Setting the Stage.
On January 24, 2011, the U.S. Department of Health and Human Services (HHS) announced that the government’s health care fraud prevention and enforcement efforts recovered more than $4 billion in taxpayer dollars in fiscal year (FY) 2010 (FY 10). This is the highest annual amount ever recovered.
• In FY 10, the total number of cities with Strike Force prosecution teams was increased to seven. Enforcements in all seven cities during FY 10 included:
  – 140 indictments involving charges filed against 284 defendants who collectively billed the Medicare program more than $590 million;
  – 217 guilty pleas negotiated and 19 jury trials litigated, obtaining guilty verdicts against 23 defendants; and
  – Imprisonment for 146 defendants during FY 10, averaging more than 40 months of incarceration.

• Federal prosecutors opened 1,116 criminal health care fraud investigations as of the end of FY 10, and filed criminal charges in 488 cases involving 931 defendants. A total of 726 defendants were convicted for health care fraud-related crimes during the year.

• 2010 was also a record year for recoveries obtained in civil health care matters brought under the False Claims Act – more than $2.5 billion, which is the largest recovery in the history of the Department of Justice (DOJ).
The Health Care Fraud and Abuse Control Program (HCFAC), a joint effort of HHS and DOJ, with the assistance of the Health Care Fraud Prevention & Enforcement Action Team (HEAT), coordinated federal, State, and local law enforcement activities to fight health care fraud and abuse. Its annual report can be found at oig.hhs.gov/publications/hcfac.asp.

It’s all about money.

Our Ambitious Agenda

- **Health Reform Law**
  - 32 provisions plus new rules first announced on January 24, 2011, target fraud, waste, and abuse in Medicare, Medicaid, and the Children’s Health Insurance Program (CHIP)

- **Increased Requirements and Enforcement**
  - False claims, kickbacks, audits, exclusions, etc.

- **How Pharmacies and Facilities Can Prepare**
  - Compliance programs, training, audit preparation, etc.

- **Questions and Comments Throughout**

- **Horror Stories**
  - Real pharmacy examples
Background: A History of Growing Enforcement

Rapid Expansion of Enforcement

- **2003:** Medicare Modernization Act
  - More audits by government and Medicare Part D plans
- **2006:** Deficit Reduction Act
  - Major funding for enforcement jobs, data mining
- **2009:** Fraud Statute and Rules
  - Easier fraud convictions, training requirements
- **2010:** Health Reform Law (the Affordable Care Act)
Record Enforcement Growth

• 2009 Federal Health Care Enforcement
  – Over $3 billion recovered by HCFAC alone
  – 4,492 under criminal investigation
  – 2,041 under civil investigation
  – 2,556 excluded from Medicare and Medicaid

• 2010 A Record Year
  – OIG reports $3 billion recovered in 1st half of FY 10
  – 1,935 excluded in 1st half of FY 10

Why Is Enforcement Increasing?

1. More Health Spending
2. Deficit Pressure - federal and State
3. Enforcement is Profitable!
   – 600% return on investment
   – Bounty hunters find free money
4. Horror Stories
New Audits, Screening and Payment Controls
New Funding For Enforcement

• The Patient Protection and Affordable Care Act (PPACA) Adds $350 Million Over 10 Years
  – New investigators, contractors, and programs

• Many Agencies Involved
  – Office of Inspector General (OIG)
  – Centers for Medicare & Medicaid Services (CMS)
  – U.S. Department of Justice (DOJ)
  – Federal Bureau of Investigation (FBI)
  – Drug Enforcement Administration (DEA) - DEA’s statement of policy regarding “authorized agents” in communicating controlled substance prescriptions
  – Medicaid Fraud Control Units (MFCUs)
  – Attorneys General
  – New CMS Center For Program Integrity

• Programs Sprouting Like Weeds
  – HCFAC, HEAT, SMP, Medi-Medi Data Match, NCCI, ZPICs, DME Stop Gap, CERT, PERM, MSFS, RACs, MIPS
Expanded Federal Audits

• Greater Access To Pharmacy Records
  – New Medicare rule says CMS can “audit, evaluate and inspect any books, contracts, records [or] documentation” of pharmacies
  – Medicare plans must make available “any books, contracts, records and documentation” from pharmacies
    ➢ Check new network contracts

• More Data Mining By OIG And DOJ
  – New “Integrated Data Repository” with all payment claims data from Medicare, Medicaid, CHIP, VA, etc.

