

KING & SPALDING LLP

**Pharmaceutical Compliance Summit
Preconference Symposium**

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

March 30, 2005

John D. Shakow
jshakow@kslaw.com
202-626-5523

Copyright 2005
King & Spalding LLP

Agenda

- Legal Guidance
- Every Manufacturer is Unique
- Classification and Filtering
- Identification and Treatment of Price Concessions
- Treatment of Lagged Payments and Receipts
- Monitoring for Reference Pricing
- Formal Policies and Procedures
- Interdepartmental Communications
- Conducting a Price Reporting Assessment

Legal Guidance

Legal Guidance

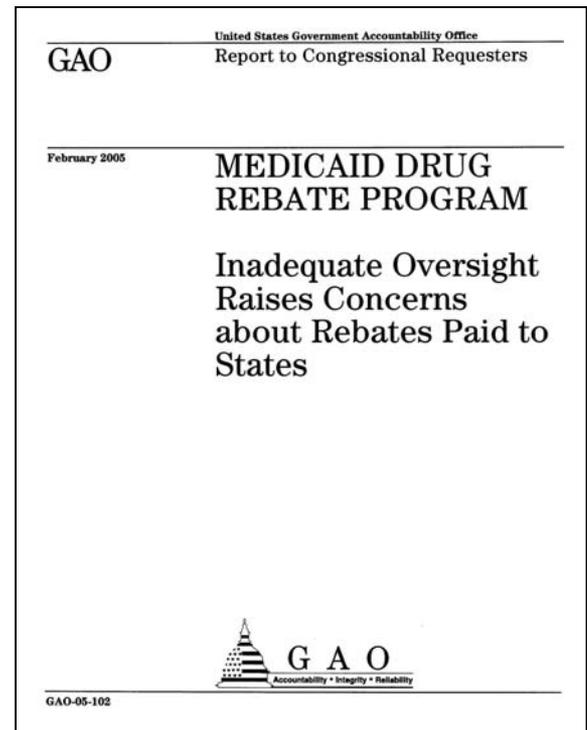
- Available price reporting authority
 - Statutes
 - Regulations
 - Medicaid Rebate, VA and PHS Agreements
 - Sub-Regulatory guidance
 - Communications with regulators

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 ...”

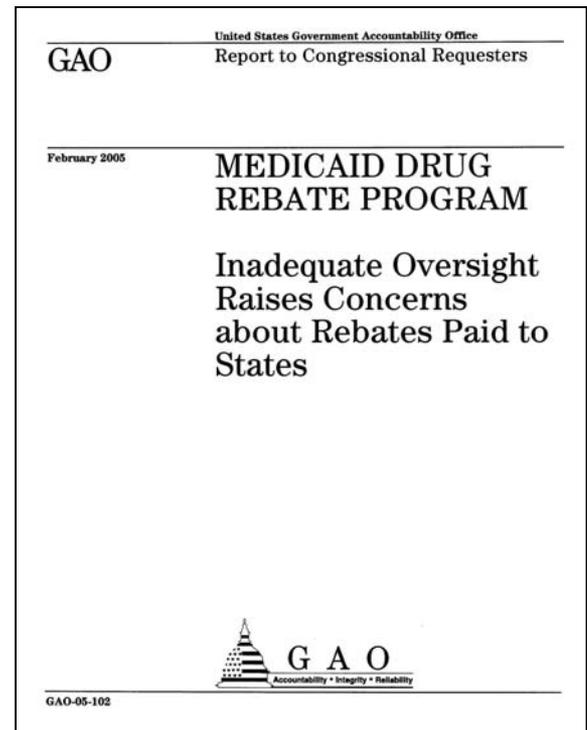
“CMS ... has not provided clear program guidance for manufacturers to follow when determining [best price and AMP]”



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

Every Manufacturer is Unique

Every Manufacturer is Unique

- Product mix (sole source/innovator v. non-innovator)
- Product distribution scheme
- Internal corporate structure
- Rising prices / falling prices
- System limitations and interfaces
- Government Price Reporting methodology due to interpretation of legislation and guidance

Classification and Filtering

Classification and Filtering

- One of the principal parameters of each calculation is what sales are included in the calculation, and what sales are excluded from the calculation
- Two key characteristics per sale:
 - Customer classification (e.g., wholesaler, retail pharmacy, hospital, 340B entity)
 - Transaction type (e.g., sale, sample, international)
- Each calculation is partly defined by its own set of includable and excludable sales

Classification and Filtering (cont'd)

- By examining the characteristics of each sale, the manufacturer determines if the sale is *eligible* or *ineligible* for consideration in the AMP, Best Price, ASP and Non-FAMP calculations
- This process is known as “filtering”
- For instance, sales to the federal government, state pharmacy assistance programs, the Public Health Service, international sales, state supplemental rebates, free goods and inter-company transfers are ineligible for all calculations

Classification and Filtering (cont'd)

Representative customer class of trade “buckets:”



Retail
Pharmacies



Mail Order
Pharmacies



Wholesalers

Etcetera...

Classification and Filtering (cont'd)

Representative transaction type “buckets:”



Donations or
Free Goods



International
Sales



340B Contract
Sales

Etcetera...

