Managed Care Contracting Risks: An Antitrust, Government Pricing and Fraud & Abuse Analysis

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Presenters

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Overview of Presentation

• Introduction & General Principles
• Why are Managed Care Contracting Risks Now Increased?
• Applicable legal Authorities
  — Antitrust
  — Drug Pricing
  — Fraud & Abuse
• Principal Legal and Compliance Issues by Type of Arrangement
  — Price Reductions/Concessions (“Rebates”)
  — Bundled Discounts
  — Combining Services with Price Reductions
• Recommendations and Key Takeaways

General Principles

• Assessing legal issues associated with managed care contracting can be challenging
  — Managed care contracting risks have increased (see next slide)
  — Assessments of legal exposure often have to be made quickly and under significant pressure from clients
• Overlapping (and sometimes inconsistent) areas of law
  — Multi-agency enforcement (DOJ, FTC, HHS)
  — What may be “good” facts for antitrust analysis may be “bad” facts for anti-kickback analysis
  — Terms may have different meanings, depending on area of law (for example, “bundling” in antitrust vs fraud & abuse vs pricing)
• Purpose of this presentation: to provide you with the key questions you should ask to quickly evaluate potential legal exposure, and to prepare you to practically reduce your risk
Increased Managed Care Contract Risks

- Steadily increasing drug prices
  - Lack of pricing transparency
  - Manufacturer defenses to “high prices” are that the WAC prices do not reflect actual gross-to-net due to many price concessions in the system
  - Generally incorrect perception that the federal government pays more than others
  - Perception that federal program prescribing is influenced (if not directed) by managed markets access
- New efforts to develop more creative “value” arrangements
  - Increased efforts to seek discounts based on exclusivity or preferred access
  - Potentially influence prescriber and patient decision-making
  - May effectively block access to competitors
- Lack of available protections
  - Lack of safe harbor protections subject arrangements to scrutiny
- Lack of clarity in antitrust laws; increased FTC focus on pharmaceutical industry

Contracting Parties

- **Product movement**
- **Payments**
- **Discounts/Rebates**

**Seller**
- Manufacturer
- Distributor
- PBM
- GPO

**Payers/Intermediaries**
- IDN/System
- Payer/Plan

**Buyers**
- Pharmacies/Hospitals/Physicians

**King & Spalding**
Applicable Legal Authorities

Antitrust

• Purpose of the antitrust laws: To protect consumers and ensure that there is freedom of competition and freedom of choice in the marketplace
  — Not intended to protect competitors
  — To outlaw unreasonable restrictions on competition

• Legal Framework: Sherman Act
  — Section 1: Conspiracy that Unreasonably Restrains Trade
  — Section 2: Monopolization, Attempt to Monopolize & Conspiracy to Monopolize
Antitrust

• Pricing is a key way for pharmaceutical companies to introduce new products and gain a competitive advantage; many creative ways to sell products to enter markets and increase sales (e.g., multi-product promotions, giving products away
• But…there can be antitrust issues with some of these strategies
  — Predatory Pricing
  — Exclusive Dealing and Discounts
  — Tying
  — Price Discrimination (Robinson-Patman)
• Ideal approach is to find acceptable levels of antitrust risk while maximizing profits

Government Pricing Laws

• Purpose: By reporting prices and price concessions in the commercial market, manufacturers establish government payor program prices, discounts and reimbursement amounts
• Principal governing statutes:
  — Medicaid (AMP & Best Price): 42 U.S.C. §1396r-8
  — Medicare Part B (ASP): 42 U.S.C. §1395w-3a
Government Pricing Laws

- Under the price reporting laws, manufacturers must track and include in pricing metrics price concessions extended to managed markets purchasers, among others
- Reports are due monthly, quarterly and annually, and most must be certified for accuracy and completeness
- Lowest commercial price on a single unit can set Medicaid rebate liability nationally (Best Price; BP rip-cord clauses)
- Significant commercial discounts can suppress Average Sales Price: doctors’ reimbursement metric under Medicare Part B

Government Pricing Laws

- Even non-possession taking entities like PBMs, GPOs and payers set ‘prices’ reportable under the laws
- Manufacturers are incentivized to offer steep discounts to government and safety net entities by excluding discounted sales to them from reporting
- If manufacturers pay service fees to these and other entities, they must be evaluated for inclusion under the multi-part ‘bona fide service fee test’
Government Pricing Laws

- Contingent price concessions across products or periods may have to be reallocated in price reporting, potentially creating unintended discount/reimbursement consequences
- Those contingencies can relate to a purchase or a performance requirement, including formulary placement
- Managed Medicaid
  - Many state programs engage a commercial provider to manage Medicaid spend on capitated basis
  - While mandatory rebates to Medicaid are excluded from pricing, rebates to Managed Medicaid organizations are commercial and are included in pricing metrics

