



Minimizing Stark Law Execution Risk

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Program Purpose: Equip In-House Counsel to Meet Professional Obligation to Provide Competent Stark Law Advice

- The overriding purpose of this program is to enable attendees to fulfill their ethical and professional obligations to provide competent representation under the Illinois Rules of Professional Conduct when providing Stark Law advice.
 - Rule 1.1 stipulates that “A lawyer shall provide competent representation to a client. Competent representation requires the legal knowledge, skill, thoroughness and preparation reasonably necessary for the representation.”
 - Accordingly, attorneys who provide Stark Law advice must be knowledgeable regarding the intricacies of the highly complex Stark Law regulations and spot issues requiring expert advice.
 - This program will highlight Stark Law pitfalls and recent changes to enable attendees to meet this requirement.
 - We also will discuss some of the ethical quandaries that arise in the provision of Stark Law advice and implementation of physician arrangements.

Ethical Dilemmas in Stark Law Counseling: Relevant Rules of Professional Conduct

- Several Rules are potentially implicated by the rendition of complex Stark Law advice, including:
 - Client Compliance with Law (Rule 1.2(d))
 - Organization as Client (Rule 1.13)
 - Conflict of Interest (Rule 1.7)
 - Terminating Representation (Rule 1.16)
 - Alteration and Concealment of Evidence (Rule 3.4)
 - Advocate in Non-Adjudicated Proceedings (Rule 3.9)
 - Misconduct (Rule 8.4)

Client Compliance With Law (Rule 1.2(d))

- A lawyer shall not counsel a client to engage, or assist a client, in conduct that the lawyer knows is ***criminal*** or ***fraudulent***, but a lawyer may discuss the legal consequences of any proposed course of conduct with a client and may counsel or assist a client to make a good faith effort to determine the validity, scope, meaning or application of law.

Rule 1.7 – Conflict of Interest

- A lawyer shall not represent a client if the representation involves a concurrent conflict of interest.
- A concurrent conflict of interest exists if:
 - the representation of one client will be directly adverse to another client; or
 - there is a significant risk that the representation of one or more clients will be materially limited by the lawyer's responsibilities to another client, a former client or a third person or by a personal interest of the lawyer.

Rule 1.7

- Commentary:

- For example, a lawyer asked to represent several individuals seeking to form a joint venture is likely to be materially limited in the lawyer's ability to recommend or advocate all possible positions that each might take because of the lawyer's duty of loyalty to the others.
- The critical questions are the likelihood that a difference in interests will eventuate and, if it does, whether it will materially interfere with the lawyer's independent professional judgment in considering alternatives or foreclose courses of action that reasonably should be pursued on behalf of the client.

Rule 1.7 – Exceptions

- The only exceptions are:
 - the lawyer reasonably believes that the lawyer will be able to provide competent and diligent representation to each affected client;
 - the representation is not prohibited by law;
 - the representation does not involve the assertion of a claim by one client against another client represented by the lawyer in the same litigation or other proceeding before a tribunal; and
 - each affected client gives informed consent.

Organization as Client (Rule 1.13)

- A lawyer employed or retained by an organization represents the organization acting through its duly authorized constituents.
- If a lawyer for an organization knows that an officer, employee or other person associated with the organization is engaged in action, intends to act or refuses to act in a matter related to the representation that is a violation of a legal obligation to the organization, or **a crime, fraud or other violation of law** that reasonably might be imputed to the organization, and that is likely to result in **substantial injury to the organization**, then the lawyer **shall** proceed as is **reasonably necessary in the best interest of the organization**.
 - Normally, this involves referral to a higher authority within the organization.
 - However, referral may not be necessary if a constituent had an innocent misunderstanding of law and reconsiders action on advice of counsel.
 - If highest authority within organization refuses to address action that is clearly a **crime** or **fraud**, lawyer **may** reveal information reasonably necessary to prevent substantial injury to the organization but **not** if information arose from lawyer's involvement in an investigation or defense of client.
- In dealing with an organization's directors, officers, employees or other constituents, a lawyer shall explain the identity of the client when the lawyer knows or reasonably should know that the organization's interests are adverse to those of the constituents with whom the lawyer is dealing.
- A lawyer representing an organization may also represent any of its directors, officers, employees, or other constituents, subject to Rule 1.7 on joint representation.

Terminating Representation (Rule 1.16)

- Withdrawal is appropriate when:
 - Representation would violate the Rules of Professional Conduct or law.
 - The client persists in a course of action involving the lawyer's services that the lawyer reasonably believes is criminal or fraudulent.
 - The client has used the lawyer's services to perpetrate a crime or fraud.
 - The client insists upon taking action that the lawyer considers repugnant or with which the lawyer has a fundamental disagreement.

Alteration and Concealment of Evidence (Rule 3.4)

- A lawyer shall not unlawfully obstruct another party's access to evidence or unlawfully alter, destroy or conceal a document or other material having potential evidentiary value.
- A lawyer shall not counsel or assist another person to do any such act.

