



Pharmaceutical Diversion in Medicare

Leslie W. Hollie

Assistant Inspector General for Investigations
Office of Inspector General/ Office of Investigations
U.S. Department of Health and Human Services
Washington, DC 20201





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 common healthcare fraud/ drug diversion schemes and 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 Medicare & Medicaid, plus 300 other HHS programs
- Largest Inspector General's office in Federal Government





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.
- **Office of Management and Policy:**
 - Provides mission and administrative support to the OIG
- **Office of Investigations:**
 - Law enforcement arm of OIG, which uses both traditional law enforcement techniques along with contemporary data analytic tools to identify trends and targets for investigations and prosecution



OIG Statistics

OIG Action	FY08	FY09	FY10	FY11	FY12	FY13	Total
Criminal Actions	575	671	647	723	778	960	4,354
Civil Actions	342	394	378	382	367	472	2,335
Exclusions	3,129	2,556	3,340	2,662	3,131	3,214	18,032
HHS Investigative Receivables	\$2.3 Billion	\$3.0 Billion	\$3.2 Billion	\$3.6 Billion	4.3 Billion	\$3.9 Billion	\$20.5 Billion
Non-HHS Investigative Receivables	\$846.3 Million	\$1.0 Billion	\$576.9 Million	\$952.8 Million	1.7 Billion	\$1 Billion	\$6.0 Billion
Total Investigative Receivables	\$3.2 Billion	\$4.0 Billion	\$3.8 Billion	\$4.6 Billion	6.0 Billion	\$5 Billion	\$26.7 Billion





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**





Highest percentage increase in controlled substances 2010 to 2013 is Flint, MI

Highest dollar amount for CS in 2013 was the NY-NJ area (\$364M)

Metro area with fewest number of CS prescriptions is Dillon, SC

Total Medicare prescriptions written for CS 2/3 in 2010: 54.2 million

Total Medicare prescriptions written for CS 2/3 in 2013: 69.5 million (increase of 28%)

Number of Medicare prescriptions for hydrocodone written in 2013: 35 million

Medicare pay outs for oxycodone products in 2013: \$1.1 Billion





Recent OIG Drug Reports

- **Inappropriate Medicare Part D Payments for Schedule II Drugs Billed as Refills**
- **Prescribers with Questionable Patterns in Medicare Part D**
- **Retail Pharmacies with Questionable Part D Billing**
- **Medicare Inappropriately Paid for Drugs Ordered by Individuals Without Prescribing Authority**





Collaborative Effort

- Work with DEA and TDS Task Force Units
- Work with FBI on HEAT initiative (Strike Force operations in select cities)
- Work with state, local law enforcement
- Use/encourage Prescription Drug Monitoring Programs (PDMP)
- Support education of industry, patients, providers, pharmacists -can't prosecute our way out of this problem



Where Does OIG Get Referrals?



