

Presentation to Second National Medicare Prescription Drug Congress

Marketing Part D Plans: Fraud and Abuse Concerns

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Fraud and Abuse Statutory Framework

Anti-Kickback Statute, 42 U.S.C. §1320a-7b(b), applies to transactions under Part D

Public Contracts Anti-Kickback Statute, 41 U.S.C. 52 applies to transactions under Part D

False Claims Act, 31 U.S.C. §§ 3729-3733

Civil Monetary Penalties, 42 U.S.C. § 1320a-7a

Stark, 42 U.S.C. § 1395nn et seq., which could apply to dealings with physicians

State Anti-Kickback and pharmacy practice anti-referral statutes apply to transactions under Part D to the extent they involve licensed entities within a state

Anti-Kickback Statute

It is a FELONY to:

- Knowingly and willfully
- Offer, solicit, pay or receive
- Any remuneration (of any type)
- Directly or indirectly
- In return for or to induce or arrange
 - A referral of any **Medicare** or Medicaid business or
 - **Buying, leasing, arranging or recommending any** service, **goods** or item paid for by **Medicare** or Medicaid
- “[T]he gravamen of Medicare Fraud is inducement.”
U.S. v. Bay State Ambulance and Hosp. Rental Serv., 874 F.2d 20 (1st Cir. 1989)



Anti-Kickback Statute (cont'd)

- Each criminal conviction can lead to:
 - Fine up to \$25,000
 - Imprisonment for up to 5 years
 - Exclusion from the Medicare program
 - Exclusions are mandatory or permissive
- *Civil Monetary Penalty* for violation of fraud and abuse prohibition
- State laws largely repeat violations
- All claims for reimbursement made while an illegal kickback arrangement exists may constitute false claims under the *False Claims Act*



Penalties – the two most frequent are:

Civil Monetary Penalties

- Treble damages + \$50,000 per violation + possible Medicare exclusion

False Claims Act Penalties

- \$11,000 fine + treble damages for *each* false claim filed
- Requires knowledge, but reckless disregard or deliberate ignorance will suffice
- *Qui tam* plaintiffs can bring action in name of U.S. and can receive up to 30% of recovery
- False claim and civil monetary penalty claims brought together whenever Medicare or Medicaid is involved

Part D Penalties – the new & additional possibilities

- Part D regulations provide for the following potential sanctions and civil money penalties:
 - Civil money penalties ranging from \$10,000 to \$100,000 depending upon the violation.
 - Suspension of enrollment of Medicare beneficiaries.
 - Suspension of payment to the Part D sponsor for Medicare beneficiaries who enroll.
 - Suspension of all Part D plan marketing activities to Medicare beneficiaries for the Part D plan subject to the intermediate sanctions.

Source: 42 CFR §§ 423.509(a), 423.750, 752, 758.

Nexus Between Part D Marketing & Fraud And Abuse

Statutory Nexus: Part D plan sponsors must comply with federal laws and regulations designed to prevent fraud, waste, and abuse, including the False Claims Act and the Anti-kickback statute. 42 CFR § 423.505(h).

Practical Nexus:

- Part D applies to broad spectrum of oral medications not previously covered by Medicare
- Part D introduces Federal health plan regulatory structure to full range of detailing, marketing, and CME activities (previously enforcement focused on limited Medicare Part B and Medicaid covered drugs)
- Almost everything you do is done “to arrange” for the purchase or sale of drugs reimbursable under Part D – a potential kickback
- Limited safe harbors (discounts, rebates) GPOs, service agreements, exist to protect some activities, but, government questions remain
 - Prebates
 - Some rebates
 - Formulary Fees
 - Marketing payments
 - “Compliance” and disease management

Cornucopia of Government Enforcement

Department of Health and Human Services

- Food and Drug Administration
- Office of the Inspector General

Department of Justice

- Each US Attorney has a Health Care Fraud Coordinator
- FBI
- Medicaid Fraud Control Units

Veterans Administration

U.S. Postal Service

- Plaintiff lawyers focus on deep pockets – Yours

State and local enforcement

- State Attorneys General

Every disgruntled employee especially sales reps, billing clerks, and finance – is a potential relator in a *qui tam* action



CMS' Specialized Efforts to Curb Fraud

- CMS is working with eight Medicare Rx Integrity Contractors (MEDICs) that will:
 - Analyze data to find trends that indicate fraud or abuse;
 - Investigate potential fraudulent activities surrounding enrollment, eligibility determination or distribution of the prescription drug benefit;
 - Investigate unusual activities that could be considered fraudulent as reported by CMS, contractors, or beneficiaries;
 - Conduct fraud complaint investigations; and
 - Develop and refer cases to the appropriate law enforcement agency as needed.



