I. MAJOR LEGAL RISKS

Providers are increasingly being challenged to establish that physician relationships are at fair market value. The failure to establish fair market value can have the following implications.

A. Loss of Federal Income Tax Exemption. Payment in excess of fair market value can result in inurement/impermissible private benefit, resulting in:
   1. Loss of exemption, and potential spillover to other tax-exempt affiliates
   2. Payment of taxes
   3. Loss of tax-exempt status of bonds

B. Intermediate Sanctions. Payment in excess of fair market value in a transaction to a disqualified person is an excess benefit transaction resulting in excise taxes on the disqualified person and the organization managers.

C. Violation of Anti-Kickback Statute. Payment in excess of fair market value generally means that no safe harbor exists and that there is a presumption that the excess payment is in consideration of referrals.

D. Violation of Stark. Payment in excess of fair market value can result in a structure where physician cannot refer to hospital or its affiliate for designated health services, and hospital or other entity cannot bill or collect for such services. Submission of claims in violation of Stark may create liability under the False Claims Act.

E. Inducements to Reduce or Limit Services. Payments by a hospital that induce a physician to reduce or limit services to Medicare or Medicaid patients can subject the hospital to civil monetary penalties.

F. Contract Issues. Payment in excess of fair market value that violates Stark or the anti-kickback statute can void a contract based on illegality. The parties may find that they do not achieve what they contracted for.
G. Beyond Scope of Public Body (in the case of a transaction by a public hospital or other public entity). Payment in excess of fair market value may exceed powers of public body, resulting in potential for:

1. Personal liability of trustees
2. Taxpayer suit
3. Injunction

H. Violation of State Nonprofit Corporation Act/Fiduciary Duties of Nonprofit Directors. Payments in excess of fair market value, particularly to insiders, may violate statutory and common law, resulting in potential for Attorney General claims.

II. LEGAL BACKGROUND – ANTI-KICKBACK, STARK, AND TAX

A. Valuation Issues Under Federal Anti-Kickback Legislation

1. Fair Market Value Cannot Include Reference to Referrals.

   a. The Hanlester administrative decision of July 24, 1992 specifically addresses fair market issues. There, the respondents argued that the Inspector General failed to prove that the network's retention of 4% of collections for marketing and the laboratory's retention of 20% for distribution to the physician investors was "excessive" or "unreasonable", by any showing that they exceeded comparable arrangements or fair market value. The Departmental Appeals Board responded:

   "However, the I.G. was not required to prove that the amount obtained by respondents through the management agreement with SKBL was greater than provided for generally in such transactions, since we have pointed out that common business practices are not necessarily legitimate. The meaningful comparison would be with management contracts that do not involve the ability of a manager to channel referrals to itself, or with a reference laboratory relationship which does not involve the element of management control over the source laboratory's referral streams. The ALJ found that the benefits gained by respondents from this arrangement were greater than those available from simply referring tests to outside laboratories on a test-by-test basis. This excess value served to compensate respondents for granting SKBL control over the stream of test referrals. . . . Therein lies the illegality."

   b. In the Special Fraud Alert: Arrangements for the Provisions of Clinical Laboratory Services, issued in October, 1994, the OIG indicates as follows:
Whenever a laboratory offers or gives to a source of referrals anything of value not paid for at fair market value, the inference may be made that the thing of value is offered to induce the referral of business. The same is true whenever a referral source solicits or receives anything of value from the laboratory. By "fair market value" we mean value for general commercial purposes. However, "fair market value" must reflect an arms-length transaction which has not been adjusted to include the additional value which one or both of the parties has attributed to the referral of business between them.

c. The OIG Compliance Guidance for Individual and Small Group Practices (October, 2000) states:

"The OIG’s definition of ‘fair market value’ excludes any value attributable to referrals of Federal program business or the ability to influence the flow of such business. See 42 U.S.C. 1395nn(h)(3). Adhering to the rule of keeping business arrangements at fair market value is not a guarantee of legality, but is a highly useful general rule."

2. Fraud and Abuse Safe Harbors. Safe harbors for space rentals, equipment rentals, and personal services require that the aggregate rental charge be set in advance, is consistent with fair market value in arms-length transactions, and is not determined in a manner that takes into account the volume or value of any referrals or business otherwise generated between the parties for which payment may be made in whole or in part under Medicare or a state health care program.

3. Fair Market Value Is Not the Sole Test of Safe Harbor Qualification. The First Circuit held in United States v. Bay State Ambulance and Hospital Rental Service, Inc., 874 F.2d 20 (1st Cir. 1989) that the proposed safe harbor did not exempt every transaction in which the amount paid for services is an amount consistent with fair market value, but rather that only a small subset of such transactions were excepted by the safe harbor – those that met all of the terms of the safe harbor.

The Secretary’s comments accompanying the November 19, 1999 revised safe harbors confirm that the opportunity for referrals may be sufficient to trigger a violation, and that the absence of remuneration (or the fact of fair market value remuneration) may not be sufficient to avoid a violation.

4. Relationship to IRS Standards. The Secretary at 56 Fed. Regis. 35972 (July 29, 1991) commented in response to a suggestion that the safe harbor requirements under the anti-kickback statute should be the same as the fair market value assessments by the IRS in order to
determine whether inurement or private benefit existed. The Secretary responded:

"We do not believe that procedures for assessing the fair market value of hospital/physician arrangements under the Internal Revenue Code are relevant to safe harbor requirements under the anti-kickback statute. The anti-kickback statute is concerned with prohibiting fraud and abuse by individuals and entities participating in the Medicare and Medicaid programs; a statute providing tax exemptions to nonprofit institutions under specified conditions does not share this focus. The requirements we have set forth for determining fair market value under the safe harbor regulation are not undermined by the fact that they do not replicate the requirements under the Internal Revenue Code. Moreover, we cannot see, nor has any commenter adequately explained, how these regulations impede health care providers’ ability to obtain tax exempt status under the Internal Revenue Code."