INDUSTRY



HOTLINES



LAW ENFORCEMENT PARTNERS



DATA ANALYTICS



SENIOR MEDICARE
PATROL



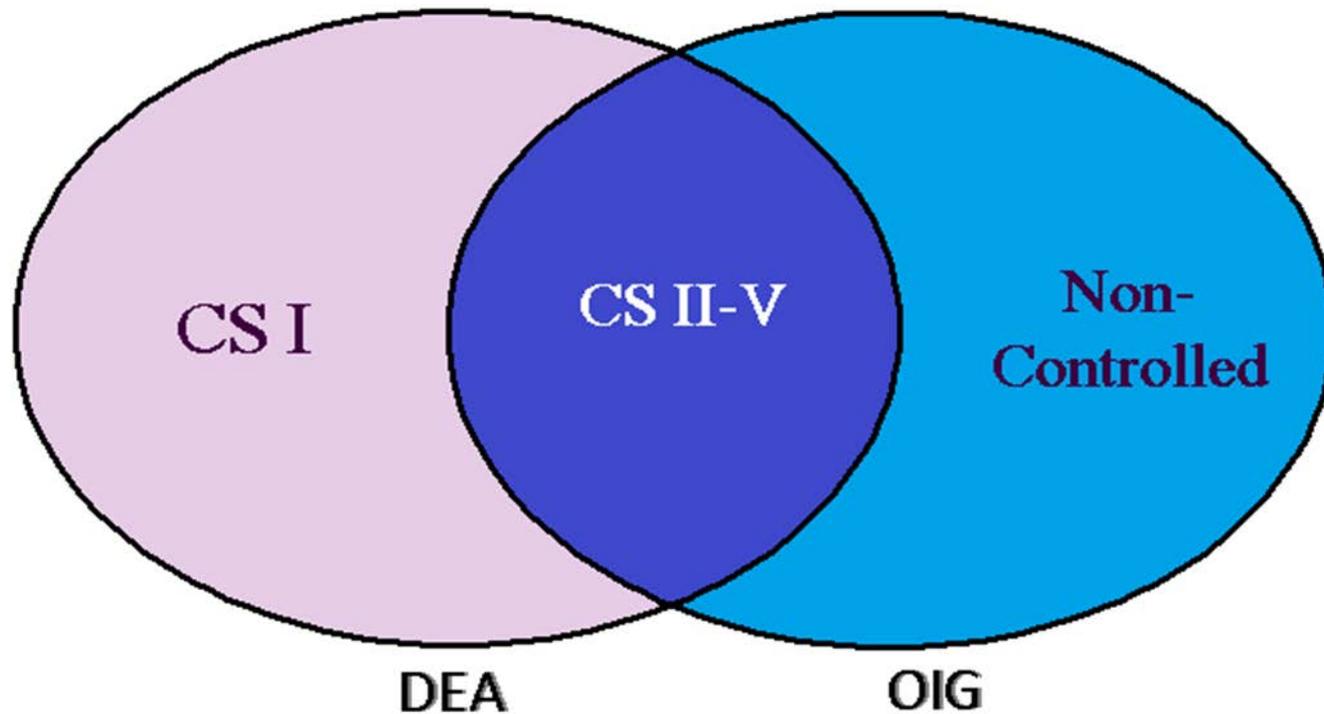


Different Drug Jurisdictions

- **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
 - Impact the Programs and Operations of HHS



DEA & HHS/OIG Authority



Increasing Trend in Medicare Pharmaceutical Payments

Medicare Part D Expenditures

- **2012 - \$66.9 Billion**
- **2022 - \$165 Billion**
 - Projection by Centers for Medicare and Medicaid Services,
Office of the Actuary





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.





THE ANTI-KICKBACK STATUTE (42 USC § 1320a-7b(b))

Prohibits offering, paying, soliciting or receiving anything of value to induce or reward referrals or generate Federal health care program business





OIG Popular Diverted Drugs

Examples

- **Controlled:** Oxycodone and hydrocodone products, Opana, Dilaudid, Suboxone, Soma
- **Non-Controlled:**
 - Antipsychotics: Abilify, Zyprexa, Seroquel
 - Diabetic: Januvia, Actos
 - Respiratory: Spiriva, Advair
 - Statins: Lipitor, Crestor, Zetia
 - HIV: All anti-retrovirals, protease inhibitors
 - Topical: Solaraze, Lidoderm





Why Divert Non-Controlled?

- **Controlled Drugs:**
 - Diverted for recreational/abuse
 - Potential Profit
- **Non-Controlled:**
 1. High reimbursement. Not dispensed, just billed. Not addiction/recreation, pure profit motivation. Not “the Government’s money” it’s YOUR money.
 2. Some diverted to other countries
 3. Others mixed into street cocktails with controlled substances