Enforcement Efforts To Date

- Recovery in FY2004 under the FCA \$667,782,529
- Recovery in FY2004 under the *qui tam* provisions of the FCA: \$554,626,506 (83% of FCA recovery)
- Recovery under the FCA since 1986:
> **\$13,500,000,000**

Source: Civil Division, U.S. Department of Justice

Perspectives on Fraud Potential

- Medicare prescription drug benefits allows for “**huge opportunities for fraud.**” (Jim Sheehan, Associate US Attorney – Philadelphia)
- The Medicare Part D benefit “is going to draw a **lot more scrutiny** just because of the sheer size of the benefit.” (Virginia Gibson, Assistant US Attorney – Philadelphia)
- “Within the Medicare and Medicaid programs, . . . prescription drugs are **especially vulnerable to fraud, waste, and abuse.**” (Daniel Levinson, Inspector General, HHS)
- Under the Part D benefit, “**every detailing activity** between sales representatives and physicians, as well as **every drug covered, is subject to federal [oversight]**” (Jim Sheehan, Associate US Attorney – Philadelphia)



Snapshot of Recent Settlements

- Serono Laboratories: \$704 million and criminal liability for conspiring to increase the market for Serostim by offering kickbacks to doctors and manipulating a test for AIDS patients (October 2005).
- GlaxoSmithKline: \$150 million to resolve allegations about fraudulent drug pricing and marketing of Zofran and Kytril (September 2005)
- Schering-Plough: \$345 million and criminal liability for fraudulent drug pricing. Schering Sales Corp. excluded from participating in all federal health care programs for at least 5 years (July 2004)
- Pfizer Inc., Warner-Lambert Company LLC, and the Parke-Davis Division: \$430 million global settlement a 5-year corporate integrity agreement between Pfizer and OIG for marketing Neurontin for off-label uses not approved by the FDA (2004).



Why Marketing Is So Important – The Size Of The Market

- CMS calculated annual drug spending of \$207 billion last year
- CMS projects annual drug spending of \$519 billion in 2013
- Drug spending will be 15.5% of total health expenditures in 2013



Source: Office of the Actuary, Centers for Medicare and Medicaid Services

Why Marketing Is So Important – Perceived Size Of 2003 Pharmaceutical Marketing Efforts

| <u>Drug Company</u> | <u>Research and Development*</u> | <u>Marketing/Selling, General and Administrative Expenditures*</u> |
|-----------------------|----------------------------------|--|
| Abbott | \$1.7 billion (9%) | \$5.1 billion (26%) |
| Bristol-Meyers Squibb | \$2.3 billion (11%) | \$6.1 billion** (29%) |
| GlaxoSmithKline | \$5 billion (13%) | \$13.6 billion (36%) |
| Merck | \$3.2 billion (14%) | \$6.4 billion (28%) |
| Pfizer | \$7.1 billion (16%) | \$15.2 billion (34%) |
| Roche | \$3.7 billion (15%) | \$7.8 billion (32%) |

*2003 costs and (percentage of sales)

** Included \$1.4 billion for “advertising and product promotion”

Source: amfAR (August 2004)

Anticipated Part D Marketing Efforts

- UnitedHealth, PacifiCare, Aetna and Cigna have reportedly budgeted a total of **more than \$200 million** for marketing and related operating expenses.
- Of the 42 million people eligible for Part D, many marketing programs are suspected to be aimed at only 13 million beneficiaries who currently have no drug insurance and whose incomes are too high for them to automatically receive the benefit.

Source: *New York Times* (October 3, 2005)

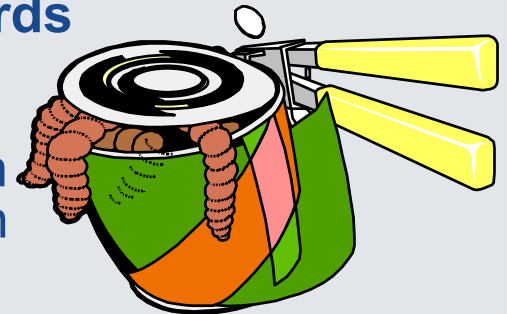
Areas of Potential Focus

- Newsletters to physicians
- Switching arrangements
- Patient file review programs
- Closed category fee
- Drug samples
- Providers as marketers (white coat marketing)
- Prebates
- Formulary fees
- Price manipulation
- Data Fees
- Consulting and advisory payments
- Price concessions to induce the purchase of drugs
- Disease management programs
- Other remuneration, including entertainment, recreation, travel, meals, sponsorship or other financing for educational conferences, including grants and scholarships, gifts and gratuities.