Fraud and Abuse Laws

- Anti-Kickback Statute, 42 U.S.C. § 1320a-7b(b)
- Broad anti-fraud prohibition:
  - “Whoever knowingly and willfully offers or pays (or solicits or receives) any remuneration (including any kickback, bribe or rebate) directly or indirectly, overtly or covertly, in cash or in kind to any person to induce such person to purchase, lease, order or arrange for or recommend purchasing, leasing, or ordering any good, facility, service or item for which payment may be made, in whole or in part, under a Federal healthcare program, shall be guilty of a felony…, shall be fined not more than $25,000 or imprisoned for not more than five years, or both.”
Anti-Kickback Statute

- Principal Policy Objectives
  - To prevent inappropriate clinical decision-making as a result of financial incentives
  - To prevent overutilization and increased federal health care program costs
  - To prevent unfair competition
  - To ensure the proper reporting of costs to the government

- AKS applies only to items and services covered by federal health care programs (“FHCPs”)

Anti-Kickback Statute – Reason 1

- Medicare beneficiaries have the option to receive benefits through privately managed health plans – called Medicare Advantage, or Medicare Part C. Through these privately managed health plans, beneficiaries receive:
  - Hospital/inpatient services (Medicare Part A), and
  - Physician, physician-administered drug, outpatient, home health, and preventive services (Medicare Part B)
  - Beneficiaries may also get basic drug coverage (Part D)
- Medicaid beneficiaries also may receive their benefits through commercially managed plans
**Anti-Kickback Statute – Reason 2**

*Lifesavers or kickbacks? Critics say patient-assistance programs help keep drug prices high*

By Lisa Schencker | March 7, 2015

“... Critics say patient-assistance programs [even when aimed solely at commercial business] help manufacturers keep prices high and demand for their branded products strong, and discourage patients and doctors from switching to cheaper alternative medications. . . .”

- Could one purpose of commercial discount and access programs be to affect prescribing patterns of practitioners, such that the prescription of federal health care program covered products may be impacted?

**Anti-Kickback Statute – Safe Harbors**

- 25 safe harbors, covering a wide-range of arrangements
- Protect arrangements that meet all enumerated criteria
- Potentially relevant to managed care contracting:
  - Discount safe harbor (42 C.F.R. 1001.952(h))
  - GPO safe harbor (42 C.F.R. 1001.952(j))
  - Personal Services safe harbor (42 C.F.R. 1001.952(d))
- Various other safe harbors appear relevant, but do not in fact apply:
  - Price reductions offered to health plans (42 C.F.R. 1001.952(m))
  - Price reductions offered to eligible managed care organizations (MCOs) (42 C.F.R. 1001.952(i))
  - Price reductions offered by contractors with substantial financial risk to MCOs (42 C.F.R. 1001.952(u))
- In general, such safe harbors not designed to align with current structures and arrangements
Anti-Kickback Statute – Discount Safe Harbor

- Discount is defined as a “reduction in the amount a buyer ... is charged for an item or service based on an arms-length transaction”
- Definition of “Discount” does not include (among others):
  - Discounts on one product to induce the purchase of another product, unless both products are reimbursed under the “same payment methodology” (affecting most “bundles”)
  - A reduction in price offered to one payer, but not FHCPs
  - Routine reductions of co-payments or co-insurance obligations
- Definition of “Rebate”:
  - Any discount the terms of which are fixed and disclosed in writing to the buyer at the time of the initial purchase to which the discount applies, but which is not given at the time of sale

Anti-Kickback Statute – Applicable Legal Authorities

- Broad but useful generalization in this context:
  - Antitrust and Fraud & Abuse considerations go to the substantive effect (actual or intended) of the managed markets arrangement
  - Government Price Reporting considerations go to the procedural/mathematic reflection of the managed markets arrangement in pricing to the government
Principal Legal and Compliance Issues by Type of Arrangement

Common Managed Market Arrangements

(1) Structured Price Concessions: Discounts or Rebates
   - Volume
     - Concept: Buy more; pay less
   - Formulary Status/Tiering
     - Concept: Discount dependent on level or availability of access
   - Market Share
     - Concept: Discount dependent on growth vis-à-vis competitors
   - Exclusivity
     - Concept: Discount based on blocking competitors’ access
   - Below Cost Sales (aka “Predatory Pricing”)
     - Concept: Discount resulting in a financial loss on sale [to be made up through other purchases]
Common Managed Market Arrangements

(2) Bundled Discounts  (Concept: sale of a group of products at total prices less than if purchased individually)

• Numerous types of bundles without common nomenclature
• Common umbrella terms – “bundles” or “combination purchases”
• Accomplished via discounts, rebates, or other forms of aggregate pricing
• Three main types:
  – (1) Single Purchase (Non-single-SKU kit): a company sells two or more products at a single lower combined price than the total price for which it would sell each of the included products separately
  – (2) Fixed Percentage: a company provides a single discount percentage (e.g., 15%) when a purchaser agrees to buy multiple types of products (percentage must be same for all products in the “bundle”)
  – (3) Tied Products (“If, then”): a price reduction on one product conditioned on the purchase of another product