• Greater OIG Subpoena Power
  – OIG can subpoena information from providers, manufacturers, plans, etc.
    ➢ Even if target did not submit claim
  – Access to any documents needed to validate claims

More Federal Contractor Audits

• Recovery Audit Contractors (RACs)
  – Expanded to Medicare Parts C and D
  – Bounty hunters paid based on how much they recoup
    ➢ RACs use extrapolation audits
  – RACs will review Part D plan compliance programs
    ➢ Including review of pharmacy claims

• Part D Audits by MEDICs
  – Additional funding for Medicare fraud investigations
Increased State Audits

- **States Must Hire RACs for Medicaid Audits**
  - PPACA requires by end of 2010
- **Aggressive New York OMIG Audits**
  - Paying HHS by collecting from providers
- **Florida Seeks CMS Waiver For Data Mining**
  - Review all Medicaid data without probable cause
- **Many States Increasing Investigations**
  - Pressure from budget deficits and Medicaid growth

More Medicare Drug Plan Audits

- **Plans Must Implement New Fraud Programs**
  - Expect additional requirements in network contracts
- **CMS Guide Says Plans Should . . .**
  - Review “prescriptions, invoices, pharmacy licenses, claim transaction records, signature logs, purchase records”
  - Review “rebate, discount, and all other relevant agreements”
  - Verify that pharmacies “are in compliance with the minimum standards [of] pharmacy practice as established by the States”
  - Interview pharmacy staff “to gauge whether applicable Part D requirements are being followed”
Increased Screening

- **Rigorous Screening in Medicare, Medicaid, and CHIP**
  - For new and current providers and suppliers
  - Background checks, licensure reviews, fingerprinting, database searches, unannounced inspections, etc.
  - More rigorous for “high risk” categories
    - CMS proposed rule lists new Medicare DME suppliers
    - States will decide if pharmacies are “high,” “medium” or “low” risk Medicaid providers
- **CMS and States Can Temporarily Halt Enrollment**
  - For specific locations or types of providers/suppliers
  - Proposed rule: Will halt if identify fraud “trend”

More Payment Controls

- **Mandatory NPI Use**
  - In Medicare and Medicaid claims and applications
- **Prepayment Review and Payment Caps**
  - Up to one year for new providers and suppliers
- **May Suspend DME Supplier Payments**
  - If significant risk of fraud by type of supplier or geographic area
- **Must Submit Medicare Claims Within 12 Months**
- **Prescription Filling Requirements – Seven Days – Why?**
Increased Transparency

• Part D Plans and Pharmacy Benefits Managers (PBM) Must Report to CMS:
  – Generic dispensing rates and number of prescriptions
    ➢ Report for mail order vs. community pharmacies
  – Amounts and types of rebates and discounts
  – Difference between plan’s payments to PBM and PBM’s payments to pharmacies

• Manufacturer Disclosures to HHS:
  – Reporting on drug samples and physician benefits
  – 340B pricing information (plus new audits, fines, etc.)
  – Expanded audits of Part D “donut hole” discounts
    ➢ Fined 125% of any discounts manufacturer fails to provide

OIG 2010 Work Plan – LTCF and Pharmacies

OIG 2010 Work Plan (Cont.)

• Use of Antipsychotic Drugs in Nursing Homes

OIG Work Plan (Cont.)

