KING & SPALDING LLP

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and Best Practices Forum
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Government Pricing Compliance: Threats, Frustrations and How to Sleep at Night

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Agenda

- Recent Pricing Compliance Threats
- The Uncertain and Ever-Changing Pricing Compliance Environment
- Conducting a Price Reporting Assessment

Recent Pricing Compliance Threats

King Settlement

- $124 million settlement of a false claims act allegation
- Payments to the Federal Medicaid program, several states, the Big 4 and PHS covered entities
- Based on the following conduct (performed "knowingly"):
  - failing to collect and analyze its pricing information in a manner to ensure that it would be able to accurately report AMP and BP;
  - failing to adequately train its personnel to accurately calculate AMP and BP;
  - failing to provide its employees with appropriate software and other tools for calculating AMP and BP correctly; and

King Settlement (cont'd.)

- The "false records" are alleged to have been the calculations themselves, included in the quarterly CMS submissions
- King's failure to have adequate systems and training -- not that they set out to mislead or defraud -- that was enough to trigger an FCA investigation and settlement
- Attendant invasive CIA

Other Pricing Settlements

- TAP – $875 million – AWP and best price
- AstraZeneca – $355 million – AWP and best price
- Schering Plough – $345 million – best price
- Bayer – $250 million – concealed discounts
- GSK – $150 million – AWP
- GSK – $88 million – concealed discounts
- Pfizer – $49 million – best price
- Schering Plough – $27 million – AWP

Pricing Litigation

- Boston AWP class action case
- New York Counties' Medicaid case
- State AGs' AWP/Medicaid cases
- Alabama and California 340B class actions
- Reportedly scores of *qui tam* cases

Congressional Inquiries

- Senate Finance Committee
- House Energy and Commerce Committee
- Medicare pricing
- Medicaid pricing
- Nominal pricing

The Uncertain and Ever-Changing Pricing Compliance Environment

Legal Guidance

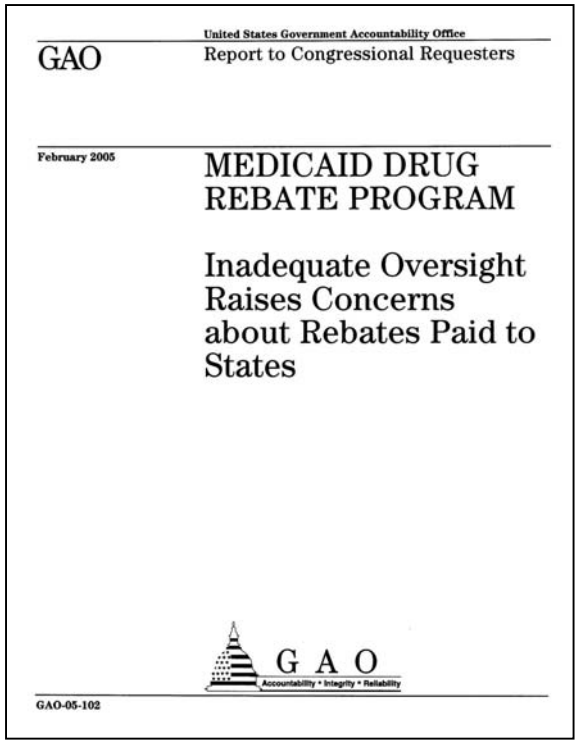
- Available price reporting authority
  - Statutes
  - Regulations
  - Medicaid Rebate, VA and PHS Agreements
  - Sub-Regulatory guidance
  - Communications with regulators (federal and state)

GAO Criticism

- Recent GAO criticism of CMS price reporting 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]"*


United States Government Accountability Office

GAO

Report to Congressional Requesters

February 2005

MEDICAID DRUG REBATE PROGRAM

Inadequate Oversight Raises Concerns about Rebates Paid to States

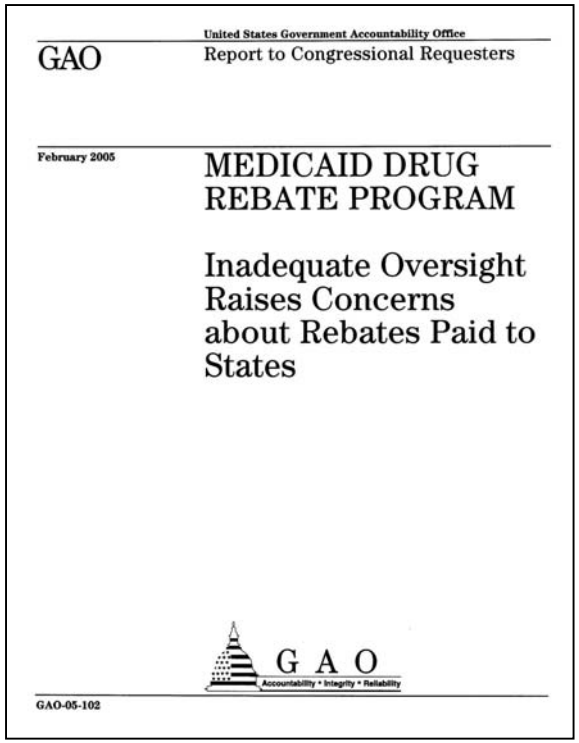
GAO

Accountability • Integrity • Reliability

GAO-05-102

GAO Criticism (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."*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Five OIG 340B Reports in 3 Years

