

Hot Topics in Retail Pharmacy Compliance

2019 Healthcare Enforcement Compliance Conference

November 5, 2019

Daniel Fitzgerald

Commercial Litigation Department, Walgreen Co.

Selina Coleman

Reed Smith LLP

1

Agenda

- I. Pharmacy Enforcement Landscape
- II. Pharmacy Enforcement Risks
- III. The Effect of *Escobar* on False Claims Act Cases in the Retail Pharmacy Environment

2

I. Pharmacy Enforcement Landscape

3

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
 - High number of qui tam cases, including challenges to:
 - Gifts, coupons, and other potential inducements
 - Club programs and price matches affecting U&C prices
- ◆ Consumer Class-Action Lawsuits
 - Effects of club programs on U&C pricing reported to commercial payers

4

State Medicaid Audits

- 
- A map of the United States is shown with text overlays. The text is organized into three bullet points, each with sub-bullets. The first bullet point is 'Each state has its own audit process, which gives:' followed by three sub-bullets: 'Authority to request records to justify payments', 'Ability to recoup overpayments', and 'Afford appeal rights to challenge state findings'. The second bullet point is 'States are taking action as a result of:' followed by two sub-bullets: 'State budget pressures' and 'Increased federal requirements'. The third bullet point is 'Potential areas for review:' followed by three sub-bullets: 'Incorrect diagnosis codes', 'Failure to sufficiently document counseling', and 'Failure to use tamper-resistant prescription pads'.
- Each state has its own audit process, which gives:
 - Authority to request records to justify payments
 - Ability to recoup overpayments
 - Afford appeal rights to challenge state findings
 - States are taking action as a result of:
 - State budget pressures
 - Increased federal requirements
 - Potential areas for review:
 - Incorrect diagnosis codes
 - Failure to sufficiently document counseling
 - Failure to use tamper-resistant prescription pads

5

Active OIG Work Plan Items: Pharmacy

- ♦ Opioids
 - Prescription opioid drug abuse and misuse prevention
 - FDA oversight of risk evaluation and mitigation strategies
 - Concerns about high Medicare Part D spending on opioids
- ♦ Proper Billing
 - Documentation of pharmacies' Prescription Drug Event data
 - Are claims adequately supported by documentation?
 - Additional reviews of pharmacies with questionable billing
 - Invalid prescriber identifiers
 - Payments after patient death
- ♦ Compounded drugs
 - Substantial growth in Part D spending on compounded drugs

6

Legislative and Administrative Priorities

- ♦ Trump Administration's focus on lowering drug prices and increasing transparency in pricing
 - *American Patients First: The Trump Administration Blueprint to Lower Drug Prices and Reduce Out-of-Pocket Costs*, May 2018
 - **Banning** in Medicare Part D contracts “**gag clauses**” that prevent pharmacies from telling customers their copay is more than the total cost of the drug and that they could pay less by not using insurance
 - “Know the Lowest Price Act,” signed into law October 10, 2018
 - Prohibits “gag clauses” in any contracts
 - *Executive Order on Improving Price and Quality Transparency in American Healthcare to Put Patients First*, June 24, 2019
 - Seeking to provide access to information about out-of-pocket costs
 - Increased access to cost data so patients can make informed decisions

7

II. Pharmacy Enforcement Risks

8

Pharmacy Enforcement Risks

- Billing Errors & Overpayments
- Improper Patient Referrals
- Usual & Customary Pricing

9

9

Billing Errors & Overpayments

10

Common Causes of Pharmacy Billing Errors

- ◆ Prescription Billing Errors Including:
 - Incorrect information submitted on the claim
 - Failing to reverse claims for services not provided
 - Failing to have adequate documentation to support claim (prior authorization, physician orders, purchasing records)
 - Double billing / coordination of benefits

11

Examples of Prescription Billing Errors

- ◆ Target (December 2018)
 - \$3 million to resolve allegations that it improperly billed Massachusetts' state Medicaid program by automatically refilling prescriptions that were not explicitly requested by a MassHealth patient or caregiver, in violation of state regulations
 - Massachusetts' Attorney General had previously settled similar allegations with PharmaHealth, Neighborhood Diabetes, and AllCare Pharmacy
- ◆ Nashville Pharmacy (January 2016)
 - \$7.8 million to resolve billing errors, including automatically refilling medication against contractual requirements, billing for medications after the date of the beneficiary's death, and billing for prescriptions from unlicensed prescribers
- ◆ Rhine Drug Company (June 2017)
 - \$2.2 million to resolve allegations that it violated the FCA by billing for medication not provided and failing to follow Controlled Substance Act requirements; resulted in a Corporate Integrity Agreement with the OIG