5. OIG Supplemental Compliance Guidance for Hospitals (January 2005). The Guidance states:

“The general rule of thumb is that any remuneration flowing between hospitals and physicians should be at fair market value for actual and necessary items furnished or services rendered based upon an arm’s length transaction and should not take into account, directly or indirectly, the value or volume of any past or future referrals or other business generated between the parties. Arrangements under which hospitals (i) provide physicians with items or services for free or less than fair market value, (ii) relieve physicians of financial obligations they would otherwise incur, or (iii) inflate compensation paid to physicians for items or services pose significant risk. In such circumstances, an inference arises that the remuneration may be in exchange for generating business.”

The Guidance notes that the OIG asks whether the determination of fair market value is based upon a reasonable methodology that is uniformly applied and properly documented. If fair market value is based on comparables, the hospital should ensure that the market rate for the comparable services is not distorted (e.g., the market for ancillary services may be distorted if all providers of the service are controlled by physicians).

The Guidance further provides:

“Depending on the circumstances, an exclusive contract can have substantial value to the hospital-based physician or group, as well as to the hospital, that may well have nothing to do with the value or volume of business flowing between the hospital and the physicians. By way of example only, an exclusive arrangement may reduce the costs a physician or group would otherwise incur for business
development and may eliminate administrative costs otherwise incurred by the hospital. In an appropriate context, an exclusive arrangement that requires a hospital-based physician or physician group to perform reasonable administrative or limited clinical duties directly related to the hospital-based professional services at no or a reduced charge would not violate the anti-kickback statute, provided that the overall arrangement is consistent with fair market value in an arm’s-length transaction, taking into account the value attributable to the exclusivity. Depending on the circumstances, examples of directly-related administrative or clinical duties include, without limitation: participation on hospital committees, tumor boards, or similar hospital entities; participation in on-call rotation; and performance of quality assurance and oversight activities. Notwithstanding, whether the scope and volume of the required services in a particular arrangement reasonably reflect the value of the exclusivity will depend on the facts and circumstances of the arrangement.”

6. **OIG Advisory Opinions.** Section 1128D(b)(3)(A) prohibits the OIG in its advisory opinions from addressing whether fair market value will be or was paid or received for any goods, services, or property. In the regulations issued on January 9, 1998 at 42 CFR 411.370(c)(1) dealing with advisory opinions, the Secretary comments:

"As explained above, even if a party requested, we will not address the issue of whether fair market value was, or will be, paid or received for any goods, services, or property." 63 Fed. Regis. 1645.

Notwithstanding this, several OIG advisory opinions clearly consider fair market value issues in their analysis:

a. **99-2.** The OIG views as suspect discounts below fully loaded costs, and discounts less than prices given to others with similar volumes but no potential for referrals.

b. **03-8.** The OIG declined to rule favorably on a per patient per day management fee, noting that "per patient", "per click", and “per order” and similar payment arrangements with referral sources are disfavored.

c. **04-08.** The OIG had significant concerns with respect to fair market value of an arrangement involving multiple, overlapping, part-time leases of shared physical therapy services where the rental was an equal, fixed monthly rental amount. The OIG noted that the overlapping, as needed aspect of the leases, made it difficult to monitor, assess, and document fair market value, and increased the risk that
some physicians would pay more or less than FMV for the services used.

d. **09-05.** The OIG notice that on-call coverage compensation potentially creates considerable risk that physicians may demand such compensation as a condition of doing business at a hospital, even when neither the services provided nor any external market factor (e.g., a physician shortage) support such compensation. Similarly, payments by hospitals for on-call coverage could be misused to entice physicians to join or remain on the hospital’s staff or to generate additional business for the hospital.

The OIG further lists problematic compensation structures that might disguise kickback payments could include, by way of example:

i. “lost opportunity” or similarly designed payments that do not reflect *bona fide* lost income;

ii. payment structures that compensate physicians when no identifiable services are provided;

iii. aggregate on-call payments that are disproportionately high compared to the physician’s regular medical practice income; or

iv. payment structures that compensate the on-call physician for professional services for which he or she receives separate reimbursement from insurers or patients, resulting in the physician essentially being paid twice for the same service.

7. **OIG Settlements.** Recent OIG settlements include settlements related to payments in excess of fair market value, payments in excess of those set out in contracts, payments not supported by written agreements, and provision of support services at free or reduced cost.

B. **Valuation Issues Under Stark.**

1. **Fair Market Value Defined.** Fair market value is defined by Section 1877(h)(3) as the value in arms-length transactions, consistent with general value market, and, with respect to rentals or leases, the value of rental property for general commercial purposes (not taking into account its intended use).
The regulations at 42 CFR 411.351 state:

"Fair market value means the value in arm's-length transactions, consistent with the general market value. 'General market value' means the price that an asset would bring, as the result of bona fide bargaining between well-informed buyers and sellers who are not otherwise in a position to generate business for the other party, or the compensation that would be included in a service agreement, as the result of bona fide bargaining between well-informed parties to the agreement who are not otherwise in a position to generate business for the other party, on the date of acquisition of the asset or at the time of the service agreement. Usually, the fair market price is the price at which bona fide sales have been consummated for assets of like type, quality, and quantity in a particular market at the time of acquisition, or the compensation that has been included in bona fide service agreements with comparable terms at the time of the agreement, where the price or compensation has not been determined in any manner that takes into account the volume or value of anticipated or actual referrals."

2. Commercial Reasonableness. A number of the compensation exceptions under the Stark regulations require that the remuneration be commercially reasonable even if no referrals were made between the parties.

a. CMS comments state:

"An arrangement will be 'commercially reasonable' in the absence of referrals if the arrangement would make commercial sense if entered into by a reasonable entity of similar type and size and a reasonable physician (or family member or group practice) of similar scope and specialty, even if there were no potential DHS referrals."

b. Includes requirement that items or services not exceed that which is reasonably necessary to accomplish legitimate business purposes.


