

# Practitioner Diversion Awareness Conference

### **Pharmaceutical Diversion in Medicare**

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## Disclaimer

### I have no financial relationships to disclose.



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# Learning Objectives

- Understand the mission of HHS/OIG
- Recognize that drug diversion and health care fraud includes 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





# Pre-Test Questions to Consider

- Does HHS/OIG have oversight for controlled drugs, non-controlled drugs, or both?
- Will Medicare Part D payments for prescription drugs double, triple or quadruple by 2023?
- Can diversion occur with 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





# Example HHS Programs

- Medicare (CMS)
- Medicaid (CMS)
- Center for Disease Control (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)





# **OIG Collaborative Effort**

- Tactical Diversion Squads (with DEA)
- Strike Force Units (FBI on HEAT initiative)
- With state, local LE
- Use/encourage Prescription Drug Monitoring Programs (PDMP)
- Support education of industry, patients, providers, pharmacists
   -Can't prosecute our way out of this problem







# HHS/OIG: Components

### • Office of Evaluations & Inspections:

- Conducts and publishes studies on various vulnerabilities in Medicare/Medicaid. Reports on OIG website with recommendations. Several drug related reports.
- Office of Audit:
  - Conducts independent audits of HHS programs/grantees. Also create reports and make recommendations.
- Office of Council to IG:
  - Provides legal counsel to IG and other components. Performs civil monetary penalties, provider self disclosures, collaborates with DOJ on national cases, provide advisory opinions to industry.
- Office of Management and Policy:
  - Provides mission and administrative support to the OIG. Data analytic unit.
- Office of Investigations:
  - Law enforcement arm of OIG. Traditional law enforcement techniques with contemporary data analytic tools to identify trends and targets for investigations and prosecution





# **Recent OIG Drug Reports**

- Inappropriate Medicare Part D Payments for Schedule II Drugs Billed as Refills
  - \$25M
- Prescribers with Questionable Patterns in Medicare Part D
  - 736 general care physicians
- 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, etc.



## 2015 OEI Report



### HHS OIG Data Brief • June 2015 • OEI-02-15-00190

### Questionable Billing and Geographic Hotspots Point to Potential Fraud and Abuse in Medicare Part D

### Key Takeaways:

 ✓ Since 2006, Medicare spending for commonly abused opioids Prescription drug abuse is a growing problem in this country. In 2011, the Centers for Disease Control and Prevention (CDC) declared prescription drug abuse an epidemic.<sup>1</sup> That year alone, over 1.4 million emergency department visits were caused



## 2016 OEI Report



HHS OIG Data Brief • June 2016 • OEI-02-16-00290

### High Part D Spending on Opioids and Substantial Growth in Compounded Drugs Raise Concerns

The Office of Inspector General (OIG) has uncovered striking trends in Part D spending for opioids and compounded drugs that warrant further scrutiny. This data brief describes these trends. It also provides information that can assist efforts to ensure the appropriate use of these drugs, protect the integrity of the Part D program, and promote the safety of beneficiaries and others.

Key Takeaways:

Prescription drug abuse, especially opioid abuse, remains a problem in this country. More people in



## New OIG Report: Specialty Drugs

#### Report in Brief January 2017 OEI-02-16-00270

### U.S. DEPARTMENT OF HEALTH & HUMAN SERVICES

#### Why OIG Did This Review

Members of Congress and others have raised concerns about the high prices of certain drugs and the impact these high prices have on Medicare beneficiaries and the health care system.

An important part of the Medicare Part D benefit is catastrophic coverage, which beneficiaries enter when their out-of-pocket costs exceed a certain threshold. In catastrophic coverage, most beneficiaries pay a 5-percent coinsurance for drugs, while the Federal Government pays the vast majority of the remaining costs.

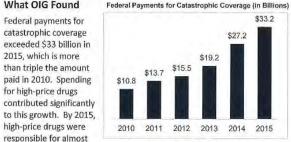
Understanding the effect that high drug prices have on spending in catastrophic coverage is crucial. In catastrophic coverage, beneficiaries' out-of-pocket costs are not capped, and the Federal Government's share of drug spending is the highest.