• Health Care Fraud
  – Billing fraud
  – Failure of care
  – Manipulation of payment codes
OIG Compendium of Unimplemented Recommendations

- Medicare Part D Drugs
  - Examining whether pharmacies disclose drug rebates to physicians

New False Claims Standards
Federal False Claims Act

• The False Claims Act Prohibits Knowingly:
  – Presenting false claim for payment to government
  – Making or using false record or statement to get claim paid by government
  – Conspiring to get false claim paid by government
  – Using false record to avoid obligation to pay government

• “Knowingly” Means:
  – Actual knowledge . . . or deliberate ignorance . . . or reckless disregard for the truth
  – Specific intent to defraud is not required

False Claims Examples

• Submit Claim for Drugs Not Dispensed
  – Forged, altered, or “purchased” prescriptions

• Double Billing
  – Multiple claims to payor(s) for same prescription

• “Shorting” or Partial Fill
  – Partially fill but charge for full prescription
  – No arrangements for remainder of prescription
  – If not filled, may need to reverse part of claim

• Dispense Generic, Bill For Brand
  – Pharmacist writes “dispense as written” on prescription

• Returned Drugs Issues
Stronger False Claims Penalties

- **20-50% Longer Prison Terms**
  - Stronger sentencing guidelines with new offense “multipliers” for health fraud over $1 million

- **Larger Fines**
  - $50,000 plus six times actual damages for some fraud
  - For each prescription?

- **Reimbursement Suspension**
  - Easier to halt Medicare and Medicaid payments during fraud investigations
  - HHS and States can halt reimbursement if “credible allegation of fraud”

New Liability for Indirect Claims

- **2008: Supreme Court Decision**
  - Held False Claims Act applies only if defendant submits false claim directly to government
  - Pharmacies ask Part D plans to pay, not government

- **2009: Fraud Enforcement and Recovery Act**
  - False Claims Act liability even if claim not directly submitted to government
  - Submitting false claim to Part D plan may violate False Claims Act
Increased Liability For Overpayments

- **2009: Fraud Enforcement and Recovery Act**
  - Knowingly keeping overpayment by Medicare or Medicaid violates False Claims Act
  - Even if defendant never submitted a false claim

- **2010: Health Reform Law (PPACA)**
  - Must return overpayment within 60 days of discovery
    - Must also “explain in writing the reason for the overpayment”
  - Penalties if fail to repay: $10,000 fine for each overpayment plus three times actual damages

- **Required settlement agreement and possible corporate integrity agreement**

False Claims Act – *Qui Tam* Lawsuits

- **Whistleblower Lawsuits**
  - Employee or private citizen sues on behalf of government
  - Plaintiff can receive 30% of the total award
    - Remainder goes to the government

- **Whistleblower Protections**
  - Employers may not retaliate against employees who report or help investigate false claims
    - Fired, demoted, suspends, harassed, etc.
  - Remedies against retaliation include job reinstatement with double back pay and other “special” damages
Whistleblower Lawsuits Made Easier

• **PPACA Allows Easier Whistleblower Suits**
  – Relaxes “public disclosure” and “original source” rules
  – Basic law remains:
    ➢ Lawsuit based on publicly disclosed information may be dismissed unless whistleblower is the original source of the information

• **Old Law Had Broader Limits on Lawsuits**
  – Public disclosure could occur in State proceedings
  – Whistleblower needed “direct and independent” knowledge of information to be original source

• **New Public Disclosure Rule**
  – Disclosure in State proceedings not “public disclosure”
    ➢ Dismiss only if disclosure in federal investigations, audits, reports, hearings, etc., or by news media
  – Dismiss lawsuit only if whistleblower’s information is “substantially the same” as publicly disclosed information

• **New Original Source Rule**
  – Whistleblower is “original source” if:
    ➢ Disclosed information to government prior to public disclosure, OR
    ➢ Has independent knowledge of information that “materially adds” to publicly disclosed information (and told government prior to lawsuit)

• **No Dismissal if “Opposed by the Government”**
State False Claims Acts

- **States Have Their Own False Claims Acts**
  - Many track the federal law but apply to false claims made in State programs
  - Most States includes *qui tam* provisions and whistleblower protections

- **States Are Strengthening False Claims Acts**
  - Federal law gives more Medicaid money to States that enact stronger false claims statutes
  - Illinois and New York enacted revisions last year
  - See www.taf.org for statutes
New Anti-Kickback And Health Crime Standards

Anti-Kickback Laws

- **Federal Law**
  - It is a crime to “knowingly and willfully”...
  - Offer, pay, solicit or receive any “remuneration”...
  - To induce or reward “referrals” of patients or residents...
  - Who receive items or services covered by government program

- **Many Similar State Laws**

- **Dozens of Complicated “Safe Harbors”**
  - Personal services contracts based on fair market value of time, not volume or value or referrals
  - Must have written agreement(s) with pharmacy – why?

