

Pharmacy Compliance

HCCA Regional Conference

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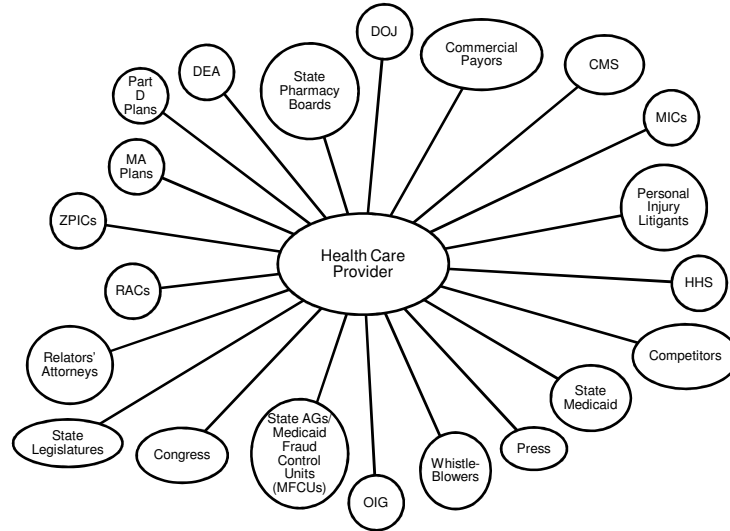
HHS Office of the Inspector General

Historical Pharmacy Compliance Programs

- ♦ Fee-for-service business
- ♦ Focused on getting the correct drug to the patient and on handling controlled substances
- ♦ State regulation through Boards of Pharmacy and federal DEA for controlled substances
 - *E.g.*, HCA Compliance Process Review, Pharmacy Director Questionnaire

<http://hcaethics.com/CPM/Pharmacy%20CPQ%20Template.pdf>

Oversight - Many Watchful Eyes



State Medicaid Audits

- ♦ Each state has its own audit process
- ♦ Some common features:
 - Authority to request records to justify payments
 - Ability to recoup overpayments
 - Afford appeal rights to challenge state findings
- ♦ States are taking action, especially because of state budget pressures and increased federal requirements
- ♦ Recent potential areas for review:
 - Incorrect diagnosis codes
 - Failure to sufficiently document counseling
 - Failure to use tamper-resistant prescription pads

Recovery Audit Program

- ♦ CMS must contract with Recovery Audit Contractors (RACs) to review providers, such as through the Part D RAC program
- ♦ Enables recovery of overpayments
- ♦ RAC reviews
 - Coverage determinations
 - Coding determinations
 - Medical necessity determinations
- ♦ Payments to RACs limited to amounts recovered (contingency basis)

Medicaid Integrity Program

- ♦ Requires CMS to contract with Medicaid Integrity Contractors
 - Review provider claims
 - Audit providers
 - Identify overpayments
 - Educate with respect to payment integrity and quality of care
- ♦ Provides support and assistance to states:
 - Support, not supplant, state Medicaid program integrity efforts
 - Work closely with states
 - Provide technical assistance and training to state program integrity staff

Possible Consequences of Errors with Prescription Claims

- ♦ Recoupment of Reimbursement
 - Pressure on prescription drug plans to audit
- ♦ Violation of payor policies or requirements, leading to allegations of fraud
- ♦ Medicaid payment holds and referral to state Medicaid Fraud Control Units (State AG's)

Excluded Individuals & Entities

- ♦ OIG bulletin on best practices related to excluded individuals (May 8, 2013)
 - When checking List of Excluded Individuals/Entities, maintain documentation of initial name search
 - Checking monthly would best minimize potential overpayment and CMP liability
- ♦ Report violations through OIG's self-disclosure protocol or to other government officials

Usual & Customary Pricing and Prescription Discount Card Programs

- ♦ Retail pharmacies often offer prescription discount card programs
- ♦ Members pay an enrollment fee and receive discounted prices on prescription drugs and other benefits
- ♦ According to some state Medicaid agencies, the discounted drug price should be used as the pharmacy's U&C price

Controlled Substance Compliance

- ♦ CDC: abuse of Rx pain meds is a "growing epidemic"
- ♦ 12 million admitted using Rx pain meds for nonmedical reasons in 2010 alone
- ♦ Emergency room visits for abuse doubled in 5 years
- ♦ Enough Rx pain meds were prescribed in 2010 to drug every U.S. adult for a month
- ♦ "Pill mills" spread from FL → GA → TN/KY/OH → MO

DEA Enforcement Activity

♦ DEA's Response: Increased Enforcement

- Rx drug abuse is a "top priority"
- Increased enforcement at all levels
 - ♦ Manufacturers, wholesalers, prescribers, pharmacies, users
- DEA says pharmacists are "last line of defense"

♦ DEA Enforcement Options

- Letter of admonition
- Civil fines of \$10,000 per violation
- Criminal prosecution
- Forfeiture of proceeds up to 2x gross profits
- Immediate suspension or "show cause"
 - ♦ Revoke registration to prescribe/distribute/dispense