#### How OIG Did This Review

We analyzed data from the Centers for Medicare & Medicaid Services to determine the amount that the Federal Government spent for catastrophic coverage through the reinsurance subsidy. We also analyzed the Part D Prescription Drug Event records to identify specific drugs dispensed in catastrophic coverage. What OIG ConcludesThe cSecuring the future of the Part Dpaymprogram while ensuringand tbeneficiaries have access topriceneeded drugs is a complex issuethat calls for a multifacetedapproach. OIG remainspricecommitted to examining theseentimeissues. Recently, CMS has takenhighe

The dramatic growth in Federal payments for catastrophic coverage and the underlying issue of high drug prices must be analyzed and addressed to secure the future of the Part D program. The issue of highprice drugs is not exclusive to catastrophic coverage; it affects the entire Part D benefit and can lead to higher costs for all beneficiaries.

#### High-Price Drugs Are Increasing Federal Payments for Medicare Part D Catastrophic Coverage What OIG Found Federal Payments for Catastrophic Coverage (in Billion



Source: OIG analysis of CMS Payment Reconcillation System data, 2016.

drug spending in catastrophic coverage. This is a significant increase from 2010, when high-price drugs were responsible for one-third of the spending.

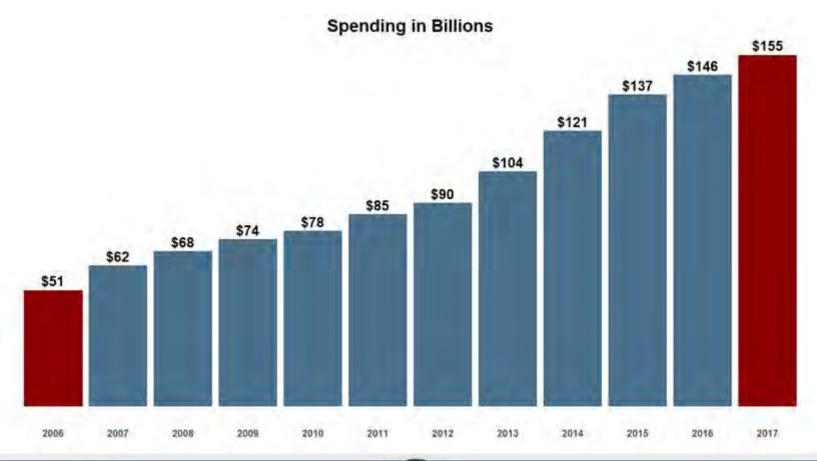
Moreover, 10 high-price drugs accounted for nearly one-third of all drug spending for catastrophic coverage in 2015. Most of these drugs cost thousands of dollars per month. They treat conditions such as hepatitis C, cancer, and multiple sclerosis. The average prices for each of these drugs ranged from \$1,200 to almost \$34,000 per month, leading to high out-of-pocket costs for some beneficiaries in catastrophic coverage.

prices. It published information about certain drugs with substantial increases in price. CMS also stated that action is necessary to address rising drug costs and asked the industry to partner with the agency to find solutions that allow for both innovation and affordability. Moving forward, CMS will likely need

two-thirds of the total

#### 6/24/2019

## Spending for Part D Drugs 2006-2017







6/24/2019

# Part D Breakdown

- \$9.3 B spent on controlled drugs (6%)
- \$145 B spent on non-controlled drugs
- Predicted to double by 2023
- Spending on Part D benefits is projected to rise from 14% to 17% of total Medicare spending
- Due to increase drug use, more benes, and <u>specialty drugs</u> and biologics





### Basis for Many Pharmaceutical Frauds Involve KICKBACKS

### Antikickback Statute - 42 U.S.C. Section 1320a-7b(b) provides:

- (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.





## Interpretation

Statute is violated if person:

- 1. Knows the law prohibits offering or paying remuneration to generate business
- 2. Engages in prohibited conduct with <u>specific intent</u> to disobey the law







- Pharmacy paid money to physician to write for expensive brand medications without regard for medical necessity
- Pharmacy receiving dinners, cash, rebates and discounts from drug companies
- Pharmacy hired "marketing firm" to hire recruiters to find patients and physicians to write for expensive compounding cream
- Offer physician a percent of insurance reimbursement to write scripts and send them to your pharmacy



