FAIR MARKET VALUE IS MORE THAN
SIMPLY A MATTER OF “SURVEY SAYS.”

How to assess commercial reasonableness and create compliant compensation processes to mitigate Stark and False Claims Act risk

Health Care Compliance Association
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FIRST, SOME FUN
(AND ONLY 5 SLIDES MENTION TUOMEY OR HALIFAX)

Name something it would take a 100 year old man 30 minutes to do.
SURVEY SAYS:
Eat (5)
Climb stairs (6)
Get dressed (8)
Make love (9)
Get out of bed (15)
Walk any distance (16)
Go to bathroom (24)

THE 2015 RISK ENVIRONMENT
(THE GOVERNMENT WAS BUSY)

1. HHS OIG Team Dedicated to Civil Monetary Penalties (CMPs) (June 2015)
2. HHS Fraud Alert: Physician Compensation Arrangements May Result in Significant Liability (June 2015)
3. DOJ Compliance Counsel (July 2015)
4. Corporate Cooperation Credit Requires a corporation to give up responsible corporate officials (September 2015)
5. HHS OIG Board of Director Guidance (April 2015)
6. SDNY Case enforcing PPACA 60 Day Rule (August 2015)

On October 30, 2015, CMS released the final 2016 Medicare Physician Fee Schedule which contains, among other things, significant changes to the Stark Law.

- **Written Arrangements.** The Final Rule clarifies that exceptions to the Stark Law that require an arrangement to be in writing do not require a single written contract.
- **One Year Requirement.** The Final Rule clarifies that the Stark Law exceptions that require arrangements to have a term of at least one year (including the exceptions for office space rental, equipment rental and personal service arrangements), do not require a contract provision specifically identifying a one-year term.
- **Signature Requirement.** The parties do not need to sign a single formal written contract to meet the signature requirement. A signature is required on a contemporaneous writing documenting the arrangement.

THE 2015 RISK ENVIRONMENT
(THE GOVERNMENT WAS BUSY AND...SOME OF IT WAS GOOD!)

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THE 2015 RISK ENVIRONMENT
(WHISTLEBLOWERS CONTINUED TO BE REALLY BUSY)

- Adventist Health System paid the government $118.7 million to settle allegations it offered doctors excessive compensation for referrals. September 2015.
- North Broward Hospital District paid $69.5 million to settle allegations that it paid doctors for more than fair market value based, in part, on their referrals. September 2015.
- Columbus (Ga.) Regional Healthcare System paid the government $35 million to settle allegations it violated the Stark law and False Claims Act based partly on referrals. September 2015.
- The involved physician paid $425,000.00, perhaps signaling an increased individual accountability focus consistent with recent DOJ policy.

I.  NON STULTAS

1. ACT CONSISTENT WITH AND NOT CONTRARY TO BOARD COMPLIANCE POLICY.
   A. All Children's Hospital settled in 2014 a whistle-blower lawsuit brought under the False Claims Act for $7 million. The Stark allegations involved alleged payment to physicians above Fair Market Value for their services.
   B. The whistle-blower developed a compensation model that would guarantee physicians a base salary between the 25th and 75th percentile nationwide, which was developed from the aggregate of three salary surveys.
   C. The Board approved the compensation model that also stated physicians would not be compensated below the 25th percentile or above the 75th percentile.
   D. The hospital allegedly hired several physicians and provided them with base salaries above the 90th percentile, which was not supported by any model or survey.
MORE STUPID THINGS
(THAT CREATE A BAD AND LASTING IMPRESSION)

1. ACT CONSISTENT WITH AND NOT CONTRARY TO BOARD COMPLIANCE POLICY.
   1. The whistleblower, Schubert, was operations director for the hospital's doctors practice from 1998 to 2011. She created a plan to keep salaries and benefits in line with industry norms. The practice's board of directors adopted the plan in 2007.
   2. The whistleblower drew on three nationwide salary surveys to determine fair-market salary ranges. The pay package guaranteed a base salary that would be at least in the 25th percentile, but not above the 75th percentile.

2. Respond to economic events in a deliberative manner
   According to her lawsuit, around 80 physicians were added to the staff at least through 2011 — nearly a third of them with salaries that exceeded the 75th percentile of comparable salaries, with no justification. The lawsuit also alleged the reason for the conduct was that All Children's was losing business just as the health system broke ground on a $400 million facility. It needed referrals to boost revenue.
   - Nine emergency room doctors were paid salaries of $250,000 to $330,000 — yet the compensation plan called for no more than $179,800.
   - Fearing it was losing surgical business to Tampa General Hospital, All Children's successfully courted a pediatric surgeon by agreeing to pay a $600,000 base salary and also hire his physician wife on a per diem basis. The salary alone put him above the 90th percentile of pediatric surgeons nationwide.