“In addition, because many exceptions to the Stark law require fair market value compensation for items or services actually needed and rendered, hospitals should have appropriate processes for making and documenting reasonable, consistent, and objective determinations of fair market value and for ensuring that needed items and services are furnished or rendered.”
4. **Exceptions.**

   a. Under Stark, the exceptions generally require that the amount of the remuneration for a transaction be consistent with fair market value and not be determined, directly or indirectly, in a manner that takes into account the volume or value of referrals by the physician. This applies with respect to the exception for personal services contracts, fair market value arrangements, and employment contracts.

   b. The fair market value exception at Section 411.357(l) provides an exception for any compensation for the provision of items or services by the physician or group practice if the arrangement is set forth in an agreement that meets certain conditions, if the compensation is set in advance and is consistent with fair market value and is not determined in a manner that takes into account the volume or value of any referrals, or any other business generated between the parties.

5. **Highlights of FMV Provisions of Stark Regulations.**

   a. It is not possible to list appropriate benchmarks or objective measures.

   b. Methodology must exclude valuations where the parties are in a position to refer.

   c. No single means of determining FMV will apply.

   d. Good faith reliance on a proper valuation may be relevant to a party's intent but does not establish the ultimate issue of the accuracy of the figure itself.

6. **CMS Advisory Opinions.** Section 1877(g)(6) (added by the Balanced Budget Act of 1997) requires that the Secretary issue written advisory opinions concerning whether a referral relating to designated health services is prohibited under Stark. Like the anti-kickback opinions, the statute prohibits CMS in its advisory opinions from addressing whether fair market value will be or was paid or received for any goods, services, or property. Unlike the OIG advisory opinions, there is no history of CMS opinions that take fair market value issues into account.

7. **Goodstein v McLaren, 202 F. Supp. 2d (E.D. Mich. 2002).** The Government alleged that lease rates paid by a hospital to physician owners of a building were in excess of fair market value and were determined in a manner that took into account the volume or value of referrals. The Court held that it was the Government's burden to show that lease rates were determined in a manner that took into account the volume or value of referrals, and that the Government had not
established this. It noted specifically that hospital's demand for exclusivity and non-competes in the leases, and a provision allowing the hospital to vacate the space if the physicians moved out of the building did not establish such connection.

C. Valuation Issues Under Tax Exemption.

1. Inurement/private Benefit.
   a. Inurement focuses on individuals having a personal and private interest in the activities of the organization.
   b. 2004 CPE: Health Care Provider Reference Guide – Physicians may be insiders depending on whether they exercise control.
   c. Private benefit applies more broadly to require both a qualitative analysis (charitable benefits cannot be achieved without benefiting private individuals) and a quantitative analysis (amount of private benefit cannot be substantial when measured in the context of overall public benefit).

   a. Definition of an Excess Benefit Transaction. The regulations at 26 CFR Section 53.4958-4(a) define an excess benefit transaction as any transaction "in which an economic benefit is provided by an applicable tax-exempt organization directly or indirectly to or for the use of any disqualified person, and the value of the economic benefit provided exceeds the value of the consideration (including the performance of services) received for providing the benefit.” An excess benefit transaction also includes certain revenue-sharing transactions that have yet to be set out in Section 53.4958-5. An economic benefit shall not be treated as consideration for the performance of services unless the organization providing the benefit clearly indicates its intent to treat the benefit as compensation when the benefit is paid.
   b. Rebuttable Presumption of Reasonableness. The Regulations implement the Congressional statement of intent that a rebuttable presumption be included in the regulations. An organization manager can generally protect himself or herself from intermediate sanctions with a valuation opinion. Under the Regulations, at 26 CFR 53.4958-1(d), an organization manager's participation is due to "reasonable cause" if the manager has exercised his responsibility with ordinary business care and prudence. Reliance on the advice of legal counsel, a CPA, or an independent valuation expert expressed in a "reasoned written opinion" that the transaction is not an excess benefit transaction will ordinarily be considered due to reasonable cause even if the
transaction is later held to be an excess benefit transaction. A "reasoned written opinion" must address itself to the facts and applicable law. A written opinion is not reasoned if it does nothing more than recite the facts and express a conclusion.

If the organization manager fails to get a reasoned written opinion, its absence does not by itself give rise to an inference that the organization manager acted without reasonable cause.

c. **Tax on Organization Managers.** The statute provides that organization managers are liable for a tax of 10% of the excess benefit (up to a maximum of $20,000) unless their participation was not willful and was due to reasonable cause. The Regulations state that "willful" means voluntary, conscious, and intentional. No motive to avoid the restrictions of the law or the incurrence of any tax is necessary to make the participation willful. The Regulations provide that a transaction shall be presumed to be reasonable and at fair market value if three conditions are satisfied:

i. Approved in advance by the board or a board committee or an entity controlled by the organization – board or committee members are unrelated to and not subject to control of the disqualified person.

ii. Obtained and relied upon appropriate data as to comparability.

iii. Adequately documented the basis for its determination concurrently with making the determination.

However, this is a rebuttable presumption, not absolute protection.

3. **Key Valuation Cases.**

a. **LAC Facilities.**

i. The LAC Facilities hospital was reorganized in 1984 to purchase and operate physician practices. It purchased 7 practices in 1986-1987 for $17.4 million and entered into service agreements with physicians. One practice was appraised at $6.8 million but with tangible assets of only $170,093 and purchased for $6 million.

ii. The IRS found flaws in appraisal due to incorrect capitalization rate and elimination of normal expenses determined by the appraiser to be discretionary. It also noted minutes of board indicated a conscious overpayment
in order to gain patients and credibility. Physician compensation was projected in the appraisal at $265,000 but was $400,000 in the service agreement.

iii. Practices valued at $7.3 million in 1992 were then sold to physician investors and others for a $4.5 million promissory note, which by 1994 was written down to $253,614 due to doubtful collection.

iv. IRS found inurement/private benefit based on these matters and other matters dealing with officers and executive personnel.

v. LAC Facilities brought suit in the Court of Claims contesting this revocation. However, the suit was voluntarily dismissed by LAC Facilities on July 23, 1998.


i. **Background.** NFP board sold psychiatric hospital to FP corporation. Directors of NFP owned the FP. IRS issued favorable advance ruling in 5-82 so long as FMV was present. Appraised at $3.5 to $4.3 million in 9-81. Sold 5-83 for $6.3 million (CON approved for 31 additional beds in interim). FP corporation sold to AMI for $29.6 million in 10-85.


ii. **Key Principles:**

(a) The timeliness of the appraisal is critical. Here, the valuation appraisal occurred in September 1981 and the sale occurred in May 1983.

