Lithotripsy in the ASC Environment:
Relationships, Economics, and Valuation Issues

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High Level Look at an Agreement

- Extracorporeal Shock Wave Lithotripsy (ESWL)
- Per Procedure (per "Click") payment
- Provider typically provides equipment and a technologist
- Equipment is delivered to Facility and removed daily
- Services are provided to Facility on a scheduled basis

The Typical Agreement

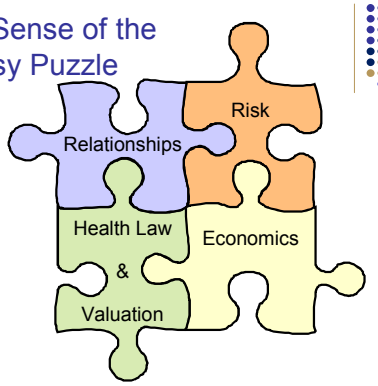
Provided by Provider

- Equipment, including
  - Repairs & maintenance
  - Property Insurance
  - Property & other taxes
- Transportation of Equipment (if applicable)
- Lithotripsy technologist (and separate driver, if applicable)
- Liability insurance
- Licenses/certifications
- Scheduling

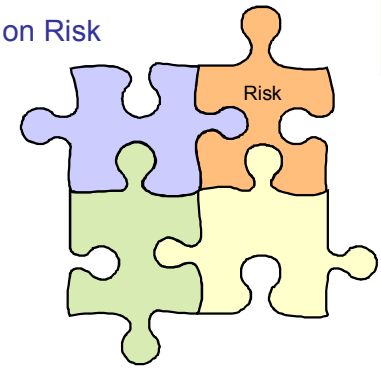
Provided by Facility

- Surgical staff (pre, peri, & post)
- Space, including utilities
- Supplies
- Medical Records
- Reception
- Insurance
- Medical waste removal
- Linen services
- Scheduling
- Billing & collections
- Marketing
- Physician Supv. / Med. Director

Making Sense of the Lithotripsy Puzzle



Focus on Risk



Typical Risk of Equipment Investment

- Facilities seek to minimize the risk associated with new capital purchases.
- In the case of lithotripsy equipment, Facilities' primary risk falls into three categories.

Facility's Risk
Collections Risk
Equipment Obsolescence
Volume

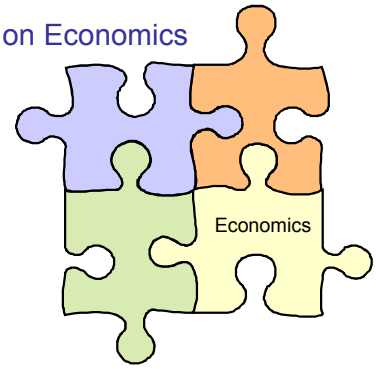
Providers Shift the Risk Profile

- Ability to enter into per-use arrangements for high-risk equipment shifts the risk to the services provider

Facility's Risk		Provider's Risk
Collections Risk		
Equipment Obsolescence		X
Volume	→	X

- When Provider is physician-owned, however, the Provider's risk is minimized as volume is more predictable.

Focus on Economics



Annual Usage Targets

- Purchasers of Capital Equipment desire a threshold volume.
- Discussions with owners of lithotripsy equipment indicate volume threshold to range from 200 to 1,000 Procedures per year.
- Transportable Equipment allows Providers to coordinate volume across multiple delivery sites by contracting with multiple Facilities.
- Providers not taking advantage of the transportable nature of the Equipment and not achieving minimum annual usage may try to increase the per-use payment.

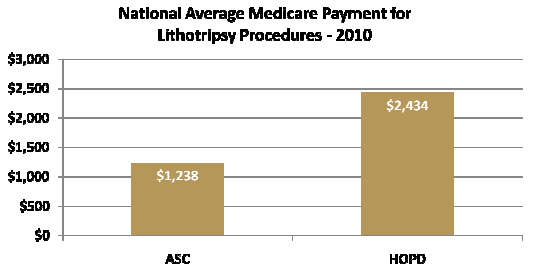
Factors Influencing Price

- Price is influenced by how effectively the Equipment can be utilized
- Facility Volume
  - Procedures per year
  - Procedures performed per visit
- Delivery schedule
- Equipment not utilized to target volumes
- Travel distance and travel time