   Four neurosurgeons who had also been practicing at TGH and St. Joseph's Hospital in Tampa were hired at All Children's with compensation packages — salaries, bonuses and on-call pay — capped at just over $1 million a year. When hiring three cardiologists from a contractor, the hospital also agreed to hire their attorneys should their former employer sue them for breach of contract — without capping their liability.
   The two executives who oversaw the hiring — former chief executive officer Gary Carnes and vice president William Horton — were "rewarded handsomely for their efforts," the lawsuit says. Carnes' salary of $405,181 in 2007 soared to $1.2 million in 2008. Horton's salary of $225,829 in 2007 more than doubled to $526,128 the next year.
3. ACT CONSISTENT WITH AND NOT CONTRARY TO BOARD DIRECTIVES

- ALL CHILDREN'S HOSPITAL DEMONSTRATED THE IMPORTANCE OF ACTING CONSISTENT WITH BOARD COMPLIANCE POLICY; THUS VINDICATING THE HHS OIG VIEW EMBODIED IN THE APRIL 2015 COMPLIANCE GUIDANCE OF ENSURING BOARD INVOLVEMENT IN COMPLIANCE MATTERS TO PROMOTE COMPLIANCE!

- BUT WHAT ABOUT BOARD PROMOTION OF ALLEGED STARK VIOLATIONS OVER THE OBJECTION OF SENIOR EXECUTIVE MANAGEMENT?

WHO SAYS THE BOARD IS MORE COMMITTED TO COMPLIANCE THAN SENIOR EXECUTIVE MANAGEMENT GIVEN THE BOARD'S ALLEGED LONG TERM INTERESTS ON BEHALF OF THE HOSPITAL?

- The whistleblower, Phillip Schaengold, served as President and Chief Executive Officer of Defendant Memorial Health, Inc., and Defendant Memorial Health University Medical Center, Inc., from June 1, 2009 until his alleged retaliatory discharge on January 5, 2011.

- Memorial was under a CCA, Certification of Compliance Agreement, during the relevant period.

ALLEGATIONS IN THE COMPLAINT AND ON MOTION PRACTICE:

- CEO IDENTIFIES MULTIPLE PHYSICIAN COMPENSATION ARRANGEMENTS EXCEEDING THE 90TH PERCENTILE OF FMV.
- SEEKS TO TERMINATE CONTRACTS TO REDUCE SIGNIFICANT HOSPITAL FINANCIAL DISTRESS
- CEO PROPOSES COMPLIANT COMPENSATION MODEL
- BOARD REJECTS, PROVIDES MORE GENEROUS BENEFITS
- FIRES CEO
- BOARD COMPRISED OF DIRECTORS, IN PART, DIRECTLY AND INDIRECTLY, AFFECTED BY COMPENSATION CHANGES
- NO RECUSAL OR COI FORM EVEN COMPLETED BY CERTAIN BOARD MEMBERS
- AFFECTED PHYSICIANS THREATENED TO TAKE THEIR REFERRALS ELSEWHERE

MEMORIAL HEALTH, INC
2014 U.S. DIST LEXIS 174977

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The prosecutor’s best friend is the prism of cause and effect.
- Cause and effect make the complex simple.
- Cause and effect obviate dense legal analyses of Stark, inducement and other areas defense lawyers seek to legitimately exploit.

WESTCHESTER MEDICAL CENTER

The government intervention complaint stipulates that Westchester advanced monies to the physician cardiology practice for the express purpose of generating referrals to the hospital.
- When the cardiology practice was about to make payments to Westchester to repay the advances, Westchester entered into retroactive, no-work consulting agreements under which it paid the cardiology practice tens of thousands of dollars.
- MORE EFFECT: Westchester permitted the cardiology practice, at about the same time, to use cardiac fellows free of charge contrary to Westchester’s historic practice of charging the cardiology practice.

CAUSE AND EFFECT: WESTCHESTER
MAY 2015, SDNY, $18.8M

Good cases, criminal or civil, exist on a temporal continuum.
- The government is able to point to certain transactional events and relate them to probable financial loss or actual gain.
- The complex becomes easy with the additional and generally available email or contractual evidence that demonstrates referrals are the reason for the transactional event.
- Throw in inflated FMV and the modest government definition of commercial unreasonableness and presto, wah la, abracadabra: Stark and AKA violation.

CAUSE AND EFFECT
“Survey Says” without justification creates increased financial risk.

