**Pharmacy Compliance**

**HCCA Compliance Institute**  
**April 2, 2014**

Don Bell  
Senior VP & General Counsel, National Ass’n of Chain Drug Stores  
Daniel Fitzgerald  
Senior Attorney, Pharmacy Law Department, Walgreens Co.  
Selina Coleman  
Senior Associate, Norton Rose Fulbright

---

**Audience**

- Hospital
- Retail
- Institutional
- PBM / Pharmacy Benefit Manager
  - Interplay with your company or institution

---

**Historical 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
Heightened Enforcement

- Federal False Claims Act strengthened by Affordable Care Act
- States must update their own false claims act laws to reflect federal changes
- Likely to expand liability for providers and opportunities for whistleblowers

Controlled Substance Compliance

- CDC: abuse of Rx pain meds is a “growing epidemic”
- Rx drugs are second only to cannabis as the drugs most abused by 12th graders
- 12 million admitted using Rx pain meds for nonmedical reasons in 2010 alone
- 15,000 die each year from Rx pain med overdoses
  - More than heroin and cocaine combined
- Emergency room visits for abuse doubled in 5 years
- 300% increase opioid sales since 1999
  - 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

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

Patient Red Flags

• Has insurance but pays cash
• Seeks early refills
• “Doctor shopping”: Patient gets Rxs from multiple doctors
• Travels long distance to doctor or pharmacy
• Has Rxs for several drugs that treat same condition
• Uses “street names” for drugs or requests specific brand
  • “Xanies” – “purple drank” – “blues”
• Group arrives at pharmacy with similar Rxs from same doctor
• Customers from same address have similar Rxs from same doctor
• “Runner” submits Rx for someone else
• Exhibits “drugged” behavior
Prescriber Red Flags

- Prescribes “drug cocktail”
  - Oxycodone, hydrocodone, alprazolam, etc.
- Prescribes large number or % of controlled substances
  - Compared with other prescribers
- Writes multiple Rxs for large quantities and large doses
  - Especially if may cause medical complications
- Prescribes depressants and stimulants for same patient
- Lack of individualized dosing
  - Pattern of prescribing same dose of same drug to different patients
- Drug not consistent with doctor’s practice
  - Fentanyl prescribed by dentist
- State board or law enforcement are investigating doctor
- No DEA registration

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”
- Rx does not use acceptable standard abbreviations or “appear to be textbook presentations”
- Quantities, directions or doses differ from usual practices
- Rx appears to be photocopied
- Rx written in different color inks or different handwriting
- Apparent erasure marks

Pharmacist Red Flags

- Dispenses refills too early
- Fails to question and counsel patients
- Fails to follow documentation requirements
- Located to close to pain clinic … or too far away
- Relies solely on prescriber’s assurance that Rx is legit
- Fails to contact other pharmacists to inquire why they refused to fill Rx
- Dispenses excessive volume of controlled substances
- “Suspicious Order” Monitoring:
  - DEA requires wholesalers and manufacturers to implement systems to identify and report suspicious orders
  - Recently some pharmacies have been “cut-off” by wholesalers
Recent DEA Enforcement Actions

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

Compliance Strategies

- Know Your Patients & Prescribers
  - Check state databases (PDMPs)
  - 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

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)

OIG: Medicaid Part D

- OIG report on retail pharmacies on Part D billing (May 2012)
  - Pressure on prescription drug plans to audit
  - OIG found that about 4% of retail pharmacies had questionable billing practices on identified measures
  - OIG determined that independent pharmacies were 8x more likely than chains to have questionable billing

Hot Topics for Enforcement

- Credit balances
- 340B programs
  - Contract pharmacies services
  - “Eligible patients” of the covered entity
- Pharmacy-related provisions of CIAs
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
  - E.g., use of incorrect NPI on submitted claims
- Medicaid payment holds and referral to state Medicaid Fraud Control Units (State AG’s)

Potential Inducements: Prescription Transfers

- Retail pharmacies often offer gift cards / checks for prescription transfers
- Government (DOJ, OIG, State AG’s) are investigating whether these are improper inducements
  - Walgreens settled investigation in April 2012
  - S.D. Illinois denied a motion to dismiss and a summary judgment motion in a qui tam lawsuit against Sears Holdings Corp. / Kmart Corp. alleging that they gave Medicare and Medicaid beneficiaries gift cards in exchange for filling prescriptions in their pharmacies; matter settled in November 2013

Potential Inducements: Gifts & Pricing

- Retail “gifts” provided to customers in the pharmacy setting
- Other retailers may have discount “pricing” on select medications
- Retail pharmacy may “match price”
  - At point of service, based on customer request or complaint
  - During “patient responsibility” time of year
Potential Inducements: Other Rewards

