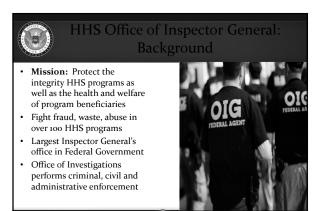


Pharmaceutical Diversion in Medicare

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





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:
- $Conducts\ independent\ audits\ of\ HHS\ programs/grantees.\ Also\ create\ reports\ and\ make\ recommendations.$
- 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





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,





2015 OEI Report



U.S. DEPARTMENT OF HEALTH & HUMAN SERVICES

OFFICE OF INSPECTOR GENERAL

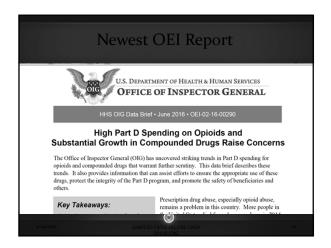
Questionable Billing and Geographic Hotspots Point to Potential Fraud and Abuse in Medicare Part D

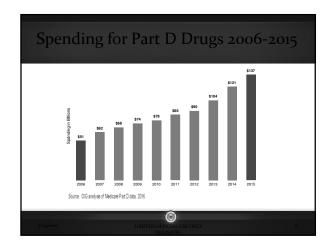
Key Takeaways:

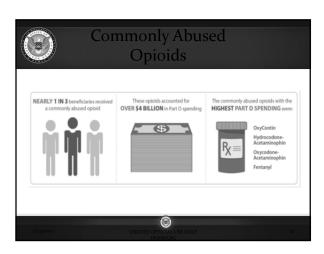
✓ Since 2006, Medicare spending for commonly abused opioids

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











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
 - But also includes Non-Controlled Substances





DEA & HHS/OIG Authority CS II-V CSI Controlled DEA OIG



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. Not "government" money
 - 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

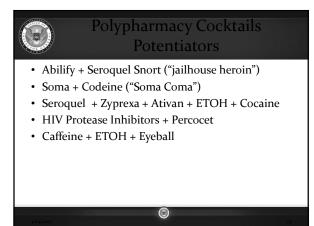


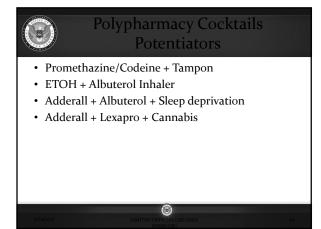














Prescription Drug Fraud

- 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





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.





Slide 25

TJA(5

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

Slide 27

TJA(5

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



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.





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



