

Michigan Practitioner Diversion Awareness Training Pharmaceutical Diversion in Medicare

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Disclaimer

I have no financial relationships to disclose.





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





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.¹ 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

OFFICE OF INSPECTOR GENERAL



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.

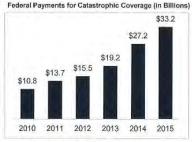
How OIG Did This Review

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.

High-Price Drugs Are Increasing Federal Payments for Medicare Part D Catastrophic Coverage

What OIG Found

Federal payments for catastrophic coverage exceeded \$33 billion in 2015, which is more than triple the amount paid in 2010. Spending for high-price drugs contributed significantly to this growth. By 2015, high-price drugs were reponsible for almost two-thirds of the total



Source: OIG analysis of CMS Payment Reconciliation 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.

What OIG Concludes

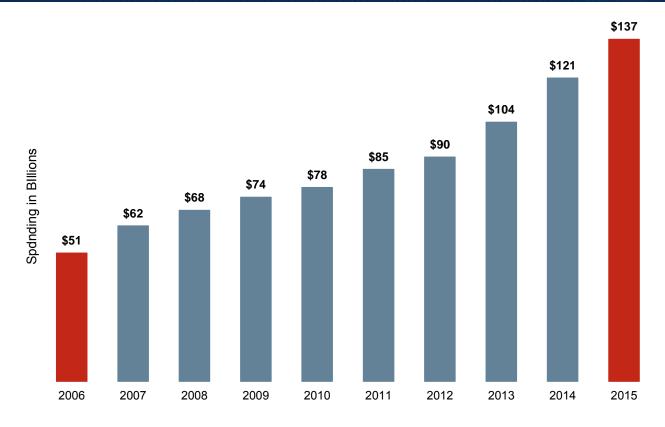
Securing the future of the Part D program while ensuring beneficiaries have access to needed drugs is a complex issue that calls for a multifaceted approach. OIG remains committed to examining these issues. Recently, CMS has taken steps in response to rising drug

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.

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

Spending for Part D Drugs 2006-2015



Source: OIG analysis of Medicare Part D data, 2016.



Part D Breakdown

- \$8.4 B spent on controlled drugs (6%)
- \$129 B spent on non-controlled drugs
- Predicted to double by 2023



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:

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



Examples

- 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



Exclusion Authorities

- Social Security Act (Sections 1128 and 1156)
- Approximately 3000 actions per year
- Duration from 3 years to Permanent
- 47% Based on License Revocation/Suspension/Surrender
- 48% Based on Convictions
 - Health Care Fraud or other Program Related Offense,
 - Patient Abuse/Neglect,
 - Controlled Substance
- Covers Medicare, Medicaid, Tricare, federal w/c, SCHIP,
 VA, and IHS (home mortgages, student loans)



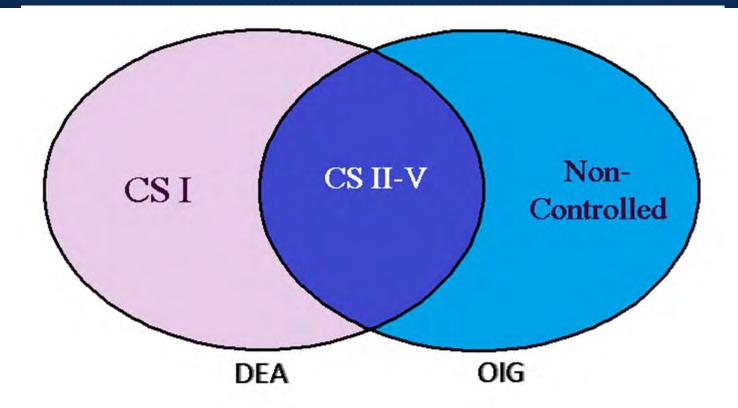


Different Drug Jurisdictions

- 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

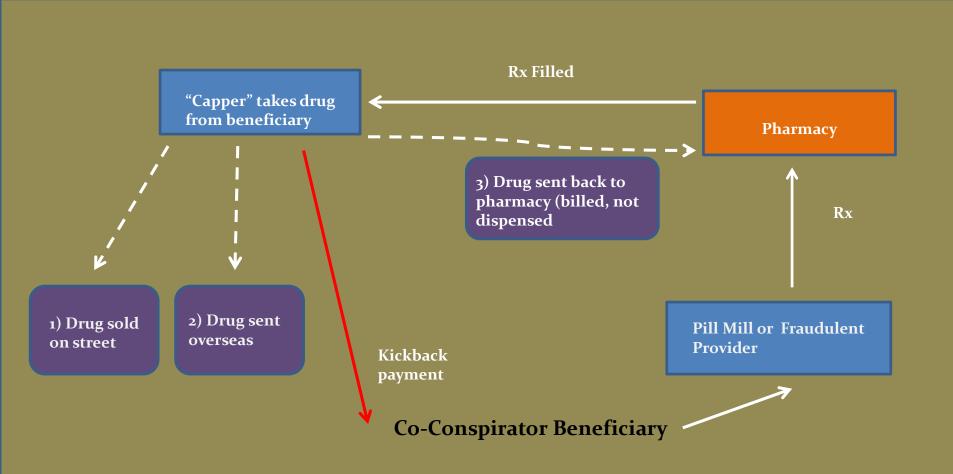


DEA & HHS/OIG Authority





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 90 count bottle

 (mixes lot numbers and expiration dates!)







Why Divert Non-Controlled?

