

MEDICARE SAFE HARBOR AND SUPPLIER BUSINESS MODELS

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**2006 Health Policy Forum:
A Supply Chain Forecast
February 2, 2006
Washington, D.C.**

- They got paid?! Money changed hands? I'm shocked!
 - Result risk: Cramped legal doctrine limiting legitimate market behavior and price competition
- Where do I get my slice?
 - Result risk: Ignoring boundaries and loose treatment of “other people’s money”

- Bars knowing offer or receipt of remuneration for referring, ordering or recommending the ordering of any item or service covered by a Federal health benefit program
 - Very broad scope
 - Can reverse normal posture -- arguably makes even seemingly legitimate deal illegal, except where something says it's OK

- Statutory exceptions and regulatory “safe harbors”
 - Some give OK to conduct that, on the facts, doesn’t seek to induce referrals or orders
 - Some give OK to conduct that does seek to induce referrals or orders, but which is not abusive
- Absence of safe harbor does not mean conduct violates law
- Advisory opinions give further guidance

- GPOs
- Discounts
- Personal services and management contracts
- Price reductions to health plans and managed care organizations
- Safe harbors not yet updated to reflect 2003 Medicare Modernization Act creation of Part D drug benefit

- Payment to GPO from vendor exempt where:
 - GPO has written agreement with purchaser to act as purchasing agent
 - Agreement sets fee from vendor at 3% or less; or
 - If fee not fixed at 3% or less, agreement states the payment amount or percentage of purchase value
 - If purchaser is provider, GPO must disclose in writing at last annually amount received from each vendor with respect to purchases by each purchaser
- Exemption not applicable to fees paid for purchases by GPO, GPO subsidiary, or subsidiary of GPO's parent

- GPO safe harbor based on disclosure and transparency premise
 - If buyer thinks GPO fee from vendor is too high, so that price to purchaser will be impacted, purchaser can take business elsewhere
 - GPO safe harbor does not address vendor pricing to purchasers, pass-through of GPO administrative fees or income to purchasers or payments where GPO members are not purchasers

- Safe harbor protects price reductions by sellers and “offerors” to buyers
 - Reporting and disclosure obligations may apply
 - Post point-of-sale rebates can be protected
 - “Offeror” protection allows protected discounts to run, for example, from manufacturer to customer, even where customer buys from wholesaler

- Exception only applies to price concessions to buyers so payment to GPO itself not protected
- OIG position that discounts to wholesalers not within express protection, but not to be challenged where no risk of abuse

Service and management contracts

- Safe harbor requires written agreement
- Aggregate compensation must be set in advance, be consistent with fair market value, and not determined in manner that takes into account volume or value of business otherwise generated between the parties paid under federal health program
- Percentage deals will normally not comply with safe harbor
- Compliance of deals outside safe harbor depend on facts and circumstances

Safe harbor for price reductions to health plans

- Protects price reductions from “contract health care provider” to a health plan
 - Requirements include written agreement, and, as applicable, disclosure and reporting
 - “Health plan” includes insurers and HMOs that charge premiums under state regulatory scheme, employers or union welfare funds, and companies licensed by the state that contract with an employer, welfare fund or insurer and are paid a fair market value administrative fee.
 - OIG has implied that pharma manufacturer could be “contract health care provider”

Price reductions to “eligible” managed care organizations

- Safe harbor protects payment between MCO and “first tier” contractor for covered items and services
- Also protects some arrangements between “first tier” and “second tier” contractors
- Applicable only to MCOs with certain direct managed care contracts with Medicare

Prescription benefit manager role

- Analysis of PBM rebates can depend on population served, type of payor, purpose of payment, and role of PBM
 - PBM may be “buyer” for purposes of its own mail service pharmacy purchases
 - PBM could be “health plan” if it sponsors program under new Medicare Part D
 - OIG guidance to pharma suggested possible reliance on GPO safe harbor for some relationships with PBMs
 - Customer consent, transparency and accurate reporting in government programs, not guaranteed solution to all legal issues, but goes far

Change in wholesaler business model

- Wholesaler charges separate fee to manufacturer for functions for which no separate charge previously applied
- For drug manufacturers, may complicate analysis under Medicaid “best price” or Medicaid average manufacturer price calculations
- If proper disclosures and reporting is done, and risk of abuse or overreaching is absent, kickback risk appears low

Provider GPOs for prescribed items

- Some health care providers are seeking to organize GPOs for products their members prescribe or order for patients, but which the providers do not purchase.
 - Fees from vendors to these GPOs will not fit GPO safe harbor
 - Percentage fee deals will not fit management or personal services safe harbor either

Impact of change in GPO safe harbor

- Change in GPO safe harbor could have collateral impact
 - Change could imply that there is harm to be prevented even where customer has agreed that GPO may receive payment in excess of 3%.
 - Impact on PBMs, GPOs, health plans and wholesalers could depend on specifics of change and message sent on willingness to rely on market forces, with disclosure, to prevent abuses