Advocate in Non-Adjudicated Proceedings (Rule 3.9)

- A lawyer representing a client before a legislative body or administrative agency (e.g., as a lobbyist) in a non-adjudicative proceeding shall disclose that the appearance is in a representative capacity and shall conform to the provisions of Rules 3.3(a) through (c), 3.4(a) through (c), and 3.5.
- Rule 3.3 requires “candor toward the tribunal.”
- Rule 3.4 precludes falsification of evidence and assisting a witness in giving false testimony.
- Rule 3.5 bars *ex parte* communications unless authorized by law or court order, as well as seeking to influence an official by unlawful means.

Misconduct (Rule 8.4)

- Among other things, it is professional misconduct for a lawyer to:
 - Violate or attempt to violate the Rules of Professional Conduct, knowingly assist or induce another to do so, or do so through the acts of another.
 - Commit a criminal act that reflects adversely on the lawyer's honesty, trustworthiness, or fitness as a lawyer in other respects.
 - ***Engage in conduct involving dishonesty, fraud, deceit, or misrepresentation.***
 - State or imply an ability to influence improperly a government agency or official or to achieve results by means that violate the Rules or other law.
 - Present, participate in presenting, or threaten to present criminal or professional disciplinary charges to obtain an advantage in a civil matter.
 - Violate an anti-discrimination law.

The Yates Memo: DOJ's Increased Focus on Individual Accountability

The 6-pronged memorandum regarding “Individual Accountability for Corporate Wrongdoing” issued by Deputy Attorney General Sally Quillian Yates to federal prosecutors on September 9, 2015 changes DOJ’s policy on the resolution of criminal **and civil** cases.

1. To be eligible for any cooperation credit, corporations must provide to the Department all relevant facts about the individuals involved in corporate misconduct.
 - Failure to conduct a robust investigation may disqualify the company for credit.
2. Both criminal and civil corporate investigations should focus on individuals from the inception of the investigation.
3. Criminal and civil attorneys handling corporate investigations should be in routine communication with one another.
4. Absent extraordinary circumstances, no corporate resolution will provide protection from criminal or civil liability for any individuals.
5. Corporate cases should not be resolved without a clear plan to resolve related individual cases before the statute of limitations expires and declinations as to individuals in such cases must be memorialized.
6. Civil attorneys should consistently focus on individuals as well as the company and evaluate whether to bring suit against an individual based on considerations beyond that individual’s ability to pay.

Ethical Implications of Yates Memo

- Under Rule 1.1 (competence), it is important for in-house counsel to take the Yates Memo into account when advising on the conduct of investigations.
 - The memo's emphases on diligent and thorough investigations of individual culpability makes a robust, timely, independent investigation essential.
 - It also means that individuals are more likely to insist on having their own counsel present for investigational interviews.
 - Robust "*Upjohn*" warnings must be given at the start of investigational interviews and in-house counsel should not downplay the potentially divergent interests of the company and the individual if questions arise.
- Not only is it an ethics violation to counsel a client or assist a client in criminal or fraudulent conduct under Rule 1.2(d), in-house counsel faces a pronounced risk of individual liability for doing so in light of the Yates Memo.

Ethical Implications of Yates Memo

- The Yates memo exacerbates potential conflicts of interest between the organization and any officer, director or other constituent potentially involved in wrongdoing, making joint representation more problematic under Rules 1.7 and 1.13.
- However, the Yates memo gives in-house counsel a lever to urge individual constituents to reconsider action involving potential violations of law before they take it.
 - Such reconsideration would obviate in-house counsel's ethical obligation to refer matter to a higher authority under Rule 1.13.
 - But if a constituent refuses to reconsider, referral up the chain becomes all the more essential in light of the heightened potential consequences for the organization.

Ethical Quandary #1

- Your hospital client receives a Government subpoena in connection with an sealed *qui tam* case. In reviewing potentially responsive documents, you find an email from the health system CFO to the CEO indicating that the hospital's group practice mistakenly took into account DHS collections in productivity bonus distributions for the past 5 years.
- The CEO responded that the past is water under the bridge but instructed the CFO to correct the issue going forward.
- The CEO calls your office, acknowledges the email trail and directs you not to produce it. He also asks for your advice on how to minimize his exposure.

What Do You Do?

- A. Suppress document and advise CEO on personal exposure
- B. Produce document
- C. Counsel CEO on consequences of suppression for the Hospital/ hope he changes his mind
- D. Go to Chairman of the Board
- E. Terminate representation

Stark Exceptions - What is Needed?

