

***Defending Physician Compensation
Arrangements in the Current
Enforcement Environment***

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**Lessons Learned from Recent
Enforcement Actions**

Hypothetical #1

- Employed oncologist
 - wRVU production compensation
 - Stipend for medical director services with documented time records of 60-80 hours per month
 - Compensation above 90th percentile but reasonable based upon consistent historical level of production

Hypothetical #1 (cont.)

- Follow Up FMV report: Questioned reasonableness of compensation based on current data when physician paid "above all established benchmarks"
 - Lower wRVU conversion factor moving forward
- Third FMV report: Compensation exceeds FMV after additional review shows physician paid for productivity of another physician
- Review of time records show physician working fewer than 5 days a week but medical director time logs showing 60-80 hour per month

U.S. ex rel. Barker v. Columbia Regional Healthcare System Inc.

- \$35 million settlement to resolve former executive's FCA claim accusing Georgia hospital chain of overpaying lead referring oncologist, Dr. Andrew Pippas
- Additional Allegations
 - Chief Compliance Officer File Notes
 - "The base compensation is an issue for me because I believe the 'impossible day' as well as 'reasonableness test' needs to be considered.... "It is very difficult to support the idea that here in Columbus Ga. We have the top producer in the entire United States..."
 - "[N]ow we have the top or second top wRVU producer in the country AND he is doing so in less than 5 days a week."

Takeaways

- Thorough review and confirmation of assumptions for FMV report at outset of arrangement
- Regular monitoring of production compared to compensation needed for production-based models
- Confirmation that all medical directorships and other hourly based services are provided
 - Review of time logs
 - Asking questions of staff

Hypothetical #2

- 7-year term employment agreement as part of practice acquisition
 - Includes increase in compensation to account for the value of ancillary services being lost by physicians due to acquisition by hospital
 - Tiered compensation formula paying higher amounts for higher wRVU levels
 - Agreement includes requirement to refer to hospital
- Tracking of imaging referrals to hospital

U.S. ex rel. Hammett v. Lexington County Health Services District

- \$17 million settlement with Lexington Medical Center in West Columbia, SC to resolve Stark and FCA allegations that the hospital acquired physician practices and employed physicians on terms in excess of FMV and not commercially reasonable

Takeaways

- Build out reasoned rationale for acquisition supported by data
- Consider total picture when considering increase in compensation as part of acquisition
- Tiered compensation formulas are risky due to ability to exceed FMV at higher tiers and difficult to administer
- Focus on appropriate use of referral data
 - Quality and service concerns can be appropriate
 - Use of referral data to make compensation or employment decisions is not appropriate

Hypothetical #3

- Physicians sell infusion center to hospital and employed based on wRVU compensation model
- Purpose of sale is for hospital to take advantage of increased revenue from 340(b) program
- Physicians also paid management fee for managing center
- Physicians concerned about loss of income from change of ownership
- Hospital promises physicians would be "made whole" for lost income due to sale
- Proposed compensation model margin replacement based on wRVU drug administration rather than physician work, resulting in payment for 500% total work wRVUs for clinic
- Physicians perform no management services

U.S. ex rel. Holden v. Mercy Hospital Springfield f/k/a St. John's Regional Health Center

- \$34 million settlement by Missouri hospital and its affiliated clinic to resolve FCA and Stark Law allegations related to above FMV and commercially unreasonable physician employment arrangements

Takeaways

- Compensation based on FMV for services being provided
- Management or administrative services
 - Business justification
 - Actually performed

Understanding Legal Requirements for Physician Compensation Arrangements

Stark Law

The Physician Self-Referral Statute ("Stark Law"), 42 U.S.C. 1395nn, prohibits:

1. Physicians from referring Medicare/Medicaid patients for certain designated health services (DHS) to an entity with which the physician or a member of the physician's immediate family has a financial relationship—
2. It also prohibits an entity from presenting or causing to be presented a bill or claim to anyone for a DHS furnished as a result of a prohibited referral.

Unless an exception applies.



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Strict Liability Law



- Intent is Not Relevant
 - Does not matter if the prohibited financial relationship results from innocent error or inadvertence
- Technical Violations = Violations

**Bona Fide Employment
(42 C.F.R. §411.357(c))**

- Employment for identifiable services
- Remuneration is:
 - Consistent with fair market value
 - Not determined in a manner that takes into account (directly or indirectly) volume or value of referrals, except for productivity bonus based on services performed personally by the physician
 - Commercially reasonable even without referrals

**Personal Service Arrangements
(42 C.F.R. §411.357(d))**

- Signed writing specifying all services furnished by physician
 - Incorporate other agreements by reference or cross-reference master contract list maintained and updated centrally
- 1-year term
- Compensation:
 - Set in advance
 - Does not exceed fair market value
 - Except for "physician incentive plan," is not determined in a manner that takes into account the volume or value of referrals
- Reasonable and necessary services for legitimate business purposes of the arrangement
- Services do not involve counseling or promotion of business arrangement or other activity that violates any Federal or State law

Anti-Kickback Statute

- Criminal offense to knowingly and willfully offer, pay, solicit or receive any remuneration to induce referrals of items or services reimbursable by a federal health care program
 - No actual knowledge or specific intent required
- "Remuneration" includes the transfer of anything of value, in cash or in kind, directly or indirectly, covertly or overtly

