are delayed or something, it also feels really hard to move, like i weigh about another 100 pounds. Even my eyes seem very slow when i move them from one place to another or when i try to read. 2040 is the time right now, so it took about 7 minutes in order to type this...

Well, after that last entry i just kind of passed out, i remember seeing something out of the corner of my eyes and trying to grab for it but never actually catching it. Once i passed out i was GONE, people tried to wake me and i was completely unresponsive, they almost called 911 but decided against when they could see i was still breathing. So... yea... i am going to do it again pretty soon probably...

**“I just took 300mg lyrica, 10mg percocet, and 1 fioricet. I also have one of those power energy shots that I’m thinking of taking when I get really tired. Looking back at all of that typed out makes me think it may not have been the best idea ever...I’m going to have to see where this takes me”**



# How to Prepare IV Opana

ads/622554-Preparing-new-new-Opana-ER-for-snorting-injecting-retal

Extra Supplies for Injection (IV/IM) or Rectal (IR):

- 1) Spoon
- 2) Lighter (preferably butane torch)
- 3) Water
- 4) Syringe (1cc or 3cc with 29 gauge needle if injecting)
- 5) Moch (Q-Tip, Cotton Ball, Cigarette Filter, Gauze)

Optional Supplies for Injection (IV/IM) or Rectal (IR):

- 1) Second Spoon
- 2) Micron Filter
- 3) Citric Acid/Vinegar/Lemon Juice/Vitamin C

Process:

(Optional)- Crush Opana ER in table clamp.

Step One- Using PedEgg and it's designed 'skin catcher,' grate the Opana ER TRF into small chunks. Tweezers will allow you to handle the pill once most of it has been grated. Grate the pill over a piece of aluminum foil (folded in half to create a single piece two layers thick) to catch any chunks the PedEgg's 'skin catcher' misses.

Step Two- Preheat oven to 400 degrees Fahrenheit while grating the Opana ER with the PedEgg.

Step Three- Once the entire Opana ER has been grated as small as possible, dump the PedEgg's 'skin catcher' onto the layered aluminum foil. Use your credit card/driver's license/plastic card to scrape pill chunks into a quarter/fifty-cent piece sized pile. The pile should not have much height to it, but there should be as few spots of aluminum foil visible through it as possible.

Step Four- Place the aluminum foil with the grated Opana ER on it into the preheated oven.

Step Five- Watch the pile of Opana ER as it heats in the oven. The pill chunks should turn brown in color and appear to melt/become 'goosey.' Do not let any of the pill turn black, but as soon as it all has turned some shade of brown, remove the aluminum foil from the oven and place it directly in the freezer. Due to variations in oven heating patterns, altitude, etc. the amount of time the pill will take to cook varies. DO NOT LET IT TURN BLACK. Better to remove the pill with one or two white spots than burn it. Make sure to place the aluminum foil and cooked pill directly into the freezer.

Step Six- Let the pill sit in the freezer for 5-7 minutes. Any 'goosey' spots should be hardened when the pill is removed from the freezer.

Step Seven- Remove aluminum foil and now 'frozen' pill from freezer. Using credit card/driver's license/plastic card, scrape pill off of aluminum foil. Be careful not to tear aluminum foil while scraping pill off of it. The pill should come off the aluminum foil easily, but if it is 'goosey,' then it needs more time in the freezer.

Based on the planned ROA, proceed to the specific instructions...

Insufflation (IN) Specific Process:





# Sustiva (efavirenz)

The screenshot shows a PubMed article page. At the top, there are navigation links for 'NCBI Resources' and 'How To'. The main header includes the 'PMC' logo and a search bar. The article title is 'The HIV Antiretroviral Drug Efavirenz has LSD-Like Properties'. Below the title, the authors are listed: Michael B. Gatch, Alexey Kozlenkov, Ben Qi Huang, Wanjuan Yang, Jacques D. Nguyen, Janet Gonzalez-Mason, Kenneth C. Rice, Charles E. Emme, Glenn H. Dillon, Michael J. Forsler, and John A. Siebz. The abstract text describes the behavioral effects of efavirenz in rodents, comparing it to LSD. The article is cited by other articles in PubMed, with a list of related articles provided on the right side of the page.

