

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)

3/24/2017



LIMITED OFFICIAL USE ONLY

3



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



3/24/2017



5



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
- 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.







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

3/24/2017

LIMITED OFFICIAL USE ONLY

9

Newest 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.

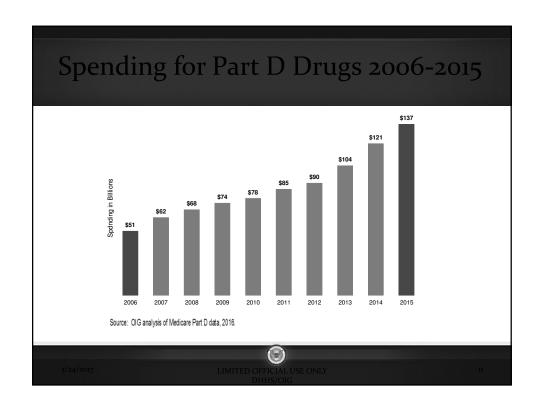
Key Takeaways:

Prescription drug abuse, especially opioid abuse, remains a problem in this country. More people in

3/24/2017

LIMITED OFFICIAL USE ONI

10







Part D Breakdown

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

3/24/2017

OFFICIAL USE ONL

13



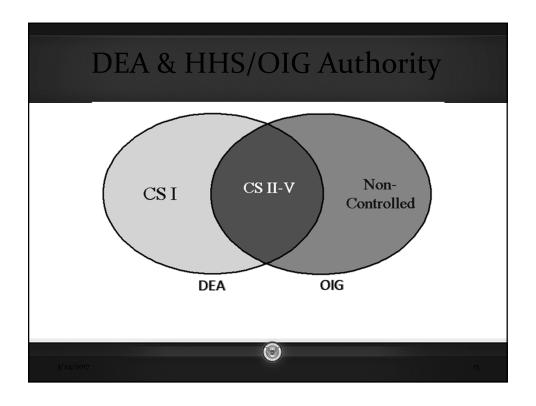
Different Drug Jurisdictions

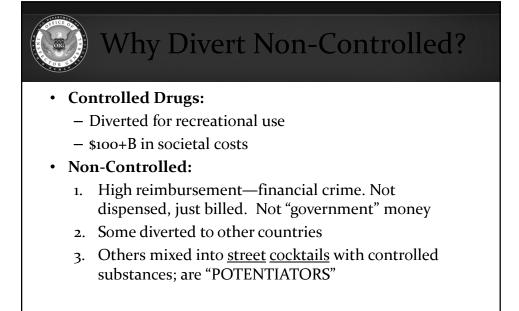
- DEA: Controlled substance laws and regulations of the United States
- **HHS/OIG:** Pharmaceuticals billed to federal healthcare programs
 - Those paid by Medicare, Medicaid
 - Includes Controlled Substances paid by federal programs
 - But also includes Non-Controlled Substances

3/24/2017



14







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

3/24/2017

ITED OFFICIAL USE ONLY

17



New Paradigms for Death

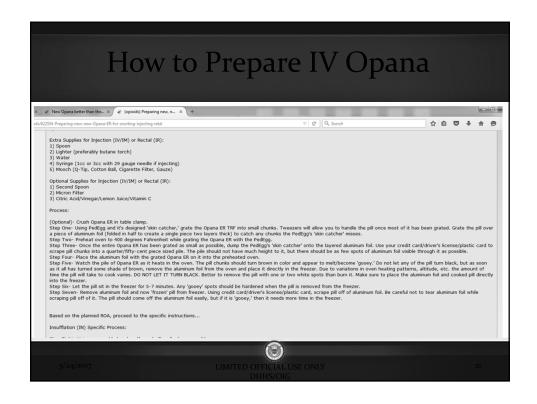
- Extraction methods for pure product
- Heavy use with potentiators (Mixed Drug Ingestions)
- New portals of entry (anywhere there is a good vascular bed) to avoid first-pass effect

3/24/2017

OFFICIAL USE ONLY











Polypharmacy Cocktails Potentiators

- Abilify + Seroquel Snort ("jailhouse heroin")
- Soma + Codeine ("Soma Coma")
- Seroquel + Zyprexa + Ativan + ETOH + Cocaine
- HIV Protease Inhibitors + Percocet
- Caffeine + ETOH + Eyeball

3/24/2017



23



Polypharmacy Cocktails Potentiators

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

3/24/2017



IMITED OFFICIAL USE ONI



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

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



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.



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



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.

3/24/2017



000 m

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

2/24/2017



LIMITED OFFICIAL USE ONLY

15

