Healthcare Supply Chain & GPOs: Legal and Regulatory Overview

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Laws, Laws, Everywhere Laws!

- Healthcare, including supply purchasing, is one of the most heavily regulated industries in the United States.
  - Extensive and overlapping federal, state and local regulations
- Healthcare industry and GPOs can also raise issues under antitrust laws and regulations.
  - ALSO includes extensive and overlapping federal and state regulations

Watch out for traps!
Anti-Kickback Statute

• Federal **criminal offense** to knowingly and willingly offer, pay, solicit or receive any remuneration to induce referrals and/or the purchase of items or services reimbursable by any federal health care program
  
  – Similar state laws in many states.

• Prohibited payments can be direct or indirect, in cash or “in kind” (e.g., golf, sports tickets, trips, etc.)
Anti-Kickback Statute (cont.)

- Potential sanctions (per violation) include:
  - Imprisonment of up to 5 years
  - Criminal fines up to $25,000
  - CMPs up to $50,000
  - Exclusion from Medicare / Medicaid programs

- Corporate Integrity Agreement likely included in any settlement
Anti-Kickback Statute (cont.)

- Violations can create liability for providers, suppliers, distributors and GPOs

- Provider exposure for Anti-Kickback violations includes:
  - Substantial fines
  - Jail time
  - Civil Monetary Penalties
  - Exclusion from Medicare and Medicaid
  - Whistleblower lawsuits
  - False Claims Act lawsuits
Safe Harbors

- GPO Safe Harbor protects administrative fees
- Discount Safe Harbor protects discounts and rebates
  - Detailed transparency and reporting requirements for suppliers and hospitals.
  - Discounts are price reductions at the time of sale of the goods
  - Rebates are discounts subsequent to the sale.
    - The terms of the rebate must be fixed at the time of sale
Other Payments

- Potential problem areas include so-called: Prebates, Up-Front Discounts, Conversion Bonuses and Signing Bonuses

- In 2000, the DHHS Office of Inspector General issued formal guidance on prebates and similar payments.
  - In the OIG’s view “…up-front rebates, prebates, signing bonuses and similar payments are suspect under the anti-kickback statute, placing persons offering or receiving them potentially at risk.”
False Claims Act

- Federal **criminal offense** to knowingly and willingly make false statements or representations in connection with the furnishing of items or services for which payment may be made under a federal healthcare program

- Sanctions include: imprisonment of up to 5 years; criminal fines up to $25,000; exclusion from federal healthcare programs
False Claims Act (cont.)

- Can be triggered by kickback violations / allegations
- Individual “relators” (i.e., “whistleblowers”) can bring suit on behalf of the US Government
- “Whistleblower” can receive up to 30% of the recovery with no government intervention; 15-25% with government intervention
Anti-Kickback

- **2011**: Medline settles allegations of violations of the Anti-Kickback Statute and False Claims Act with the U.S. Dept. of Justice
  - Cash Settlement: $85M
  - Whistleblower Share: $23.375M
  - Plaintiff’s Attorney Share: $6M

- **2010**: St. Jude & two hospitals settle allegations of violations of the Anti-Kickback Statute and False Claims Act with the U.S. Dept. of Justice (including prebates)
  - St. Jude Cash Settlement: $3.7M
  - Hospital Cash Settlement: $175k
Antitrust, “Own Use” and Class of Trade

- Antitrust Primer
- Robinson-Patman Act / “Own Use” Overview
- Contractual Class of Trade Restrictions
Basic Objective of U.S. Antitrust Law

To protect the process of competition for the benefit of consumers, making sure there are strong incentives for businesses to:

1. Operate efficiently,
2. Keep prices down, and
3. Keep quality up.

Protects competition…not competitors. The question to ask is:

Is it pro-competitive or anti-competitive?
Section 1:

“Every contract, combination in the form of trust or otherwise, or conspiracy, in restraint of trade or commerce among the several States, or with foreign nations, is hereby declared to be illegal.”

By its literal terms, it could outlaw ALL contracts, so judges had to find a way to narrow its applicability to:

1. An agreement which
2. Unreasonably restrains competition and
3. Affects interstate commerce
The Sherman Antitrust Act, cont.

Section 2:

“Every person who shall monopolize, or attempt to monopolize ... any part of the trade or commerce among the several States ... shall be deemed guilty of a felony.”

Requires:

1. Monopoly power in the relevant market
2. Acquisition or maintenance of that power by means other than natural market forces.

Regulates the conduct of a SINGLE company that has MONOPOLY power
Other Antitrust Laws

The Clayton Act (1914)
- Permits treble (triple) damages

Federal Trade Commission Act (1914)
- Gives the FTC power to enforce antitrust laws (in addition to the DOJ)

Robinson-Patman Act (1936)
- Prohibits price discrimination

Case Law
- Fill in the gaps of broad statutory language

State Statutes and Case Law
- Generally modeled after federal law

Oh, the tangled webs…
The “Big House,” the “Poor House” or Both

Penalties for violating Antitrust Laws include:

• Up to a $100 million fine for a corporation

• $1 million fine and 10 years in prison for an individual

You—yes, you—can be imprisoned, fined, or sued
**GPOs and Antitrust Law**

GPOs, by their nature, involve collective action among competitors and face continued scrutiny.

Many hospital aggregation / affiliation groups are also engaged in “group purchasing.”

**Remember…You are all competitors!**

Currently, the FTC and DOJ have generally decided that the pro-competitive effects of GPOs outweigh any potential anti-competitive effects.

