Pharmacy Diversion Awareness Conference

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

Pre-Test Questions to Consider

- Does HHS/OIG have oversight for controlled drugs, non-controlled drugs, or both?
- Pharmacist-owner who gives a local physician two tickets to next months playoff game in exchange for sending patients to your pharmacy.
- 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

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

U.S. DEPARTMENT OF HEALTH & HUMAN SERVICES

OFFICE OF INSPECTOR GENERAL

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

U.S. DEPARTMENT OF HEALTH & HUMAN SERVICES
OFFICE OF INSPECTOR GENERAL

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

2017 OEI Report

U.S. DEPARTMENT OF HEALTH & HUMAN SERVICES
OFFICE OF INSPECTOR GENERAL

HHS OIG Data Brief • OEI-02-17-00250

Opioids in Medicare Part D: Concerns about Extreme Use and Questionable Prescribing

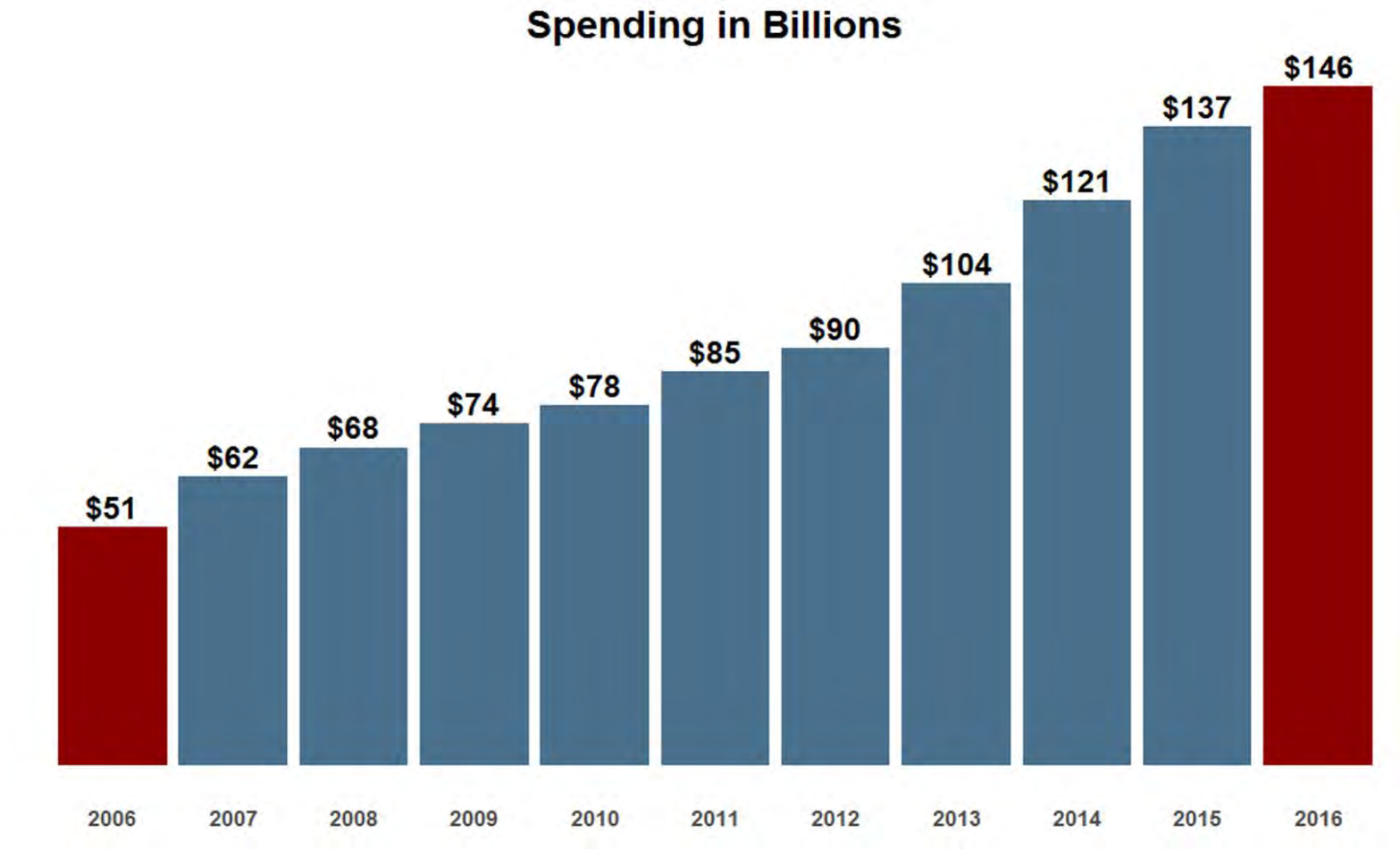
Key Takeaways:

- ✓ *One in three Medicare Part D beneficiaries received a prescription opioid in 2016*
- ✓ *About 500,000 beneficiaries received high amounts of opioids*

Opioid abuse and overdose deaths are at epidemic levels in the United States. In 2015, the number of opioid-related deaths exceeded 33,000 for the first time.[1] Nearly half of these deaths involved prescription opioids.

Opioids include narcotics intended to manage pain from surgery, injury, or illness. They can create a euphoric effect, which makes them vulnerable to abuse and misuse (i.e., taking opioids in a way

Spending for Part D Drugs 2006-2016



Part D Breakdown

- $8.7 B spent on controlled drugs (6%)
- $137 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:

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

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

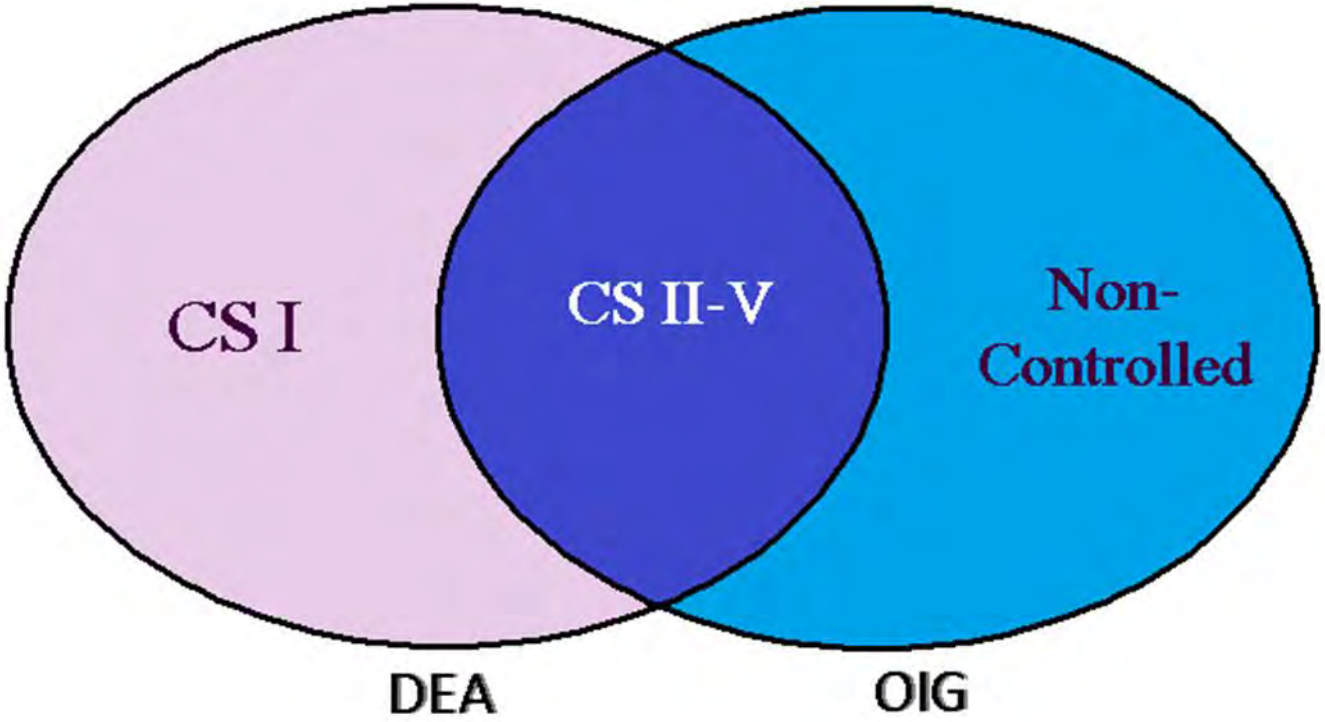
Exclusion Authorities

- Social Security Act (Sections 1128 and 1156)
- Approximately 3000 actions per year
- Duration from 3 years to Permanent
- 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)

