Compliance Risks & Hot Topics in Pharmacy Law

HCCA Compliance Institute
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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
Enforcement Landscape

- General Enforcement / Scrutiny
  - Heightened levels of scrutiny and obligations
  - Government auditing of claims for reimbursement
  - Duty to return overpayments from federal payers
- “New Frontiers” for Whistleblowers
  - Record number of *qui tams*, including challenges to:
    - Gifts, coupons, and other potential inducements
    - Loyalty programs, price matching, and U&C pricing

Oversight - Many Watchful Eyes

- DOJ
- Commercial Payors
- CMS
- MICs
- Personal Injury Litigants
- HHS
- Competitors
- State
- Medicaid
- Press
- Congress
- OIG
- State AGs/Medicaid Fraud Control Units
- Whistle-blowers
- State Legislatures
- Relators’ Attorneys
- RACs
- ZPICs
- MA Plans
- Part D Plans
- DEA
- State Pharmacy Boards
- Health Care Provider

OIG Report: Medicare Part D

- OIG report (June 2015): retail pharmacies’ Part D billing
- Found about 2% of retail pharmacies had questionable billing practices
- Determined that independent pharmacies were more likely than chains to have questionable billing
- Focused on commonly abused opioids: Part D spending has grown 156% in the last 9 years; $3.9 billion in 2014
OIG Report: Medicare Part D

- OIG report shows increased scrutiny on geographic hotspots:
  - Los Angeles, California
  - McAllen, Texas
  - San Juan, Puerto Rico
  - Miami, Florida
  - New York City, New York
- Metro areas where average Medicare payments per beneficiary for certain drugs are higher than national averages
- OIG recommended expanding utilization review programs to include drugs susceptible to fraud, waste, and abuse

OIG 2016 Workplan

- Review of pharmacy enrollment in Part D
- CMS inability to oversee enrolled pharmacies
- Review of data submitted by select retail pharmacies with questionable billing

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
- Potential areas for review:
  - Incorrect diagnosis codes
  - Failure to sufficiently document counseling
  - Failure to use tamper-resistant prescription pads
Possible Consequences of Errors with Prescription Claims

- Recoupment of Reimbursement
  - Pressure on prescription drug plans to audit
- Violation of payer 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)
- Overpayment liability, including FCA liability for improper retention of overpayments

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
  - S.D. Illinois denied motion to dismiss / summary judgment in a qui tam against Sears Holdings Corp. / Kmart Corp. alleging that they gave Medicare and Medicaid beneficiaries gift cards in exchange for filling prescriptions; settled in November 2013

Potential Inducements: Prescription Transfers

- Kmart Corp. (September 2015)
  - $1.4 million to resolve allegations that it violated the FCA by using drug manufacturer coupons and gasoline discounts as improper Medicare beneficiary inducement
- Rite Aid Corp. (December 2014)
  - $2.99 million to resolve allegations that it violated the FCA by inappropriately using gift cards as inducements to federal beneficiaries to transfer their prescriptions to Rite Aid pharmacies
- Walgreens Co. (April 2012)
  - $7.9 million to resolve allegations that it violated the FCA by inappropriately using gift cards as inducements to federal beneficiaries to transfer their prescriptions to Walgreens pharmacies, including by allegedly violating company policy
Potential Inducements:

**Manufacturer Coupons**

- OIG Special Advisory Bulletin & report (Sept 2014):
  - Found that drug manufacturers may have permitted millions of Medicare Part D members to access copay coupons that could be viewed as improper kickbacks.
  - OIG places primary responsibility on drug manufacturers for ensuring that Part D members do not redeem copay coupons, but pharmacies that accept coupons could also be held liable under the AKS and the CMP Law.
  - Potential government enforcement or whistleblower lawsuits based on heightened awareness of this issue.

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.

Potential Inducements:

**Other Rewards**

- Physician Pharmacy Alliance, Inc. (May 2015)
  - $5 million to settle claims that, under prior ownership, the company gave improper gift cards to induce referrals or enrollments of Medicare and Medicaid patients, and routinely waived copayments of Medicare and Medicaid patients.