The inconsistency and associated risk between physicians’ compensation and net losses generated by the hospital based physician practice is not mitigated by physician compensation survey data.

DON'T RELY ON ONLY SURVEY DATA TO SUPPORT A PROPOSED TRANSACTION

Hospitals use surveys from professional associations, such as the Medical Group Management Association (MGMA) and the American Medical Group Association, to identify fair-market valuation ranges for every specialty. This is a function of outdated language and simplicity. Phase II of the Stark II regulations recommended survey use in valuations; however, CMS dropped the language from Phase III of Stark II.

DON'T RELY ON ONLY SURVEY DATA TO SUPPORT A PROPOSED TRANSACTION

The use of survey data is also simple—and limited—since using survey data is only one approach to valuing compensation, and it doesn’t usually account for other economic factors, such as reimbursement differences from one market to another, the universe of other valuation methods (e.g., market and cost), and post-acquisition losses.

DON'T RELY ON ONLY SURVEY DATA TO SUPPORT A PROPOSED TRANSACTION
“Relators also allege that Citizens operated a separate kickback scheme with a group of cardiologists. Relators identify five cardiologists, including Defendant Dr. William Campbell, Jr., that Citizens employed at above-market salaries and provided with various financial incentives in order to induce them to refer their patients for cardiac surgery and other services at the hospital. See Docket Entry No. 49 ¶¶ 27-32, 46, 73-78. The list of incentives and benefits allegedly provided to the cardiologists is lengthy. According to Relators, three of the cardiologists — Defendant Dr. Campbell, as well as Drs. Krueger and Oakley — saw their salaries more than double after being employed at Citizens in 2007, even though market conditions did not justify the increases. See id. ¶ 76 (alleging that these three doctors’ combined salary rose from $630,000 in 2006 to $1,400,000 in 2007, the first year of their employment at Citizens).”

“Relators allege that Citizens gave the cardiologists all these benefits in order to induce them to refer their patients for services at Citizens, particularly for cardiac surgery with the hospital’s exclusive cardiac surgeon, Dr. Yahagi. According to Relators, the cardiologists have been “extremely valuable to [Citizens] because of their patient referrals,” and Citizens has consequently turned “enormous profits” from the cardiologists’ Medicare and Medicaid referrals. Id. ¶¶ 30, 36. Additionally, Relators claim that the cardiologists’ office practices have systematically lost money even while Citizens has prospered, including losses of $400,000 in 2008 and $1,000,000 in 2009, “but [Citizens] continues to employ them because of the volume and value of their patient referrals.” Id. ¶¶ 36, 81. Relators, practicing cardiologists themselves, also allege that Citizens and Defendant Brown instructed them to refer their own patients to Citizens for surgery by Dr. Yahagi, and that Citizens and Brown attempted to revoke their hospital privileges in favor of Dr. Campbell and the other cardiologists when Relators refused to do so.”

“Citizens also argues that Relators’ allegations are insufficient because they do not allege that the cardiologists actually made above-market income and, instead, that an expert report they rely on shows that the cardiologists’ salaries are below the national median, id. at 24-27. They thus argue Relators have not sufficiently alleged that the cardiologists are receiving improper remuneration as is required for AKS- and Stark-based liability.”

“Particularly, the Court notes Relators’ allegations that the cardiologists’ income more than doubled after they joined Citizens, even while their own practices were costing Citizens between $400,000 and $1,000,000 per year in net losses. Even if the cardiologists were making less than the national median salary for their profession, the allegations that they began making substantially more money once they were employed by Citizens is sufficient to allow an inference that they were receiving improper remuneration. This inference is particularly strong given that it would make little apparent economic sense for Citizens to employ the cardiologists at a loss unless it were doing so for some ulterior motive — a motive Relators identify as a desire to induce referrals.”
The use of the median or another specific percentile as a universal guideline for setting physician compensation is also not recommended by one of MGMA's lead data analysts. In a 2013 webinar entitled "The Use and Abuse of MGMA Data in Healthcare Valuations," Meghan M. Wong, with MGMA's Data Solutions Department, provided the following commentary on the use of selected percentiles from MGMA's survey data as the basis for a one-size-fits-all approach to compensation setting for physicians:

- I think there is not one flat target rate for everyone within the marketplace. Compensation per work RVUs is no different than just regular compensation. There are going to be different factors at play, not just the location of the practice, but also what the provider's patient mix looks like, and also the ability of the practice to reimburse on those things. There are many different factors that are involved with compensating particular physicians and there should never really be a catch all for everyone regardless.


WHAT IS THE VALUE OF SURVEY DATA?