Classification and Filtering (cont'd)

- Release 29 AMP/BP eligibility chart

AVERAGE MANUFACTURER PRICE/BEST PRICE CALCULATIONS

| SALES | INCLUDED IN AMP | INCLUDED IN BP | REBATES DUE | ADDITIONAL INFORMATION |
|------------------------------------------------------------------------------------------------------------|--------------------|-------------------|----------------|----------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|
| Direct Hospital Sales | No | Yes | Note 1 | <p>Sales discussed in this chart may be affected by subsequent sales to an excluded/included entity for AMP/BP purposes.</p> <p>Note 1 - Yes, if the drug is used in the outpatient pharmacy and the Hospital bills Medicaid for reimbursement for dispensing the outpatient drug. Otherwise, no.</p> <p>Note 2 - Yes, except for sales to wholesalers which can be identified with adequate documentation as being subsequently sold to any of the excluded sales categories.</p> <p>Additional note - All pricing adjustments affecting the price of any sales must be taken into account if the sales were included in the calculation of AMP/BP.</p> |
| HMOs (Drugs Dispensed Under Capitated Rate) | No | Yes | No | |
| HMOs (Drugs Dispensed Under Fee-for-Service) | No | Yes | Yes | |
| Mail Order Pharmacy | Yes | Yes | Yes | |
| Retail Pharmacy | Yes | Yes | Yes | |
| PHS Covered Entities | No | No | No | |
| State-Funded Only - Pharmacy Assistance Programs | No | No | No | |
| VA/DOD Excluded Sales | No | No | No | |
| Federal Supply Schedule Sales | No | No | No | |
| Nursing Home Primary/Contract Pharmacy Sales | Yes | Yes | Yes | |
| Sales to Other Manufacturers Who Repackage/Relabel Under the Purchaser's NDC | No | No | No | |
| Sales to Other Manufacturers Who Act as Wholesalers and Do Not Repackage/Relabel Under the Purchaser's NDC | Yes | Yes | Yes | |
| Wholesalers | Note 2 | Note 2 | Note 2 | |

Classification and Filtering (cont'd)

- 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, BP and non-FAMP ineligible, AMP eligible
 - Senator Chuck Grassley (R-IA) and the Senate Finance Committee sent letters to 19 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

Classification and Filtering (cont'd)

- Classification and filtering recommendations:
 - Develop written policies and procedures clearly identifying how customers should be classified and transactions should be assigned to the correct “buckets”
 - Ensure that price reporting methodologies conform to the customer and transaction classes
 - Train those responsible for assigning customer class of trades and transactions
 - Perform a risk assessment to ensure the policies and procedures that are in place are actually being followed

Consider how information can be overridden and who has the ability to perform overrides

Identification and Treatment of Price Concessions

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-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:
 - 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
 - Difficult for manufacturers to account for and allocate the potential windfall
 - *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

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 and Receipts

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

Treatment of Lagged Payments & Receipts

(cont'd)

- Formal written policies and procedures clearly identifying how these transactions should be applied
- How these transactions being valued and what is the effect on the government pricing calculations
- How can information be overridden and who has the ability to perform overrides
- Assess whether appropriate data retention and audit trails exist

Monitoring for Reference Pricing

Monitoring for Reference Pricing

- 340B Sales

- The obligation to ensure that 340B entities receive PHS pricing falls on the manufacturer
- June, 2004 OIG report:
 - *“Manufacturers are responsible for ensuring that the 340B discount is passed onto the covered entity, regardless of whether the entity purchases drugs from a wholesaler, or directly from the manufacturer.”*
- The industry is struggling to determine the practical limits of this obligation, given PHS’s management of the database
- Moreover, must discounted sales to customers who no longer qualify but are still on the government website be considered for Best

Monitoring for Reference Pricing (cont'd)

- VA most favored customer sales
- Nominal sales
- Unintended Best Price sales

Formal Policies and Procedures

Formal Policies and Procedures

- Most companies have few written SOPs regarding government price reporting, if any
- Important to have them for several reasons:
 - Drafting forces self-scrutiny and comprehensive treatment
 - Consistency from quarter to quarter
 - Continuity in the event of personnel change
 - Clarification of responsibilities
 - Useful in the event of an audit or investigation
- All pricing-related Corporate Integrity Agreements require them, indicating that the authorities believe them to be best practice

Interdepartmental Communications

Interdepartmental Communications

- Manufacturers should have open lines of communication between sales & marketing, finance, legal, information technology and the government pricing team to ensure the following:
 - Timely communication of new promotional programs and other off-invoice price concessions
 - Complex or “one-off” contract or promotional program are evaluated in the context of government pricing regulations and are incorporated into existing government pricing models
 - Capabilities, changes and limitations of IT systems are continuously considered for their effect on government price reporting

Conducting a Price Reporting Assessment

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

Conclusion

Government price reporting requirements can be daunting and demanding, particularly for executives, lawyers and business managers who do not have the time to master and stay abreast of the detailed legal and regulatory requirements. But companies that use such complexity as an excuse for not ensuring the accuracy and integrity of the data they report to the government are taking significant risks in today's regulatory environment. The consequences of performing the calculations improperly can be truly disastrous to a pharmaceutical manufacturer that hopes to continue selling its products in the United States. Most companies that have taken the time to review and update their pricing policies and procedures have found it to be a **very worthwhile investment**.

KING & SPALDING LLP

For further information, please feel free to call.

John Shakow

jshakow@kslaw.com

202-626-5523