- Carmel v. CVS Caremark Corp.
  - Jurisdictionally barred by the FCA's public-disclosure rule based on:
    - CVS’s advertisements stated that customers, including Medicare and Medicaid beneficiaries, could receive cash discounts for buying prescriptions / services.
    - Relator lacked first-hand knowledge of certifications or safeguards, meaning that he was not an original source of the allegations.
**Proposed AKS Safe Harbors**

- 2014 proposed rule would codify ACA / MMA changes
- New proposed safe harbors would cover:
  - pharmacy cost-sharing waivers for Medicare Part D beneficiaries with financial need
  - cost-sharing waivers for emergency ambulance services provided by state or municipal-owned organizations
  - manufacturer discounts for drugs available through the Medicare Coverage Gap Discount Program
  - certain interactions between Medicare Advantage plans and federally qualified health centers

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**Expanded Approach to CMP Protection**

- Would codify ACA’s “retailer rewards” exception:
  - Key definitions proposed (e.g., who’s a retailer?)
  - Need an “attenuation” between federally payable items and services and a loyalty program’s rewards.
  - Earning or redeeming the reward could not require the purchase of goods or services reimbursed by federal program
  - Prescription transfers vs. coupon for general store spending
  - More relaxed approach to “tying,” but will require close analysis

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**Pharmacy Relationships with Drug Manufacturers**

- OIG advisory opinions:
  - 14-05 (July 28, 2014): **Favorable opinion** on program that would allow patients to purchase the manufacturer’s brand-name products for a fixed cash price from an online retail pharmacy vendor
  - 14-06 (August 15, 2014): **Unfavorable opinion** on a specialty pharmacy’s proposal to pay local retail pharmacies a fee for support services they provide in connection with patient referrals to the specialty pharmacy
### Prescriber & Employee 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
  - Resolve through OIG’s self-disclosure protocol

### Usual & Customary Pricing and Prescription Discount Card Programs

- Retail pharmacies often offer prescription discount card programs
- Members pay an enrollment fee to 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
Usual & Customary Pricing and Prescription Discount Card Programs

• Settlements
  • Texas ex rel. Schutte v. HEB Grocery Co.
    • February 2014
    • $12 million
    • September 2010
    • $21 million

• United States ex rel. Garbe v. Kmart Corp.
  • Court found that members of Kmart’s generic discount programs were part of the “general public” because anyone is eligible to join the program; aspects of decision have been appealed to the Seventh Circuit
  • United States ex rel. Doe v. Houchens Indus., Inc.
    • Before settlement, the district court denied a motion to dismiss based on analysis in the Garbe case

• Are commercial payers next?
  • Corcoran et al. v. CVS Health Corporation
  • Podgorny & Cauley v. CVS Health Corporation
    • Alleging that discount program pricing should have been passed on as the U&C price reported to private payers, causing insured customers to pay higher copayments for generic prescription drugs than cash-paying customers
Usual & Customary Pricing and Prescription Discount Card Programs

- Compliance considerations
  - Eligibility & requirements for loyalty programs (e.g., receipt of marketing, payment of enrollment fee)
  - Eligibility for gift cards & coupons
  - Marketing of all promotional programs
  - Mechanisms to track compliance

Overpayments: Grounds for Liability

- New overpayment rule for Parts A & B in February 2016; guidance on Part D payments in May 2014
- Overpayments become “obligations” 60 days after they are “identified”
- Up to six months of “reasonable diligence” before the 60-day clock starts ticking
- Even after a provider 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;
  - Duplicate charges or duplicate claims;
  - Payments tainted by kickbacks;
  - Incorrectly coded services; and
  - Payments violating Medicare-as-secondary-payer rules
Refunding Overpayments

- Six-year lookback
- 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
  - Would toll 60-day deadline to return obligations
  - Standard 1.5 multiplier of single damages
  - Guidance on reporting interactions with excluded individuals; kickbacks
  - Note that OIG will coordinate with DOJ
- CMS disclosure 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 depends on the circumstances
- All work to identify and quantify the overpayment refund should be defensible and as airtight as possible
- Need to look back full period of 6 years, even if audit report / identified issues are more limited
- An organization’s monitoring systems need to be on the lookout for the overpayments the government might later deem to have been foreseeable

Questions?

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