- OIG advisory opinions on rewards, including pharmacy
  - 12-05 (May 2012)
  - 12-14 (October 2012)
- Would not sanction. No remuneration because:
  - rewards are coupons, rebates, or other retailer rewards;
  - rewards are offered or transferred on equal terms to the general public, regardless of health insurance status; and
  - the offer or transfer of the rewards is not tied to the provision of other items or services reimbursed in whole or in part by the Medicare or Medicaid programs

Prescriber Exclusion

- OIG bulletin on best practices related to excluded individuals (May 8, 2013)
  - No CMP liability if federal health care programs do not pay, directly or indirectly, for items or services, and if these were furnished only to non-federal beneficiaries
  - 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 (discussed later)

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
Usual & Customary Pricing and Prescription Discount Card Programs

- Many states define the U&C charge as the price charged to the general public.
- Who is the “general public”? Excludes those customers who pay the membership fee.
- Examples of other state definitions:
  - Lowest price charged to any segment of general public
  - Lowest price charged to any payer
  - Specific references to prescription drug programs

Overpayments: Grounds for Liability

- Overpayments become “obligations” 60 days after they are “identified.”
- FCA and CMP have similar grounds for liability for retaining overpayments:
  - FCA: Obligations cannot be knowingly and improperly retained (31 USC § 3729(a)(1)(G) and (b)(3)).
  - CMP: Cannot be knowingly retained (42 USC § 1320a-7a(a)(10)).
- Even after a provider discloses and repays an overpayment, a provider can still be liable for retaining the overpayment for more than 60 days after identifying it.

When Could You Have Overpayments?

- Overpayments may result from:
  - Payment when benefits have been exhausted, or during a period of non-entitlement;
  - Incorrect calculation of deductible or coinsurance;
  - Payment for noncovered or medically unnecessary items and services;
  - Duplicate charges or duplicate claims;
  - Payments tainted by kickbacks;
  - Incorrectly coded services; and
  - Primary payment in violation of Medicare-as-secondary-payer rules.
When Does the 60-Day Clock Start?

- Proposed rule: Acting with actual knowledge of, in deliberate ignorance of, or with reckless disregard to the overpayment’s existence
  - Unclear when a provider’s ignorance becomes “deliberate,” or when disregard becomes “reckless” – but failing to conduct an inquiry would trigger this standard
  - 60-day clock does not start running until an investigation identifies an actual overpayment
  - Conduct inquiry “with all deliberate speed”

How Do You Review the Claims?

- Do you return what you’ve found, or broaden the focus of the review? On what basis?
  - Review a sample, or do a 100% review?
    - Most overpayment refund forms require a description of the methodology; consider involving someone with statistical expertise
    - Sampling may be more likely to be challenged (may need to “prove up” the methodology)
  - Will need to follow OIG’s guidance on sampling if submitting self-disclosure

The Look-Back Period

How Far Back Do You Look?

- Proposed 10-year look-back period for overpayments
- Troubling because:
  - Medicare recoupment is generally limited to 3-4 years after notice of payment (See Medicare Financial Management Manual, ch. 3 § 80)
  - False Claims Act’s statute of limitations is 6-10 years. (See 31 U.S.C. § 3731(b))
  - Note that federal courts have concluded that the FCA’s 6-year statute of limitations does not apply because the U.S. is “at war” with Iraq and Afghanistan
    - United States v. BNP Paribas, SA, Case No. 11-3718 (S.D. Tex. 2012)
**Disclosing Overpayments**

- Many overpayment refund forms allow the refund reason of “Other”
  - Generally not intended for violations of civil laws (vs. correcting the date of service or other billing errors)
- Providers can use the OIG Self-Disclosure Protocol to resolve matters relating to fraud or violations of law
  - Revised on April 17, 2013
  - Would toll 60-day deadline to return obligations
  - Standard 1.5 multiplier of single damages
  - Guidance on reporting interactions with excluded individuals and kickback violations
  - Note that OIG will coordinate with DOJ
- ACA created a protocol for Stark-only violations

---

**Key Takeaways on Disclosing Overpayments**

- Whether a provider extrapolates from a sample, reviews 100% of all relevant claims, or broadens its inquiry to include other Medicare claims depends on the circumstances
- But all work to identify and quantify the overpayment refund should be as defensible and as airtight as possible
- Could need to look back 10 years based on the proposed rule
  - CMS’s SRDP contemplates a 4-year lookback
  - OIG’s SDP contemplates a 6-year lookback
- No matter how the overpayment is disclosed and repaid, you lose control of the disclosure when you submit it

---

**Questions?**

Don Bell
- dbell@NACDS.org

Daniel Fitzgerald
- dan.fitzgerald@walgreens.com

Selina Coleman
- selina.coleman@nortonrosefulbright.com