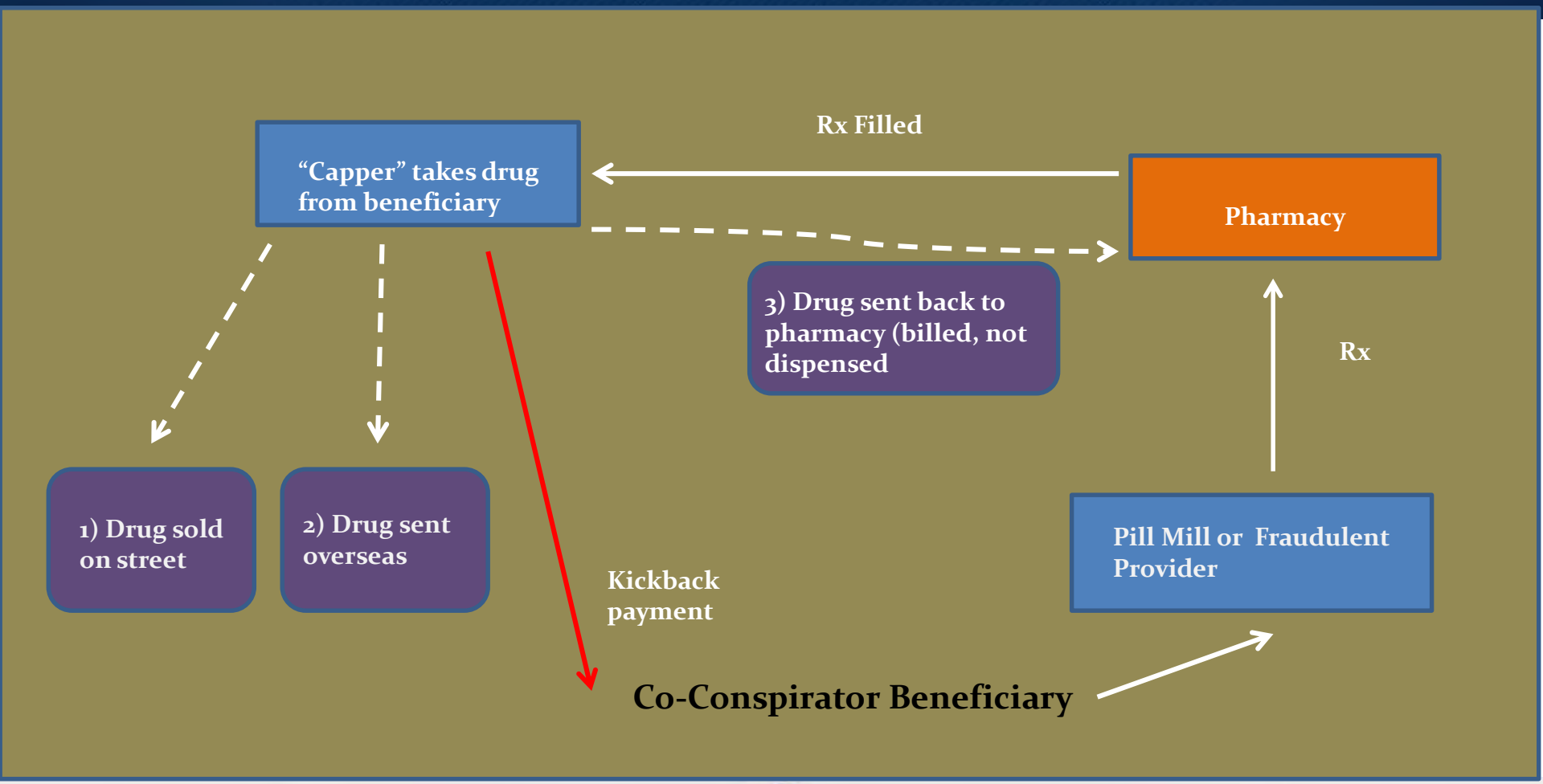
Different Drug Jurisdictions

- **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 Non-Controlled Substances

DEA & HHS/OIG Authority



Drug Recycling Scheme



Re-shelving of "dispensed" Drug

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

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)

Controlled Drug Fraud

- Oxycodone (now #1)
- Hydrocodone (Zohydro, Vicodin)
- Fentanyl (SubSys, Fentora, patches)
- Buprenorphine

Why Divert Non-Controlled?

- **Controlled Drugs:**
  - Diverted for recreational use
  - $100+B in societal costs
- **Non-Controlled:**
  1. High reimbursement—financial crime. Not dispensed, just billed. Not "government" money
  2. Some diverted to other countries
  3. Others mixed into street cocktails 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)

Drug Blogs

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

Erowid Recipe Blog

Erowid Experience Vaults: Percocet, Fioricet, Elavil & Lyrica - Knocked Out!!! - 77361 - Mozilla Firefox

File Edit View History Bookmarks Tools Help

Erowid Experience Vaults: Percocet, Fiori...

www.erowid.org/experiences/exp.php?ID=77361

Erowid Experience Vaults

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Spread the word that Erowid improves health. [Write a Review]

Knocked Out!!!

Percocet, Fioricet, Elavil & Lyrica

by webguy16

Citation: webguy16. "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)

"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....."

focus on it at all, its now 2016 and I am still typing...

2033-- My thinking and even my movement seams 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 seam 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...

Exp Year: 2008 ID: 77361

Gender: Male

Age at time of experience: Not Given

Added: Mar 21, 2010 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