12

Examples of Prescription Billing Errors

- ◆ Omnicare (January 2017)
 - \$8 million to resolve allegations that it submitted false claims to Medicare and Medicaid programs by billing for incorrect NDC codes, causing it to submit claims for different generic drugs than dispensed
- ◆ Med-Fast (October 2017)
 - \$2.7 million to resolve allegations that it improperly billed for recycled medication and failed to credit government health care programs for medication that was returned or not delivered to patients; resulted in a Corporate Integrity Agreement with OIG

13

Consequences of Billing Errors

- ◆ As noted in the OIG Workplan, an area of focus for 2018 includes review of pharmacy Prescription Drug Event data for billing accuracy
 - **Recoupment of Reimbursement**
 - Likely to increase as Prescription Drug Plan face more pressure to audit
 - Self disclosure if identified internally
 - **Overpayment Liability**
 - Medicare / Medicaid: Failure to report and return overpayments within 60 days could result in FCA violations / penalties
 - Commercial: Overpayments may violate a pharmacy's contractual obligations to the payor, which can result in allegations of fraud, legal action, or contract termination
 - **Qui Tam Relators** – Relators may identify billing mistakes and bring cases
 - **M&A Complications** – Proposed transactions may be delayed, cancelled, or face significant price concessions
 - **Monitorships** – Settlements may require CIA with HHS-OIG

14

Improper Patient Referrals

15

Improper Patient Referrals

- ◆ The Anti-Kickback Statute and Civil Monetary Penalties Law prohibit the referral of patients in exchange for anything of value to healthcare providers
- ◆ Could support False Claims Act lawsuits, including treble damages and per-claim penalties
- ◆ OIG has warned pharmacies about directly linking payments to patient referrals
- ◆ Pharmacies are scrutinized by the government and whistleblowers for improper patient referrals

16

Examples of Potentially Improper Patient Referrals

Patient Kickbacks

- ◆ Manufacturer Copay Coupons
- ◆ Pharmacy Marketing Programs
 - Discount / Reward Programs

Third Party Kickbacks

- ◆ Marketing Companies
- ◆ Physicians
- ◆ Relationships with Manufacturers

17

17

Examples of Alleged Improper Patient Referrals

- ◆ Florida Pharmacy Solutions (Owner/employee convicted in Sept. 2017)
 - Alleged to have provided a marketing firm over \$12 million dollars to steer TRICARE beneficiaries to the pharmacy resulting in over \$30 million in TRICARE reimbursement in 6 months (up from about \$4 million annually)
 - Many similar cases have been pursued in Florida against compounding pharmacies
- ◆ NY Pharmacy Inc. (Owner and companies pled guilty in Feb. 2019)
 - Alleged to have provided kickbacks to patients to fill their HIV prescriptions and then used an auto-refill program to continue to bill for those prescriptions, even when the medication was not delivered
 - Sentenced on March 15, 2019 to 2-6 years in state prison and forfeiture of over \$3.6 million

18

Examples of Alleged Improper Patient Referrals

- ◆ Rxpress Pharmacy and Xpress Compounding (Owners/marketers indicted in Dec. 2018)
 - Texas pharmacies alleged to have provided individual marketers over \$9 million dollars to refer TRICARE and DOL beneficiaries to the pharmacies for expensive compound drugs resulting in approximately \$92 million in compound drug claims to TRICARE and DOL over the course of about two and a half years

19

Key AKS Safe-Harbors and CMP Exceptions

- ◆ December 2016: OIG published a Final Rule amending the AKS Safe Harbors and the exceptions to the CMP rule; can impact pharmacies:
 - AKS Safe-Harbors
 - Pharmacy cost-sharing waivers for Medicare Part D beneficiaries with financial need
 - Manufacturer discounts for drugs available through the Medicare Coverage Gap Discount Program
 - CMP Exceptions
 - Certain remuneration that poses a low risk of harm and promotes access to care
 - Retailer rewards
 - Remuneration to financially needy individuals
 - Copayment waivers for the first fill of generic drugs

20

“Retailer Rewards” Exception

1. A “**retailer**”... (defined term)
2. May offer “**coupons, rebates, or other rewards**”
3. To government program beneficiaries...
4. If offered on “**equal terms**” to the “**general public**” regardless of health insurance status... and
5. Not “**tied**” to the provision of other covered items or services (*no sole / preferential accumulation based on purchases of federally reimbursable items, such as prescription transfers*)
No corresponding protection under Anti-Kickback Statute