Common Managed Market Arrangements

(3) Managed Markets Services: Fees and/or Price Concessions

• Common service arrangements:
  – Data reporting
  – Compliance and adherence
  – Patient assistance
• Service fees must be fair market value
  – Consider how to determine valuation
• Key issues:
  – How to apportion service fees versus discounts
  – How to analyze risks
Overview of Analysis: Price Reductions

- Various types of price reductions (e.g., volume discounts, market share rebates)
- In general, as long as price concessions are incorporated into government pricing accurately, no risk, but government liability effect
- Arrangements involving price concessions and other remuneration may present AKS risks:
  - (1) Increase costs to federal health care programs
  - (2) Unduly influence prescribing patterns
  - (3) Increase utilization
- Arrangements also present antitrust risks and price reporting challenges
- Overall risk continuum:

Price Reductions/Concessions: Formulary Status

Rebates for Formulary Status/Tiering

Formulary placement: rebates or discounts are contingent upon a drug having certain formulary status or being in a certain tier (e.g., “preferred tier”); this would also include requirements related to being one or two or three; for example, on a formulary.

- **Key Concept:** Include us as an option; receive discounts based on the number of available options – from just being available on a formulary all the way through exclusive 1:1 formulary status
### Formulary Status/Tiers: Implications and Analysis

**Issue:** Does the discount/rebate impact clinical decision-making regarding which drug to prescribe?

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<th>Antitrust</th>
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<td>• May be considered low risk, but depends on market dynamics.</td>
<td>• Bundled discounts can be created through a purchase requirement (e.g., volume discounts) or a performance requirement (e.g., formulary placement). Therefore, we may need to reallocate price concessions contingent upon performance activity like placement on a tier among products or periods.</td>
<td>• Rebates are “remuneration” under the AKS and not SH protected</td>
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<td>• Key issue is whether it will “foreclose” competition.</td>
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<td>• Risk:</td>
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<td>• Generally the Agencies consider the competition to achieve status on formulary is procompetitive.</td>
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<td>— PBMs can “arrange for/recommend”</td>
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<td>— Formulary status may impact patient moves from one therapy to another</td>
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<td>— Risk level tied to exclusionary nature of specific formulary requirements</td>
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<td>— Not as likely to be scrutinized like market share rebates, absent non-transparent “incentives”</td>
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<td>— See US ex rel. DiMattia et al. v. AstraZeneca LP et al. (Feb. 2015)</td>
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<td>— AZ allegedly “made illegal in-kind value payments” to Medco to induce it to: 1) provide Nexium with a preferred tier; 2) recommend Nexium to network physicians; and 3) buy Nexium</td>
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### Exclusivity: Implications and Analysis

**Issue:** Does the discount/rebate impact clinical decision-making regarding which drug to prescribe?

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<td>• Generally acknowledged that exclusive dealing can be procompetitive.</td>
<td>• Exclusivity arrangements can be performance-based bundles requiring reallocation across products or periods.</td>
<td>• Rebates are “remuneration” under the AKS and not SH protected</td>
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<td>• Factors include length of the agreement, competitive landscape, and ease of entry.</td>
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<td>• Risk:</td>
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<td>• Example/Recent Development: Eisai Inc. v. Sanofi-Aventis U.S. LLC et al., case number 14-2017 (Third Cir. 2016): Third Circuit dismissed case against Sanofi re discount contracts with hospitals that purchased large amounts of anti-coagulant drug Lovenox because the contracts did not substantially foreclose competition.</td>
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<td>— Payments inherently tied market manipulation, influencing prescriber patterns and beneficiary utilization</td>
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<td>— Furthest along risk continuum</td>
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<td>— Risk may be calibrated by arrangements that are less than sole source, for example, one of two, instead of exclusive status</td>
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Recommendations and Key Takeaways

- Ensure that ALL areas of law are considered
  - Antitrust
  - Fraud and Abuse
  - Government Price Reporting
  - Product Liability
- Examine business and strategic rationale
  - How will entering into contract affect your sales? Your government program liability?
  - How will competitors react?
- Carefully develop contracts/terms
  - Beware of third party “template” terms
  - Avoid managed markets jargon – think about how an enforcement official might view the agreement
  - Pay attention to how contract provisions may be impacted by longer term agreements
- Semantics matter
  - “Buy 10 of X for $1,000 and get one Y for free” is not the same as “buy 10 of X and one of Y for a total of $1,000”
Recommendations and Takeaways

- Account for “stacking” of discounts/rebates across all arrangements
  - Does the cumulative effect of price concessions result in a below cost sale/new Best Price?
  - Do federal health care programs appropriately receive the benefit of all discounts applied?

- Swaying clinical judgment
  - Is the arrangement effectively or implicitly coercive?

- Pulling through FHCP business
  - Are any price concessions on commercial business intended to move federal business?

- Exclusion of FHCP beneficiaries
  - Are FHCP beneficiaries properly carved-out of applicable programs to avoid kickback implications?

- Documents and careful communications are important
  - Documents discussing entering into an exclusive arrangement to “dominate” the market or “kill our rivals,” that include FHCP business, or that discuss HCP prescribing increase risk.
  - Corporate messaging, management responsibilities, and budgeting also factor into risk

Questions
## Contact Information

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