Pharmaceutical Diversion in Medicare

Office of Inspector General
Office of Investigations
U.S. Department of Health and Human Services

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)

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 creates reports and makes 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.
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: Results

- Over the last 5 years:
  - 4,478 Criminal Actions
  - 2,762 Civil Actions
  - 18,109 Exclusions
  - $21.9 Billion in Monetary results
- Since 1997 - $31 Billion returned to the Medicare Trust Fund
- Over last 3 years: $5 to $1 return on Investment
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)

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. That year alone, over 1.4 million emergency department visits were caused...

Newest 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 the United States died from drug overdose in 2014...
Spending for Part D Drugs 2006-2015

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

Commonly Abused Opioids

- NEARLY 1 IN 3 beneficiaries received a commonly abused opioid.
- These opioids accounted for OVER $4 BILLION in Part D spending.
- The commonly abused opioids with the HIGHEST PART D SPENDING were:
  - OxyContin
  - Hydrocodone-Acetaminophin
  - Oxycodone-Acetaminophin
  - Fentanyl
Part D Breakdown

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

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
Why Divert Non-Controlled?

- **Controlled Drugs:**
  - Diverted for recreational use
  - $100+B in societal costs
- **Non-Controlled:**
  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
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 pretty soon probably....."
How to Prepare IV Opana

Extra Supplies for Injection (IV/IM) or Rectal (RE)
1. Syringe
2. Needle (preferably butterfly
3. IV tubing
4. Taper (12c or 12c with 20 gauge needle for injecting)
5. Needle (10g, Cotton Ball, Cigarette Filter, Gloves

Optional Supplies for Injection (IV/IM) or Rectal (RE)
1. Record Sheet
2. Copic Acid/Vinegar/Lemon Juice/Water C

Procedure

(Pharmacy)
1. Crush Opana ER to make slurry
2. Step One: Using HCl 10% in 100 ml of water make a 10% solution
3. Step Two: Mix the HCl solution with the Opana ER to form a slurry
4. Step Three: Once the slurry has been formed, use a 100 ml syringe to inject
5. Step Four: Place the slurry in the stomach

(Non-Pharmacy)
1. Place the Opana ER in a 100 ml syringe
2. Fill the syringe with water
3. Inject the Opana ER

WARNING!
- Do not inject Opana ER directly into the vein. Alkaline solutions can cause a reaction and can cause death. 
- Use only 10% HCl solution for injection. 
- Use the needle to inject only when necessary. 
- Use the needle only when necessary. 
- Do not inject Opana ER directly into the vein. Alkaline solutions can cause a reaction and can cause death. 

Zohydro Abuse

First, get your hands and face right. Don't let your hands and face get too hot or too cold.

Second, you may want to cover up the bottle to hide the label. To get a better retail price of $4.50, you may try to hide the bottle and sell it for less.

Third, you may want to change the label to make the bottle look like a new pill.

Fourth, you may want to change the label to make the bottle look like a new pill.

Fifth, you may want to change the label to make the bottle look like a new pill.

Sixth, you may want to change the label to make the bottle look like a new pill.

Seventh, you may want to change the label to make the bottle look like a new pill.

Eighth, you may want to change the label to make the bottle look like a new pill.

Ninth, you may want to change the label to make the bottle look like a new pill.

Tenth, you may want to change the label to make the bottle look like a new pill.

Eleventh, you may want to change the label to make the bottle look like a new pill.

Twelfth, you may want to change the label to make the bottle look like a new pill.

Thirteenth, you may want to change the label to make the bottle look like a new pill.

Fourteenth, you may want to change the label to make the bottle look like a new pill.

Fifteenth, you may want to change the label to make the bottle look like a new pill.

Sixteenth, you may want to change the label to make the bottle look like a new pill.

Seventeenth, you may want to change the label to make the bottle look like a new pill.

Eighteenth, you may want to change the label to make the bottle look like a new pill.

Nineteenth, you may want to change the label to make the bottle look like a new pill.

Twentieth, you may want to change the label to make the bottle look like a new pill.
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
Prescription Drug Fraud

• A physician wrote illegal prescriptions for co-conspirator patients – more than 700,000 pills passed along to 6 different drug trafficking organizations.

• Norman Werther along with 61 associates received a combined 253 years in prison. Dr. Werther received 20 years and ordered to forfeit $10 million.

Inside Pharmacy
Double check this photo. This, as well as several other slides, came from presentations I have created in the past and I believe there was a problem with the Werther photo. Unfortunately the link is archived so I can't double check it.

Trussell, Jennifer A (OIG/OI), 1/18/2017
Prescription Drug Fraud

- January 2016, Jaime Guerrero admitted to distributing and dispensing Schedule II and III controlled substances to patients without a legitimate medical purpose beyond the bounds of professional medical practice – resulting in patient death.

Case Example

- Jaime Guerrero, a medical physician with offices in Louisville, Kentucky, and Jeffersonville, Indiana.
- Charged in a 32 count indictment with unlawfully dispensing pain medications to 30 patients, without a legitimate medical purpose and beyond the bounds of professional medical practice.
- Allegedly prescribed pain medications that resulted in the deaths of five patients.
Double check this photo. This, as well as several other slides, came from presentations I have created in the past and I believe there was a problem with the Werther photo. Unfortunately the link is archived so I can't double check it.

Trussell, Jennifer A (OIG/OI), 1/18/2017
Case Example

- He saw more than 100 patients on each of the dates, by himself, and spent approximately 3 minutes or less with each patient, and fraudulently billed various health care benefit programs, for office visits at a higher code than the service provided.
- He travelled outside of the United States and directed staff personnel to provide group counseling sessions for patients in his absence. The group sessions were then billed as individual counseling sessions, and as if Guerrero personally provided the service.

Case Example

Department of Justice
U.S. Attorney’s Office
Western District of Kentucky

FOR IMMEDIATE RELEASE
Thursday, May 12, 2016

Kentuckiana Anesthesiologist Sentenced To 100 Months For Unlawful Distribution Of Controlled Substances, Health Care Fraud, Conspiracy, And Money Laundering
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