21

Expanded Approach to CMP Protection

- ◆ Codified ACA’s “retailer rewards” exception:
 - Key definitions provided: e.g., limitations of who is a “retailer,” and broad scope of “other rewards”
 - No sole or preferential accumulation of rewards based only on purchases of federally reimbursable items (impermissibly “tied”)
 - Prescription transfers vs. coupon for general store spending, including redemption as copayment
 - More relaxed approach to “tying,” but will require close analysis to ensure compliance

22

Pharmacy Marketing – Rewards Programs

- ◆ Many pharmacies have implemented programs offering patients discounts or rewards
- ◆ Highest risk programs have included gift cards for patients to transfer prescriptions
- ◆ Historically, these programs have excluded government beneficiaries and claims paid by government health care programs. But under the new Final Rule, depending on the structure of the program, these exclusions may no longer be necessary
- ◆ **OIG Advisory Opinion No. 17-05** (September 7, 2017)
 - Ruled that a retail pharmacy's Benefit Program satisfied the requirements of the exception to the definition of remuneration related to retailer rewards for the purposes of the Beneficiary Inducement CMP and had low risk of fraud and abuse under AKS
 - Discounts only available on out-of-pocket services
 - Program applied to a broad range of products and services (not just pharmacy)
 - Rebates could not be used to purchase prescription drugs
 - Doesn't offer any extra bonus or other reward for transferring prescriptions, nor offer greater rewards for dollars spent on copays than on general grocery items

23

Manufacturer Copay Coupons

- ◆ Drug manufacturers offer copay coupons to reduce patients' costs and encourage purchase of specific items (often for brand drugs)
- ◆ Federal anti-kickback statute prohibits pharmacies from accepting copay coupons on claims paid by federal health care programs
 - Often difficult to identify federal program beneficiaries
- ◆ **OIG Advisory Opinion No. 16-07** from June 2016 allowed for coupons be offered to Medicare Part D beneficiaries
 - Claims could not be billed to Medicare Part D if coupon used
 - Additional responsibility on pharmacies that accept coupons

24

Usual & Customary Pricing

25

Usual & Customary Allegations

- ◆ Retail pharmacies have made available discount programs, such as membership-based programs or price matching upon request
- ◆ Plaintiffs have brought two types of lawsuits alleging improper U&C submissions against retail pharmacies
 - *Qui tams*: alleged overbilling of government payers
 - Consumer class actions: alleged overbilling of commercial payers
 - Claim that prices of membership clubs or price matches should be charged as usual & customary prices to federal and commercial payers

26

Setting the Stage: *U.S. ex rel. Garbe v. Kmart*

- Overview
 - Whistleblower alleged that Kmart misrepresented its U&C prices of generic prescriptions to government payers, violated FCA
 - e.g., whistleblower claimed Kmart charged a customer \$5 for a 30-day supply of Simvastatin via Kmart's prescription club program, but billed Medicare for "U&C price" of \$152.97
 - Government declined to intervene
- Outcome
 - 7th Circuit upheld argument that "general public" included customers who were members of Kmart's prescription club program
 - Kmart settled the case for \$59M in December 2017

27

Recent Case Trends and Developments

- U&C allegations have extended beyond retail pharmacies to implicate PBMs
 - Arbitrations between plans and PBMs
- Courts have recently issued rulings regarding U&C allegations
 - *Corcoran et al. v. CVS Pharmacy*
 - *Schutte v. Supervalu, Inc. et al.*
 - *Omlansky v. Walgreen Co.*

28

Corcoran et al. v. CVS Pharmacy

- Overview
 - Class alleged that CVS misrepresented its U&C prices of generic prescriptions to commercial payers, caused inflated cost sharing
 - Class consisted of insured customers who did not receive discounted prices available to CVS's prescription club program members
- Outcome
 - 9th Circuit reversed district court's grant of summary judgment to CVS, which had been based on declarations issued by key PBMs who confirmed prescription club programs did not affect U&C submissions
 - Case has been remanded for further proceedings

29

Schutte v. Supervalu, Inc. et al.

- Overview
 - Whistleblower allege that Supervalu misrepresented their U&C prices to government payers by reporting their retail prices, rather than competitor prices honored upon customer request, as their U&C prices
 - Government declined to intervene
- Outcome
 - District court issued opinion granting partial summary judgment to whistleblower, found based on *Garbe* that price matches affected Supervalu's U&C submissions to Medicare Part D and Medicaid
 - Pending request to certify for interlocutory appeal to 7th Circuit

30

Omlansky v. Walgreen Co.