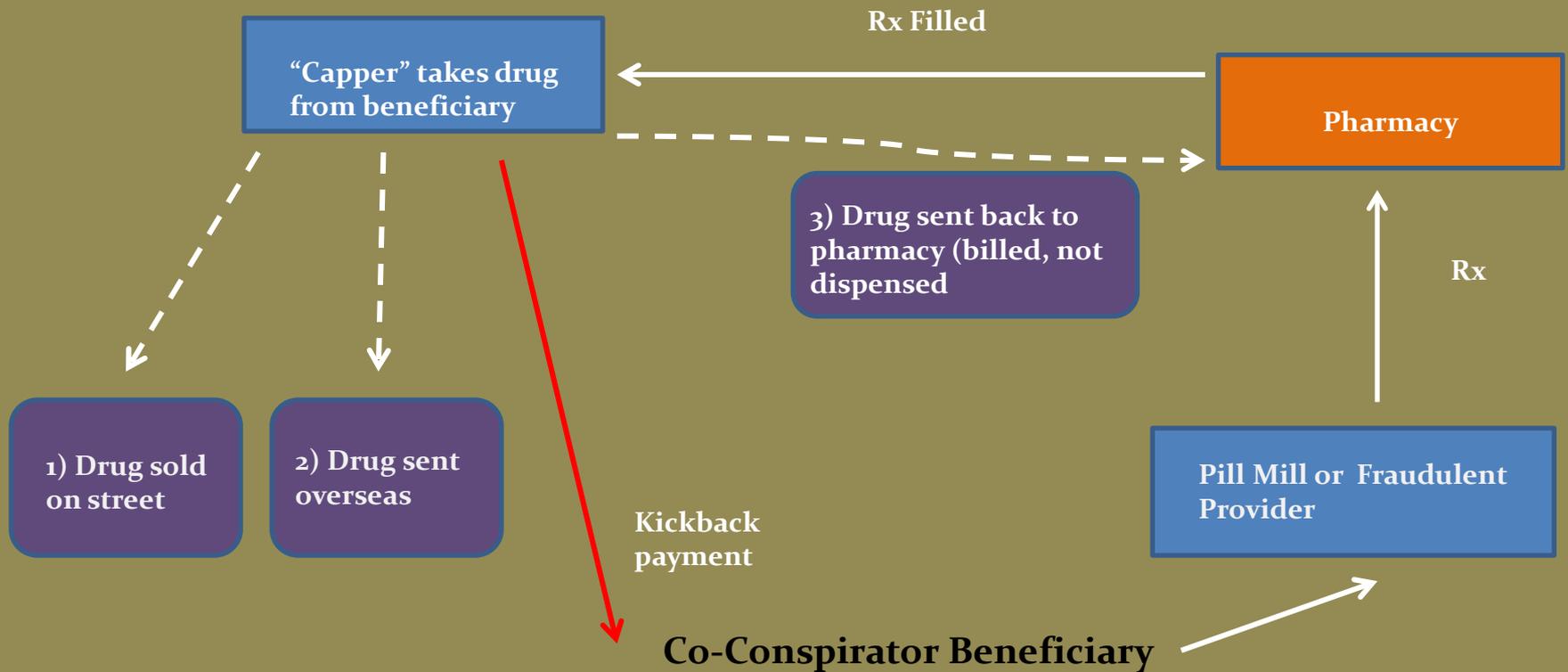


Red Flag Cocktails to Watch For

- Vicodin + Xanax + Soma = “Trinity”
- Soma + Codeine = “Soma Coma”
- Retronavir (HIV) + Oxycodone (new)
- Sporanox + Oxycodone
- Seroquel + Zyprexa + Ativan + Cocaine
- Meth/Ecstasy/Viagra (Rectally)=“Royal Flush”



Drug Recycling Scheme





Re-shelving of “dispensed” Drug

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





Purdue Pharma



- Criminal charges for Misbranding for OxyContin
- Described drug as “less likely” to cause addiction
- 3 executives pled guilty in federal court
- Purdue paid \$600M, Execs paid \$34.5M in fines
- All 3 executives excluded from federal healthcare programs





Case Study

- Detroit pharmacist (Babubhai “Bob” Patel) owned 26 pharmacies
- Provided kickbacks to induce physicians to write prescriptions and present them to his pharmacies
- Pharmacist/owner arrested and sentenced to 17 years





Case Example Continued

- 13 Additional Defendants Charged in February 2013
 - Including 5 doctors, 4 Pharmacists, and a Home Health Agency owner
- 7 have since been convicted or pled guilty, including
 - 3 of 4 pharmacists
 - 4 of 5 doctors
 - 1 marketer/recruiter
 - One trial scheduled for 7/2014 (2 defendants), and one pharmacist defendant is a fugitive



One of Patel's "Apartments"



Boxes Confiscated from Search Warrant



Pharmaceutical Fraud Now Mimics Street Drug Activity





Miami Pharmacy

- Operators of two pharmacies in downtown Miami
- Decided more money operating a “phantom pharmacy” that only exists on paper
- Billed > \$770,000.00 to Medicare
- Used a “nominee owner” for the pharmacy





Other Pharmaceutical Fraud to Watch For

- Be wary purchasing from secondary wholesalers with unreal prices (often counterfeit, expired-repackaged, knock-offs)
- Never give patients, providers, etc. anything of value in exchange for sending patients to your pharmacy
- If you bill Medicare for brand, don't dispense generic
- Don't allow corporate to pressure you into filling illicit/questionable scripts to meet "quotas"
- Watch use of compounding billing code when no compounding actually occurred.
- Refund Fraud





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

OIG Hotline
REPORT FRAUD
Report fraud, waste, and abuse in HHS programs.

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





HHS- Office of Investigations
St. Louis Field Office
Robert Young Federal Bldg#9309
1222 Spruce Street
St. Louis, MO
314-539-3403





Thank You

Questions

