Models for Surgeon Alignment to Achieve Cost Saving in Medical Device Supply

Legal Considerations

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## Applicable Federal Laws

<table>
<thead>
<tr>
<th>Law</th>
<th>Prohibits price fixing agreements, conspiracies between horizontal competitors that restrain competition, or exchange of competitively sensitive information among competitors (e.g. cost, price)</th>
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</thead>
<tbody>
<tr>
<td>Anti-kickback Statute and regulations</td>
<td>Prohibits the knowing and willful offer or payment of “remuneration” in exchange for the referral of items and services that may be paid for by Federal health care programs.</td>
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<tr>
<td>Stark Statute and regulations</td>
<td>Prohibits a physician from making referrals for Designated Health Services (DHS) to an entity with which he or she (or an immediate family member) has a financial relationship (ownership, investment, or compensation), unless an exception applies</td>
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<tr>
<td>Civil Monetary Penalty Provisions (anti-stinting rule)</td>
<td>Prohibits a hospital (or critical access hospital) from making a payment to a physician to reduce or limit items or services provided to Medicare or Medicaid beneficiaries.</td>
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*State laws may also apply to the models, but will not be reviewed in this presentation.*
The Quick Summary

- Each of the Models can be organized and operated in compliance with applicable federal laws.
- The Models facilitate inclusion of the surgeon in the purchasing of implantable medical devices, which should result in value-added, cost savings to hospitals, payors and patients.
- Key Characteristics for Compliance → Relate to Proper Intent:
  - Independent medical judgment is not influenced nor restricted
  - Quality of goods and services is maintained or improved
  - No overutilization
  - No leveraging of surgical business with hospitals
  - Fair market value for goods and services
  - Transparency
  - Results in cost savings of implantable medical devices
Group Purchasing Organizations ("GPOs")

- **Antitrust**
  - Low risk of Antitrust concerns
  - Efficiencies must outweigh anti-competitive risks

- **Stark Law**
  - Permitted under Indirect Compensation Exception
  - Compensation to GPO from manufacturer on a per unit basis is FMV and does not take into account the volume or value of referrals
  - Documented in writing, signed by parties, identifies all products

- **CMP Law**
  - GPOs will presumably offer implantable medical devices of equal or better quality
  - Substitution of a comparable quality, but less costly, implant is acceptable
GPOs - Anti-kickback Law

1. Fees from manufacturer to GPO → GPO Safe Harbor
2. Discounts to purchaser from manufacturer → Discount Safe Harbor
3. Dividends to Surgeon Owners from GPO
   - No Safe Harbor will likely apply
   - GPOs can comply with the Anti-kickback Statute
     - Proper intent
     - Include safeguards
     - Avoid OIG’s “suspect” criteria
Surgeon Owned Commercial Bundled Payment Program (CBPP)
Surgeon Owned Bundled Payments

Antitrust

- Within a single group practice – No risk
- Among many groups (Forum Commercial Bundle)
  - Antitrust rules prohibit price-fixing, collaborating on prices or exchanging competitively sensitive information among competing providers
  - Solution = Clinical Integration and Financial Integration
  - Pro-competitive efficiencies must outweigh anti-competitive effects
Surgeon Owned Bundled Payments

Anti-kickback

- Limited or no Anti-kickback risk in bundled payment programs for commercial, private and self-pay patients
  - Anti-kickback applies only for Medicare/Medicaid
  - Allocations among providers reflect value added contributions and risk assumed
- If Anti-kickback Law were deemed to apply, then the following safe harbors may apply:
  - Personal Services Arrangements
  - Provider Discounts to Health Plans/Managed Care Plans
**Surgeon Owned Bundled Payments**

**Stark Law**
- May not be applicable where no “remuneration” is paid between referring physicians and hospitals
- If Stark were deemed to apply, available exceptions include:
  - Personal Services Arrangements
  - Fair Market Value (same criteria as above)
  - Indirect Compensation Arrangement and Exception
  - Risk Sharing Arrangements (42 CFR § 411.357(n))
- Allocations of bundled payment should be FMV based on services, value added, risk assumed
Surgeon Owned Bundled Payments

**CMP Law**

- Applies only to reductions in medically necessary services to Medicare and Medicaid patients
- OIG Advisory Opinion 08-16 - Permits hospital to share with physician entity P4P dollars received from managed care company, where hospital needed physician involvement to achieve measures
Institutional Stocking Distribution Company (ISD) with Surgeon Mgmt

- **Surgeons**
  - Management FMV Compensation

- **Hospital System**
  - Funds Inventory Cost Savings

- **ISD**
  - Purchase of Implants and Instruments
  - Products and Representation

- **Medical Device Manufacturers**

- **Hospital / ASC**

- **Hospital / ASC**

- **Hospital / ASC**
Surgeon Owned Stocking Distribution Company (SOD)

- Medical Device Manufacturers
- SOD
  - Funds and Management
  - Return on Investment
  - Products and Representation
- Hospital / ASC
- Hospital / ASC
- Individual Surgeons or Forum
  - Purchase of Implants and Instruments
Distributorships – ISD and SOD

Antitrust

- Does not restrict institutional or surgeon owned stocking distributors
- How does it apply to Distributorships?
  - Territory restrictions generally allowed to promote interbrand competition
  - Exclusive dealing restraints are not uncommon and generally lawful
  - But closed, exclusive distributorships subject to closer scrutiny
- Broad geographic customer base is preferred
Distributorships – ISD

Anti-kickback Statute

- Statutory Exception and Discount Safe Harbor would apply
- Personal Services and Management Contracts Safe Harbor applies to compensation for physician management
  - Signed written contract specifying all services
  - FMV Compensation - can be hourly rate, % based, performance incentives or a combination of these
  - % based compensation (or % cost-savings) is outside of Safe Harbor, but okay where arrangement is otherwise in compliance
  - Keep time records of services actually provided
Surgeon Owned Distributorships

