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The HHS OIG Guidance: An In-Depth Analysis of Risk Areas

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Disclaimers

- The following comments are intended to summarize the HHS OIG Compliance Program Guidance for Pharmaceutical Manufacturers (the “Guidance”).
- These comments are not intended to provide interpretive guidance or legal advice.
- The statements in this slide deck and comments during the discussion do not necessarily represent the views of any Company (and maybe not even individual panelists).

Summary of Presentation

- Government price reporting and AWP (Stuart Fullerton)
- Gifts, business courtesies, and consulting arrangements (Beth Levine)
- Relationships with PBMs (Karen Lines)
- Education and research funding (Pat Davish)
- Discussion, Questions & Answers

Government Price Reporting

- Integrity of data reported “directly or indirectly” by manufacturers is a key risk area
- Compliance = Policies + Training + Auditing
- What the Guidance says:
 - “Where appropriate,” manufacturers’ reported prices should take into account discounts, rebates, “free goods contingent on a purchase agreement . . . up-front payments, coupons, goods in kind, free or reduced-price services, grants, or other price concessions or similar benefits” offered to purchasers
 - Accurate net prices must be calculated in bundled sales: “any discount . . . offered on purchases of multiple products should be fairly apportioned among the products.”

Government Price Reporting (cont'd)

- OIG position: Knowing or reckless failure to report accurate information can result in FCA liability
- Two types of cases
 - *Front-end liability*: inaccurate data in
 - Systems/process issue: SOP + training + auditing
 - *Back-end liability*: recharacterized payments
 - Anti-kickback violations often lead to Best Price claims

Average Wholesale Price (AWP)

- “It is illegal for a manufacturer knowingly to establish or inappropriately maintain a particular AWP if *one purpose is to manipulate the ‘spread’* to induce customers to purchase its product.”
- “We recommend that manufacturers review their AWP reporting practices and methodology *to confirm that marketing considerations do not influence the process.*”
- “Manipulation of the AWP to induce customers to purchase a product with *active marketing of the spread* is strong evidence of unlawful intent.”

AWP -- Analysis

- Are sales representatives actively marketing the spread?
 - “actively marketing the spread includes ... promoting the spread as a reason to purchase the product”
- Is there a spread guarantee?
 - “actively marketing the spread includes ... guaranteeing a certain profit or spread in exchange for purchase”
- Do “marketing considerations” influence AWP reporting practices or methodology?
- Is AWP set in a manner intended to “manipulate the spread”?

Gifts, Business Courtesies and Consultants

- Gifts, entertainment and personal services compensation have a *“high potential for fraud and abuse”*
- Is the manufacturer providing a valuable tangible benefit to physician with intent to induce or reward referrals?
 - Offered to eliminate business/overhead expense?
 - Provided at less than fair market value?
 - Tied to federal healthcare program business?
- Single Purpose Rule
 - A legitimate purpose will not protect remuneration if there is also an illegal purpose (i.e., inducement)
- Arrangements should fit into personal services or employee safe harbors

Gifts, Business Courtesies and Consultants (cont'd)

- The PhRMA Code “will substantially reduce the risk of fraud and abuse and help demonstrate a good faith effort to comply with the applicable federal health care program requirements”
- Gifts & Entertainment
 - Gifts must primarily benefit patients and must not have substantial value (\$100 or less)
 - No cash (unless FMV compensation for services)
 - Items of minimal value may be offered if they're primarily associated with a physician's practice (e.g. pens)
 - Items for personal benefit of physician should not be given (e.g. tickets to sporting events, golf etc.)
 - Modest meals with presentation OK if conducive to scientific or educational exchange

Gifts, Business and Consultants (cont'd)

- Service (Consulting) arrangements:
 - Written agreement
 - Need for services/Appropriate qualifications
 - Actual provision of services
 - Fair market value
 - Documentation prior to payment