Geography Does Not Influence Price

- Major cost drivers do not vary market to market
  - Equipment costs
  - Transportation vehicle costs
- Those costs that may vary are minimal in comparison, and therefore, have a minimal effect on price.
  - Labor: What is the variance for a few hours of labor
  - Gasoline: What is the effect on each procedure

One Challenge for ASC Facilities



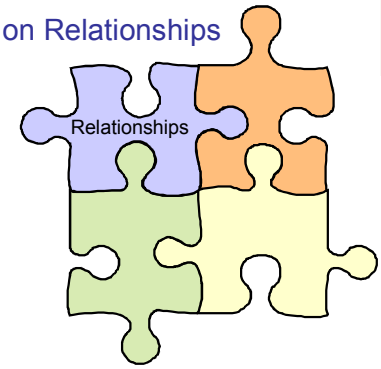
Managing Reimbursement Challenges

- How much does it cost per Procedure to provide:
  - Surgical staff (pre, peri, & post)
  - Space, including utilities
  - Supplies
  - Medical Records
  - Reception
  - Insurance
  - Medical waste removal
  - Linen services
  - Scheduling
  - Billing & collections
  - Marketing
  - Physician Supv. / Med. Director
- Some ASC Facilities elect to "cherry-pick" cases.

Summary of the Economics

- Technical component reimbursement for lithotripsy procedures may be very attractive to a Facility, and therefore, the Facility can "afford" to pay physician-owned lithotripsy providers at rates that may be in excess of FMV while still realizing attractive profitability from the procedures.
- Nevertheless, as they would with non physician-owned service providers, Facilities should endeavor to negotiate a payment structure that complies with FMV and applicable healthcare regulations.

Focus on Relationships



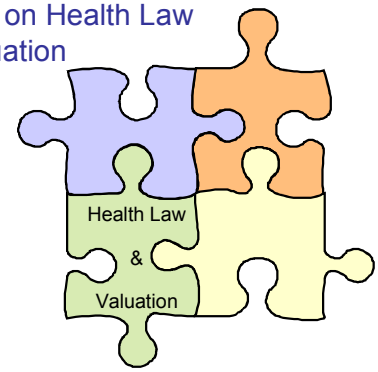
Relationships Do Matter

- Physician-owned companies generally control much or all of the volume of the patients requiring lithotripsy services. In addition, physician owners of these companies often control referral volume for other urology procedures at the hospital/ASC where lithotripsy is provided. Therefore, Facilities will continue to face difficult decisions regarding selection of their lithotripsy provider and the rates paid for the services.

Relationships Do Matter

- While you can't pay for the value or volume of referrals, we certainly understand that they do have a value.
  - The value of the lithotripsy referrals
  - The value of other urology referrals
- Provider owners may also be owners of the ASC.
- Provider owners may sit on the ASC board and participate in the decision to contract with the Provider.

Focus on Health Law & Valuation



A Regulatory Hot-Button

- On July 30, 2008, CMS issued its final rule regarding the Hospital Inpatient Prospective Payment System (IPPS). CMS elected to allow healthcare service providers until October 1, 2009 to restructure or unwind certain current arrangements that were impacted by the final rule. Those following the developments leading up to and following IPPS *(aka Stark III)* may recall the significant discussion surrounding lithotripsy services. Industry participants have somewhat universally agreed that in January 2009, CMS cleared the way for the continuation of *per click* lithotripsy services arrangements
- The discussion surrounding these arrangements should have signaled to those involved that the Office of the Inspector General (OIG) was aware of the potential abuses involved in the provision of lithotripsy by physician-owned companies.

A Strong Warning

- On July 8, 2010 the OIG entered into a $7.3 million Civil Monetary Penalty settlement agreement with three physician-owned providers of lithotripsy and urology laser services companies (United Shockwave Services, United Prostate Centers, and United Urology Centers) based in the Chicago area and serving hospitals in Illinois, Indiana and Iowa.