- **Penalties include $50,000 Fine, Exclusion, Prison**
Kickback Examples

- **Pharmacy Referrals**
  - Pharmacy pays physician for each referred patient or resident
  - Pharmacy pays patient or resident for submitting prescriptions

- **Marketing for Medicare Part D Plans**
  - Pharmacist paid to “steer” patient or resident to plan

- **Some Drug “Switching” Programs**
  - Manufacturer pays pharmacist to discuss drug with patient or resident
  - Could be kickback if payment based on success in switching to manufacturer’s product

- **Incorrectly Structured Drug Rebate Programs**

Kickbacks Cause False Claims

- **PPACA Amends Anti-Kickback Statute**
  - Payment claims “resulting from” kickback violates False Claims Act

- **Impact**
  - Additional penalties for kickbacks
  - Impose False Claims Act liability on manufacturers and others who do not submit claims
    - If claims result from their kickback schemes
Criminal Liability For Kickbacks

- Less Proof of Intent Required for Convictions
- Prior Court Decisions:
  - No criminal liability unless defendant had actual knowledge of anti-kickback statute and specific intent to violate statute
- PPACA:
  - Legislatively overrules court decisions
  - Defendant need not know about or specifically intend to violate statute

Stronger Health Crimes Statute

- Definition of “Federal Health Care Offense” Expanded to Include:
  - Violation of anti-kickback statute
  - Misbranding or adulteration of drugs
  - Mail fraud, ERISA violations, etc.
- Impact
  - Expanded investigational powers: more subpoenas
  - Additional penalties: injunctions and forfeitures
Expanded Private Pay Fraud Liability

• **HIPAA Health Care Fraud Law**
  – Criminal penalties for “knowingly and willfully” defrauding any “Health Care Benefit Program”
  – Includes any public or private health plan

• **PPACA Expands Criminal Liability**
  – Defendant need not have actual knowledge of this law . . . or specific intent to violate the law

New Exclusion Standards
Program Exclusion

• Individuals and Companies can be Banned
  – Excluded from Medicare, Medicaid, other programs
  – Reasons for exclusion include:
    ➢ Violating fraud and abuse laws
    ➢ Licensing board actions (e.g., Board of Pharmacy revokes license)
    ➢ Controlled substances violations
    ➢ Default on federal student loans, other crimes, etc.

• OIG Posts Exclusion List
  – At http://oig.hhs.gov/fraud/exclusions.asp
    ➢ List updated regularly
  – GSA and States maintain separate lists

Employing Excluded Individuals

• Limit on Pharmacy Employment
  – OIG: Pharmacies cannot bill for “services performed by excluded pharmacists or other excluded individuals who input prescription information for pharmacy billing or who are involved in any way in filling prescriptions” in Medicaid or Medicare programs
  – Prohibition “extends to payment for administrative and management services not directly related to patient care, but that are a necessary component of providing items and services to federal program beneficiaries”

• Penalties
  – Recoup payments, treble damages and $10,000 fine “for each item or service”
Expanded Exclusion Authority

• **Additional Medicaid Exclusion**
  – State *must* exclude if excluded from Medicare or other State’s Medicaid program

• **Exclusion for Obstructing Audit**
  – Also fined $15,000 per day if fail to give OIG “timely” access during audit or investigation

Expanded Exclusion Authority (Cont.)