(b) Equally important is the significance of material intervening events. Here, a CON for 31 additional beds granted in the interim, and prices in other sales appeared to show significant market changes.
(c) Too much success or failure in and of itself can impact the issues. This is instructive for practice purchase unwindings.

(d) There is no one precise FMV number, but rather a range. The Tax Court stated: “Rather, the question to be resolved is whether the sale was the product of an arm's-length transaction which produced a sale price that is sufficiently close to the fair market value of the property at the time of the sale, so that one can fairly conclude that there was no prohibited inurement. Or to put it another way, recognizing that what is fair market value presents an inherently imprecise issue (which even respondent admits), we see our task as one of determining whether the sale price was within a reasonable range of what could be considered fair market values.”

(e) Arms-length negotiations are not determinative in and of themselves.

(f) Events that occur after closing are not relevant except to the extent they were reasonably foreseeable at valuation.

(g) A difference of $7.8 million v $6.6 million in this case was too large – 18%.

(h) A private letter ruling is no protection if FMV is not present.

c.  

United Cancer Council Inc. v Comm'r, 165 F.3d 1173 (7th Cir. 1999).

i. The United Cancer Council had a contingent fee advertising contract with an outside party.

ii. The IRS revoked its exempt status based on inurement of net earnings to the advertising company, finding that it constituted excessive and unreasonable compensation.

iii. The Tax Court agreed.

iv. The Seventh Circuit reversed the Tax Court’s finding that United Cancer Council’s professional fund raiser was an insider based on the structure and effect of the fund raiser’s contract with UCC. The Seventh Circuit found nothing in the facts to support the IRS theory and the Tax Court’s finding that the fund raiser seized control through
the fund raising contract and thereby became an insider. The case was remanded for an analysis of whether the contract resulted in improper private benefit to the fund raiser. This case has been watched closely by health care organizations because of its potential application to management contracts and its application to intermediate sanctions issues. The Seventh Circuit decision makes it likely that such contracts will be evaluated under the private benefit standard rather than the inurement standard.

d.  **Caracci v Commissioner** 118 T.C. 379 (May 22, 2002).

i. Exempt home health agencies were transferred to new for-profit entities owned by board/management. The consideration was assumption of the liabilities.

ii. IRS contends the agencies were worth $19.6 million and revoked exemption and assessed intermediate sanctions.

iii. The taxpayers contend that the agencies were not profitable and had negative book value. The taxpayers relied on valuation by a Big 5 firm appraiser with extensive experience with home health agencies in Mississippi.

iv. The IRS discounted the valuation report as so understating of value as to make it unrealistic. It cited the moratorium on home health licenses in Mississippi, a large market share, comparable sales, and generous employee bonuses.

v. The Tax Court assessed intermediate sanctions but did not revoke exemption, because the intermediate sanctions were an adequate remedy for a single transaction violation, the exempt entities have not otherwise been operated in violation of their exempt status, and the maintenance of the tax exemption allows for correction by returning the assets.

vi. The Tax Court found that the transferred assets exceeded the liabilities by $5,164,000, which therefore constituted an excess benefit of this amount to the for-profit entities and their shareholders. The key finding was in the fair market value of the transferred assets. The Tax Court was persuaded by the IRS engaged expert, who followed a comparable value method, citing with favor an approach that compared the market value of invested capital to publicly traded businesses. The Tax Court did, however, decrease the value identified by the IRS expert.
III. IMPACT OF AFFORDABLE CARE ACT

A. Change in Substantive Standards.

1. Section 6402(f) – Anti-kickback violations now constitute false claims. This impacts the burden of proof since the prosecution can now be civil rather than criminal. This also greatly expands the potential liability and penalties.

2. Section 6402(f) – No longer an obligation to prove knowledge of statute or specific intent to commit a violation.

3. Section 6402(d) – Obligation to return overpayments. An overpayment includes any funds received or retained under Title XVIII or XIX to which the person, after applicable reconciliation, is not entitled. Admissions and services received from physicians for whom a Stark exception does not apply (due to a non-FMV relationship) exist fall into this category.

B. Enforcement.

1. Significant new enforcement dollars allocated to enforcement.


   b. Combination of Overpayment Reporting obligation and Self-Disclosure Protocol increases the likelihood that FMV issues are reported.

C. Whole Hospital/Rural Provider Exceptions.

1. Section 6001 contains many new restrictions:

   a. No new physician owned hospitals.

   b. Percentage of physician ownership cannot increase.

   c. Number of beds, operating rooms, and procedure rooms cannot increase (absent special exceptions).

   d. Other conditions for small entity safe harbors are now statutory requirements.

   e. No ASC conversions.

2. New barriers to entry may impact valuation, but also reduces the potential market for sale.
D. **New Delivery Models.**

1. **IRS Statement on ACOs.** IRS Notice 2011-20 (April 1, 2011)
   
   a. Participation by 501(c)(3) is subject to inurement/private benefit rules.
   
   b. IRS “expects” there will not be inurement/private benefit where:
      
      i. Terms of participation (including share of MSSP losses/expense) are in negotiated agreement
      
      ii. CMS has accepted ACO into MSSP
      
      iii. EO’s share of ACO benefits is proportional to its contributions to ACO, including any capital interest
      
      iv. EO’s share of ACO losses does not exceed its share of ACO benefits to which it is entitled
      
      v. All contracts/transactions are at FMV
   
   c. The structure of ACOs will be subject to significant valuation issues.