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 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 'gooey.' 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 'gooey' 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 'gooey,' then it needs more time in the freezer.

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

Insufflation (IN) Specific Process:

Zohydro Abuse

dirzted
Bluelighter
Join Date: Mar 2013
Location: California
Posts: 526

24-01-2015 07:16

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).
Jesus, you might even be able to snort them! Gahhhh you are so[redacted]g lucky.

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 crushing about half of them, and taking that to start with. Should yield around ~15mg of hydrocodone, which is a perfect starting dose.

QUOTE

HughesJu777
Greenlighter
Join Date: Nov 2014
Posts: 10

31-01-2015 07:17

> Originally 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... [redacted]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")
- 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

Sustiva (efavirenz)

NCBI Resources How To Sign in to NCBI

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Journal List > Neuropsychopharmacology > v.38(12); 2013 Nov > PMC3799056

Neuropsychopharmacology

Neuropsychopharmacology. 2013 Nov; 38(12): 2373–2384. PMCID: PMC3799056
Published online 2013 Jul 3. Prepublished online 2013 May 24. doi: 10.1038/npp.2013.135

The HIV Antiretroviral Drug Efavirenz has LSD-Like Properties

Michael B Gatch,[1] Alexey Kozlenkov,[2] Ren-Qi Huang,[1] Wenjuan Yang,[3] Jacques D Nguyen,[1] Javier González-Maeso,[2] Kenner C Rice,[4] Charles P France,[3] Glenn H Dillon,[1,5] Michael J Forster,[1,5] and John A Schetz[1,5,6,7,8,*]

Author information ▶ Article notes ▶ Copyright and License information ▶

This article has been cited by other articles in PMC.

