

**DECIPHERING THE COMPLIANCE
PRESCRIPTION -
Understanding RETAIL Pharmacy
Compliance & Enforcement Risks**

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Today's Presentation

- ◎ Regulators' Expectations for Compliance Programs
- ◎ DOJ/OIG Focus on Management and Board
 - Criminal Prosecution:
 - Company/Management
 - Board and Compliance role to avoid prosecution
 - Exclusion from Federal Programs:
 - Company/Management
 - Civil Liability
 - How to Deal with the Era of the Whistleblower
- ◎ Retail Pharmacy Compliance Risks
 - Anti-Kickback and False Claim
 - DEA/Drug Diversion
 - Other

Regulators' Expectations for Compliance Programs

1. Policies and Procedures re: compliance expectations, program, and problems
2. Compliance Officer and Compliance Committee
3. Training and Education
4. Communication
5. Discipline
6. Auditing and Monitoring/Risk Area Identification
7. Reporting and Response
8. Non-Retaliation

Regulators' Expectations – Well-Resourced and Proactive Compliance Programs

- ◎ Compliance resources should be commensurate with size/risk profile of company
- ◎ Be out in front of the risks:
 - Compliance work plans
 - Risk assessments
 - Monitor enforcement activity/OIG & Medicaid work plans
 - Compare best practices
- ◎ Proactive Auditing:
 - Test and monitor risk areas
 - Audit programs
- ◎ Robust compliance program decreases risk/severity of civil/criminal enforcement:
 - Both for company and individuals
- ◎ Board committee reporting and oversight

Regulators' Expectations – Management

- Establish compliance “tone from the top”
- Ingrain compliance into the “fabric” of the organization
- Set business goals that are achievable in a compliant manner
- Ensure that employees can report concerns free from fear of retaliation
- Provide sufficient resources to be both proactive and reactive
- Investigation followed by verified remediation
- Consistent and firm discipline

Regulators' Expectations – Questions to Consider

◎Operational Questions:

- Has the organization implemented policies and procedures that address compliance risk areas?
- Is management setting the appropriate tone?
- Is compliance embedded into operations?
- Is the importance of the Code of Conduct understood across the organization?
- Do employees feel free to raise compliance related concerns?
- Has management developed a system that establishes accountability for proper implementation of the compliance program?
- What is the scope and breadth of compliance related training?



CRIMINAL PROSECUTIONS

A Range of Risks

Criminal Penalties - Federal

◎ DOJ Targeting Management:

- **Health Care Fraud (18 USC § 1347)**
 - Up to 10 years imprisonment
- **False Statements (42 USC § 1320a-7b(a) / 18 U.S.C. § 1001)**
 - § 1320a - Up to 5 years imprisonment
 - § 1001 - Up to 5 years imprisonment
- **Anti-Kickback Act (42 USC § 1320a-7b(b))**
 - Up to 5 years imprisonment
- **False Claims (18 USC § 287)**
 - Up to 5 years imprisonment

◎ Corporate Criminal Liability:

- Fines up to twice the gross gain or loss caused by offense

A Range of Risks

Criminal Penalties - State

▣ New York State Example (Aggressive AG and OMIG):

- **Health Care Fraud (PL § 177) -**
 - Up to 8 1/3 to 25 years imprisonment

- **False Written Statements (PL § 175) -**
 - Up to 1 1/3 to 4 years imprisonment

- **Insurance Fraud (PL § 176) - intentional filing of false insurance claims**
 - Up to 8 1/3 to 25 years imprisonment

- **Grand Larceny (PL § 155) - intentional and fraudulent deprivation of property**
 - Up to 8 1/3 to 25 years imprisonment



EXCLUSION FROM PARTICIPATION IN GOVERNMENT PROGRAMS

A Range of Risks: Exclusion

- ▣ No payment will be made by health care program for items or services furnished or ordered by an excluded individual or entity
- ▣ Federal Exclusion (42 USC § 1320a-7):
 - Grounds for exclusion include:
 - ▣ Convictions related to health care or controlled substances
 - ▣ License revocation or suspension
 - ▣ Claims for excessive charges/unnecessary services
 - ▣ Fraud, kickbacks, other prohibited activities
 - ▣ Entities controlled by a sanctioned individual
 - ▣ HEAL loan default
 - Federal exclusion = mandatory state exclusion
- ▣ State Exclusion (e.g. 18 NYCRR § 515.5)
- ▣ New Focus on Excluding Owners/Managers – not just pharmacists/techs