   
   a. Waivers are limited to distribution of shared savings received by an ACO under the Medicare Shared Savings Program to or among ACO participant and providers during the year such shared savings were earned by the ACO, or for activities necessary for and directly related to the ACO’s participation in and operations under the MSSP.
   
   b. All other financial relationships involving physician or entities participating in the MSSP that implicate Stark would still need to satisfy an existing exception or otherwise comply with the anti-kickback law.
   
   c. Comments requested:
      
      i. Arrangements related to the establishment of an ACO for remuneration directly related to forming the ACO, implementing the governance and administrative requirements applicable to the ACO, or building technological or administrative capacity (including provider training) needed to achieve the MSSP cost and quality goals. This includes payments used to finance actual investment or startup expenses as well as non-monetary
benefits transferred for the purpose of establishing the ACO.

ii. Arrangements between or among ACO participants and providers related to ongoing operations of the ACO and achieving ACO goals. This includes financial arrangements necessary for and directly related to operation of the ACO, or necessary for and directly related to achieving the integrated care, cost savings, and quality goals of the MSSP.

iii. Arrangements between the ACO, its participants, and its ACO providers and outside individuals or entities. This includes remuneration necessary for and directly related to establishing the ACO or necessary for and directly related to achieving the integrated care, cost savings, and quality goals of the MSP.

iv. Distributions of shared savings or similar payments received from private payors.

v. In all cases, whether protected remuneration should be required to be commercially reasonable.

3. The starting point for moving physician compensation away from volume (wRVUs, percentage of collections).

IV. RECENT CASES AND ENFORCEMENT AFFECTING VALUATION

A. *Kosenske v Carlisle HMA*, 554 F.3d 88 (3rd Cir. 2009).

1. Court determined that an exclusive service arrangement by a hospital with an anesthesia group to provide pain management services at an outpatient clinic constituted a financial relationship, and that this relationship did not meet the personal services exception under Stark.

2. The Court found no written agreement and no evidence that the space, equipment, and staff services provided to the anesthesia group at the pain clinic or the mutual exclusivity rights were at fair market value.

3. The Court rejected the District Court’s view that because the consideration was the result of negotiation between unrelated parties, it by definition reflected fair market value. It noted specifically that Stark is predicated on the recognition that when one party is in a position to generate referrals for the other, negotiated agreements are often designed to disguise non-fair-market-value compensation.

4. District Court subsequently dismissed cross-motions for summary judgment and ordered the matter to go to trial. 2010 U.S. Dist. LEXIS 31619 (March 31, 2010). Action subsequently settled by the parties.
Lex 119355 (W.D. Pa, November 10, 2010).

1. This qui tam action involved two internal medicine physicians who
installed a nuclear medicine camera in their office and stopped making
referrals to the hospital for such services.

2. The physicians eventually subleased the camera to the hospital and
signed a non-compete. The sublease rate was supported by an
accountant’s FMV valuation comparing revenues the hospital would
generate with the sublease to those without the sublease. The
payment was fixed, and included a pass-through of the amount owed
to the prime lessor plus $23,655 per month for other rights including
the non-compete. The camera remained at the physician's office, so
that the hospital also paid rent and a 10% billing fee to the physicians.
The physicians eventually leased a new camera, paid the early
termination fee on this camera, and the hospital guaranteed the new
lease and reimbursed the physicians for it.

3. The court found a direct financial relationship and concluded that the
hospital consultant valued the covenant not to compete to protect three
revenue streams: CT/MRI revenues, inpatient revenue, and outpatient
revenue. He compared expected hospital revenues with the non-
compete in place with such revenues without the non-compete. The
Court concluded that the valuation was thus based in part on
anticipated referrals.

4. The Court concluded that where a defendant claims an exception, then
the burden of proof to show that the compensation is consistent with
FMV rests with the defendant. The Court concluded that the amount
of compensation was arrived at by taking into account the anticipated
referrals from the physician and therefore the compensation was not
FMV under Stark.

5. Important point: A fixed fee can still be based on anticipated referrals.


1 Hospital employed surgeons on a part-time basis to provide surgery at
the hospital’s new ASC. The agreement was ten years in length, and
the physicians were required to exclusively perform outpatient surgery
at the ASC, but would otherwise maintain their private practices.

2. The government argued that the payment which was based on a
percentage of the physician's personally performed services will
automatically vary based on the volume or value of referrals because it
is inherently linked to the hospital's technical component, that the
payment was offered in response to the potential loss of referrals, and
therefore took into account the volume or value of referrals. The
government also argued that the compensation was in excess of FMV in that it exceeded 130% of the physician’s net collections from the services.

3. Government also pointed to unusual length (10 years), full-time benefits for part-time employees, and payment of base salary for no services.

4. The jury found that the hospital violated Stark, but not the False Claims Act. Damages of $44 million were assessed. A new trial was ordered based on the exclusion of certain evidence.

5. Important points:
   a. Employment does not solve all Stark problems.
   b. Underlying facts (arrangement developed in response to fear of lost business) raises concerns.

V. PROCESS ISSUES – APPROVAL AND DOCUMENTATION OF FAIR MARKET VALUE

A. Are Good Faith Dealings Enough?

1. Generally the presence of arms-length, good faith negotiations is substantial evidence that a fair market price will result.

2. Rev. Rul. 76-91 holds that there is a presumption that negotiations with arms-length independent third party result in payment of fair market value, but this presumption does not exist when there is a close relationship between the purchaser and seller.

3. The presumption that arms-length negotiations results in fair market value is also inapplicable when there is a possibility of an illegal motive (i.e., to illegally induce referrals). See discussion at Page 5.

4. In revoking exemption for excessive and unreasonable compensation, the Tax Court in the United Cancer Council case gives little weight to the fact that the contract was arrived at by arm's length negotiations.

5. The Tax Court in the Anclote Psychiatric Center v Comm, T.C. Memo 1998-273, affd per curium, 190 F.3d 541 (11th Cir 1999) also rejected the argument that arms-length negotiations were themselves sufficient.

