

More Evidence of a New Lithotripsy Landscape

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 (through FAQ #9556 response). 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.

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. 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").

FMV Pitfall

The settlement is yet another reminder of the challenges associated with *per click* lithotripsy arrangements. When entering into lithotripsy transactions, providers and facilities need to recognize the following fundamental challenges associated with ensuring compliance with federal regulations:

- 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 where lithotripsy is provided. Therefore, hospitals will continue to face difficult decisions regarding selection of their lithotripsy provider and the rates paid for the services.
- Technical component reimbursement for lithotripsy procedures is usually very attractive to hospitals, and therefore, hospitals 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, hospitals should endeavor to negotiate a payment structure that complies with healthcare regulations.
- Determining FMV using a market approach requires that market comparables be based on transactions involving *arm's-length* parties. However, the market for lithotripsy services is largely dominated by physician-owned entities. 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).

The challenges above reveal the extent to which the deck seems stacked against entering into a compliant *per click* lithotripsy transaction with a physician-owned provider. Participants in this market must continue to pay close attention to the motives and financial outcomes of these transactions when establishing FMV.