Recent DEA Enforcement Actions

- ♦ Cardinal (May 2012)
- ♦ Omnicare (May 2012)
- ♦ UPS (March 2013)
- ♦ CVS (April 2013)
- ♦ Walgreens (June 2013)

Pharmacy Compliance Standards

- ♦ **Technical Compliance Not Sufficient**
 - Prescriber DEA number, signature, date, etc.
- ♦ **“Corresponding Responsibility” Rule (21 CFR 1306.04)**
 - Rx must be “for a legitimate medical purpose” by prescriber “acting in the usual course of his professional practice”
 - Prescriber is responsible, “but a corresponding responsibility rests with the pharmacist who fills the prescription”
- ♦ **Compliance Depends On Facts Of Each Situation**
 - DEA and courts have not defined “legitimate medical purpose” and “usual course of professional practice”
 - They know it when they don’t see it
- ♦ **Pharmacists Must Investigate And Resolve “Red Flags”**
 - Otherwise cannot dispense controlled substance despite Rx
 - DEA keeps identifying new red flags

Prescription Red Flags

DEA Pharmacist’s Manual

- ♦ “Prescription looks ‘too good’; the prescriber’s handwriting is too legible”
- ♦ “Directions written in full with no abbreviations” or does not use acceptable standard abbreviations
- ♦ Quantities, directions or doses differ from usual practices
- ♦ Rx appears to be photocopied or has apparent erasure marks
- ♦ Rx written in different color inks or different handwriting

Prescriber Red Flags

- ♦ Prescribes “drug cocktails” like oxycodone, hydrocodone, alprazolam, etc.
- ♦ Prescribes large number or % of controlled substances compared with other prescribers
- ♦ Prescribes depressants and stimulants for same patient
- ♦ Drug not consistent with doctor’s practice
 - Fentanyl prescribed by dentist
- ♦ No DEA registration or law enforcement investigating doctor

Compliance Strategies

- ♦ **Know Your Patients & Prescribers**
 - Check state licensing and sanctioning databases
 - Manage physician pushback (AMA)
- ♦ **Know Your Pharmacies**
 - Look for outliers that dispense unusual amounts; find out why
 - Avoid “suspicious order” accusations
- ♦ **Inform Your Pharmacists**
 - Heightened training, checklists



Prescription Drug Fraud Schemes

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Office of Inspector General
Office of Investigations
Puerto Rico Field Office



Inspector General Community

- Inspector General Act of 1978, as amended, established the duties, responsibilities, and authorities of a Federal Inspector General.
- Conduct independent and objective audits, investigations, inspections, evaluations;
- Prevent and detect fraud, waste, and abuse





Offices of Inspector General

- Department of Justice
- Department of Commerce
- Department of Interior
- Department of Defense
- Department of Energy
- Central Intelligence Agency
- Federal Depository Insurance Corporation
- Office of Personnel Management
- Federal Communications Commission
- Department of Labor
- Federal Trade Commission
- General Services Administration
- Department of Veteran Affairs
- Social Security Administration
- Department of Housing & Urban Development
- Treasury Inspector General for Tax Commission
- Department of Homeland Security
- Department of Health & Human Services
- Department of Education
- United Postal Service
- Department of Treasury



Office of Investigations

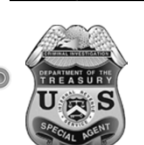
- The OIG-OI was created in 1976 as the principle investigative arm of the Department of Health & Human Services.
- The mission of OI is to detect and prevent waste, fraud and abuse within over 300 Departmental programs.
- Conduct criminal and civil investigations mainly related to Medicare, Medicaid and/or grant fraud; child support enforcement
- Secretarial Protection
- PRFO – 1 ASAC, 5 Special Agents





Partnership with other agencies

- United States Attorney's Office
- US Secret Service
- United States Trustee Office
- Federal Bureau of Investigation
- Food & Drug Administration
- Immigration & Customs Enforcement
- Internal Revenue Service
- Drug Enforcement Administration
- Local Law Enforcement



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What is health care fraud?

“Knowingly and willfully executing, or attempting to execute, a scheme or artifice to defraud any health care benefit program or to obtain by means of false or fraudulent pretenses, representations, or promises, any of the money or property owned by, or under the custody or control of, any health care benefit program”



Title 18 United States Code 1347





Prescription Drug Fraud

- OIG Limited Jurisdiction (Medicare or Medicaid)
- Individuals
- Providers



Case Examples



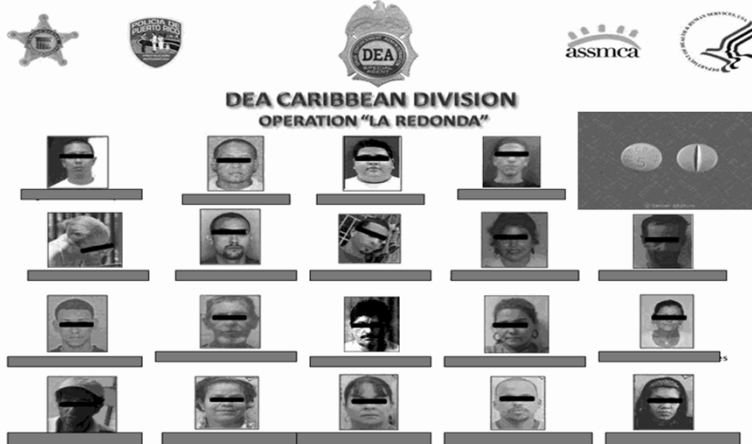


Prescription Drug Schemes (Individuals)

