Health Care Compliance Association
Pharmaceutical Diversion in Medicare

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Disclaimer
I have no financial relationships to disclose.

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
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

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)

DEA & HHS/OIG Authority
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

- 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.

Newest OEI Report

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

HHS OIG Data Brief - June 2015 - OEI-ID-15-00160

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
  - 1.4 million enrollees, department visits, home care
Common Problem Areas with Plan Sponsors

- Invalid prescriber numbers
- Excluded providers
- Illegal refills
- Drug refills for deceased beneficiaries

Criminal Areas of Concern

- Increase in criminal enterprises
- Increase in pharmacies with questionable billings
- Compounding
- Internal pharmaceutical diversions (e.g. Pyxis systems)
- Adulterated drugs in manufacturing
- Illegal importation
- Off label marketing

Spending for Part D Drugs 2006-2014
(10% of Medicare Spending)
Part D Breakdown

- $7.8 B spent on controlled drugs (6%)
- $113 B spent on non-controlled drugs
- Predicted to double by 2023

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)

FDA Guidelines

- Physical barriers
- Sequestered opioid antagonist (e.g., Naloxone)
- Aversion i.e. release of irritating chemicals,
- Non-oral delivery systems (depot injection or slow release implant,
- Prodrug, i.e., administered in an inactive state.
Why Divert Non-Controlled?

- **Controlled Drugs:**
  - Diverted for recreational use
  - $57B in societal costs
- **Non-Controlled:**
  2. Some diverted to other countries
  3. Others mixed into street cocktails with controlled substances; are "POTENTIATORS"

Drug Recycling Scheme

Re-shelving of "dispensed" Drug

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

Medical Identity Theft

$3,713,202
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

Lastly

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

Common Drugs for Diversion

• Opiates, anxiolytics, stimulants
• Nexium
• Lipitor
• Flexeril, soma
• Advair
• Lidocaine patches
• Anti-psychotics (Abilify, Seroquel)
• Solaraze
• HIV meds
New Diversion Drugs of Concern

- Hepatitis C: (Sovaldi, Viekira Pak, Olysio, Harvoni, Daklinza)
- PCSK-9: Repatha, Praluent
- Controlled: Subsys
- MS Drugs
- DM Drugs: Victoza, Farxiga

Farxiga

New Drug Delivery Systems
3D Drug Printing

• Dissolves quickly in water (porous structure)
• Conforms to needs of patients with trouble swallowing
• Helps children in particular
• Created by layer upon layer of powdered drug
• Gives each pill a uniform/predictable dose
• Can make endless dosages, strengths, shapes
• Instead of mass produced; custom in local pharmacy

3D Printed Drugs

• Discovered that different shape pills affected the speed at which the drug was released in the body
• E.g. a pill with a hollow center dissolved at a different rate
• Customized medicine always comes at a price

Spritam

• Manufacturer Aprecia
• Approved by FDA 8/3/15
• Dissolves with a sip of water
• Delivers high drug load
• Used for seizures
• Cost?
Drug Ring

- Swallowable dissolvable ring device
- Unfurls in the stomach
- Delivers medication through the stomach for a week
- Prevents rapid stomach elimination
- Goal is to have it last for months
- E.g. only take one dose of antibiotic
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Polymer Ring

Questions?