Journal List: Neuropsychopharmacology • 38(12): 2373-2384  
PMCID: PMC376958

### Neuropsychopharmacology

Neuropsychopharmacology 2013 Nov; 38(12): 2373-2384.  
Published online 2013 Jul 3. (Prepublished online 2013 May 24. doi: 10.1007/s11331-013-3326-4)

## The HIV Antiretroviral Drug Efavirenz has LSD-Like Properties

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[Author disclosures of potential conflicts of interest and author contributions are found at the end of this article.](#)

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[DOI: 10.1007/s11331-013-3326-4](#)

This article has been cited by other articles in PMC.

### Abstract

Anecdotal reports have surfaced concerning misuse of the HIV antiretroviral medication efavirenz ((4S)-6-chloro-4-(2-cyclopropylethynyl)-4-(trifluoromethyl)-2,4-dihydro-1H-3,1-benzoxazin-2-one) by HIV patients and non-infected teens who crush the pills and smoke the powder for its psychoactive effects. Molecular profiling of the receptor pharmacology of efavirenz pinpointed interactions with multiple established sites of action for other known drugs of abuse including catecholamine and indolamine transporters, and GABA<sub>A</sub> and 5-HT<sub>2A</sub> receptors. In rodents, interaction with the 5-HT<sub>2A</sub> receptor, a primary site of action of lysergic acid diethylamine (LSD), appears to dominate efavirenz's behavioral profile. Both LSD and efavirenz reduce ambulation in a novel open-field environment. Efavirenz occasions drug-lever responding in rats discriminating LSD from saline, and this effect is abolished by selective blockade of the 5-HT<sub>2A</sub> receptor. Similar to LSD, efavirenz induces head-twitch responses in wild-type, but not in 5-HT<sub>2A</sub>-knockout, mice. Despite having GABA<sub>A</sub>-potentiating effects (like benzodiazepines and barbiturates), and interactions with dopamine transporter, serotonin transporter, and vesicular monoamine transporter 2 (like cocaine and methamphetamine), efavirenz fails to maintain responding in rats that self-administer cocaine, and it fails to produce a conditioned place preference. Although its molecular pharmacology is multifarious, efavirenz's prevailing behavioral effect in rodents is consistent with LSD-like activity mediated via the 5-HT<sub>2A</sub> receptor. This finding correlates, in part, with the subjective experiences in humans who abuse efavirenz and with specific dose-dependent adverse neuropsychiatric events, such as hallucinations and night terrors, reported by HIV patients taking it as a medication.

**Keywords:** hallucinogen, adverse neuropsychiatric events, side effects, AIDS

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LSD but not ibuprofen disrupt prepulse inhibition in rats by activating the 5-HT<sub>2A</sub> receptor [Psychopharmacology (Berl). 2010]

Behavioral tolerance to lysergic acid diethylamide is associated with reduced serotonin-2A receptors [Neuropsychopharmacology. 2006]

Multiple receptors contribute to the behavioral effects of indoleamine hallucinogens [Neuropharmacology. 2011]

Animal models of serotonergic psychedelics [ACS Chem Neurosci. 2013]

See reviews  
See all

### Cited by other articles in PMC

Antiretroviral drug use in a cross-sectional population survey in Africa: NIMH Project Accept III [Journal of acquired immune Deficiency Syndromes and Human Retrovirology. 2013]

Pharmacogenetics of Efavirenz Discontinuation for Reported Central Nervous System Side Effects [Pharmacogenetics and Genomics. 2013]

Molecular mechanisms of serotonergic action of the HIV-1 antiretroviral efavirenz [Pharmacological Research. 2010]

Pharmacologic rationale for the NK1R antagonist aprepitant as adjunctive therapy in HIV [Journal of Translational Medicine. 2013]

Substance Use in Older HIV-Infected Patients [Current Opinion in HIV and AIDS. 2013]