- Citizens demonstrates there are 21,750,000 reasons to ensure Stark compliance is more than a simplistic paper exercise that ignores commercial reasonableness and other concerns
- Median value is not the equivalent of Stark compliance

MITIGATE STARK EXPOSURE: ACCOUNTABILITY FOLLOWS RISK

- Tensions:
  - Street FMV versus Stark FMV
  - "What everyone is getting paid in the market"
  - "What the hospital down the street is paying"
  - "What a senior business development hospital official negotiated prior to compliance input"
- Limited evidentiary value of Survey FMV
MITIGATE STARK EXPOSURE: ACCOUNTABILITY FOLLOWS RISK

- Timing of compliance input
- Disconnect between acquisition of physician practice and management of Stark risk
- Non-Financial contractual terms inimical to Stark compliance
- Recognizing particularly suspect specialties; e.g., medical oncology

RECOGNIZE AND SCRUTINIZE SUSPECT SPECIALTIES MIGRATING TO A HOSPITAL PRACTICE

- All patients at a 340b facility, including uninsured and insured patients—and in the latter category, patients insured through Medicare or private insurance—can be treated with drugs purchased at deep discounts under the 340b program.
- These discounts can be substantial, ranging from 30% to 50%. Given the high and escalating cost of oncology drugs, these margins can generate huge profits for qualifying institutions.
- Just one oncologist employed by an eligible hospital can create up to $1 million of profit under the program through typical use of chemotherapeutic and supportive care drugs. Larger institutions can derive profits of tens of millions of dollars per year—in addition to the significant ancillary services generated throughout treatment of the oncologic disease.

- The deep 20% to 50% drug discounts for eligible hospitals under the 340b program are at a substantial discrepancy compared private oncology offices, which are reimbursed by Medicare at average sales price (ASP) +6%—and currently closer to ASP + 4% under the sequester cuts.
- If one type of care delivery system is financed more advantageously than another, it is predictable that the universe of oncology care will migrate towards the advantaged system. Additionally, the enormous profits derived from the 340b program create a large appetite among hospitals for the acquisition of private oncology clinics.

Medical oncologists no longer derive the drug administration revenue from the private office setting.

Eligible hospitals derive significant profit from oncologic drugs.

The Stark risk: the private medical oncologist courted by the eligible 340B hospital knows the 340B profit and seeks to participate in that profit.

The problem: wRVUs are based on Total RVUs for a given procedure/CPT code is composed of three separate factors: physician work (52%), practice expense (44%), and malpractice expense (4%).

There are only so many medical directorships worth so much and the administrative position compensation pales compared to the oncologist’s drug and ancillary revenue generated for the hospital.


STARK FMV

Stark Definition:

FMV is defined as the value in arm’s-length transactions, consistent with the general market value. General market value means 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.

Stark and commercial reasonableness

“An arrangement is commercially reasonable if the arrangement would make commercial sense if entered into by a reasonable hospital of similar type and size and a reasonable physician of similar scope and specialty, even if there were no potential referrals.”

Tuomey 2nd Trial Jury Instructions
STARK EXCEPTIONS REQUIRING COMMERCIAL REASONABLENESS

- Rental of office space
- Rental of equipment
- Personal services
- FMV compensation
- Indirect compensation
- Isolated transactions

COMMERCIAL REASONABLENESS

Commercial Reasonableness Analysis in Tuomey and Halifax

Ms. McNamara’s approach to assessing CR in the Tuomey and Halifax cases involved a variety of considerations and factors, including analysis of contractual terms and evaluating the community need for the services. One area for particular focus that has a valuation nexus is the analysis of losses on physician employment arrangements. The issues of losing money on physicians, and more specifically, of compensation formulas that do not allow the employer health system to break even or make money were central points in Ms. McNamara’s CR analysis in both cases.

In the Tuomey case, Ms. McNamara’s [Government Expert] initial report found that all of the physician employment agreements were not commercially reasonable:

- Combined with the cost of billing fees, each physician’s compensation and benefits paid materially exceeds his or her Tuomey outpatient collections.
- Since their inception, Tuomey’s physician practices have incurred material financial losses.

"It is not a prudent business practice to enter into business agreements where it is unlikely the enterprise will ever break even or become profitable."