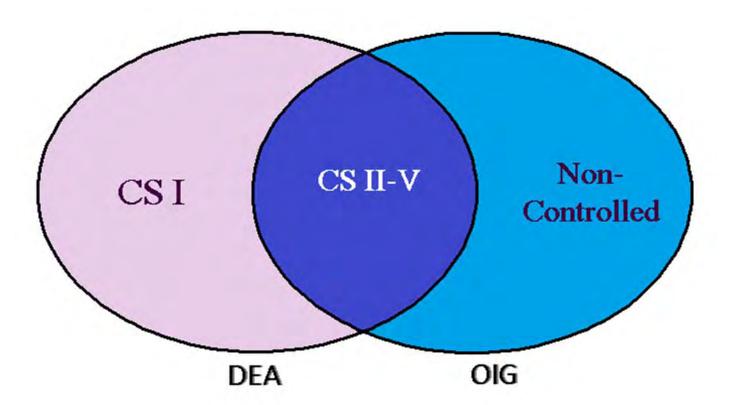


# **Different Drug Jurisdictions**

- **DEA:** Controlled substance laws and regulations of the United States
- HHS/OIG: Pharmaceuticals billed to federal healthcare programs
  - -Those paid by Medicare, Medicaid
  - -Includes Controlled Substances paid by federal programs
  - -But also includes <u>Non-Controlled</u> Substances

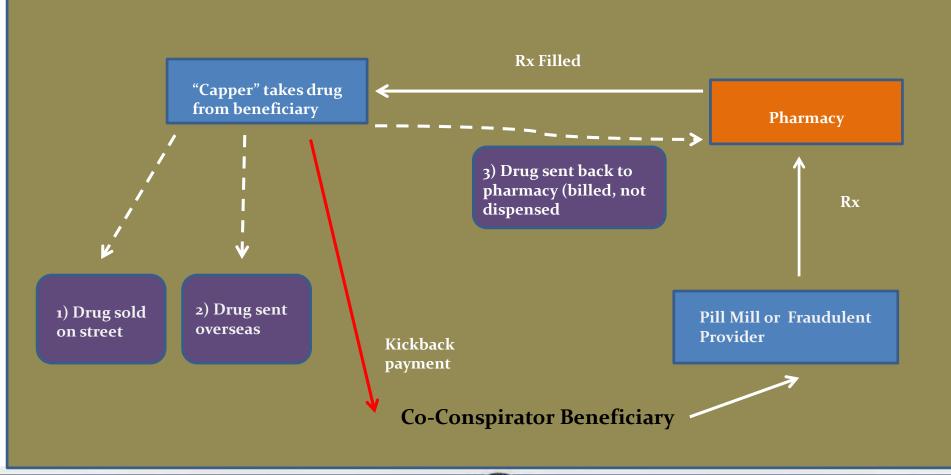


# DEA & HHS/OIG Authority





# Drug Recycling Scheme







# **Common Pharmacy Schemes**

- Billed but not dispensed
- Fictitious scripts/name
- Auto refills
- Add-on scripts
- Dispense generic/bill for brand
- Paying patients for scripts
- Payment for referrals

Other Issues:

- Medical Identity Theft
- Prescription shorting
- Narcotics without prescriptions (backdoor sales)





# Re-shelving of "dispensed" Drug

 Over 200 pills jammed into a 90count bottle

• (mixes lot numbers and expiration dates!)







# Why Divert Non-Controlled?

- Controlled Drugs:
  - Diverted for recreational use
  - \$72B in societal costs
- Non-Controlled:
  - 1. High reimbursement—financial crime. Not dispensed, just billed.
  - 2. Some diverted to other countries
  - 3. Others mixed into <u>street cocktails</u> with controlled substances; are "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





# New Paradigms for Death

- Extraction methods for pure product
- Heavy use with potentiators (Mixed Drug Ingestions)
- New portals of entry (anywhere there is a good vascular bed) to avoid first-pass effect