Abstract

Go to:

Anecdotal reports have surfaced concerning misuse of the HIV antiretroviral medication efavirenz ((4*S*)-6-chloro-4-(2-cyclopropylethynyl)-4-(trifluoromethyl)-2,4-dihydro-1*H*-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 $GABA_A$ and $5\text{-}HT_{2A}$ receptors. In rodents, interaction with the $5\text{-}HT_{2A}$ 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 $5\text{-}HT_{2A}$ receptor. Similar to LSD, efavirenz induces head-twitch responses in wild-type, but not in $5\text{-}HT_{2A}$-knockout, mice. Despite having $GABA_A$-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 $5\text{-}HT_{2A}$ 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 lisuride disrupts prepulse inhibition in rats by activating the 5-HT(2A) recept [Psychopharmacology (Berl). 2010]

Behavioral tolerance to lysergic acid diethylamide is associated with reduced serotonin-2A rece [Neuropsychopharmacology. 2005]

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

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

See reviews...

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Cited by other articles in PMC

Antiretroviral drug use in a cross-sectional population survey in Africa: NIMH Project Accept (H [Journal of acquired immune def...]

Pharmacogenetics of Efavirenz Discontinuation for Reported Central Nervous System Sy [Pharmacogenetics and genomics....]

Molecular mechanisms of serotonergic action of the HIV-1 antiretroviral efavirenz [Pharmacological research. 2016]

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

Substance Use in Older HIV-Infected Patients [Current opinion in HIV and AID...]

Polypharmacy Cocktails Potentiators

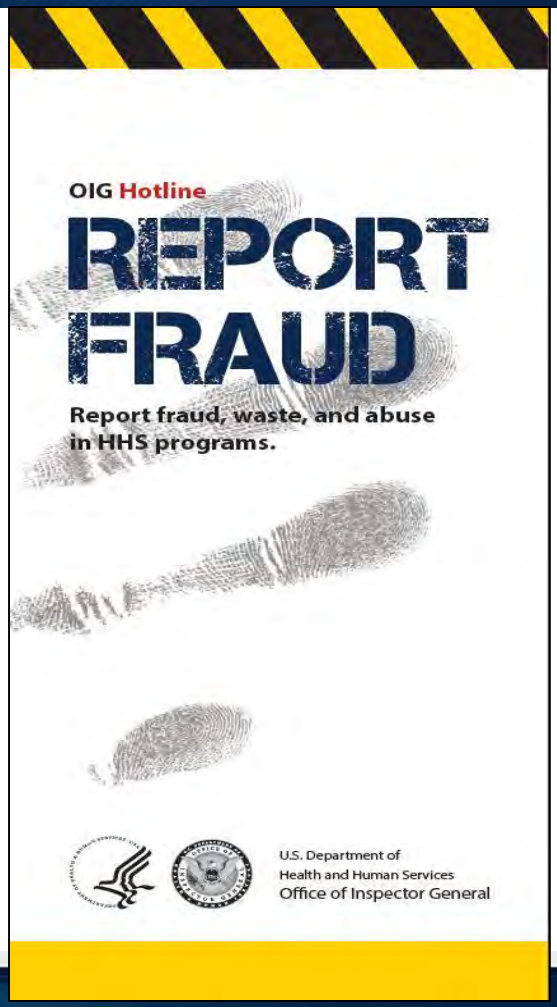
- Promethazine/Codeine + Tampon
- ETOH + Albuterol Inhaler
- Adderall + Albuterol + Sleep deprivation
- Adderall + Lexapro + Cannabis

Finally….

- Meth/Ecstasy/Viagra (Rectally)=“Royal Flush”

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



Post-Test Discussion

- Does HHS/OIG have oversight for controlled drugs, non-controlled drugs, or both?
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Thank You