• **Exclusion for False Statements/Omissions**
  – In provider agreements or enrollment applications
    ➢ Even if no false claim for payment
  – Also $50,000 fine plus three times actual damages

• **Owner Exclusion from Medicaid**
  – Mandatory exclusion if own, control, manage or “affiliated with” excluded company
  – Ends settlement practice
New Compliance and Training Requirements

PPACA Mandatory Compliance Programs

• **Required For Medicare, Medicaid, and CHIP**
  – OIG rule will identify content for particular industries

• **OIG’s Seven Elements Of Compliance Programs**
  1. Written policies and procedures
  2. Compliance officer and committee
  3. Employee training and education
  4. Method to report problems confidentially
  5. Routine internal monitoring and auditing
  6. Promptly respond to problems with corrective action
  7. Enforcement through disciplinary standards
CMS Training Requirement

- **Confusing History of CMS Expectations**
  - 2006: CMS guide says Part D plans “should” require training for pharmacies
  - 2007: Rule mandates training for pharmacies beginning 2009
  - 2008-09: Series of conflicting CMS statements
    - Part D plans should establish training content
    - Pharmacies “should not develop their own training”
- **2010 CMS Rule Requires Annual Training**
  - OIG sent pharmacies questionnaires to evaluate training
- **But 2010 Rule Creates New Exception!**
  - Training not mandated by CMS if pharmacy is DMEPOS accredited or enrolled in Part B

Plan Training Requirements

- **Will Part D Plans Require Training Anyway?**
  - Requirement has appeared in network contracts
- **CMS Suggests Plans Should Mandate Training**
  - Medicare Guide says training should describe:
    - Fraud and abuse laws and rules
    - Examples of potential fraud and abuse
    - Obligations to have policies and procedures in place
    - Process for reporting suspected fraud
    - Protections for employees who report fraud and abuse
  - CMS recommends “specialized” training for pharmacists
  - Train upon hiring, “annually”, and when problems occur – who?
- **Problem: Potential for multiple training programs**
How You Can Prepare

Review CMS Guide

- **Medicare Fraud, Waste and Abuse Guidance**
  - www.cms.hhs.gov/PrescriptionDrug CovContra/Downloads/PDBManual_Chapter9_FWA.pdf
- **Applies to Part D Plans and Pharmacies**
  - Pharmacies referred to as "downstream entities"
- **70 Pages of Compliance “Requirements” and “Recommendations”**
  - Plans turn “recommendations” into “requirements” for pharmacies in network contracts
  - Many specific examples of pharmacy fraud and compliance
    - Gives good idea of which pharmacy compliance problems most interest CMS and, therefore, impact facility
Update Compliance Program

• Required Soon . . . If Not Already
  – Can revise program when OIG issues rules

• Can Help Avoid Liability
  – Shows OIG and courts you try to prevent fraud
  – Lack of effective compliance program could constitute “reckless disregard” under False Claims Act

Update Employee Handbooks

• Deficit Reduction Act Already Required “Education” of Employees
  – Employee handbook must include:
    ➢ “Detailed” description of False Claims Act
    ➢ Whistleblower protections
    ➢ Fraud and abuse policies

• Applies to Providers with $5+ Million in Medicaid Revenues
Provide Training

• Can be Good Idea Even if Exempt
  – Demonstrates commitment if government investigates
• Whose Training Program?

Complete Conflicts Policies

• CMS Medicare Guide
  – Part D Plans “should obtain certifications from [pharmacies] that these entities will require its managers, officers and directors responsible for the administration or delivery of Part D benefits to sign a conflict of interest statement, attestation, or certification . . . annually . . . certifying that the manager, officer or director is free from any conflict of interest in . . . delivering Part D benefits.”
  – Network contracts requiring pharmacies to certify
• Content?
  – What constitutes a conflict?
• Who are “Managers, Officers And Directors”?
Monitor Exclusions Lists

• CMS Guide Says Pharmacies Should Certify to Part D Plans:
  – That pharmacies “will review the . . . exclusions lists . . . annually . . . to ensure that any employee or manager responsible for administering or delivering Part D benefits is not excluded”
  – And certify that if a pharmacy employee “responsible for the administration or delivery of any Part D benefits is on such lists, that employee will immediately be removed from any work related directly or indirectly to all Federal health care programs”

• Review Legal Update on Exclusions
  – Includes model contract language for pharmacy employees and contractors

Prepare For Audits

• Know Audit Requirements
  – Rules, network contracts, provider manuals, record retention obligations, etc.

• Know Your Audit Rights
  – Extrapolation audit should use “statistically valid sample”
  – See In re Rite Aid of New York, Inc. ALJ decision
Horror Stories - time permitting


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