# 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)



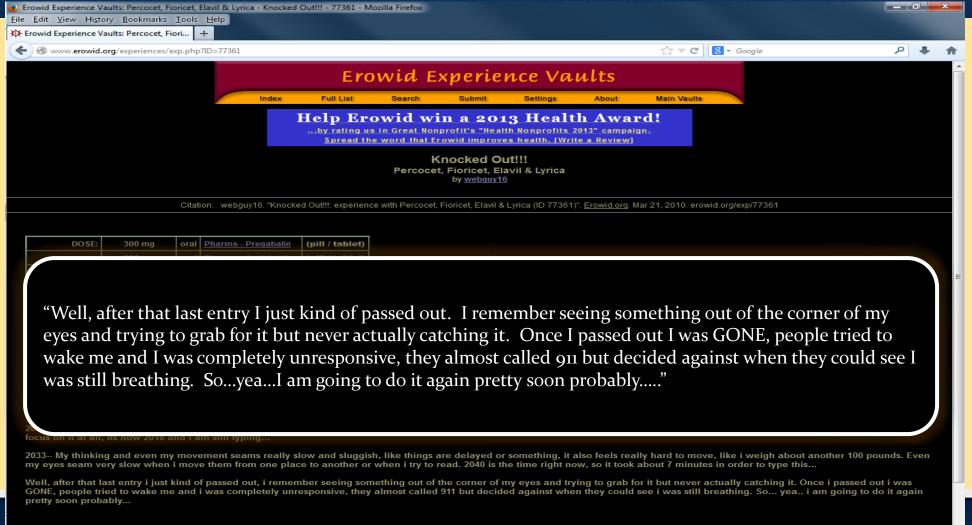




- Erowid.org
- Bluelight.org
- Drugs-Forum.com
- Opiophile.org



## Erowid Recipe Blog



### 6/24/2019

Age at time of experience: Not Given Added: Mar 21, 2010

Exp Year: 2008

Gender: Male

ID: 77361

Views: 17177

# How to Prepare IV Opana

× 🛛 🖋 New Opana better than the × 🔗 (opioids) Preparing new, n × +									
ads/622554-Preparing-new-new-Opana-ER-for-snorting-injecting-retal	⊽ 6'	Q. Search		☆	ê		+	⋒	ø
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) Mooch (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 sm a piece of aluminum foil (folded in half to create a single piece two layers thick) to catch Step Two- Preheat oven to 400 degrees Fahrenheit while grating the Opana ER with the Step Three- Once the entire Opana ER has been grated as small as possible, dump the P scrape pill chunks into a quarter/fifty-cent piece sized pile. The pile should not have much Step Four- Place the aluminum foil with the grated Opana ER on it into the preheated ovy Step Four- Place the aluminum foil with the grated ID pana ER on it into the preheated ovy Step Five- Watch the pile of Opana ER as it heats in the oven. The pill chunks should tur as it all has turned some shade of brown, remove the aluminum foil from the oven and pla time the pill will take to cook varies. DO NOT LET IT TURN BLACK. Better to remove the p into the freezer. Step Siv- Let the pill sit in the freezer for 5-7 minutes. Any 'gooey' spots should be harded Step Seven- Remove aluminum foil and now 'frozen' pill from freezer. Using credit card/dri scraping pill off of it. The pill should come off the aluminum foil easily, but if it is 'gooey,'	n any chunks the PedEgg's 'ski PedEgg. edEgg's 'skin catcher' onto the ch height to it, but there shou en. rn brown in color and appear t ace it directly in the freezer. E pill with one or two white spot ened when the pill is removed iver's license/plastic card, scr.	in catcher' misses. e layered aluminum foil. Use your credi Ild be as few spots of aluminum foil vis to melt/become 'gooey.' Do not let any Due to variations in oven heating patte ts than burn it. Make sure to place the from the freezer. rape pill off of aluminum foil. Be careful	t card/dri ble throu of the pi ms, altitu aluminum	iver's Igh it ill tu ude, n foil	s lice t as p rn bla etc. l and	ense/p possib ack, b the a cooke	lastic le. ut as moun ed pill	card soon it of direc	to
Based on the planned ROA, proceed to the specific instructions Insufflation (IN) Specific Process:									

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# Zohydro Abuse

dirzted o	24-01-2015 07:16					
Bluelighter	First, get on your knees and thank whichever god you happen to believe in. Second, you may want to crush up the beads inside the capsule in order to get a better initiation of effects (i.e. rush).					
Join Date: Mar 2013	Jesus, you might even be able to snort them! Gahhhh you are so					
Location: California	Jk, don't snort them, but it all depends on your tolerance, are you fairly experienced with opiates? If you are opiate naive i would recommend taking the beads out of one capsule and					
Posts: 526	about half of them, and taking that to start with. Should yield around ~15mg of hydrocodone, which is a perfect starting dose.					
	QUOTE					