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See Tuomey Report, 11.
See Tuomey Rebuttal Report, 7. See also Tuomey 1 Trial Testimony, 919, 962, 1092, and Tuomey 2 Trial Testimony, 1155-56.
COMMERCIAL REASONABLENESS CONSIDERATIONS

Community Need—What is it and what it isn’t:
- There has to be a legitimate business reason, meaning that there’s a community need that’s unmet, in order for a hospital to sustain these kinds of losses. And what I mean by that and the unmet need, let’s say a hospital is accredited and licensed as a level one trauma center. That means they have to have a cardiologist on staff 24 hours a day, seven days a week. There is simply not a cardiologist to be found in their service area, so that is an unmet need. So that would be a commercially reasonable reason to enter these agreements. Now, you measure that against any potential loss that that practice may generate, and you have to make a business decision, does the loss offset that community need. Some cases it does. In this instance I didn’t feel there was a legitimate community need so there is no justification for continuing to sustain these types of losses.

See Tuomey 2 Trial Testimony, 1220-21.

COMMERCIAL REASONABLENESS CONSIDERATIONS (continued)

Community Need—What is it and what it isn’t:
I believe that if a compensation arrangement is structured that the hospital is guaranteed to lose money then given the particular—In this case given these particular facts and circumstances I would say is not commercially reasonable. Now, there are situations whereby the hospital owns and operates a free clinic, obviously they need to enter an arrangement with the physician, and that’s pretty much guaranteed to lose money. So there are different circumstances where, yes, it’s okay for a hospital to lose money on their physician practice, that’s why each one is evaluated separately.

See Tuomey 2 Trial Testimony, 1220-21.

COMMUNITY NEED IS NOT A SLOGAN JUSTIFYING INFLATED COMPENSATION

Community need for the services was not established by Tuomey because the physicians indicated in their depositions they had no intention of leaving the community.

See Tuomey 1 Trial Testimony, 977-78; Tuomey 2 Trial Testimony, 1160, 1195
COMMERCIAL REASONABLENESS CONSIDERATIONS

- Payor mix
- Charity Care
- Demonstrated community need
- All providers are not created equal: Bariatric vs. Cardiac

The above factors are meaningless based on a credible demonstration of hospital losses, materially increased physician compensation based on value or volume of referrals, as well as unique fringe benefits:

- Car allowances
- Paid for insurance coverage
- Other benefits unavailable to the general hospital physician community

BUILD THE BUSINESS CASE

Consider and document pre-transaction business purposes and objectives such as:

- Strategic objectives
- Demonstrated community need for specialty or service
- Objective to add or expand services to community or segment of patients (e.g., indigent, submarket)
- Quality improvement goals
- Unique skills of the physician

BUILD THE BUSINESS CASE

Consider contract/business terms

- Net cost of arrangement to hospital
- Scope of duties
- Length of term; termination rights
- Reason for any non-standard terms
- Ability to review / change / update compensation
BUILD THE BUSINESS CASE

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- Strategic objectives
- Demonstrated community need for specialty or service
- Objective to add or expand services to community or segment of patients (e.g., indigent, submarket)
- Quality improvement goals
- Unique skills of the physician
  - Be careful, not everyone is "The Father of..." or the "Rock Star"

BUSINESS AND LEGAL CONSIDERATIONS

Commercial reasonableness is the enforcement focus

- Apply common sense
- Ask: "Does this deal make sense?"
- Ask: "Is this arrangement typical or consistent with the organization’s usual approach to similar arrangements?"
- If it’s too good to be true for the physician, it probably is!
- Try to back to avoid deal inertia
- Is it sustainable over time?
- Don’t be afraid to restructure or walk away

HOW NOT TO DO IT APPROACH: NO SENIOR MANAGEMENT ACCOUNTABILITY FOLLOWS THE DEAL

1. Heightened Risk Approach to Physician Contracting
   - Hospital personnel operate in silos
   - Business Development negotiates the deal including the dollar value
   - Compliance input is sought after the handshake and adoption of the value of the deal
   - The deal "hangs" on the decision of a single person; the compliance officer
   - Artificial deadlines dominate the compliance assessment
   - WE NEED TO GET THE DEAL DONE NOW BECAUSE:
     - BEFORE THE NEXT BOARD MEETING
     - BY THE END OF THE WEEK, OR MONTH
     - BECAUSE THE PHYSICIAN NEEDS THE DEAL DONE NOW (DESPITE THE NEGOTIATION OVER THE LAST SEVERAL MONTHS)
     - BEFORE A VACATION BY SOMEONE, SOMEWHERE IN THE ORGANIZATION
ACCOUNTABILITY APPROACH: KEY CONSIDERATIONS

- Accountability follows the deal
- Use contractual terms that promote stark compliance
- No opt-out clause
- Contractual reset
- Third party risk assessment for proposed compensation package above a certain benchmark
- Cannot be a prophet in your own land
- Avoid the normalization of deviance or the parable of the boiled frog
QUESTIONS?

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Experience
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- Assistant County Prosecutor
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