## Ancillary Revenue and Healthcare Cost Savings:

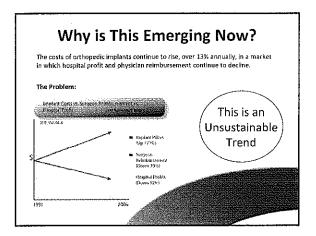
The Case for Surgeon Owned Implant Distribution

> Paul Burton, DO Arrowhead Orthopaedics Redlands, California

## Disclosures Alfiance Surgical Distributors (Partner) Inland Spine and Orthopedic Products (Partner) Synergy Surgical Technologies (Partner)

#### Outline Surgeon Owned Distribution

- · Why is this Emerging Now?
  - ✓ Escalating Implant Prices
  - ✓ Decreasing Surgeon Reimbursement
  - ✓ Decreasing Hospital Profit
- Compare Alternative Solutions
- · Legal and Ethical Considerations
- Case Study
- Set-up of a Surgeon Owned Distribution Common Street



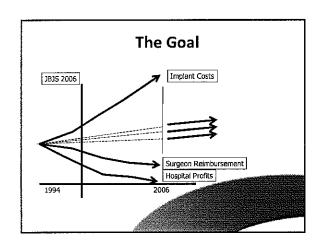
## Key Factors in the Problem and Solution

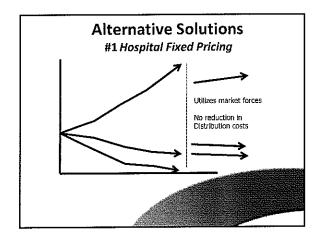
#### Problem

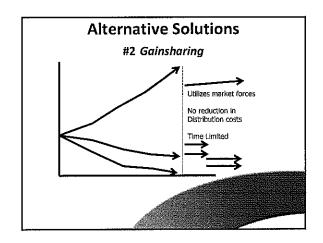
- Decision maker is not the purchaser
- Absence of effective price negotiation and price control
- Highly paid distributors and product reps

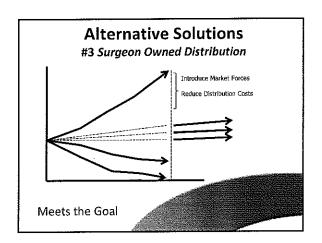
#### Solution

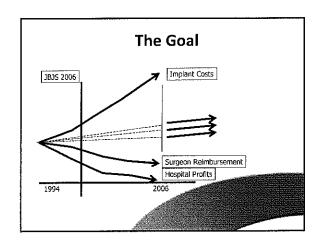
- Surgeon becomes the purchaser
- Surgeon negotiates and controls price
- Surgeon determines the product rep salary











#### **Surgeon Owned Distribution**

What it IS: Stocking Distribution Model

- Purchase Inventory
- Hire Product Reps
- · Contract Directly with Hospitals
- True Ancillary Business

#### What it IS NOT: Commissioned Model

- No inventory purchase and little financial risk
- Guaranteed percent of sales (passing ugr)

## Is it Legal? Federal

- 2005 Crowell and Moring
- 2007 updated 2009) Hooper, Lundy & Bookman, Inc. (Largest healthcare law firm in the US)

"Based upon the facts, assumptions and legal analysis set forth, we conclude that Manufacturers sales of medical devices to the Physician Owned Distribution Company, physicians investment in the Distribution Company and sales of implants by the Distribution Company to the hospitals and ASC's should not be found to be prohibited by federal anti-kickback or self-referral laws or by California similar laws."

"With respect to federal Stark law, we continue the exception for indirect remungration (4 ± 6 ± ik 3 capacity 411.357(p)) will be available."

#### Is it Legal? California

• California Attorney General Bill Lockyer

Opinion #05-614 February 27, 2006

"A physician generally may prescribe for a patient a medical device that is distributed by a company in which the physician has an ownership interest, provided that any return

on investment is based upon the physician's proportional

ownership share and requisite disclosing

#### Is it Legal? Hospitals

Cleared by the Legal Departments of:

- Catholic Healthcare West
- · Arrowhead Regional Medical Center
- Redlands Community Hospital
- Centura Health System
- Exempla Lutheran
- · Gerald Champion Regional Medical Center

#### **Surgeon Owned Distributorship**

Legal Requirements Include:

- · Adhere to all state and federal self-referral and antikickback laws
- · Demonstrate financial risk (investment)
- · Perform all functions typical of medical device distributorships
- . Offer pricing that represents the lowest average cost for like implants
- . Sell membership interest at fair market value without concern for volume or value of referral
- Distribute profits based on investment access.

#### **Surgeon Owned Distributorship**

#### Is this ethical?

- · Depends on the actions of the individual using the model
- Providing you intend to act ethically its ethical.
- · Only distribute products that meet or exceed the quality of your current products.
- · Hire qualified and competent product rep
- Provide complete disclosure to your patients.
- Transparent to the hospital and colleagues.
- · Demonstrate merit (cost savings)

#### **Surgeon Owned Distributorship**

- · Baseline product utilization is recorded and any increase is critically evaluated.
- · Utilization data is open to audit by contracting hospitals and government

#### **Product Quality**

- · All products used have been critically assessed by the surgeons
- · All products have been cleared by the FDA

#### Case Study

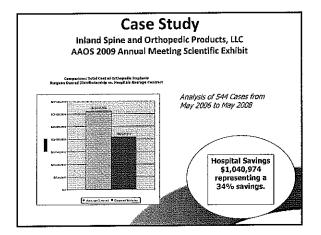
Inland Spine and Orthopedic Products, LLC

#### 4 Orthopedics Surgeons formed a LLC distributorship

- contracted with local hospitals
   hired a product rep
- leased space
- purchased inventory stock
   Padicle Screw System Total Hip Total Knee
   Interbody Cage Cervical Plate System

#### Continued Effects:

- Prices have not increased since 2006
- 2010 7% price reduction
- Outstanding Return in Investment



#### Surgeon Owned Distribution Initial Steps

- · Identify surgeon partners
- · Consider a corporate partner
- · Identify suitable products
- · Create a business pro forma
- Secure legal opinions
- · Create the legal entity with name and corporate documents
- · Contract with Hospitals and Product Companies
- · Recruit a product Rep
- · Identify office space, operational software etc

#### **Product Selection**

Surgeons decide to purchase and distribute implants based on:

- Adherence to specific design criteria
- FDA Clearance
- Visual inspection of implants and instruments
- Personal communication with surgeons currently using the implant
- Surgical trials

Implants must be equal or better than count used currently.

#### **Summary**

- The trend reported by the Journal of Bone and Joint Surgery, vol.88-A, 2006, should concern us all and truly is unsustainable.
- The surgeon owned distribution model depicted in this presentation appears to be the most efficient of addressing this trend and has proven to:
  - a, lower overall healthcare costs
  - b. improve hospital profitability
  - c. create more reasonable surgeon compensation
- 3. Importance of Obtaining Expertise
  - a. Legal Expertise
  - b. Operational Assistance
  - c. Contracting Expertise

# Thank You Questions?