The Allegations

- With respect to their activities from January 2005 to September 2009, the OIG alleged:
  - The company and certain of its physician owners, "leveraged patient referrals to obtain contract business from hospitals"; and
  - The company "caused certain hospitals to submit claims for designated health services that resulted from prohibited referrals in violation of the Physician Self Referral Law (the Stark Law)".
- *We believe that this settlement sends a strong caution to providers of lithotripsy services that parties to such arrangements must assure that these transactions are based on fair market value ("FMV").*

Three Approaches to Fair Market Value
Each with Its Own Limitations

- Income Approach
- Market Approach
- Cost Approach

Income Approach

- If applied, would directly reflect the volume and value of referrals
- Not applicable to lithotripsy or many other healthcare transactions

Market Approach
General Approach

- Identify data based on independent providers of lithotripsy services (*i.e.*, not physician owned)
  - However, the market is clearly dominated by physician-owned enterprise.
  - Largest non-physician owned companies are ForTec, Litho of America, and UMS.
- Determining FMV using a market approach requires that market comparables be based on transactions involving *arm's-length* parties. Therefore, though tempting and intuitive, hospitals must avoid defaulting to what the "hospital down the street" is paying for lithotripsy services as such rates may not be at arm's length (or consistent with FMV).
- Opinion must be based on non-physician owned transactions.

Market Approach
General Observations

- Independent market price data generally does not vary from market to market.
  - Cost observations provide support for this finding.
  - Exception relates to rural markets which may require additional resources to deliver the Procedures.
  - Additional exception relates to urban markets with uniquely high costs.
- Pricing varies with volume.
  - Higher volume on a daily basis yields lower pricing.
  - Higher volume on an annual basis yields lower pricing.
- Market Approach yields higher values than the Cost Approach.
  - Margins in lithotripsy are higher than in other businesses providing services on a part-time basis.

Cost Approach

- Hypothetical look at a typical Provider's Direct Costs and Margin required to deliver the Services
  - Cost for Equipment + Margin
  - Cost for Staff + Margin
  - Cost for Transportation + Margin
- Margin based on other businesses providing part-time use of certain resources
  - Margins for full-time services may be lower (*i.e.*, less risk), but assume full-time payment (*i.e.*, not based on per-use)

Conforming FMV to Recent CMS Guidance

- We note the following from CMS:
  - *We are also taking this opportunity to remind parties to per-use leasing arrangements that the existing exceptions include the requirements that the leasing agreement be at fair market value (§411.357(a)(4) and §411.357(b)(4) and that it be commercially reasonable even if no referrals were made between the parties §411.357(a)(6) and §411.357(b)(5)) … As a further example, we would also have a serious question as to whether an agreement is commercially reasonable if the lessee is performing a sufficiently high volume of procedures, such that it would be economically feasible to purchase the equipment rather than continuing to lease it from a physician or physician entity that refers patients to the lessee for DHS. Such agreements raise the questions of whether the lessee … is leasing equipment rather than purchasing it because the lessee wishes to reward the lessor for referrals and/or because it is concerned that, absent a leasing arrangement, referrals from the lessor would cease.*

Source: Centers for Medicare & Medicaid Services 42 CFR Parts 411, 412, 413, 422, and 489 (CMS-1390-F)

Conformance to Recent CMS Guidance

- We believe it is appropriate to establish a maximum annual payment to a Provider and that such payment should not exceed the cost for a Facility to provide the Services in-house subject to consideration of any benefits afforded the Facility in an "outsourced" structure.

Summary

- The lithotripsy market may be counterintuitive.
- Incentives are generally aligned as elements of risk, economics, and relationships fall into place
- However, Facilities must tread carefully to assure compliance with healthcare law and FMV

Common Potential Variations

- Equipment Variations
  - Typical: electromagnetic transportable lithotripter.
  - Alternatives
    - Trailer based (which is also a treatment room) - allows for potentially different payment structure
    - fixed unit (typically older *e.g.*, Dornier HM3)
- Staff Variations
  - Typical: a lithotripter technologist
  - Alternatives
    - RN also provided
    - Staff leased from Hospital
    - No staff provided

Common Potential Variations

- Transportation Variations
  - Typical: Provider transports the Equipment to the Facility for each service day and removes the Equipment at the end of that day.
  - Variations
    - Equipment remains on site
    - Rural Location
- Payment Structure Variations
  - Typical: Per-use basis
  - Variations
    - Daily minimum
    - Daily sliding scale
  - Key Card Program