HughesJu777 o	31-01-2015 07:17					
Greenlighter						
Join Date: Nov 2014	Stephen Stephe					
Posts: 10	You don't want to snort hydrocodone, IME, I once did a CWE on 10 lortabs and evaporated the water to be left with a white-greyish powder, not very much at all, and it was quite bitter etc etc					
	Anyways I wanted to snort the crap, was the whole point of the thing, so I snorted half (appx. 50mg PURE hydro in one line) and I didn't get muchmaybe something, hard to say. But when I ate the other half the effects were much more noticeable					
	I HAVE BEEN WONDERING ABOUT THIS!!! I have done a little research on this and found the same answers. However bub, I came across a pretty cool method I had never heard before.					
	<ol> <li>You mix up some sweet kool-aid (red or purple drank)</li> <li>Then take said CWE powder and dose accordingly into each individual cube slot</li> <li>Plop into some carbonated fruit water</li> </ol>					
	It kind of intrigued me because if you're doing so discreetly in places where discretion is preferred, I think it'd be pretty cool to get sledge hammered while not expecting it due to the masking of the Kool-aid and carbonated fruit water. I think I'm going to do this next time I get some "Zo's".					
	Im sure this is probably no new idea but has anyone ever tried this?					





# **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





## Polypharmacy Cocktails Potentiators

- Abilify + Seroquel Snort ("jailhouse heroin")
- Oxycodone + Flexeril + Xanax (Holy Trinity)
- Soma + Codeine ("Soma Coma")
- Gabapentin + oxycodone (Ohio PDMP now)
- Gabapentin + Seroquel Snort (Quell, Susi-Q)
- Gabapentin + Tegretol (Morontin)
- Seroquel + Zyprexa + Ativan + ETOH + Cocaine
- HIV Protease Inhibitors + Percocet
- Caffeine + ETOH + Eyeball





Polypharmacy Cocktails Potentiators

- Promethazine/Codeine + Tampon
- ETOH + Albuterol Inhaler
- Adderall + Albuterol + Sleep deprivation
- Adderall + Lexapro + Cannabis







# • Meth/Ecstasy/Viagra (Rectally)="Royal Flush"







• Sam-Hussein AWADA, M.D.

• Michael WEISS, D.O.





## SAM-HUSSEIN AWADA, M.D.





# Case Example - AWADA

- AWADA ran a pill-mill operation out of his Warren, Michigan clinic.
- In exchange for writing controlled substance prescriptions, AWADA received up to \$12,500 per week, cash, from patient recruiters.
- AWADA also billed health insurers for services not rendered and/or medically unnecessary.





# Case Example - AWADA

- AWADA and co-conspirators charged with Health Care Fraud (18 USC 1347) and Conspiracy to Distribute Controlled Substances (21 USC 846).
- AWADA: seven-year jail sentence, three years' probation, \$1,500,000 restitution to Medicare, \$848,000 restitution to BCBS.





## MICHAEL WEISS, D.O.





# Case Example - WEISS

- Michael WEISS, D.O. wrote medically unnecessary controlled substance prescriptions at Detroit-area "house parties".
- In exchange for writing these controlled substance prescriptions, WEISS would receive case payments from the home owner/patient recruiter for each patient for whom he wrote controlled substance prescriptions.
- WEISS would also bill health insurance for services never rendered and/or medically unnecessary.





# Case Example - WEISS

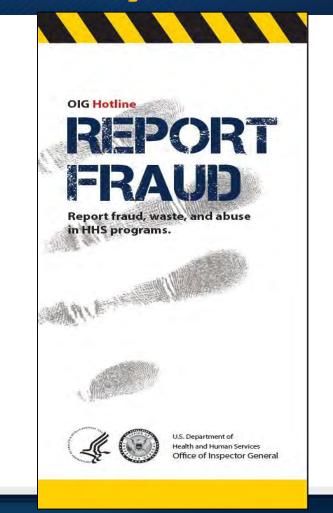
- WEISS and co-conspirators charged with Health Care Fraud (18 USC 1347), Distribution of Controlled Substances (21 USC 841(a)), and Conspiracy to Distribute Controlled Substances (21 USC 846).
- WEISS: seven-year jail sentence, three years' probation, \$214,400 restitution to Medicare, \$40,639 restitution to BCBS.





# 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 provider or beneficiary is diverting, contact
  - 800-HHS-TIPS or at
  - <u>oig.hhs.gov/report-fraud</u>





# **Post-Test Discussion**

- Does HHS/OIG have oversight for controlled drugs, non-controlled drugs, or both?
- Will Medicare Part D payments for prescription drugs double, triple or quadruple by 2023?
- Can diversion occur with both controlled and non-controlled drugs?





# Thank You