6. However, the Court in Goodstein v McLaren, 202 F.Supp. 2d 671 (E.D. Mich 2002) addressed both the Stark and anti-kickback references to arms-length transactions, discussed at length the evidence of hard bargaining, and concluded that the lease agreement was an arms-length transaction.
7. The Court in *Kosenski* rejected this and stated:

“A negotiated agreement does not by definition reflect fair market value. To the contrary, the Stark Act is predicated on the recognition that where one party is in a position to generate business for the other, negotiated agreements between such parties are often designed to disguise the payment of the non-fair-market-value compensation.”

8. In the *Bradford* case, the court noted that at best, evidence of back and forth negotiations only support that there was back and forth negotiation, and does not indicate that there was fair market value.

B. Does the Provider need to Obtain the Opinion of a Valuation Expert?

1. The commentary to the Stark regulations of January 4, 2001 states:

“We agree that there is no requirement that parties use an independent valuation consultant for any given arrangement when other appropriate valuation methods are available. However, while internally generated surveys can be appropriate as a method of establishing fair market value in some circumstances, due to their susceptibility to manipulation and absent independent verification, such surveys do not have strong evidentiary value and, therefore, may be subject to more intensive scrutiny than an independent survey.” 66 Fed. Regis 945

2. The commentary to the intermediate sanction regulations of January 10, 2001 states:

“The temporary regulations clarify that a compensation arrangement in its entirety must be evaluated and also provide examples of relevant comparability data. In the case of a compensation arrangement, the temporary regulations provide that relevant information may include a current compensation survey compiled by an independent firm. As in the proposed regulations, this list of relevant comparability data is not exclusive, and the authorized body may rely on other appropriate data. ...In response to comments, the temporary regulations revise examples from the proposed regulations and add several examples illustrating appropriate comparability data.” 66 Fed. Reg. 2154

3. The intermediate sanctions regulations provide that the governing body or committee has appropriate data as to comparability if, given the knowledge and expertise of the members, the governing body or committee has information sufficient to determine whether a compensation arrangement will result in the payment of reasonable compensation or a transaction will be for fair market value. Relevant information would include but not be limited to:
For compensation:

- compensation levels paid by similarly situated organizations, both taxable and tax-exempt, for functionally comparable positions;
- the availability of similar services in the geographic area of the applicable tax-exempt organization;
- independent compensation surveys compiled by independent firms;
- actual written offers from similar institutions competing for the services of the disqualified person.

The intermediate sanctions regulations provide that for organizations with annual gross receipts of less than $1 million, the governing body or committee is considered to have appropriate data as to comparability if it has data on compensation paid by three comparable organizations in the same or similar communities for similar services.

4. Practice Pointer: Develop a board policy that sets out parameters for obtaining external valuation reports.

C. Can a Valuation Opinion Protect the Parties?

1. The Exempt Organization.
   a. LAC Facilities. The appraisal did not protect the exempt organization from revocation by the IRS.
   b. Anclote. The appraisal did not protect the exempt organization from revocation by the IRS and approval of such revocation by the Tax Court.
   c. Caracci v Commissioner. The Tax Court's opinion suggests that the appraisal may have protected the exempt organization but did not protect the disqualified persons from intermediate sanctions.

2. Parties in an Anti-kickback Case.
   a. Fair market value is not itself an absolute defense, and thus an appraisal is not a guarantee.
   b. Absence of fair market value creates a presumption that excess payments were for referrals.
   c. Market established by others with an intent to induce referrals is not market.
d. Safe harbors require that transactions be consistent with fair market value but there are no specific requirements for how this should be shown.

e. Advisory opinions have certifications of fair market value.

3. **Entities Receiving Referrals in a Stark Case.**

   a. The Secretary's comments state that while good faith reliance on a proper valuation may be relevant to intent, it does not establish the ultimate issue of the accuracy of the figure itself.

   b. Fair market value determined based on actual referrals is not FMV under Stark.

D. **Who Engages the Valuation Expert?** Options include:

1. **The acquiring entity.** The acquiring entity engages the appraiser in order to develop and support the price that it will pay for the practice. The appraisal may be kept confidential by the acquiring entity and not shared with the practice.

2. **Attorneys for the acquiring or selling entity.** The attorneys for the acquiring entity may engage the appraiser in order to assist the attorneys in providing legal opinions about the purchase or sale and its compliance with applicable laws.

3. **Both parties.** Both parties may jointly engage an appraiser. The appraisal can then be used as a basis for further negotiations or as the agreed-upon price.

4. **Separate appraisals.** Each party may obtain their own appraisal which then serves as the basis for negotiation between the parties.

   The decision is driven by the purpose of the engagement.

E. **Terms of Engagement.**

1. Engagement. The valuation appraiser typically has a standard engagement letter or contract. These vary widely. Some are little more than agreements by the client to pay while others are detailed work plans and full-blown engagement agreements.

2. **Key Issues for Consideration.**

   a. If the engagement is intended to fall under the attorney/client privilege, the engagement must be by legal counsel for the purpose of assisting counsel in providing legal advice to the client. This should be stated in the engagement letter.
b. The engagement should specifically require the appraiser not to include value elements that expressly cannot be included under Stark or anti-kickback rules.

c. The confidentiality of the work papers and the appraisal process should be addressed. Confidentiality is also important in preserving the attorney/client privilege.

d. Appraisers typically include language that limit the use of the appraisal to financial planning purposes. Since the purpose is typically not that, but rather one related to compliance with applicable laws and assistance of counsel in providing opinions to the client about these, the purpose of the appraisal should reflect this.

e. Appraisers often disclaim any responsibility for any further work following the submission of their work. Typically, a necessary part of the engagement is the ability and willingness to participate in investigations or discussions with regulators in connection with valuation, although there may be additional fees over the initial appraisal.

f. Appraisers often attempt to limit any liability exposure to the fees they received.

F. Can/Should the Valuation Expert's Work Be Privileged? – Application of Attorney/Client Privilege/Work Product to the Valuation Opinion. The notion of "privilege" denotes secrecy – an ability to withhold from third parties some document or communication or note. This is at odds with the fundamental principal of full disclosure of all relevant information in federal and most state litigation. The attorney/client privilege and the attorney work-product privilege are the two principal exceptions to the full disclosure rule.