Anti-Kickback Statute Liability

- Criminal and civil penalties
- \$25,000 per offense
- Imprisonment up to 5 years
- Civil monetary penalties (exclusion and \$50,000)
- False Claims Act liability (3 times damages)

**Employment Safe Harbor
(42 U.S.C. §1320a-7b(b)(3)(B);
42 C.F.R. §1001.952(i))**

- Paid by employer to employee
- Employee has *bona fide* employment relationship with employer
- Employment is for furnishing of any item or service reimbursable under Medicare, Medicaid, or other Federal health care programs

**Personal Services Safe Harbor
(42 C.F.R. §1001.952(d))**

- Signed writing covering specifying services that are reasonable and necessary to accomplish business purpose
 - If less than full-time, specifies exact schedule and charge
- 1-year term
- Compensation:
 - Is set in advance
 - Is consistent with fair market value
 - Does not take into account any business generated between parties for which payment may be made by Federal health care program
- Services do not involve counseling or promotion of activity that violates law

Special Considerations For FMV and Commercial Reasonableness

Focus on Fair Market Value

- Stark Statute: Value in arm's length transactions, consistent with general market value... (1877 (h)(3) of the Social Security Act)
- Narrower regulatory definition (42 CFR §411.351)
 - Value in arm's-length transactions, consistent with general market value
 - General market value means compensation as result of bona fide bargaining between well informed parties not otherwise in position to generate business for other party
 - Compensation does not take into account volume or value of anticipated or actual DHS referrals

Focus on Fair Market Value

- AKS safe harbor regulations require FMV, but AKS does not define it.
- Special Fraud Alert – Clinical Laboratory Services (October 1994)
 - Presumption: Compensation outside of FMV is in exchange for referrals
- OIG Compliance Guidance for Individual and Small Group Practices (October 2000)
 - “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 business.”

Focus on Fair Market Value

- **OIG Supplemental Guidance for Hospitals (January 2005)**
 - Need appropriate processes for making and documenting reasonable, consistent, and objective determinations of FMV
 - Is the determination of FMV based upon a reasonable methodology that is uniformly applied and documented?
 - If FMV based on comparables, ensure market rate for comparable services is not distorted.

Focus on Commercial Reasonableness

- **Stark Commentary:**
 - Subjective Concept (Phase I): Sensible, prudent business agreement from the perspective of the parties
 - Objective Concept (Phase II): Would make commercial sense if entered into by a reasonable entity of similar type and size and a reasonable physician of similar scope and specialty, even if there were no potential for DHS referrals

Best Practices for Establishing and Auditing Physician Employment Arrangements

Arrangement Review Process

- Use contract management tool to manage agreements.
- Establish centralized contracting process for consistent review and approval of all arrangements.
- Develop template agreements meeting legal requirements.
- Confirm fair market value of arrangement.
 - Consider when outside valuations will be required.
 - DON'T forum shop opinions
 - Choose experienced, reputable valuator.
- Document appropriate business justification for arrangement.
 - DON'T pay for referrals.

Compensation Structure Development

- Simple – easily administered and physicians understand it
- Consistent – minimal variation driven only by sound and appropriate principles
- Auditable – can be regularly reviewed
- Compliant – Link to production, collections, need or other compliant measure to support amount

Arrangement Tracking

- Require periodic reevaluation of FMV and commercial reasonableness
- Update arrangements if change in relationship
 - Compensation changes must follow centralized process.
- Enforce detailed payment tracking
 - NO payment without documentation.
 - If the arrangement involves services, track service and activity logs.
 - If the arrangement involves space or equipment, monitor use of leased space or equipment.

Arrangement Audit Process

- Step One – Establish audit parameters.
 - Who performs the audit?
 - Will the audit be performed under privilege?
 - What is the purpose and scope of the audit?

Arrangement Audit Process

- Step Two – Gather documents for review.
 - Master contract list
 - Copies of agreements
 - Fair market value support for compensation
 - Inventory of equipment and space in use by physicians
 - Time records and logs
 - General ledger accounts, accounts payable distribution, and vendor master file
 - Accounts payable and payroll information for payments to physicians
 - Accounts receivable for payments from physicians
 - Minutes or other similar documents to memorialize rebuttable presumption procedures followed

Arrangement Audit Process

- Step Three – Review and analyze documents.
 - Is there a written agreement for all payments to/from physicians?
 - Has the agreement expired?
 - Are payments being made in compliance with the agreement?
 - Has the relationship changed since the agreement's execution?
 - Is the agreement at FMV and commercially reasonable?
 - Are the parties complying with the agreement terms?
 - Does the agreement comply with the requirements of the applicable Stark exception/AKS safe harbor?

Arrangement Audit Process

- Step Four – Interview personnel and gather additional documentation to verify information and fill in any gaps.
 - Performance of duties
 - Continued business need
 - Change in relationship or arrangement
 - Review of facility to identify undocumented space or equipment rentals

Arrangement Audit Process

- Step Five – Take corrective action as needed to ensure continued compliance.
 - Termination or amendment of agreements
 - Implementation of new agreements
 - Consideration of potential refund or disclosure obligations

Questions