# Exploiting Human Chemistry

- Alkalinize stomach with tums
- Heat fentanyl patch in microwave
- Rub fentanyl on wrists or put heat pad on arm
- Rub isopropyl alcohol on buccal area
- Wrap heating pad around fentanyl patch





# Polypharmacy Cocktail Potentiators

- Abilify + Seroquel Snort (“jailhouse heroin”)
- Soma + Codeine (“Soma Coma”)
- Gabapentin + oxycodone
- Gabapentin + Seroquel Snort (Quell, Susi-Q)
- Seroquel + Zyprexa + Ativan + ETOH + Cocaine
- HIV Protease Inhibitors + Percocet
- Adderall + Albuterol + sleep deprivation
- Meth + Ecstasy + Viagra (“Royal Flush”)





# Basis for Many Pharmaceutical Frauds: **KICKBACKS**

## **Anti-kickback Statute: 42 U.S.C. Section 1320a-7b(b)**

- (1) Whoever knowingly and willfully **solicits or receives** any remuneration (including any kickback, bribe or rebate) directly or indirectly, overtly or covertly, in cash or in kind
  - (A) in return for referring an individual to a person for the furnishing or arranging for the furnishing of any item or service for which payment may be made in whole or in part under a Federal health care program, or
  - (B) in return for purchasing, leasing, ordering, or arranging for or recommending purchasing, leasing, or ordering any good, facility, service, or item for which payment may be made in whole or in part under a Federal health care program,

shall be guilty of a felony and upon conviction thereof, shall be fined not more than \$25,000 or imprisoned for not more than five years, or both.



