National Medicare Prescription Drug Congress

Analysis of the New Medicare Part D Drug Benefit and Changes to Medicare Part B Reimbursement: New Rules of the Road

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Objectives

- Increase industry understanding of key elements of the new Medicare Part D prescription drug benefit and changes to the Medicare Part B drug benefit
- Provide insights as to how these changes will require the industry to adjust its compliance focus from Average Wholesale Price issues to Average Selling Price interpretations and government contracts.
- Recommend how to coordinate business operations with compliance review functions in order to decrease exposure to law enforcement action and whistleblower lawsuits

The Old AWP Reimbursement Regime Swept Away

- The Legacy of *United States ex rel. Ven-A-Care v. Bayer, et al.* (January 2001): the introduction of the concept Average Selling Price as a regulatory tool
- The First Average Wholesale Price fraud settlement caused HHS and the Congress to begin an inevitable evolution away from AWP reimbursement toward something else

The Old AWP Reimbursement Regime Swept Away

- Congressional Hearings held by the House Energy & Commerce Committee (September 2001) after release of the GAO study on AWP and oncology clinic practice economics,
- Changes in Medicaid AWP spurred by action by the Department of Justice, State AG's and First DataBank (May 2000),

The Old AWP Reimbursement Regime Swept Away

- the $870 million global settlement of the United States ex rel. Durand v. TAP Pharmaceuticals (October 2001), and
- the prospect of the massive expansion of Medicare beyond the narrow boundaries of Medicare Part B and the physician's office to Part D's parity with the scope of coverage of Medicaid --

Part D Expansion of Medicare Requires a New System of Provider Reimbursement for Drugs

- **Years of federal legislative indecision about AWP evaporates in the face of painful fiscal lessons learned by State governments facing exploding Medicaid pharmacy budgets concurrent with shrinking revenue resources**
- **Medicare Part B expenditures tripled in amount in the past 5 years – that for a program very limited in scope – a harbinger of things to come in an expanded Medicare drug program**

What Was Enacted In December 2003 For Medicare Part B

- As of January 2004, Medicare Part B reimbursement methodology shifts to AWP – 15% for most drugs and biologicals
- Exemptions: some companies obtain limited relief from strict AWP-15% reimbursement
- Other products, such as renal dialysis products and blood clotting factors are exempt altogether from changes in reimbursement, remaining at AWP-5%

What Was Enacted In December 2003 For Medicare Part B

- January 1, 2005, Medicare Part B reimbursement adopts the Average Selling Price concept – The Spread Is Dead – at least as a federal government-sanctioned concept.
- Multiple Source Drug reimbursement will be at ASP + 6%. Social Security Act §1847A(b)(1)(A). How will it be done?

Manufacturer Reporting Obligations To the Government

- Quarterly ASP Price Reporting to the government – similar to quarterly Medicaid Drug Rebate price reporting
- ASP = a price reflecting (1) volume discounts, (2) prompt pay discounts, (3) free goods contingent on purchases, (4) cash discounts, chargebacks, and rebates
- All of this carries Fraud and Abuse liability exposure

What Risk Does ASP Create to Industry?

- Lengthy regulatory definitions often carry the illusion of *PRECISION* – that the precise calculations are easy to execute
- Not so, the ASP calculation will be a moving target – similar to Average Manufacturer Price and Best Price
- Will government enforcers understand?

Where's The Wiggle Room On ASP Calculation Obligations?

- Experience with the Average Manufacturer Price data discount time lag: rebates and discounts don't occur on a neat, orderly timetable. There is a lag spurring routine adjustments to AMP
- In order to mitigate the discount time lag, manufacturers should estimate discounts that would count toward ASP by a consistent methodology that refers to the prior 12 months' data. The methodology must be disclosed to the government in the ASP report

Where's The Wiggle Room On ASP Calculation Obligations?

- Opinion: there will be initial high expectations of precision among regulatory enforcers at HHS-OIG and DOJ creating higher risk of litigation and False Claims Act enforcement
- Over time: regulatory enforcers will gain greater understanding of industry data gathering capabilities and weaknesses leading to some "breathing room" for industry

What Was Enacted In December 2003 For Medicare Part D

- January 1, 2006, Medicare expands to cover most drugs, including the self-administered not just the Part B drugs
- Reimbursement by either (1) ASP + 6% or (2) supply cost for purchases from entities winning Competitive Bidding in geographic test areas gradually.

2006 Part D Benefit, cont'd

- Entities will submit bids to the government for each product, based on ingredient costs, shipping, dispensing cost, and management fees BUT NOT administration, waste, spillage, or spoilage. HHS will then determine a reimbursement amount based upon the bids.