CIVIL LIABILITY

A Range of Risks: Civil Liability

▣ Civil False Claims:

- FCA - originally signed into law by President Lincoln in 1863 to protect against fraud in government contracting during the Civil War
- Covers knowing submission of false or fraudulent claims for payment to federal agencies, contractors or grantees
- Numerous states also have False Claims Acts
- Damages and \$5,500 to \$11,000 per claim penalties

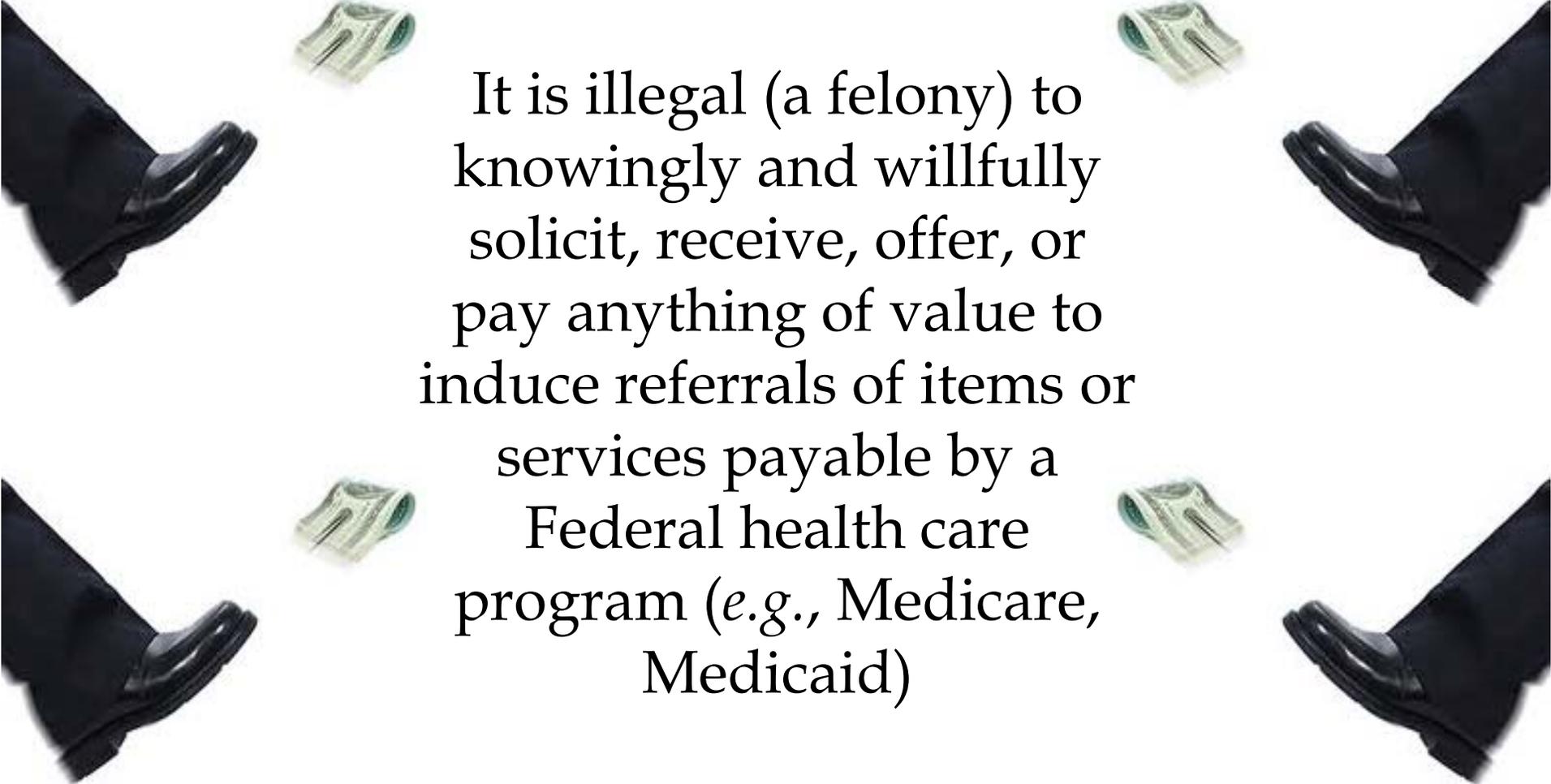
▣ Civil Monetary Penalties:

- For false claims/violations of AKS
- For knowingly employing an excluded person
- Varying penalties: \$10,000 for false claim/\$50,000 for each kickback violation

Key Features of the False Claims Act

- ▣ Redresses fraud involving federal (state) government programs, including Part D
- ▣ Potential for enormous damages and penalties
- ▣ Duty to report and refund identified Medicare and Medicaid overpayments within 60 days; failure to do so may create “reverse false claim” liability

Criminal/Civil Liability – Anti-Kickback Statute



It is illegal (a felony) to knowingly and willfully solicit, receive, offer, or pay anything of value to induce referrals of items or services payable by a Federal health care program (*e.g.*, Medicare, Medicaid)



ENFORCEMENT LANDSCAPE

Dealing With Whistleblowers

- □ Understand and act on the unique risks posed by “whistleblower” complaints
 - How do managers identify whistleblowers?
 - How protect confidential company information?
- □ Treat “whistleblower” complaints differently
 - Not as an HR problem, but as a legal problem
 - Use the privilege
- Conduct thorough and timely internal investigations
 - Be respectful of the “whistleblower”
 - Take and document corrective action
 - Thoroughly document all employment decisions
 - Be proactive with “whistleblower’s” counsel

Enforcement Landscape

- ▣ FCA recoveries since 1986 are over \$33 billion
 - Most from the healthcare industry
- ▣ For FY 2012, \$4.959 billion was recovered, of which vast majority was from healthcare industry
 - 650 new qui tam cases filed in 2012 – a new record
- ▣ Nine and Ten Figure Settlements Not Uncommon
 - Huge amount of federal and state \$\$ in healthcare

Examples of Recoveries in Health Care Fraud Cases

- GSK - \$3 Billion
- Pfizer - \$2.3 Billion
- Abbott Labs - \$1.5 Billion
- Eli Lilly - \$1.4 Billion
- Merck - \$950 Million
- Amgen - \$762 Million
- Serono - \$704 Million
- Purdue-Pharma - \$601 Million
- Allergen - \$600 Million
- Bristol Meyers Squibb - \$515 Million
- Senior Care Action Network - \$324 Million
- Actavis - \$203 Million
- Medco - \$185 Million
- Caremark - \$161 Million

Pharmacy- Related False Claims Act Settlements

- 2002 - \$5.8 Million (billing for services not provided)
- 2004 - \$2.8 Million (billing for services not provided)
- 2004 - \$7 Million (billing for services not provided)
- 2008 - \$37 Million (unauthorized drug substitution)
- 2008 - \$35 Million (unauthorized drug substitution)
- 2012 - \$5.25 Million (false price marketing)
- 2012 - \$7.9 Million (improper customer incentives)
- 2013 - \$17.5 Million (overbilling Medicaid after first collecting from primary payer)
- 2011-13 - increasingly larger fines in DEA diversion matters



RETAIL PHARMACY COMPLIANCE RISKS

Compliance Risks

- Government Customers at the Pharmacy Counter:
 - Medicaid
 - Includes Medicaid HMOs
 - Medicare
 - Includes Part D Plan Sponsors; MA Plans; Part B Diabetic Supplies
 - TRICARE
 - FEHBP
 - Government Secondary Payors
- CS Security/Controls Against Diversion
- HIPAA Privacy
- Compounding/Repackaging
- Returns to Stock/Disposal of Returns

Retail Pharmacy Compliance Risks – Some Examples

- ⊙ Accuracy in Billing
- ⊙ Obtaining and Maintaining Compliant Prescription Records
- ⊙ Customer Incentive Programs – Beneficiary Inducements
- ⊙ Patient Compliance Outreach Programs - Implications for AKS
- ⊙ Referral source relationships (e.g., LTC or first fill pharmacy and nursing home/hospice)
- ⊙ Partial Fills/Will Call Delete
- ⊙ Impact of Discounting on Usual and Customary Pricing
- ⊙ Kickbacks for Drug Switching
- ⊙ REMs
- ⊙ Pseudoephedrine/Smurfing
- ⊙ Medication Disposal/Returns
- ⊙ DEA/Controlled Substances

Retail Pharmacy Compliance Risks – Some Examples (cont.)