1. Why Try to Protect the Valuation Expert's Work?

a. The expert may turn out to be unqualified, unprofessional, unable to complete the project, conflicted, etc. In that case, you may want to keep his/her work private.

b. The client may decide it does not like the results from the expert and may then get a different and more favorable opinion from another.

c. Despite the expert's work, the client may decide there is a business necessity to ignore the work of the expert (and the advice of counsel) and proceed.
2. **Attorney/Client Privilege.**

   a. **Requirements Generally.**

      i. The party asserting the privilege must be a client.

      ii. The party to whom the communication was made or the party who incorporated that information into advice back to the client must be an attorney *acting as such* or a representative of the attorney.

      iii. The communication must have been made by the client or its employees, not by third parties.

      iv. The communication must have been made in confidence.

      v. The communication must have been based on a desire to obtain either legal advice or assistance in legal proceedings. Advice, just because it’s from a lawyer is not necessarily legal advice.

   b. **Waiver of the Privilege.**

      i. "Control group" level personnel can waive the privilege, but most courts would say that lower level personnel can also do so if within their job responsibilities.

      ii. Waiver may be no more than including those without a need to know or those outside of the corporate-attorney relationship in the communication.

      iii. Does the action of the client conflict with the fundamental underlying premise – an expectation of confidentiality.

      iv. There is no accountant-client privilege, so automatically including auditors and accountants in the flow of information waives the privilege. Similarly, if counsel advises auditors and accountants in connection with their review of financial statements, there may be a waiver as to the matters disclosed.

      v. Scope of waiver – ordinarily, a waiver is effective as to all communications on the same subject matter as the waived communications. Courts have recognized a "limited waiver rule" but parties must still be extremely cautious when waiving the privilege as to part of a communication or group of communications.

the privilege when the president of a lab disclosed the substance of the attorney’s advice to the OIG investigator – but only as to the subject matter of the disclosures.

c. Prospective Fraud or Crime Exception. The privilege does not protect communications relating to legal advice requested or obtained in order to commit a fraud.

i. The burden is on the party claiming fraud to demonstrate the application of the exception, but experience in other industries (e.g., savings and loans) shows how rapidly such an exception can expand.

ii. This exception has extreme importance in the compliance context. Presumes an overriding policy of compliance with advice sought, obtained and used in order to comply.

iii. Issue – application of the exception where the client ignores advice or uses it only to determine potential damages for ignoring the advice.

iv. The crime or fraud exception does not apply to completed acts or to legal advice concerning prior acts.

v. There is an exception if the attorney must reveal the advice to protect against a claim of malpractice or wrongful conduct on his or her part.

d. Conclusion. Availability of the privilege can be critical in a civil or criminal action or in an agency administrative action. Organizational, operational and compliance strategies and policies should be built around maximizing the availability and reach of the privilege in most cases.


a. Authority.

i. Rule 26(b)(3), Federal Rules of Civil Procedure:

"Ordinarily, a party may not discover documents and tangible things that are prepared in anticipation of litigation or for trial by or for another party or its representative (including the other party's attorney, consultant, surety, indemnitor, insurer, or agency)." But the materials may be discoverable if the party shows it has substantial need for the materials to prepare its case and cannot, without undue hardship, obtain their substantial equivalent by other means. In ordering discovery of such materials when the required showing has been made, the court shall protect
against disclosure of the mental impressions, conclusions, opinions, or legal theories of an attorney or other representative of a party concerning the litigation.

b. Requirements.

i. "In anticipation of litigation" – there must be an actual claim. This is not coextensive with the attorney-client privilege.

ii. At the heart of the privilege – protecting against disclosure of the attorney's "mental impressions, conclusions, opinions, or legal theories." It is possible to obtain documentary evidence from the attorney upon a very strong showing of need and fairness, but about impossible to obtain documents reflecting mental impressions, conclusions, opinions or legal theories.

iii. Witness statements taken in anticipation of litigation from witnesses, whether or not they are employees of the client, are protected because at the heart of the statements are the impressions of the attorney. This goes beyond the attorney-client privilege.

iv. Tests and research performed at the request of counsel in anticipation of litigation may be covered, but tests and research performed during the ordinary course of business are not, even though useful in litigation.

(a) Distinguish routine incident reports and routine compliance audits or reviews from tests, research and statements obtained in anticipation of litigation or administrative proceedings.

(b) Distinguish databases, opinions and exhibits to be used by expert witnesses.

c. Waiver. The attorney may waive the privilege, subject to any attorney-client privilege pertaining to the documents.

d. Exceptions. There is an apparent exception if it is demonstrated that the attorney's client is engaged in a prospective crime or fraud. This clearly is an exception to the attorney-client privilege but the application to the work-product doctrine is less clear.

e. Conclusion. In the face of an actual claim or suit, the attorney work-product privilege can be extremely valuable to shield the attorney's opinions, thought processes, strategies and trial preparation from the other parties. The requirement is, however, that the material be gathered by or under the attorney's actual
direct supervision in anticipation of litigation. In the face of actual claims, it may be advisable through policies to limit the authority of mid-level and upper level managers to investigate unless doing so at the request of counsel.

G. How Should Fair Market Value Be Documented?

1. **Advantages of a Worksheet.** Determining fair market value prior to entering into transactions and contemporaneous documentation of efforts to establish fair market value is critical. After the fact documentation is substantially less helpful, and efforts to document many years after the fact and in response to an investigation are virtually useless. A worksheet approach should be used in all physician transactions.

2. **IRS Approach.** The IRS has published a Rebuttable Presumption Checklist developed by Steven T. Miller, Director, Exempt Organizations (link available at www.irs.ustreas.gov/charities). The Miller article describes a "relatively simple" process for ensuring full compliance and addresses who make decisions, what data must be used, how to document, when to document, and also includes a checklist.