Gifts, Courtesies & Consulting -- High Risk Areas

- Gifts and Entertainment
 - Entertainment, travel, meals & gifts “potentially implicate anti-kickback statute”
 - Compliance with PhRMA code “should substantially reduce a manufacturer’s risk”
- Service Agreements
 - Switching Arrangements
 - Cash payments to physicians or pharmacists to change a prescription are “suspect”
 - Consulting and Advisory Payments
 - FMV payments for bona fide services vs. compensation for “passive” participation
 - Marketing & Sales Activities
 - Speaking, preceptorships “pose a risk of fraud and abuse”
 - Disclosure helps, but doesn’t eliminate risk
 - Payments for Detailing
 - Compensation for listening to sales reps or accessing websites is “strongly discouraged”

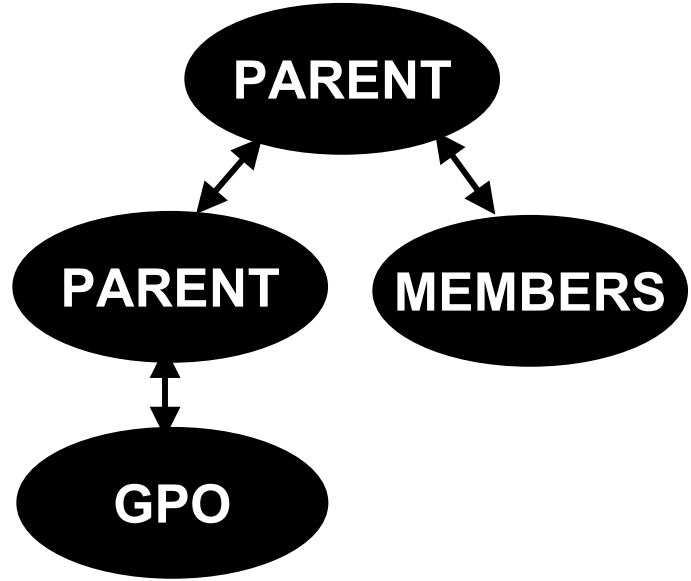
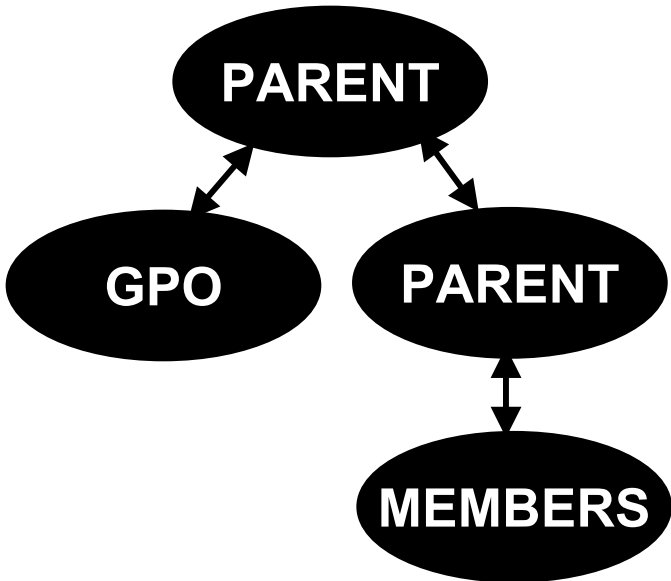
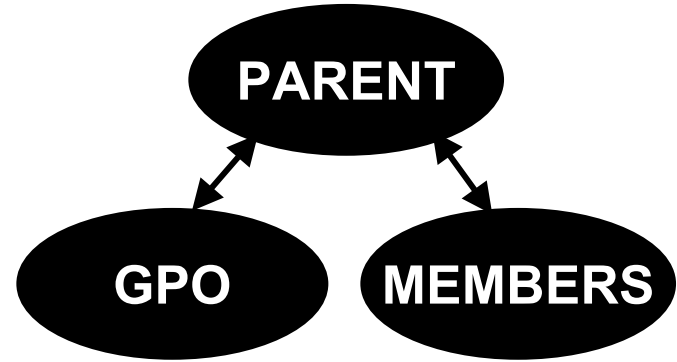
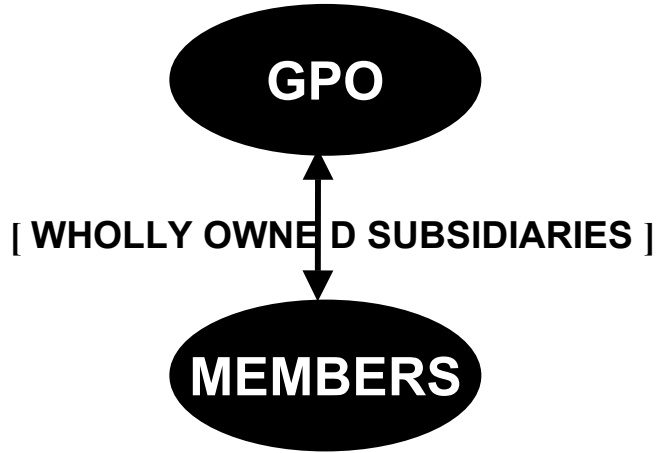
Formularies and Formulary Support Activities