- ◎ Auto-Refill Programs and delivery
- ◎ Employment of Excluded Pharmacists/Techs
- ◎ Relationships with Distributors/Manufacturers
 - purchase arrangements/discounts/rebates
 - reverse purchases for data from retail pharmacies
- ◎ Compliance with Multitude of Potentially Applicable State Laws – insurance laws, pharmacy board regs, etc.

DEA and Controlled Substances

- ▣ Know Your Customer/Physician
- ▣ Adequate Controls Against Diversion
- ▣ Medical Necessity
- ▣ Adequate and Accurate Record Keeping
- ▣ Manufacturers/Distributors
 - Adequate controls against diversion
 - Reporting suspicious orders
 - Customer due diligence

Retail Pharmacy Compliance

Risks – NY OMIG Pharmacy Audit Experience

© OMIG sought to recoup payments/threatened fraud actions for:

- Missing Prescriptions
- Conflicts in records between Ordering Prescriber and Claim Prescriber
- Prescriptions missing information such as signature, date, quantity
- Prescriptions/Fiscal Orders refilled beyond 180 days of issuance
- Billing for quantities in excess of prescribed quantity
- Filling too far beyond date of issuance (for controlled and non-controlled substances)
- Billing for product different than product ordered
- Billing for different strength ordered
- Prescriptions missing supervising MD information, when ordered by a Physician's Assistant
- Prescriptions not written on an Official NYS Prescription Form

Other Pharmacy Audit Activity

- ◎ Diabetic supplies/strips and documentation
- ◎ State Medicaid Programs spend a lot on Prescription Drugs and audit activity is increasing:
 - Medicaid requirements
 - drug utilization review (prospective and retrospective)
- ◎ Part D versus hospice

Retail Pharmacy Compliance Risks - Customer Incentive Programs

- ⊙ Customer Incentive Programs: giveaways, points, transfer offers, gift cards, co-pay waivers and other promotions
- ⊙ Implications for:
 - Federal Anti-Kickback Statute and Beneficiary Inducement Law
 - State Anti-Kickback Laws
 - Medicaid; State Health Plans; All Insurers/Payers
- ⊙ Considerations:
 - Special Advisory Bulletin “Offering Gifts and Other Inducements to Beneficiaries” (Aug. 2002) (\$10 Individually/\$50 in aggregate annually)
 - Affordable Care Act’s CMP carve out for:
 - Coupons/rebates/other rewards from retailer
 - offered on equal terms to general public regardless of insurance
 - not tied to items/services reimbursed by Medicare/Medicaid

Retail Pharmacy Compliance Risks - Customer Incentive Programs (cont.)

◎ Need to Look at State Law:

- Examples of States with All Payors or Insurers
Anti-kickback Laws: CA, Conn, Idaho, La, Mass,
Mich, NV, N.J.

Retail Pharmacy Compliance Risks – Arrangements with Referral Sources

- ◎ Retail medical clinics co-located:
 - Prescribing physicians and NPs
- ◎ Implications for:
 - Stark Anti-Physician Self-Referral Law
 - Anti-Kickback Act
 - Civil Monetary Penalties
 - False Claims Act
- ◎ Concurrent Exclusion Screening of Prescribers and Medicare Part D

Retail Pharmacy Compliance Risks - Automatic Refill Programs

- ▣ Such Programs Are Lawful When Properly Implemented
- ▣ Customer notifications and consents
 - Obtained and adequately documented?
 - Medicare and auto-delivery programs
- ▣ Consider Whether There Are Any Potential State Law Restrictions

Retail Pharmacy Compliance Risks - Discount Programs Potentially Affecting U & C

▣ **Requires Examination of Individual State Laws:**

- States define U&C differently

▣ **Recent Enforcement Action:**

- False Claims Whistleblower case
- Massachusetts U&C Municipality Workers
- Compensation Settlements
- Connecticut AG Actions

HIPAA/HITECH

- ◎ Robust systems required
- ◎ Robust training
- ◎ HHS OCR and penalties
 - Pharmacies are by no means immune
 - Almost every customer and payor transaction will contain PHI

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