

KING & SPALDING LLP

**National Pharma Audioconference:
Pharmaceutical Drug Pricing and Reporting Issues
July 28, 2005**

**Government Price Reporting:
Common Problem Areas in a
Complex Reporting Environment**

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Legal Guidance

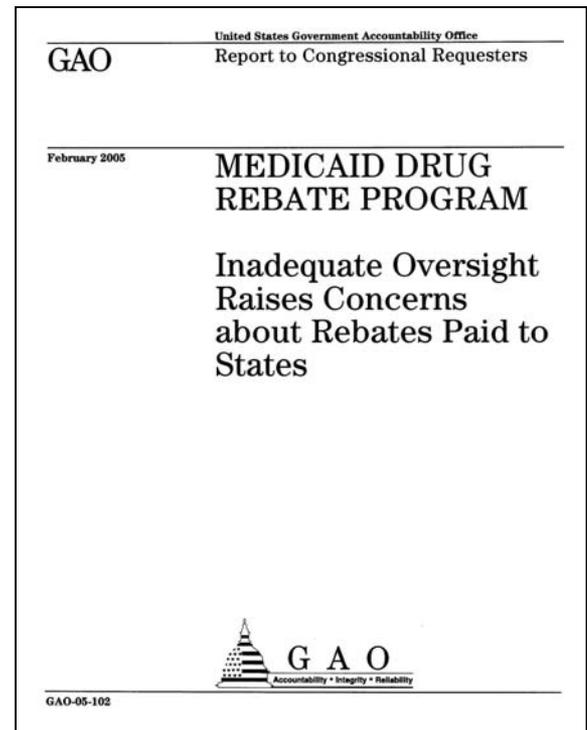
- Available price reporting authority
 - Statutes
 - Regulations
 - Medicaid Rebate, VA and PHS Agreements
 - Sub-Regulatory guidance
 - Communications with regulators (federal and state)

Legal Guidance (cont'd)

- Recent GAO criticism of CMS guidance:

“In four reports issued from 1992 to 2001, OIG stated that its review efforts were hampered by unclear CMS guidance ...”

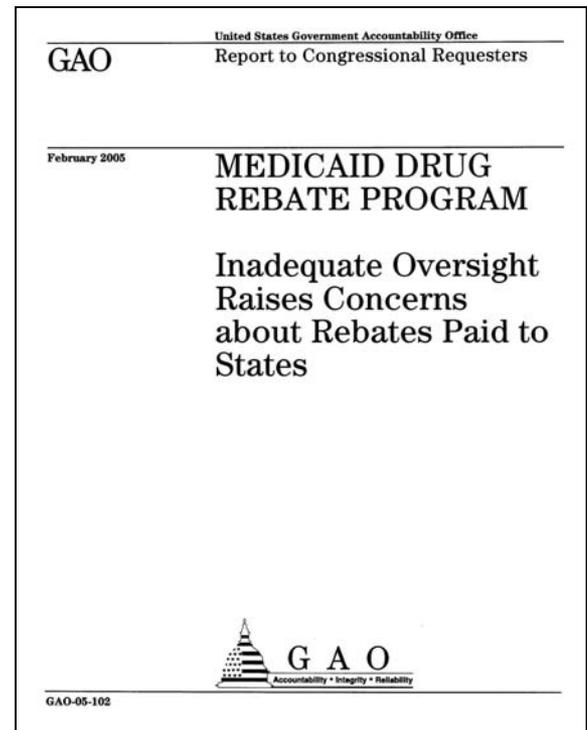
“CMS ... has not provided clear program guidance for manufacturers to follow when determining [best price and AMP]”



Legal Guidance (cont'd)

- Recent GAO criticism of CMS guidance (cont'd):

“To help ensure that the Medicaid drug rebate program is achieving its objective of controlling states’ Medicaid drug spending, we recommend that the Administrator of CMS issue clear guidance on manufacturer price determination methods and the definitions of best price and AMP, and update such guidance as additional issues arise.”



Legal Guidance (cont'd)

- Principles when there is contradictory or no authority on point
 - Accuracy
 - Financial impact on government health programs
 - Consistency
- Options when there is contradictory or no authority on point
 - Look to industry practice
 - Disclose assumptions
 - Mandatory under ASP rules
 - Must be retained, but not disclosed, under AMP rules

Legal Guidance (cont'd)

- Correcting errors
- Changes in methodology
 - Prospective
 - Retrospective
 - ASP
 - AMP/Best Price
- Submitting revised AMPs and/or Best Prices
 - Fifth quarter lookback
 - Twelve quarter limit

Classification and Filtering

- Drilling down from wholesaler (indirect) sales
 - Who is the customer?
 - “Wholesaler sales” except for those “*which can be identified with adequate documentation as being subsequently sold to any of the excluded sales categories*” (Release 29 AMP/BP eligibility chart Note 2)
 - The default is to consider the sale eligible
 - What is sufficient identification?
 - What is adequate documentation?
 - May require extensive research and painstaking categorization

Classification and Filtering (cont'd)