- Overview
 - Whistleblower alleged that Walgreens misrepresented its U&C prices of prescriptions to Medi-Cal, violated California's false claims act
- Outcome
 - Trial court dismissed the case twice
 - Claims precluded based on injunction prohibiting enforcement of California's U&C provisions
 - Lack of federal approval for California's U&C provisions additional grounds for dismissal
 - Appeal dismissed

31

III. The Effect of *Escobar* on False Claims Act Cases in the Retail Pharmacy Environment

32

Recent FCA Cases Involving Retail Pharmacies

- ~~In December 2017, Davita Rx entered into an FCA settlement with the DOJ for **\$63.7 million** to resolve allegations of fraudulent billing for prescriptions that were never shipped, that were shipped but later returned, or that did not have proper documentation~~
- ◆ In May 2018, the owners of I&L Express Pharmacy in Philadelphia agreed to pay **\$3.2 million** to resolve allegations that they billed Medicare for prescriptions that were never dispensed
- ◆ DOJ is using the False Claims Act to combat the opioid crisis as well by filing actions alleging violations of the Controlled Substances Act and FCA against pharmacies that submit claims for allegedly illegitimate prescriptions

33

Supreme Court's landmark decision in *Escobar*

34

Supreme Court's Decision in *Escobar*

- Supreme Court clarified the FCA's **materiality** standard in *United Health Services v. U.S. ex rel. Escobar* in June 2016
 - Fraud Enforcement and Recovery Act of 2009 (FERA) had defined "material" as "having a natural tendency to influence, or being capable of influencing, the payment or receipt of money"
 - Supreme Court said that:
 - Materiality standard is "rigorous" and "demanding"
 - Question is not if the government **could** have declined payment had it known of the misrepresentation, but rather **would** the government have declined payment
 - Look at what the government does in the "mine run" of cases to make that determination

35

~~"Moreover, if the **Government pays a particular claim in full** despite its **actual knowledge** that certain requirements were violated, that is very **strong evidence** that those requirements are **not material**"~~

- Justice Thomas,
delivering the opinion for a unanimous Court

36

Key Interpretations of *Escobar*

37

***United States ex rel. Spay v. CVS Caremark* (3d Cir. 2017)**

- CVS Caremark discovered that its claim submissions to CMS for thousands of prescriptions triggered errors involving prescription IDs, and CVS Caremark created “dummy IDs” for the affected prescriptions to facilitate processing
 - Court affirmed District Court’s summary judgment decision that the dummy IDs were not material because CMS continued payment of the pharmacy claims in full despite actual knowledge that the dummy IDs were in use
 - Court also noted that the case’s circumstances were “precisely the situation” alluded to in *Escobar*

38

D'Agostino v. ev3, Inc. (1st Cir. 2016)

- ~~Court found that the alleged fraudulent misrepresentation to FDA was not material to the agency that made the payment – CMS – because CMS continued to reimburse use of the device in the wake of Relator's allegations~~
- Plus, no action from the FDA:
 - Court noted that in the six years since the fraud allegations, “the FDA has apparently demanded neither recall nor relabeling . . . notwithstanding the agency's option to impose postapproval requirements . . . its clear prerogative to suspend approval temporarily, . . . and its broad authority to withdraw approval”

39

Petratos v. Genentech (3d Cir. 2017)

- ~~Court found in favor of defendant on materiality grounds because relator had disclosed evidence to the FDA and DOJ~~
 - ◆ FDA not only continued its approval of Avastin, but also it added more approved indications for the drug and did not initiate proceedings to enforce its adverse-event reporting rules, or require the defendant to change its drug's label
- Court noted that DOJ's decision not to intervene and fact that DOJ had taken no action in six years helped to show that any violations were not material under *Escobar*

40

Practical Implications for the Pharmacy Industry

41

Practical Implications for the Pharmacy Industry

- May consider potential disclosure actions in ambiguous billing scenarios
 - ~~Disclosure to the government agency in charge of payment with detailed information about the action may defeat a later FCA action if:~~
 - The government continues to pay claims because **materiality** would not be present
 - The government affirmatively agrees that the pharmacy's actions are in line with statutory or regulatory guidelines because **falsity** would not be present
 - This disclosure could be used as later evidence of pharmacy's **scienter**

42

Practical Implications for the Pharmacy Industry

- If the pharmacy finds itself involved in FCA litigation, discovery from the government becomes crucial to obtain evidence to defeat **materiality**
 - If the government has intervened in the matter, traditional discovery through requests for production, interrogatories, 30(b)(6) depositions, and requests for admission should be considered
 - If the government declines to intervene in the matter, third-party discovery through Rule 45 subpoenas should be considered
 - Need to comply with agencies' *Touhy* regulations
 - Be prepared for the government to raise volume or limited government resources

43

Thank you!

44