CMS Marketing Guidelines

- Issued August 15, 2005
- “Marketing” means: **Steering**, or attempting to steer, an undecided potential enrollee **towards a Plan**, or limited number of Plans, and for which the individual or entity performing marketing activities **expects compensation directly or indirectly** from the Plan for such marketing activities.
- “Assisting in enrollment” and “education” do not constitute marketing.
- Payment to an enrollee intended to influence selection of a particular provider is subject to a Civil Money Penalty (42 CFR § 1003.102(b)(13)).



Marketing Guidelines – Promotional Activities

General Rules for Promotional Activities

- Can not offer post-enrollment promotional items that compensate beneficiaries based on their utilization of services.
- Promotional activities or items must be:
 - Of nominal value (<\$15);
 - Offered to all eligible members without discrimination;
 - Not in the form of cash or other monetary rebates.



Provider Promotional Activities

All payments to providers must be:

- fair market value;
- consistent with an arm's length transaction;
- for bona fide and necessary services; and
- otherwise comply with all relevant laws and regulations, including the Federal and any state anti-kickback statute.

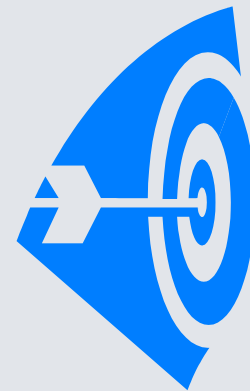
Key Rules for Provider Promotional Activities

Providers contracted with Plans (and their contractors) cannot:

- Direct, urge, or attempt to persuade, any prospective enrollee to enroll in a particular Plan
- Collect enrollment applications
- Offer inducements to persuade beneficiaries to enroll in a particular plan or organization
- Health screen when distributing information to patients, as health screening is a prohibited marketing activity.
- Offer anything of value to induce Plan enrollees to select them as their provider
- Expect compensation in consideration for the enrollment of a beneficiary
- Expect compensation directly or indirectly from the Plan for beneficiary enrollment activities.

Key Rules for Employee Promotional Activities

- Commission rate should not vary based on the value of the business generated
- Compensation must:
 - Avoid incentives to mislead beneficiaries, cherry pick certain beneficiaries, or churn beneficiaries between Plans.
 - Provide reasonable compensation in line with industry standards.
 - Not include payments by persons performing marketing to beneficiaries.
 - Withhold or withdraw payment if an enrollee disenrolls in an unreasonably short time frame (generally less than 60 days after enrollment)



Part D Marketing and HIPAA



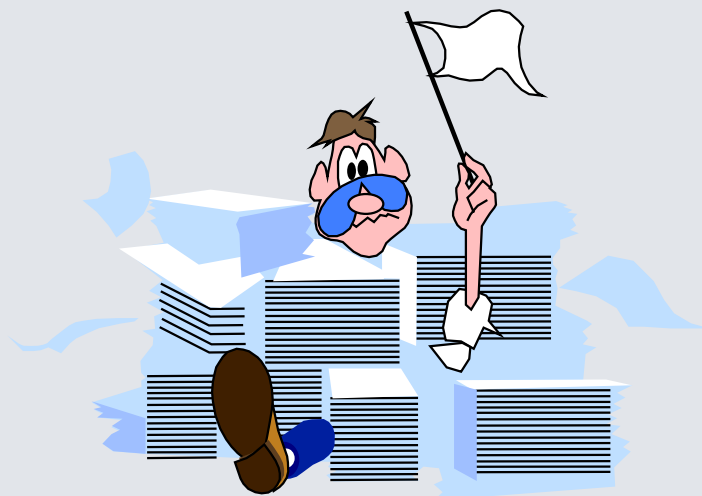
- Part D plan sponsors must comply with HIPAA Administration Simplification Rules. 42 CFR § 423.505(h).
- “Marketing” under HIPAA: a communication about a product or service that encourages recipients to purchase or use the product or service.
- Generally, if the communication is “marketing,” then it can occur only if an individual’s authorization is first obtained.
- An entity may not sell PHI to a business associate or any other third party for that party’s own purposes.
- Entities may not sell lists of patients or enrollees to third parties without obtaining authorization from each person on the list.
- Authorization is not required, even if it is marketing, if it is face-to-face by a covered entity to an individual; or a promotional gift of nominal value provided by the entity.
- *Without authorization, Part D plan sponsors can therefore only provide a nominal promotional gift or conduct face to face marketing if do not have individual’s authorization.*