- Economies of scale = volume discounts and overall better prices
- This stance could change if a GPO changed its purchasing, bidding, or negotiating practices so that potential anti-competitive effects threatened to outweigh any pro-competitive effects
Some Conduct is “Per se” Illegal

Agreements between competitors that always or almost always raises prices or reduces output:

1. **Price Fixing:** an agreement among competitors to “control, raise, lower, maintain, or stabilize” prices

2. **Market Division:** an agreement among competitors to divide customers, territories, and/or product segments

3. **Group Boycott:** a concerted refusal to deal agreement among direct competitors
Challenged Contracting Practices

The following practices have been challenged as anti-competitive:

- Bundled discounts or rebates
- Discounts based on large market share commitments
- Sole-source contract awards
- Lengthy contract terms or repeated awards to the same supplier
- Prohibition of trials or evaluations of competitive products
- Prebates and clawbacks

These might be illegal, but it depends...
The Rule of Reason

The questions that need to be answered:

1. “Do the pro-competitive benefits outweigh the anti-competitive harms?

2. Can similar efficiencies be achieved by practical, significantly less restrictive means?

The following factors are typically examined:

- The percentage of the relevant market foreclosed to competitors
- The dominance of the seller in its industry
- The relative strength of the parties
- The ease with which new outlets can be formed
Robinson-Patman Act

- Passed in 1936 to supplement the Clayton Antitrust Act
- Prohibits price discrimination when the impact lessens competition or creates a monopoly
  - Attempts to protect competing sellers AND competing buyers
  - Also forbids discriminatory allowances and promotional services
- Applies to the purchase of commodities only
  - Does not apply to services
  - Does not apply to leases
  - Originally designed to protect independent retailers from chain stores
- Price differences can be justified if based on differing costs to sell, manufacture or deliver (e.g., volume discounts)
Robinson-Patman Act (cont.)

• Both buyers and sellers can have liability under the Act

• Red flags:
  – Below-cost sales by a firm that charges higher prices in different localities, and that has a plan of recoupment;
  – Price differences in the sale of identical goods that cannot be justified on the basis of cost savings/efficiencies or meeting a competitor's prices; or
  – Promotional allowances or services that are not practically available to all customers on proportionately equal terms.
Nonprofit Institutions Act and “Own Use”

- Exempts purchases of supplies by nonprofit institutions for their “own use”
  - “Own use” is the critical limitation in this exemption

- The scope of “own use” is highly fact dependent
  - Largely established through case law and governmental guidance (e.g., FTC Advisory Opinions)
  - Advisable to engage legal counsel

- “Own use” limitations are expressly covered by most GPO agreements, but apply regardless
“Own Use” (cont.)

- **Abbott Laboratories v. Portland Retail Druggists Association (1976)**
  - Retail labs sued manufacturers who sold to nonprofit hospitals at discounted prices when the hospitals resold to patients and other persons.
  - Generally permits nonprofit hospitals sales in furtherance of the hospitals “intended institutional operation”:
    - To patients on the premises and/or on a limited take-home basis.
    - To employees, medical staff and students for their personal use.
  - Generally prohibits sales:
    - To walk-in patients, to non-hospital patients of medical staff and re-fills for former patients.
Contractual Class of Trade Restrictions

• Sometimes used interchangeably with “own use” but two separate issues
  – “Own use” often cited by suppliers and serves as the catch-all term of art
• Suppliers often establish (non-discriminatory) pricing tiers for differing classes of trade (e.g., acute care, non-acute, retail, education, etc.)
• These are contractual limits on price availability
  – Generally prohibits resale unless purchased on a retail tier
  – Open Issue: products purchased on an acute care tier and resold in full accordance with “own use” limitations (e.g., to employees)
• Supplier responses include:
  – Refusal to sell
  – Revoking all price discounts (i.e., list price)
  – Potential for breach of contract allegations/litigation
Advantages of Data Analytics

GPO investments in data and analytics supported by billions in supply chain spend from thousands of hospitals
New Level of Transparency in Healthcare Purchasing

• Comparison shopping and complete access to pricing and product information is common in many industries.

• However, this kind of purchasing transparency and visibility into supply chain is new to healthcare.

• Novation’s data analytics services lead the industry and are helping to shift the balance of power to providers.
Legal Considerations: Contractual Limitations

• Contractual Confidentiality Restrictions
  – Hospitals own their invoice/purchase order data
  – Suppliers attempt to “gag” hospitals with restrictive contract terms
    • Threaten litigation vs. hospitals and third party data service providers
Legal Considerations: Antitrust

- Exchanges of price and cost information potentially raise antitrust issues
  - Price/cost exchanges can have significant pro-competitive benefits for consumers.
  - Per the FTC/DOJ: “Without appropriate safeguards, however, information exchanges among competing providers may facilitate collusion or otherwise reduce competition…”

- Information exchanges specifically permitted by FTC/DOJ “Safety Zone”
  - Agency policy favors arrangements:
    - Managed by a third party
    - Relating to historical data (not future prices)
    - Aggregating data from multiple providers so that an individual provider’s information cannot be identified
      - 5+ providers
      - Individual provider’s data <25% of each statistic
Best Practices – 3rd Party Data Handling

- Information is shared only on an aggregated, de-identified basis. Line item information is not identified/utilized beyond the needs of the hospital.

- Analytics data is not publicly available. All disclosure is to customers and is protected by terms of use agreements.

- Staff has access to and use of data based on their job category, their operational need to know and any restrictions in applicable contracts.

- Analytical tools utilize a process where a minimum of at least 5 data points are utilized and the top and bottom deciles of pricing are not displayed.

- Utilization of physical, procedural and electronic controls to ensure that data is handled in accordance with internal policies and contractual obligations.
Questions?

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