



Distribution Issues, WAMP and the Expanding Role of OIG, Part D Fraud and Abuse Issues--and Some Predictions

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Why Are Distribution Models Changing?

- ASP Is Less Prompt Pay Discounts, But Not Less Bona Fide Service Fees.
- The Role of Prompt Pay in the Traditional Model
- ASP Plus Six Percent Really Means ASP Plus Four Percent.
- Now, Couple that with the Effect of the “Two Quarter” Lag.
- A Powerful Recipe for All Parties to Reconsider the Traditional Model.

Four Basic Models

- Model 1--The Traditional Model with Focused Attention on Service Roles and the Valuation of Those Service Roles
 - Still a Purchaser Model
 - The Issue that this Creates Around the Costs of Distribution Itself
- Model 2--Purchaser with Service Fee Basis
- Model 3--The Distribution Agent Model
 - Liability and FDA Implications
- Model 4--Self-Distribution
 - Probably Only Possible for Dominant Players
 - Can Just Dial-in the Costs to ASP
 - Don't Have to Be Efficient
 - But Need to Be Concerned about the 2 Quarter Lag

Guidance and Uncertainty

- The Traditional Medicaid Guidance
 - Administrative Fees Must Be Included in Best Price Calculation, If the Term Results in a “Reduction to the Price Realized by the Manufacturer.”
- ASP FAQ Repeats that Guidance.
- New Guidance:
 - No reduction to ASP if:
 - Bone fide service fees
 - Must be for an itemized service
 - Actually performed by an entity on behalf of the manufacturer
 - Must be paid for by the manufacturer at the same rate had these services been performed by other entities.
 - Represent fair market value
 - Not passed on in whole or in part, directly or indirectly

How Contracting and Price Reporting Are Changing

- Companies Reviewing Percentage-Based Fees
- Manufacturers Investing in Third Party Reviews of Fair Market Value
 - Benchmarking--and the Question of Apples and Oranges with “Third Parties”
- Confronting Possible “Overlap” Issues
- Emphasis on Separate Agreements
- Efforts to Find Contract Terms that Will Provide a Basis for Understanding Whether a Fee Is or Is Not Passed in Whole or in Part
- Positions Must Be Integrated with Internal Accounting Systems

Some Very Tough Legal Issues Here

- Inventory Management Fees as an Example
- Are They a Concession on Sales Entered into or Payment for Purchases Not Made?
- What Happens if the Assessment Is Incorrect?
- A Bad Moon on the Horizon
 - The False Claims Act and the Anti-Kickback Statute
- Transparency and the Importance of the Assumptions Documents

Steps to Take

- Ask and Answer the Right Questions

- Is It a Necessary Service?
- Is It Actually Delivered?
- Is It Itemized?
- Would You Pay a Third Party for It?
- Is the Payment Rate Based on Objective Data and Verified by a Third Part?
- Are the Payments Appropriate on an Itemized and on an Aggregated Basis?
- Are the Contracts Clear as to How Is Obligated to Report What?
- Are the Contracts Clear as to What Can or Cannot Be Passed on?

Predicting the Future

- ASP Is Going to Have an Effect in the Commercial and Medicaid Market
 - The Questions Are Just:
 - How?
 - By Whom?
 - How Quickly?
 - Will the Problems with Federal ASP Be Fixed?
 - How Consistent Will the Systems Be?
 - And What Effect Will Inconsistency Have on the System as a Whole?
- Medicare ASP Reform?

The Expanding Role of OIG in Pricing-- Rhetoric Is Everything

- What It Meant that the AWP Reform Provisions Were Styled as “Fraud and Abuse” Provisions
- The Story Behind the Story--How the “Saver” Section Became the “Fraud and Abuse” Section of the MMA

Signs of the OIG's Increasing Reach

- The 2004 Transition Rates Based on the OIG Survey
- ESRD Payments and the OIG Survey
- ASP as the Selected Long-Term "Solution"
- Other "Price Concessions"
 - ASP must *include* volume discounts, prompt pay discounts, cash discounts, free goods that are contingent on any purchase requirement, chargebacks, and all rebates (other than the Medicaid rebates).
 - But the MMA also says that "for years after 2004, the Secretary may include in such price other price concessions, which may be based on the recommendations of the Inspector General, that would result in a reduction of the cost of the purchaser."
- CMP Authority and ASP Audits
- And, of Course, WAMP

WAMP and AMP Issues

- WAMP = “widely available in the market price” = the prices a prudent physician or supplier would pay
- In 2005, if ASP exceeds WAMP or AMP for any particular drug or biological by 5% or more, the Secretary must disregard the ASP and substitute the lesser of the WAMP or 103% of AMP
- OIG to determine WAMP and can force CMS’s hand!
- OIG starting its process

Seeing the Potential for OIG Intervention

- Two competing single source Part B products sold in the physician's market that compete against one another.
- Both with ASPs of \$100.
- One has a price range of \$110 to \$95.
- Another has a price range of \$115 to \$80.
- How does the OIG's WAMP effect potentially matter here?
- How will the OIG exercise that authority?