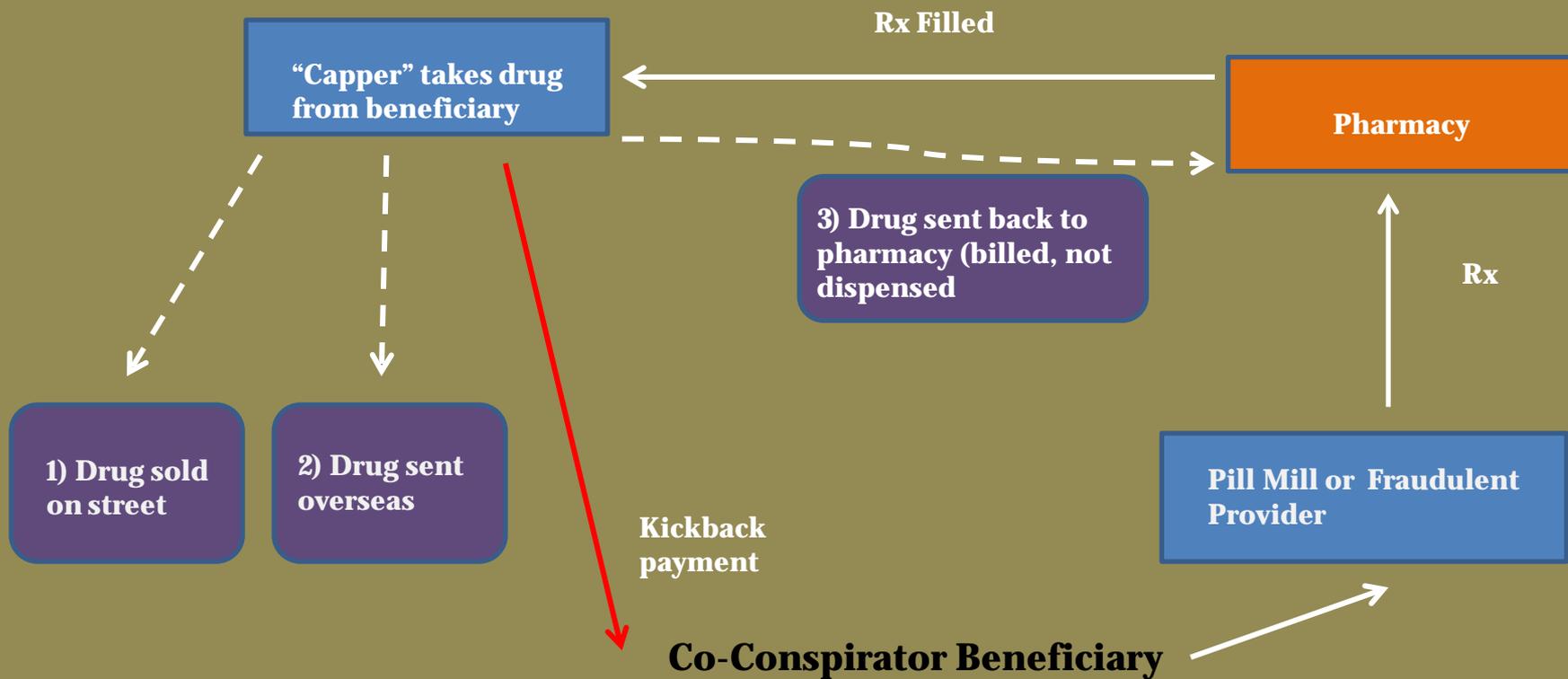


# Kickback Examples

- Pharmacy pays physician to write for expensive brand medications without regard for medical necessity
- Pharmacy pays by pharmaceutical manufacturer to promote its drug with patients
- Pharmacy receives dinners, cash, rebates and discounts from drug companies
- Pharmacy hires “marketing firm” to hire recruiters to find patients and physicians to write for expensive compounding cream
- Pharmacy pays physician a percent of insurance reimbursement to write scripts and send them to your pharmacy
- Pharmacy pays government beneficiaries monetary incentives and gives discounts to fill prescriptions at its pharmacy
- Pharmacist pays patient to surrender prescription



# Drug Recycling Scheme





# Re-shelving of “dispensed” Drug

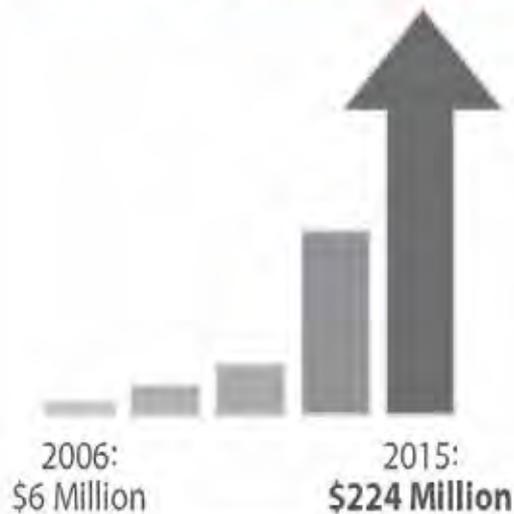
- **Over 200 pills jammed into a 90 count bottle**
- (mixes lot numbers and expiration dates!)





# Part D Trends: Compounded Rx

For compounded topical drugs,  
**SPENDING INCREASED 3,466%**



Per prescription, the average  
**COST INCREASED 720%**



The number of **BENEFICIARIES** receiving  
these drugs **INCREASED 281%**





# Exclusion Authorities

- Social Security Act (Sections 1128 and 1156)
- Approximately 3000 actions per year
- Duration from 3 years to Permanent
- 48% Based on Convictions
  - Health Care Fraud or other Program Related Offense,
  - Patient Abuse/Neglect,
  - Controlled Substance
- Covers all Federal health care programs
- Effect: individual and employer cannot bill Federal health care programs



