

## Health Care Compliance Association Pharmaceutical Diversion in Medicare

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## Disclaimer

I have no financial relationships to disclose.

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2

## 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



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3

## 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



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4

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## 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)

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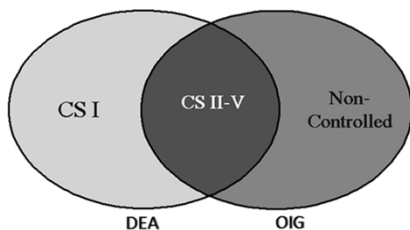
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## DEA & HHS/OIG Authority



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## 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

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7

## 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.

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8

## Newest 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.<sup>1</sup> That year alone, over 1.4 million emergency department visits were caused

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### Common Problem Areas with Plan Sponsors

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

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### 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

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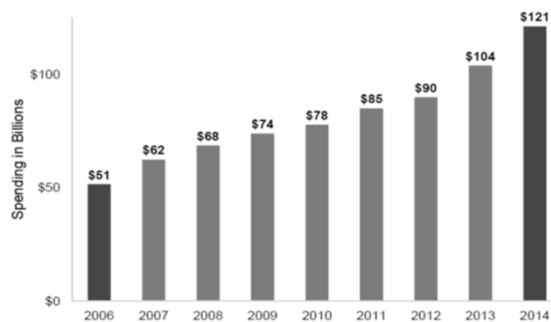
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### Spending for Part D Drugs 2006-2014 (10% of Medicare Spending)




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## Part D Breakdown

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

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## 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)

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## 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.

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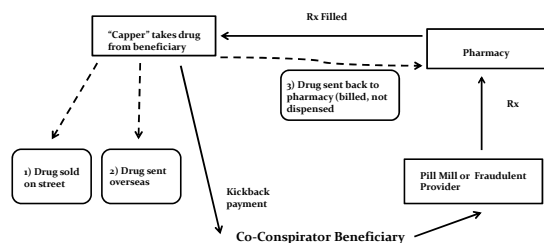
## Why Divert Non-Controlled?

- **Controlled Drugs:**
  - Diverted for recreational use
  - \$57B in societal costs
- **Non-Controlled:**
  1. High reimbursement—financial crime. Not dispensed, just billed.
  2. Some diverted to other countries
  3. Others mixed into street cocktails with controlled substances; are “POTENTIATORS”

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16

## Drug Recycling Scheme



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17

## Re-shelving of “dispensed” Drug

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



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18

### Inside Pharmacy



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### Medical Identity Theft



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[illegible]

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## Polypharmacy Cocktails Potentiators

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

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## Lastly

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

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## Common Drugs for Diversion

- Opiates, anxiolytics, stimulants
- Nexium
- Lipitor
- Flexeril, soma
- Advair
- Lidocaine patches
- Anti-psychotics (Abilify, Seroquel)
- Solaraze
- HIV meds

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## 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

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## Farxiga

The screenshot shows the Farxiga website interface. At the top, there are links for 'Important Safety Information', 'Approved Uses', 'Prescribing Information', and 'Medication Guide'. Below these is a search bar with the placeholder text 'Search by entering keyword or phone'. A navigation menu includes 'Home', 'Controlling FARXIGA', 'Taking FARXIGA', 'FARXIGA Side Effects', 'Managing Type 2 Diabetes', and 'Savings and Support Info'. The main content area features a testimonial: 'FARXIGA helped improve my A1C. It also helped lower my weight.' with a quote icon. Below the testimonial is a button 'Learn how FARXIGA may help you.' and a link 'Watch our TV commercial'. To the right, there's a 'FREE Offer' section stating 'Patients may get FARXIGA for FREE.' and a 'Start the Conversation' section with a button 'Download the FARXIGA Doctor Discussion Guide.' and a 'Get Information and Support' section with a button 'Sign up today for helpful information, savings, and prescription coverage support.' At the bottom, there is an 'Important Safety Information' section with a warning: 'Do not take FARXIGA (dapagliflozin) if you are allergic to dapagliflozin or any of the ingredients in FARXIGA. Symptoms of a serious allergic reaction to FARXIGA may include: skin rash, raised red patches on your skin (hives), swelling of the face, lips, tongue, and throat that may cause difficulty in breathing or swallowing. If you have any'.

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## New Drug Delivery Systems

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### 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

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### 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

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### Spritam

- Manufacturer Aprelia
- Approved by FDA 8/3/15
- Dissolves with a sip of water
- Delivers high drug load
- Used for seizures
- Cost?

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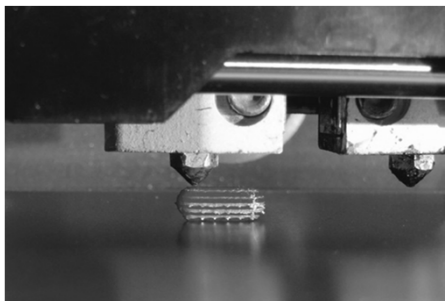
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## Printer



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## Spritam



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## 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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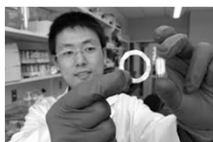
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## Polymer Ring



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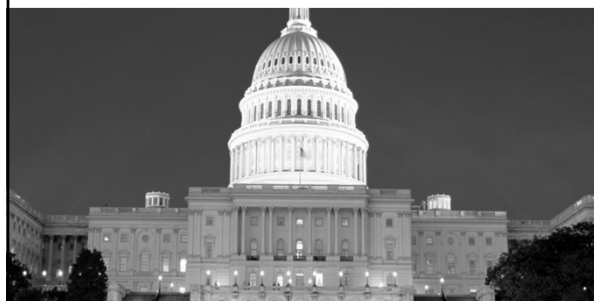
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## Questions?



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