   Concerns about this approach include:
   
   - Requires board action;
   - Involves board in total package of compensation and benefits;
   - Does not address adequacy of comparability data;
   - Presumes separate documentation for each compensation transaction akin to separate minutes and subsequent approval of them;
   - Does not seem to work for external valuations.

3. **Worksheet Approach.** The appropriate administrator should document the following fair market value information on a worksheet regardless whether an external valuation consultant was engaged. The worksheet needs to be tailored to the type and scope of transactions and the issues at stake. The board should establish a process for documenting fair market value that utilizes a worksheet. The worksheet should include a brief description of the transaction and should then address:

   a. If a bid process was used, describe that bid process, whether the lowest bid was selected, and if not, then why not; if a bid process was not used, but other proposals were received, describe those proposals and how they compare.
b. What consultants, appraisers, or experts were consulted and what opinions have they provided concerning the fair market value?

c. If no bid process or outside consultants were used, what internal investigation was conducted in order to establish fair market value and what are the results of that investigation?

d. If there is not readily identifiable external market for the services, then describe how the price was determined and why you believe it to be fair.

e. Describe initial bargaining positions and the result of that bargaining.

f. The worksheet should also contain a statement from the administrator as to whether the administrator believes that the transaction meets the fair market value test; in transactions involving physicians or others in a position to refer, then there should also be a statement that the price has been determined without regard to the volume or value of referrals.

g. The worksheet should be signed and presented to the decision-maker. In some cases, the decision-maker will be the CEO or the appropriate vice president; in other cases, it may be the full board of directors or a conflict of interest committee. The decision-maker should be satisfied that the worksheet adequately establishes fair market value and should approve or adopt the finding of fair market value as a part of its decision-making process. The decision-maker's approval should be documented in minutes (in the case of boards or board committees) or in a file memo (in the case of a CEO or vice-president's decision).


1. Attorneys often struggle in their review of valuation opinions. Attorneys need to critically evaluate such opinions. The IRS approach in several cases make it clear that the IRS will not blindly accept such opinions.

2. An attorney’s review of a valuation opinion should consider the following:

   a. Is the appraiser qualified? Will he or she be able to testify as an expert witness?

   b. Is there a definitive opinion – or just a series of observations?

   c. Do the qualifications and limitations vitiate the opinion?
d. Does it meet the reasoned written opinion standard for the organization manager's defense to intermediate sanctions – does it address facts and applicable law?

e. Does it appear to rely on appropriate data as to comparability.

f. Has market been impacted by previous or anticipated referrals?

g. Are there important factors which the appraiser ignored or was ignorant of? This requires a full understanding of the underlying facts.

h. Does it appear that the opinion would satisfy the OIG, CMS, and the IRS? Can the consultants defend their opinion?

I. Who Approves the Transaction?

1. Under the intermediate sanctions regulations, the compensation arrangement or terms of transfer must be approved by the organization's governing body or a committee of the governing body composed entirely of individuals who do not have a conflict of interest with respect to the arrangement or transaction. If a member has a conflict, the person may be present to answer questions, but must then recuse himself from the meeting and not be present during debate and voting on the transaction or compensation arrangement.

2. The governing body or committee obtained and relied upon appropriate data as to comparability prior to making its determination.

Note that a committee may make a decision that gives rise to a rebuttable presumption, but the committee members then become organization managers for purposes of the liability standard for organization managers. In addition, the committee must be able to make a decision that is not subject to ratification or other approval by the board of directors in order to become effective. The regulations are unclear as to whether a board may delegate responsibility to a single officer or individual, whose decision then gives rise to a rebuttable presumption. Generally, the regulations speak in terms of delegation to a committee, which suggests more than a single person making a decision. It is also uncertain whether a committee made up of employed administrative personnel may make a decision that gives rise to a rebuttable presumption. The regulations seem to refer only to a committee of the board of directors.

If the standards for rebuttable presumption are not met, the regulations provide that the failure to create a rebuttable presumption does not create an inference that the transaction is an excess benefit transaction.
3. Outside of intermediate sanctions, there are no regulatory standards for obtaining board approval, but board approval can be important in establishing community interests and strategic priorities and their impact on the decision.

4. In light of all the issues involving fair market value, many tax-exempt entities have established special committees that evaluate all transactions of certain types. To be effective such committees should:
   a. Be set up by resolution of all boards using the committee.
   b. Apply to all transaction of pre-identified types. Typically this means all contracts with physicians.
   c. Be populated with community volunteer board members.
   d. Review all applicable transactions before any legally binding arrangement exists.
   e. Document their findings in detailed minutes.
   f. Be presented with worksheets of the type described at F above, which includes reference to outside opinions on reasonableness.
   g. Have sufficient background, education, and training so as to make informed legally defensible decisions.

J. **Documentation of Approval.** For a decision to be documented adequately for the purposes of the rebuttable presumption under the intermediate sanctions regulations, the written or electronic records of the governing body or committee must note the following:

1. The terms of the transaction that were approved and the date it was approved.

2. The members of the governing body or committee who are present during debate on the transaction or arrangement that was approved and those who voted on it.

3. The comparability data obtained and relied upon by the board or committee and how the data was obtained.

4. The actions taken with respect to consideration of the transaction by anyone who is otherwise a member of the governing body or committee but who had a conflict of interest with respect to the transaction or arrangement.

The regulations note that if the governing body or committee determines that reasonable compensation for a specific arrangement or fair market value in a specific transaction is higher or lower than the
range of comparable data obtained, the governing body or committee must record the basis for its determination. It further notes that for records to be documented concurrently, records must be prepared by the next meeting of the governing body or committee occurring after the final action or actions of the governing body or committee are taken. Records must be reviewed and approved by the governing body or committee as reasonable, accurate, and complete within a reasonable time period thereafter.

K. When Should the Transaction be Approved – Importance of Contemporaneous Documentation.

1. The Model Nonprofit Corporation Act requires advance approval of conflict transactions in order for board action to create a presumption of reasonableness.

2. The intermediate sanctions regulations require advance approval of transactions and contemporaneous documentation in order for a presumption of reasonableness to arise.