Where You Can Find Guidance

- Office of the Inspector General (www.oig.hhs.gov)
 - Fraud Alerts
 - Advisory Opinions
 - Fraud Bulletins
 - Model Compliance Plans
 - Voluntary Disclosure Guidelines
 - Notice to Beneficiaries
 - Fraud Hot Lines
- Department of Justice (www.usdoj.gov)
- Food and Drug Administration (www.fda.gov)



Finally, they're done!

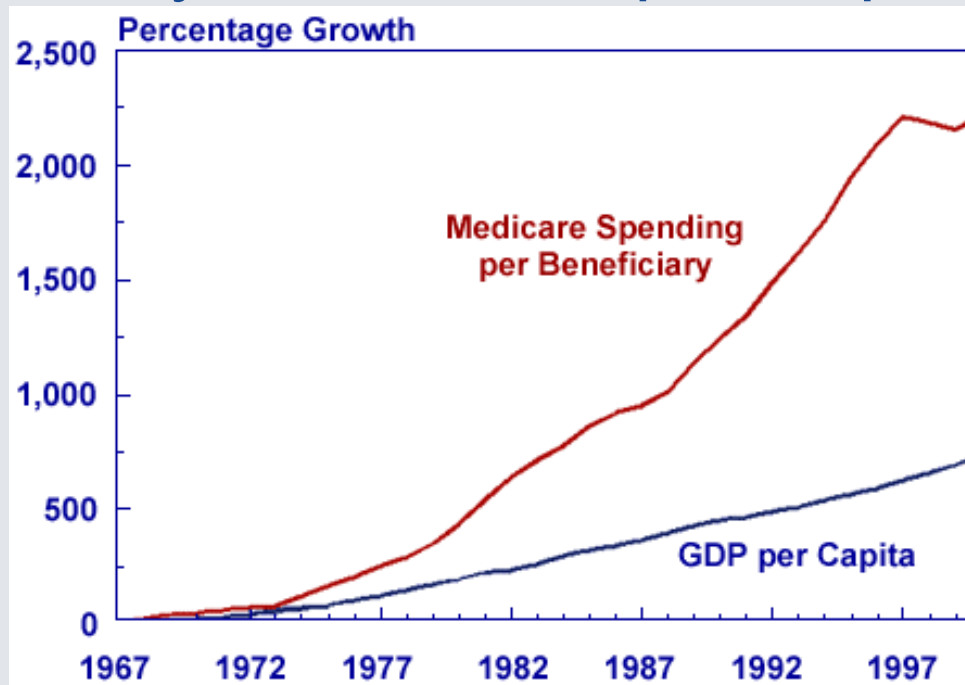


Questions?



Additional Slides

Growth Since 1967 in Medicare Spending per Beneficiary and in GDP per Capita



Source: Statement of Dan L. Crippen, Director, CBO, "Projections of Medicare and Prescription Drug Spending" before the Committee on Finance United States Senate (March 7, 2002)

CMPs for Offering Inducements to Beneficiaries

- Cannot offer **remuneration** to a beneficiary that you know, or should know, will **influence** the beneficiary's decision to **order or receive** items or services **from a particular provider, practitioner or supplier reimbursable by Medicare**.
- "Remuneration" does not include:
 - Waivers of coinsurance and deductible amounts that are:
 - not advertised or solicited,
 - not routine, and
 - are made either after a good faith, individualized determination of financial need or after reasonable collection efforts have failed;
 - Any waiver of coinsurance or deductible amounts made in accordance with a "safe harbor" to the anti-kickback statute;
 - Differentials in coinsurance and deductible amounts as part of a benefit plan
 - Incentives given to individuals to promote the delivery of preventive care.

Source: 42 CFR §1003.102(b)(13).