- False Rx to obtain medications
- Payment to physician for Rx
- Payments to Beneficiaries



Drug Diversion - DTOs





“La Redonda”



- Distribution of Oxycodone tablets in various Public Housing Projects in the San Juan metropolitan area.
- Defendants acquired over 20,000 Oxycodone tablets from 2008 to 2010.
- Defendants sold each Oxycodone tablet for \$6-\$10 per tablet, depending on the current supply.
- Investigators recovered almost 300 fraudulent prescriptions, from over 60 pharmacies, located at 27 different municipalities in Puerto Rico.
- Over 24 medical physicians, specialties ranging from General Practice to Surgeons, have been affected by identity theft.



False Prescription - Rx

CLÍNICA EXPRESO
Auxilio Mutuo

Carr. PR-1 Km 0.8
Ave. Las Candelas, Caguas, P.R.
Tel: (787) 300-2000

Nombre: [Redacted]
Dirección: [Redacted]

Rx [Redacted]

SALA EMERGENCIA

Recebo 5 mg 1525 mg
Sig 10-5 tab po
3 p.k. pr. pr.
Pr. #60

BNDD: [Redacted]
DN: [Redacted]

Se permite sustituir producto genérico. SI ☒ No ☐

Favor rotular. Repetase: 1 ☐ 2 ☐ 3 ☐ pr. ☒

I certify that the pharmacist indicated one of the possibilities to exchange the medicine(s) prescribe in this prescription, according to Law No. 11 June 29, 1976, as amended.

Exchange accepted ☒ No ☐

Pharm. Signature: [Redacted] Date: [Redacted]

Pharmacist Stamp: [Redacted]

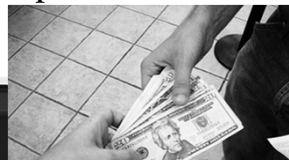
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Provider Fraud Schemes

- Billing for branded / dispensing compounded
- Dispensing of CS with no licensed pharmacist present
- Purchase and selling of Drug Samples
- Unlicensed wholesale distribution
- Remunerations to patients in return for prescriptions
- Medications billed to plan but not dispensed



Purchasing/Selling of Samples





Billing Branded/Dispensing Compounded



Unlicensed wholesale distribution





Federal Criminal Fraud and Abuse Laws

- Health Care Fraud, 18 USC 1347
- Conspiracy to Commit Health Care Fraud, 18 USC 1349
- Health Care False Statements, 18 USC 1035
- Anti-Kickback, 42 USC 1320a-7b(b)
- False Claims, 18 USC 287
- Theft or Embezzlement in Connection with Health Care, 18 USC 669



Federal Criminal Fraud and Abuse Laws (Cont.)

- False Statements, 18 USC 1001
- Mail Fraud, 18 USC 1341
- Wire Fraud, 18 USC 1343
- Obstruction of Health Care Criminal Investigations, 18 USC 1518
- Destruction, Alteration, or Falsification of Records in Federal Investigations, 18 USC 1519
- Basic Money Laundering Provision, 18 USC 1956, & Spending Statute, 18 USC 1957





Aggravated Identity Theft

Title 18 United States Code 1028A

“Whoever, during and in relation to any felony violation enumerated in subsection (c), knowingly transfers, possesses, or uses, without lawful authority, a means of identification of another person shall, in addition to the punishment provided for such felony, be sentenced to a term of imprisonment of 2 years”



How to help?

- Identify trends/patterns
- Copies of Rx (even if not filled)
- Time is essential...
- Maintain Videos
- Signature Logs
- Employee orientation
- Double check with referring Md
- Keep a record of activities
- Report appropriate parties





Consequences of Fraud



Criminal

1. Incarceration
 - a) prison (up to 10 years)
 - b) probation
2. Fines/restitution
 - a) based on severity of offense
 - b) asset seizure or forfeiture
3. Exclusion from health care plan
4. Loss of license

Civil

1. Settlement agreement
2. Pay up to 3 times the amount of damages
3. Pay \$5500 to \$11,000 for each fraudulent claim or up to \$50,000 for anti-kickback violations
4. Corporate integrity agreement



Exclusions from Federal Health Care Programs

- No federal health care program payment may be made for any items or services (1) furnished by an excluded individual or entity, or (2) directed or prescribed by an excluded physician.
- Mandatory Exclusion: Felony conviction relating to health care fraud
- Civil Monetary Penalties (CMP) of \$10,000 for each item or service furnished during the period of exclusion and/or treble damages for the amount claimed for each item or service.
- In order to avoid CMP, OIG urges to check the OIG List of Excluded Individuals/Entities
- OIG Provider Self Disclosure Protocol





Questions?

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