- Nominal sales
 - Sales at less than 10% of AMP: ASP and BP ineligible, AMP eligible
 - Non-FAMP ineligible, definition differences
 - Senator Chuck Grassley (R-IA) and the Senate Finance Committee sent letters to manufacturers asking them to detail their use of nominal prices in an attempt to discover if the best price exception was being abused
 - Feedback loops: Restatement of AMP in the normal course of business may change the level at which a nominal sale is made forcing a restatement of best price and a pinch for ASP

Identification and Treatment of Price Concessions

- Improper treatment of off-invoice price concessions has been the basis for many recent investigations and lawsuits in the pricing area
- Basic theory is that improper inducements (e.g., gifts, grants, improper fee-for-service or consulting payments) were off-invoice price concessions that would result in lower Best Prices

Identification and Treatment of Price Concessions (cont'd)

- Commonly overlooked price concessions:
 - Improper grants or gifts
 - Excessive samples
 - Non “bona-fide” administrative fees
 - Non-product-specific discounts/rebates
 - Launch services or discounts
 - New store stocking bonuses
 - Off-invoice price concessions offered in other promotional programs
 - Price protection payments

Identification and Treatment of Price Concessions (cont'd)

- Treatment of Returns:
 - *Blanton v. Biogen* (DCDC 2/18/05):
 - “Because current WAC was higher than WAC at the time of purchase (up to 24% higher) Cardinal Health was, in fact, profiting from the returns. [Plaintiff] believed that the return program created a de facto discount that raised discount/reporting concerns.”
 - At a time of rising prices, manufacturers with a return policy payout at current WAC may be giving the wholesaler or customer a windfall
 - That windfall may have to be factored into the price reporting calculations, lowering AMP and potentially setting a new Best Price

Identification and Treatment of Price Concessions (cont'd)

- Treatment of Administrative Fees
 - Whether administrative fees are to be included in or excluded from price reporting calculations depends on whether they are “*bona fide* service fees” or *de facto* price concessions. The former are excluded, the latter included.
 - *Bona fide* fees were recently described in a letter from CMS as
 - “[Fees] for an itemized service actually performed by an entity on behalf of the manufacturer that would have generally been paid for by the manufacturer at the same rate had these services been performed by other entities. . . . Bona fide service fees that are paid by a manufacturer to an entity, that represent fair market value for a bona fide service provided by the entity, and that are not passed on in whole or in part to a client or customer of the entity should not be included in the calculation of ASP, because those fees would not ultimately affect the price realized by the manufacturer.”

Identification and Treatment of Price Concessions (cont'd)

- Treatment of Administrative Fees (cont'd)
 - According to the CMS letter, *bona fide* service fees are:
 - “Fair market value;”
 - “for an itemized service;”
 - “that would generally have been paid for at the same rate if performed by other entities;”
 - “that are not passed on in whole or in part to a client or customer;” and
 - that do “not ultimately affect the price realized by the manufacturer.”
 - CMS letter specifically addressed service fees in context of ASP (Medicare), whereas IMA fees raise

Identification and Treatment of Price Concessions (cont'd)

- Treatment of Administrative Fees (cont'd)
 - Note that treatment of volume-based fees were not specifically addressed in the December 9 letter
 - Nor were fees paid to wholesalers specifically addressed
 - Appropriate treatment of IMA fees, in particular, is vexing the industry

Treatment of Lagged Payments & Receipts

- Out-of-Quarter adjustments can have a substantial impact on reportable amounts
 - Chargebacks
 - Rebates
 - Invoice adjustments (i.e. returns, credit memos, price protection, etc)
- Example: bringing a Best Price forward
- AMP/BP vs. ASP

State Price Reporting Requirements

- Texas (AMP and WAC)
- New Mexico (Total Sales, AMP, AWP, WAC, ASP, Best Price, Direct Price and DoJ Price)
- Maine (AMP and best price)
- California (ASP in 1Q07)

Conducting a Price Reporting Assessment

- What to do
 - Review your company's product line
 - Review your company's product distribution system
 - Review your company's pricing systems and practices
 - Government price calculations
 - Core transaction systems
 - Customer and transaction classifications
 - Promotional programs (including discounts and rebates)
 - Search for off-invoice price concessions

Price Reporting Assessment (cont'd)

- How to do it
 - Ensure that the review is subject to privilege
 - Review existing written policies and procedures
 - Select a sample drug or drugs to review
 - Identify and interview key personnel from relevant areas, including:
 - Finance
 - Sales & Marketing
 - Accounting
 - Pricing & Contracting
 - IT
 - Legal / Compliance
 - Review communications with relevant government agencies
 - Review selected commercial contracts

Review VA contract

Price Reporting Assessment (cont'd)

- Likely outcomes of the assessment
 - Updates to and revisions of the written policies and procedures
 - Additional training of implementing personnel
 - Establish cross-functional pricing committee
 - Enhance controls over promotional materials
 - Where necessary, communicate changed methodologies to CMS/VA
 - Where necessary, re-file properly calculated AMP and Best Price

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For further information, please call.

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