Medicare Part D Fraud and Abuse

- Medicare prescription drug benefit allows for “huge opportunities for fraud.” (Jim Sheehan, U.S. Attorney -- Philadelphia)
- The Medicare Part D benefit “is going to draw a lot more scrutiny just because of the sheer size of the benefit.” (Virginia Gibson, U.S. Attorney – Philadelphia)
- “Within the Medicare and Medicaid programs, . . .prescription drugs are especially vulnerable to fraud, waste, and abuse.” (Daniel Levinson, Nominee for Inspector General, HHS)
- Under the Part D benefit, “every detailing activity between sales representatives and physicians, as well as every drug covered, is subject to federal [oversight].” (Jim Sheehan, U.S. Attorney -- Philadelphia)

Part D Contracting Risks

- Part D Plans and Manufacturers Will Be Accused of Attempting to “Swap” Part D Concessions to Secure Favorable Terms in Other Negotiations.
 - A Short History of “Swapping”
 - Investigations, Advisory Opinions, and the Discount Safe Harbor

Substantive Analyses

- Are the Terms Provided More Favorable to Commercial Plans than to Part D Plans?
- Were the Favorable Terms Offered to:
 - Secure Coverage under Part D;
 - Secure More Favorable Coverage within a Part D Formulary; or
 - Secure Higher Rate of Payment under Part D?
- Is It Just as Simple as Having the Part D Offers Just as Good as the Commercial Offers?

Procedural Concerns

- Confidentiality and Swapping Concerns
- Isolated Personnel in Negotiations?
- How Realistic Is That?
- Confidentiality with Some Teeth

Sharing Risk as an Issue

- There is a safe harbor, but...
- Requirements are not well-tailored for a Part D environment
- Don't assume that it will actually have the effect that the Plan anticipates...
 - The “actually paid” concept

Allocation of Concessions

- Direct Subsidy vs. Reinsurance Subsidy vs. Risk Corridors
- Where the Concession Goes Matters
- Manufacturers Should Steer Clear of Allocation Issues.

Reporting of Concessions

- Plans Have a Responsibility to Report Aggregate Concessions and What Is Passed on to Beneficiaries
- It's About Transparency.
- Manufacturers Don't Want to Get in the Way of the Accuracy of Those Reports.

Dealing with Third Parties Adds to the Complications

- PBMs, as an Example
- Remember the Medco Issues
 - Transparency and Not Defeating Appropriate Clinical Decision-Making

Gap Filling as a Possible Manufacturer Tie

- Final Rule Suggests that There Is a Role for Pharmaceutical Companies
- But (and It Is a Big But) So Long as the Fraud and Abuse Laws Are Not Violated.
- No Specific Guidance
- What to Do?

What the OIG Has Said in a Part B Context

- Free Drugs Not Contingent on Sales Is One Thing ...
- Cash or Cash Equivalents Is Another
- Waiver of Co-Payments Is Problematic in the Absence of a Good Faith Financial Need.
- What OIG Is Concerned about ...
 - Defeating Utilization Control
 - Steering to More Expensive Products
- Procedural Safeguards that the OIG Likes
 - Independent Third Party--and the Separation That Brings
 - Kicking into a Communal Pot--and the Separation That Brings

But Is Part D Different?

- **Competing Concerns**
 - CMS Has an Interest in Allowing Gap Filling--Likely to Increase Participation.
 - But CMS Also Has an Interest to Decrease Costs and Gap Filling Is Likely to Increase Costs.
 - Will CMS Consider an “Even-Handedness” Requirement?
- **How Will CMS Weigh These Competing Concerns?**
- **Operational Reality: Gap Filling Has to Be Registered by the Plan to Be Effective.**
 - Won't that Be Hard or Impossible with Free Drugs?

Interactions with P&T committees

- P&T committees already publicized as a vulnerability – subject to much scrutiny
- P&T committees will be “an area of law enforcement activity over the next four or five years.” (Michael Loucks, U.S. Attorney – Boston)
- Comparative pharmaeconomic comparisons-an FDA and an FCA issue
 - Control that message.
- Concerns with “financial relationships”, too.