Anti-kickback Statute

- SODs can be operated in compliance with the Anti-kickback Law
- Three relationships in the arrangement to consider:
  - Discounts from manufacturers to SOD
  - Sales from SOD to Hospital
  - Surgeon ownership of SOD; receipt of dividends/profit distributions
Surgeon Owned Distributorships

Anti-kickback Statute

Discounts to SOD from manufacturers can comply

- Congress intended the statute not to apply to common, commercially reasonable discounts
  “Offering or receiving discounts in order to compete for business does not alone mean that an entity ‘knowingly and willfully’ induced or arranged for referrals . . . “ (U.S. v. Shaw, 106 F. Supp. 2d 103, 120 (D. Mass. 2000))

- FMV Price; volume discounts consistent with market

- SODs do not need of sales rep support from manufacturer, which contributes to discounts negotiated
Surgeon Owned Distributorships

Anti-kickback Statute

- Sales contract between SOD and hospital/ASC can comply
  - Fixed unit pricing at FMV, without volume discounts
  - Written contract specifying obligations and rights of parties
- Dividends/profit distributions from SOD to surgeon owners can also comply with the statute
  - Can be structured and operated consistent with Anti-kickback statute, relevant OIG guidance and case law
  - Must NOT be operated with intent to induce referrals of business payable under the Medicare/Medicaid programs
Guidance on SODs

The OIG in its guidance has accepted that investments by physicians in SODs are not per se unlawful, and in fact can be operated in a manner that would not result in a violation of the Anti-kickback statute.

“OIG recognizes that the lawfulness of any particular [S]OD under the anti-kickback statute depends on the intent of the parties. Such intent may be evidenced by a [S]OD’s characteristics, including the details of its legal structure; its operational safeguards; and the actual conduct of its investors, management entities, suppliers, and customers during the implementation phase and ongoing operations.”

- OIG, Special Fraud Alert: Physician Owned Entities, March 26, 2013
Conclusions from Guidance on SODs (cont.)

- OIG has stated that “[S]ODs are inherently suspect . . .”

- BUT, “inherently suspect” ≠ illegal

  “‘suspect’ does not mean arrangement is necessarily illegal or unlawful, or that it cannot be properly structured to fit in a safe harbor.”


- It does mean that SODs will be closely scrutinized to ensure proper structure, conduct and intent
SODs: Safeguards Against Anti-kickback Risk

- SODs should be structured, governed and operated in a manner that utilizes the safeguards recognized under the OIG guidance
- Safeguards include:
  - Significant investment of capital
  - Physician investors contribute to the business operations
  - Offer to invest are not based on volume of anticipated referrals
  - Distributions are made in accordance with percentage of ownership
  - Operated with appropriate management, sales and support staff
  - Achieves reduction in costs of medical devices for facility customers
  - Owners not required to use SOD’s medical devices
  - No undue influence leveraged against hospitals/ASCs
  - Transparency of arrangements to hospitals, ASCs, patient
  - Maintain a culture of regulatory compliance
Institutional Owned Distributorships

**Stark Law**
- Contract for physician management with hospital would be a compensation arrangement under the Stark law
- The following Stark exception may apply:
  - Personal Services Arrangements Exception (42 CFR § 411.357(d))
  - Fair Mark Value Exception (42 CFR § 411.357(l))
  - Indirect Compensation Arrangement Exception (42 CFR § 411.357(p))
- General requirements that must be meet:
  - Signed, written agreement describing all services, term of at least 1 year
  - FMV compensation; can be hourly, % based, performance incentives or a combination of these
  - Good practice for surgeons to maintain time records of services provided
Surgeon Owned Distributorships

Stark Law

- Results result in an indirect compensation arrangement under the Stark Law with respect to hospital purchases from the SOD

- Indirect Compensation Exception applies, where:
  - Compensation from hospital to SOD, *on a per unit basis*, is FMV and does not take into account the volume or value of referrals
  - Documented in writing, signed by parties, identifying all products
  - Arrangement does not violate Anti-Kickback statute

- Stark Law should not apply to arrangement between SODs and ASCs
Distributorships – ISD and SOD

CMP Law

- CMP Law recently amended - prohibits reducing or limiting “medically necessary” services
- Medical devices offered by distributor (institutional or surgeon owned) should be equal or better quality
- Substitution of a comparable quality, but less costly, implant, does not reduce or limit medically necessary services provided to Medicare or Medicaid patients
Surgeon Ownership of Manufacturing

Antitrust Law

- No special antitrust law considerations apply
- Same rules as apply to device manufacturers generally, regarding:
  - No price fixing or collusion with competitors or distributors
  - No agreements to boycott
Surgeon Ownership in Manufacturing

Anti-kickback Statute

- Safe Harbor for Small Investments (42 CFR § 1001.952(a)(2))
- Key Criteria for Ownership of Manufacturing:
  - Avoid outsourcing all business operations
  - Investors make significant capital contributions
  - Dividends in accordance with percentage of ownership
  - No undue influence on hospitals or ASCs
  - Manufacturer must follow good manufacturing practices and comply with FDA rules
  - Transparency with hospitals, ASCs and patients
Surgeon Ownership in Manufacturing

Stark Law

- Results in an indirect compensation arrangement with respect to hospitals that purchase medical devices from the manufacturer
- Indirect Compensation Arrangement Exception applies - Same analysis as applicable to SODs
Surgeon Ownership in Manufacturing

CMP Law

- Same analysis as applicable to GPOs and SODs
- Presumably medical devices manufactured and sold are of equal or better quality
Thank you!

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