Who will bid in 2006?

- pharmacy benefits managers?
- the big three wholesalers?
- The obligations to fulfill statutory performance requirements are enormous: distribution ability, financial wherewithal, customer service, past experience, ability to ensure product integrity

Government Contracts Issues

- Bidders will be in close proximity with the government and will face close scrutiny from regulatory enforcers in all areas of performance
- Don't invite the government into your house unless you can afford the costs of routine compliance measures

Law Enforcement Guidance For the New Medicare

- The federal False Claims Act (FCA), the United States primary civil fraud enforcement statute for claims for payment and government contract fraud
- Federal and State Anti-kickback statutes
- Other authority: the 2003 HHS-OIG Guidance to Pharmaceutical Manufacturers

Why concern yourself about the FCA?

- The Medicare Part D Benefit Will Expand Industry's Overall Medicare business substantially
- Even if your company avoided or marginalized government payor business before, Part D will change a significant part of your business model without your strategic input. You must adjust.

Why concern yourself about the FCA?

Enforcers' 3 Year Track Record – over $2 billion in Civil and Criminal Recoveries

- AWP Pricing – Bayer (2001), TAP (2001), AstraZeneca (2003), Dey Laboratories (2003)
- Medicaid Drug Rebate – Bayer (2001), Parke-Davis/Pfizer (2002), Bayer (2003), GlaxoSmithKline (2003), Ross/Abbott (2003).

Law Enforcement Guidance For the New Medicare

- Anti-Kickback Exposure – Subtext to all of the above-referenced matters.
- Emerging Issue: Higher Medicare utilization of particular drugs as a result of Off Label Usages
- Issues likely to emerge: Defective pricing or false statements in the bidding process under Part D

What is the False Claims Act?

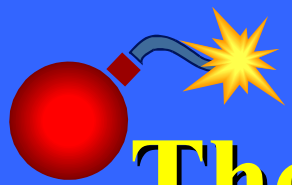
- The FCA, 31 U.S.C. § § 3729 et seq. lists a host of practices that Congress deemed fraudulent, including (i) conspiring to have false claims paid by the government, (ii) causing false claims (i.e., claims actually submitted to the government by someone else) to be paid by the government, (iii) using false statements to get false claims paid, (iv) fraudulently avoiding full payment of obligations owed to the government (reverse false claims)

Elements of the FCA

- the submission of a claim for payment (or payment of an obligation owed to the government)
- the claim was false
- the false claim was knowingly submitted
- the government suffered a loss (although some cases have been pursued for penalties alone where no loss could be established by the government)

The litigation deck is stacked in the government's favor

- No **SPECIFIC INTENT TO DEFRAUD** Is Required To be Proven By the Government.
- The "**KNOWINGLY**" Standard Can Be Met By Showing Nothing More Than A "**RECKLESS DISREGARD FOR THE TRUTH OR FALSITY OF THE CLAIM.**"



The Punitive Force of the FCA

- The FCA gives the government the following enforcement tools:
  - treble damages (3 times the government's actual loss)
  - Penalties of up to $11,000 – per false claim submitted
  - pre-judgment interest

Federal Gov't Enforcement Activity Against Industry

- Due to budgetary pressures, State Attorneys General have aggressively pursued industry under pharma fraud theories
- Under similar budgetary conditions in the future, federal enforcers will likely expand already busy enforcement agendas

Internal Compliance Coordination

- Industry is inviting regulatory enforcers in through the corporate front door – recognize the risk inherent in that
- The left operational hand must communicate with the right operational hand about transactions that involve directly or indirectly making representations to the government, such as ASP or through the Part D bidding process or, later, during the performance process under Part D.

How Can This Situation Be Managed? Attention to Front-end Compliance

- Manufacturers, PBM's, providers, and other participants in the stream of health care business and services must measure sales and marketing strategies, drug price reporting, and other direct interactions with the government against the standards set forth in the 2003 OIG Guidance while understanding that the OIG Guidance does not provide an exhaustive check list of prohibited conduct

Improved Compliance Efforts Are Needed To Reduce Risks To Your Company and Employees

- In the TAP (2001) and AstraZeneca (2003) matters, in particular, individuals and entities cooperated with the government investigation typically as part of their plea agreements meaning you cannot be assured that any internal corporate information will remain confidential.
- Compliance must be a daily, senior executive level mandate in order to manage the expanded exposure

Don't Poison the Business; Keep It Healthy. How?

All *reasonable* steps should be taken to manage such risks in a prophylactic manner by investing in sound, *top-down* compliance measures that identify critical business process points or business strategies that carry moderate to high risk so that these business elements can be assessed and coordinated and, if necessary, revised or eliminated.

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