- **Relationships with formulary committee members**
 - Payments to influence formulary decisions are suspect
 - Price negotiations should not influence PBM's decisions on clinical safety/efficacy
- **Payments to PBMs**
 - Payments to PBMs based on/related to members purchases potentially implicate anti-kickback statute
 - Use of GPO safe harbor or managed care safe harbors
 - Transparency to actual buyer is the key
- **Formulary placement payments**
 - Lump-sum payments for formulary inclusion or exclusive/restricted formulary are potentially problematic

Group Purchasing Organization (GPO)

An entity authorized to act as a purchasing agent for a group of individuals or entities who are furnishing services for which payment may be made in whole or in part under Medicare or a State health care program, and who are neither wholly owned by the GPO nor subsidiaries of a parent corporation that wholly owns the GPO (either directly or through another wholly-owned entity).

GPO Safe Harbor



GPO Safe Harbor (cont'd)

- GPO must have written agreement with each member that provides:
 - Vendors will pay fee to GPO of 3% or less of purchase price of goods/services provided by vendor
 - If administrative fee not fixed at 3% or less, then the agreement between the GPO and its members must specify the amount the GPO is to be paid by vendor or the maximum amount (fixed sum or percentage)
- If member is a HCP, GPO must disclose in writing to member at least annually, and to the HHS Secretary upon request, the amount received from each vendor with respect to purchases made by that member

PBMs -- Practical Implications

- **Agreements between manufacturers and PBMs should include:**
 - Representation that the PBM has appropriately contracted with its employers/plans regarding the fees it will be paid by the manufacturer
 - Covenant that PBM shall make the required disclosures to the employers/plans and Secretary of HHS

PBM -- Practical Implications (cont'd)

- **PBM agreements that include discount/rebate component should meet the requirements of the discount safe harbor:**
 - Manufacturer may have duties of seller if selling to PBM for mail-order business
 - Manufacturer may have duties of offeror if providing discount/rebate to employers/plans
 - Duties depend upon status of buyer: HMO/CMP with risk contract, cost reporter, claims submission
 - Seller/offeror duties include reporting discount to buyer, and refraining from impeding buyer in meeting its obligations

Educational and Research Grants

- Covered in two separate areas of the Guidance:
 - “Relationships w/Purchasers & Their Agents”
 - “Relationships w/Physicians and Others in a Position to Make or Influence Referrals”
- Substantial overlap in the sections:
 - Several references in both places on separating educational and research funding functions from sales and marketing functions within the manufacturer

Research Contracts with Physicians

- Research contracts w/physicians should fit within personal services safe harbor if possible
- Payments for research should be FMV and for “fair, reasonable and necessary services.”
- Contracts originating in sales/marketing or in connection with sales contacts particularly suspect
- Indicia of suspect research: initiated by sales or marketing agents, not submitted to or reviewed by research dept., duplicative or not actually needed

Educational Funding

- Is grant for bona fide educational purpose or related to physician prescribing practices?
- Unrestricted educational grant to medical professional org. poses little risk of fraud/abuse
- CME should not be used to channel funds to physicians or to influence control of content
- Reminder of adherence to FDA regulations
- ACCME and other guidelines are a “useful starting point”

Purchasers and Their Agents

- Grants to purchasers, GPOs, PBMs raise concerns under the antikickback statute
- Funding contingent on purchase of product implicates statute even with a legitimate purpose
- Establish objective criteria for the award of grants that take no account of purchase volume or value
- Monitor and document compliance w/ procedures
- No control over speaker or content in educational presentations