- March 2003: “Pharmaceutical Manufacturers Overcharged 340B Covered Entities”
- June 2004: “Deficiencies in the 340B Program’s Database”
- June 2004: “Appropriateness of 340B Drug Prices” ***withdrawn*** October 2004
- October 2005: “Deficiencies in the Oversight of the 340B Drug Pricing Program”
- Spring 2006: expected re-issuance of “Appropriateness of 340B Drug Prices”

Proposed ASP Revision

- On August 8, 2005, CMS issued a proposed rule requiring manufacturers to calculate one ASP for direct sales, another for indirect sales and calculate a weighted average of the two to get the final ASP
- This week, in light of the universally negative reaction received, CMS pulled the plug and will not require direct and indirect ASPs to be calculated

Medicaid Reform

- Two bills making their way toward conference
- Between them, they may affect change with respect to:
  - The Medicaid rebate percentage
  - The definition of AMP
  - What constitutes multiple source
  - Federal upper limits
  - Treatment of authorized generics
  - Definition of a bona fide service fee
  - Innovator v. generic utilization
  - Nominal pricing
  - Scope and extent of judicial review

State Price Reporting

- 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)

Principles and Options

- 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
  - Make a request for guidance
    - Written request

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

Conducting a Pricing Assessment

Conducting a Price Reporting Assessment

- What to do
  - Review your company's product line
  - Review your company's product distribution practices
  - Review your company's pricing systems and methods
    - Government price calculations
    - Core transaction systems
    - Customer and transaction classifications
    - Promotional programs (including discounts and rebates)
  - Identify areas of potential weakness and risk

Price Reporting Assessment (cont'd)

- How to do it
  - Preserve the privilege
  - Retain an outside consultant with expertise
  - Determine the scope (which calculations; which products; over what period)
  - Draft a specific workplan
  - Review existing written policies and procedures
  - Identify and interview key personnel from relevant areas
  - Review communications with relevant government agencies
  - Review selected commercial contracts
  - Review VA contract
  - Review *de facto* application of policies and

Price Reporting Assessment (cont'd)

- Potential specific areas of inquiry
  - Class of trade categorization
  - Filtering transactions as well as classes
  - Off-invoice price concessions
  - Treatment of administrative fees
  - Non-product-specific discount allocation
  - Is it really an SPAP?
  - Sales to Puerto Rico and beyond
  - Are free goods really free?
  - Federal Ceiling Price v. MFC prices
  - Non-FAMP nominal sales
  - Treatment of lagged payments and receipts
  - Meeting your state obligations?

Price Reporting Assessment (cont'd)

- Possible outcomes of the assessment
  - Updates to and revisions of the written policies and procedures
  - Additional training of implementing personnel
  - Establishment of cross-functional pricing committee
  - Where necessary, re-bill customers previously considered best price-ineligible
  - Where necessary, communicate changed methodologies to CMS/VA
  - Where necessary, re-file properly calculated AMP and Best Price
  - Where necessary, seek permission to re-file properly calculated ASP, Non-FAMP/FCP and 340B Ceiling Prices

Communicating Results of the Assessment with Regulators

- Making prospective changes in methodology
- Making retroactive changes in methodology: Release 61
  - Justification for the change in methodology
  - The methodologies used to originally calculate the reported AMPs or best prices
  - The revised methodologies used for the proposed recalculations
  - The fiscal magnitude of the changes
  - Documentation to support the changes
  - Whether these changes are retrospective and/or prospective
  - The quarters affected by the recalculation

Communicating Results of the Assessment with Regulators

- Correcting an error does not always equal revising a methodology
- Submitting revised AMPs and/or Best Prices
  - Fifth quarter lookback
  - Twelve quarter limit

The Fine Print

- The foregoing presentation was a summary of some of the complex laws, regulations and practices attendant to government price calculation and reporting. It is not, and was not intended to be, legal advice.

- The views expressed in this presentation are my own and are not necessarily shared by King & Spalding LLP or any of its clients.

KING & SPALDING LLP

John Shakow (202-626-5523; jshakow@kslaw.com) is a Counsel in the Washington, D.C. office of King & Spalding LLP. Mr. Shakow's practice is focused on the representation of pharmaceutical manufacturers on regulatory and litigation issues related to drug pricing and price reporting, including counseling, internal investigations, civil litigation and defense in government investigations.

Mr. Shakow has conducted in-depth pricing assessments for a number of pharmaceutical manufacturers and has worked with companies to develop and implement government price calculation and reporting policies, procedures and methodologies. He assists manufacturers in interactions with regulators with respect to price and reporting issues. Mr. Shakow has counseled drug manufacturers before the House Energy & Commerce and Senate Finance Committees in drug pricing investigations and inquiries. Mr. Shakow has significant litigation experience in the pharmaceutical area. He currently represents several companies in the Average Wholesale Price multidistrict litigation in Boston and related Medicaid and 340B actions around the country.

Mr. Shakow graduated from the University of Virginia School of Law in 1997. He earned his undergraduate degree in economics and public policy from Swarthmore College in 1991. From 1991 to 1994, Mr. Shakow worked for Carville & Begala, a strategic political consulting firm. He is a member of the bars of the District of Columbia and Virginia, the U.S. District Courts for the District of Columbia and the Eastern District of Virginia, and the U.S. Court of Appeals for the D.C. Circuit.