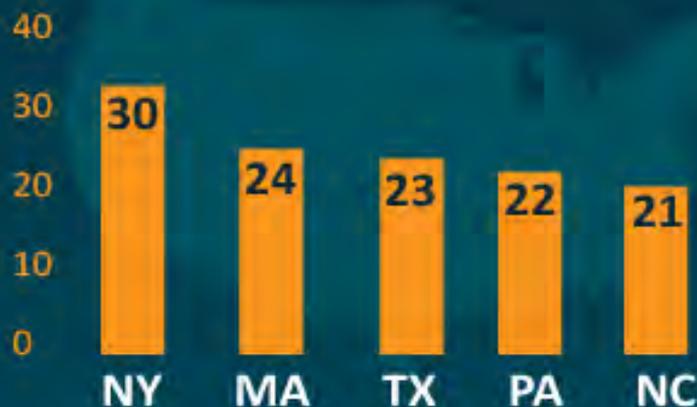


# PILL MILLS & PRESCIBERS

## Opioid-Related Exclusions

In association with the 2017 National Health Care Fraud Takedown, the Department of Health and Human Services Office of Inspector General's Exclusion Program **issued notices to 295 individuals based on the conduct related to opioid diversion and abuse**. These notices represent doctors that operate a pill mill; nurses reporting for duty impaired due to diversion from patient or employer pill stock; and pharmacists and pharmacy technicians stealing pills and other similar conduct.

### Top 5 States with Exclusions



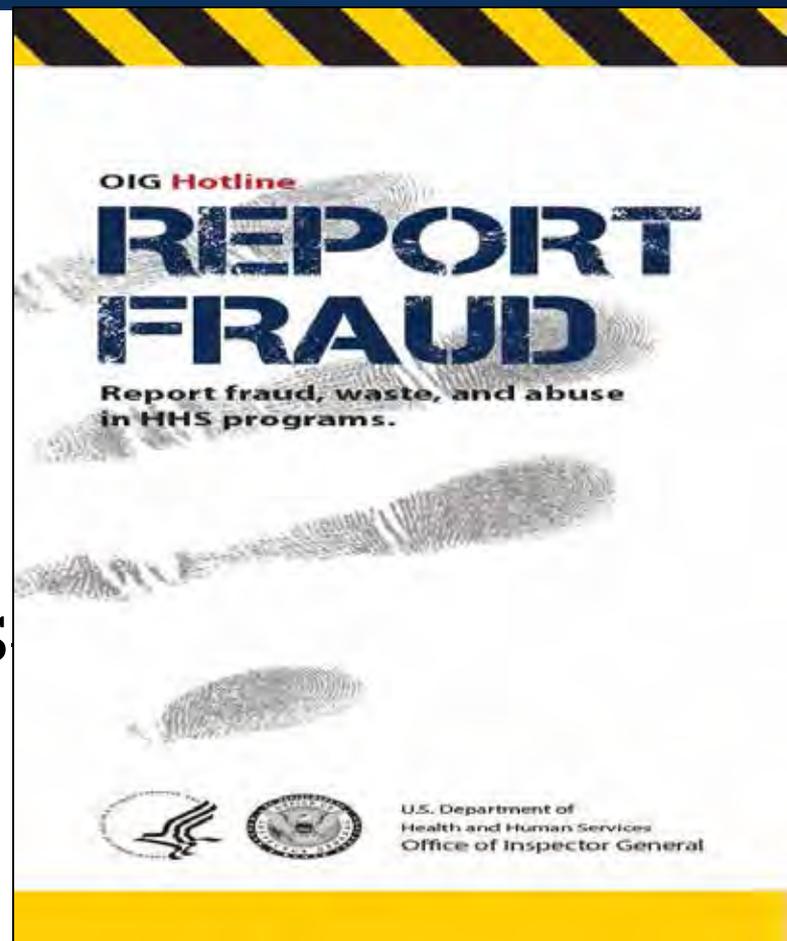
### Exclusions by Occupation





# What To Do if you Suspect Fraud or Diversion Activity?

- Use available databases to scrutinize scripts; including your state PDMP database
- If receive a clearly fraudulent script, forged script, ID theft; engage law enforcement immediately
- If you suspect a Medicare/Medicaid provider or beneficiary, contact HHS OIG
  - 800-HHS-TIPS or at
  - [oig.hhs.gov/report-fraud](https://oig.hhs.gov/report-fraud)





# HHS-OIG Contact Info

- **Boston Regional Office: (617) 565-2662**
- **Christy Wells: (202) 260 – 7073**  
**[christy.wells@oig.hhs.gov](mailto:christy.wells@oig.hhs.gov)**