Plan Sponsor Reporting Requirements

Each Part D plan sponsor must annually report to CMS:

- A description of significant business transactions between the sponsor and a party in interest, including:
 - Indication that the costs of the transactions do not exceed the costs that would be incurred if the transactions were not with a party in interest
 - If they do exceed, a justification of the higher costs
- A combined financial statement for the sponsor and a party in interest if
 - $\geq 35\%$ of the plan sponsor's cost of operation go to a party in interest OR
 - $\geq 35\%$ of the a party in interest's revenue is from a plan sponsor

Source: 42 CFR 423.514

Reporting Requirements (cont'd)

Business transaction means:

- Sale, exchange, or lease of property.
- Loan of money or extension of credit.
- *Goods, services, or facilities furnished for a monetary consideration*, including management services, but not including—
 - *Salaries paid to employees*; or
 - Health services furnished to the Part D plan sponsor's enrollees by pharmacies and other providers, by Part D plan sponsor staff, medical groups, or independent practice associations, or by any combination of those entities.

Party in interest means:

- Any director, officer, partner, or employee responsible for a plan sponsor's management or administration.
- Any person who is directly or indirectly the beneficial owner of > 5% of the organization's equity (or his or her any spouse, child, or parent).
- In the case of a PDP sponsor organized as a nonprofit corporation, an incorporator or member of the corporation.
- Any entity in which a person specified in paragraphs (1), (2), or (3) of this definition—
 - (i) Is an officer, director, or partner; or
 - (ii) Has the kind of interest described in paragraphs (1), (2), or (3) of this definition.
- Any person that directly or indirectly controls, is controlled by, or is under common control with the Part D plan sponsor.

Source: 42 CFR 423.501

Current Part D Marketing Efforts

- Cigna Senior Care has begun running TV ads featuring Florence Henderson
- UnitedHealth Group signed Willard Scott to lead a video seminar on the drug program that was broadcast to elderly audiences assembled in movie theaters across
- Humana dispatched 300 recreational vehicles to promote its Medicare drug plans outside stores operated by Wal-Mart
- Walgreen, CVS and many independent pharmacies are scheduling "Medicare days," inviting customers to chat with a pharmacist who will review the drugs they are currently taking and explain potential costs
- CVS also plans to feature the new Medicare plan in newspaper inserts delivered to 37 million households.
- Walgreen is mailing monthly newsletters to three million seniors.

Source: *New York Times* (October 3, 2005)

CMS Required Compliance Plan

1. **Written policies, procedures, and standards of conduct** articulating the organization's commitment to comply with all applicable Federal and State standards.
2. The designation of a **compliance officer and compliance committee** accountable to senior management.
3. Effective **training and education** between the compliance officer and organization employees, contractors, agents, and directors.
4. Effective **lines of communication** between the compliance officer and the organization's employees, contractors, agents, directors, and members of the compliance committee.
5. Enforcement of standards through **well-publicized disciplinary guidelines**.
6. Procedures for effective **internal monitoring and auditing**.
7. Procedures for ensuring **prompt responses to detected offenses** and development of **corrective action initiatives** relating to the organization's contract as a Part D plan sponsor.
8. A **comprehensive fraud and abuse plan to detect, correct, and prevent fraud, waste, and abuse**. This fraud and abuse plan should include procedures to voluntarily self-report potential fraud or misconduct related to the Part D program to the appropriate government authority.

Source: 42 CFR § 423.504(b)(40)(vi).

Physician Self-Referral Rules (Stark)

- Stark prohibits:
 - A physician from making referrals for certain designated health services (DHS) payable by Medicare to an entity with which the physician has a financial relationship unless an exception applies AND
 - The DHS entity from submitting claims to Medicare for DHS furnished as a result of a prohibited referral
- Outpatient prescription drugs under Part B are a DHS
- Additional outpatient drugs under Part D are also a DHS and the referral for such drugs are subject to Stark

Source: Federal Register Vol. 70, No. 18, Page 4424 (January 28, 2005)

Approval of Marketing Materials

A Part D plan may not distribute any marketing materials or enrollment forms or make any materials or forms available to Part D eligible individuals unless:

- the Part D sponsor submits the material or form to CMS for review at least 45 days before the date of distribution (or 10 days if using certain types of marketing materials that use, without modification, proposed model language as specified by CMS); and
- CMS does not disapprove the distribution of the material or form.

Source: 42 CFR § 423.50

Details About Marketing and HIPAA

- Part D plans must comply with the HIPAA Privacy Rule and obtain a written authorization from the beneficiary prior to using the beneficiary's PHI to market non-health-related products and services
- Example: a plan may obtain a general mailing list from a non-related marketing vendor to mail materials to all individuals >65 to promote its products. But, can not use beneficiaries' names and addresses obtained from a plan absent authorization.

Source: Federal Register Vol. 70, No. 18, Page 4224 (January 28, 2005)