Controlled Drugs:

- Diverted for recreational use
- \$100+B in societal costs

Non-Controlled:

- High reimbursement—financial crime. Not dispensed, just billed.
- 2. Some diverted to other countries
- 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 noncontrolled 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

DHHS/OIG



Trends in Abuse Methodologies

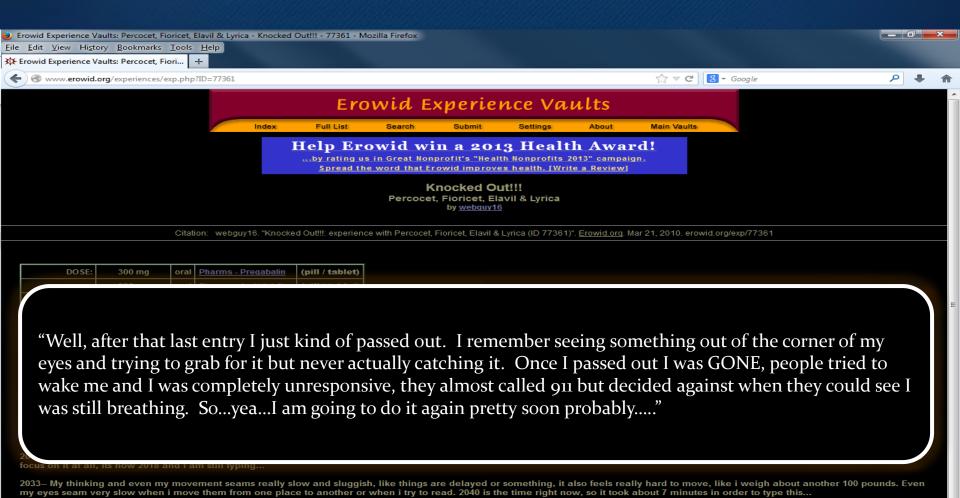
- Finding vascular beds to absorb drugs and avoid liver "first pass" effect
- Cold Water Extraction techniques
- Parachuting
- Plugging
- Insufflation (snorting)
- Vaporization/inhalation
- Alkalinization (Adderall)
- Transvaginal absorption (e.g. prometh/codeine)



Drug Blogs

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

Erowid Recipe Blog



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

Exp Year: 2008 ID: 77361

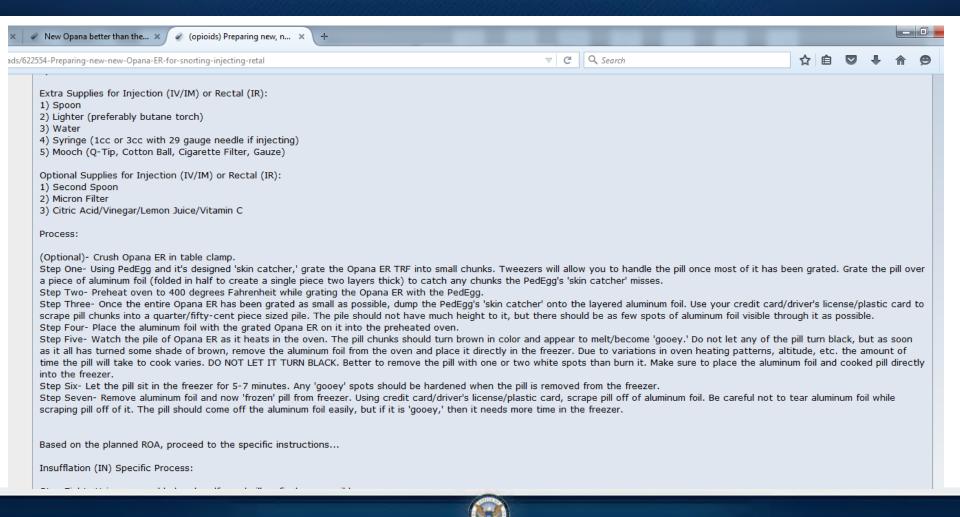
Gender: Male

pretty soon probably...

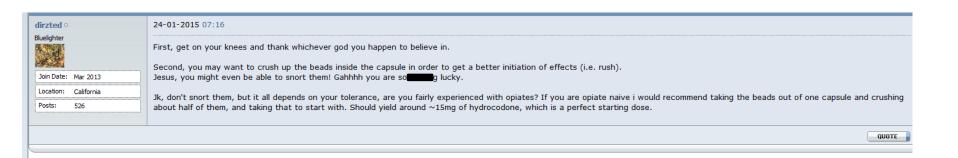
Age at time of experience: Not Given

Added: Mar 21, 2010 Views: 17177

How to Prepare IV Opana



Zohydro Abuse



HughesJu777 o

Greenlighter

Join Date: Nov 2014

Posts:

31-01-2015 07:17

Coriginally Posted by Treefa 💷

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 much...maybe 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.

- 1. You mix up some sweet kool-aid (red or purple drank)
- 2. Then take said CWE powder and dose accordingly into each individual cube slot
- 3. Plop into some carbonated fruit water... blast off.

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")
- Soma + Codeine ("Soma Coma")
- 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



Finally....

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

DHHS/OIG



Case Examples

• 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.



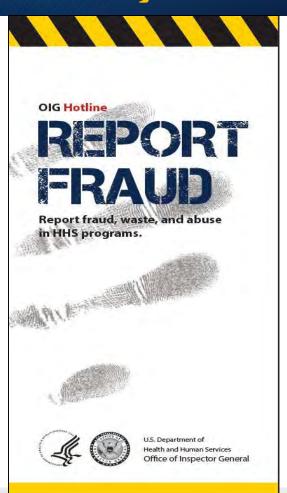
Case Example - WEISS

- 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
 - oig.hhs.gov/report-fraud







Thank You