Terms of exception	In-office ancillary services [1877(h)(4); §411.352]	Bona fide employment [1877(e)(2); §411.357(c)]	Personal services arrangements [1877(e)(3); §411.357(d)]	Fair Market Value [§411.357(1)]
Must compensation be “fair market value”?	No	Yes – 1877(e)(2)(B)(i).	Yes – 1877(e)(3)(A)(v).	Yes - §411.357(1)(3).
Must be “commercially reasonable”?	No.	Yes (remuneration) – 1877(e)(2)(C).	Yes (aggregate services reasonable and necessary) – 1877(e)(3)(A)(iii).	Yes (arrangement) - §411.357(1)(4).
Must compensation be “set in advance”?	No	No.	Yes – 1877(e)(3)(A)(v).	Yes - §411.357(1)(3).
Scope of “volume or value” restriction.	DHS referrals – 1877(h)(4)(A)(iv).	DHS referrals – 1877(e)(2)(B)(ii).	DHS referrals or other business – 1877(e)(3)(A)(v).	DHS referrals or other business - §411.357(1)(3).
Scope of productivity bonuses allowed.	Personally performed services and “incident to” plus indirect – 1877(h)(4)(B)(i).	Personally performed services – 1877(e)(2).	Personally performed services - §411.351 (“referral”) and §411.354(d)(3).	Personally performed services - §411.351 (“referral”) and §411.354(d)(3).
Are overall profit shares allowed?	Yes – 1877(h)(4)(B)(i).	No.	No.	No.
Written agreement required?	No.	No.	Yes , minimum 1-year term.	Yes (except for employment), no minimum term.
Physician incentive plan (PIP) exception for services to plan enrollees?	No, but risk-sharing arrangement exception at §411.357(n) may apply.	No, but risk-sharing arrangement exception at §411.357(n) may apply.	Yes, and risk-sharing arrangement exception at §411.357 may also apply.	No, but risk-sharing arrangement exception at §411.357(n) may apply.

FMV

...the value in arms 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 at the time of the service agreement**. Usually, the fair market price is...the compensation that has been **included in bona fide services agreements with comparable terms** at the time of the agreement ...where the...compensation has **not been determined in any manner that takes into account the volume or value of anticipated or actual referrals**.

FMV/GMV

- Included in definition:
 - Result of bona fide bargaining
 - Not in a position to generate business
 - Bona fide arrangements with comparable terms
 - Does not take into account the volume or value of referrals
- Because part of definition, will ask valuers to address
- How do you demonstrate?

Commercial Reasonableness

- No express definition in regulations, but commentary states:
 - Phase I: Sensible, prudent business agreement from the perspective of the parties
 - 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

Commercial Reasonableness

- Examples of Commercially Unreasonable Conduct/Arrangements:
 - Too many medical directors
 - Purchase of an asset, with no intention to ever use it
 - Complex arrangements with illogical components
 - No chance to earn a profit/foreseeable operating losses
 - Paying for early termination rights
 - Overbroad non-compete
 - Leasing an item for more than the cost to acquire

Safeguards for FMV Compliance

- Robust contract approval policies.
 - Require legal review for compensation arrangement outside of predefined parameters
- Document FMV rationale for all contractual arrangements.
 - Don't blindly rely on third-party valuations – conduct “critical eye” review to ensure that projected DHS revenue streams from physician do not figure into valuation and that reasonable benchmarks are used.
 - Specifically request experts to stipulate that compensation is commercially reasonable and does not take into account referrals.
- Build in automatic escalators or periodic FMV reevaluations under contractual arrangements at commercially reasonable intervals.
 - While auto renewal clauses are advisable, they make periodic FMV resets particularly important.

FMV Compensation Challenges

- Losses and “subsidiaries” – do they always result in an FMV problem?
- Limited duration of FMV opinions.
- At what time is fair market value determined?
- Comparables for value-based payments and non-productivity.
- The “opportunity cost” problem.
- MGMA and surveys – contain data not comp systems.
- Definition of FMV – doesn’t take into account the volume or value of referrals.

Isolated Transaction Definition

- An isolated financial transaction means one involving a single payment between two or more persons or entities or a transaction that involves integrally related installment payments provided that:
 - Total aggregate payment is fixed before the first payment is made and does not take into account, directly or indirectly, the volume or value of referrals or other business generated by the referring physician; and
 - The payments are immediately negotiable or are guaranteed by a third party, or secured by a negotiable promissory note, or subject to a similar mechanism to ensure payment even in the event of default by the purchaser or obligated party.

Isolated Transaction Exception

- The amount of remuneration under the isolated transaction is:
 - Consistent with the fair market value of the transaction; and
 - Not determined in a manner that takes into account (directly or indirectly) the volume or value of any referrals by the referring physician or other business generated between the parties
- The remuneration is provided under an arrangement that would be commercially reasonable even if the physician made no referrals to the entity

Isolated Transaction Exception

- There are no additional transactions between the parties for 6 months after the isolated transaction, except for:
 - Transactions that are specifically excepted under the other provisions; and
 - Commercially reasonable post-closing adjustments that do not take into account (directly or indirectly) the volume or value of referrals or other business generated by the referring physician

Valuation of Physician Practices

- Three Basic Approaches to Value:
 - Cost Approach
 - Income Approach
 - Market Approach
- Source of Basic Valuation Approaches:
 - IRS Revenue Ruling 59-60
 - Finance community – academic and practical
- FMV vs. Investment Value or “Strategic” Value

Valuation of Physician Practices

- Problems with the Cost Approach
 - Substitution of equivalent service transactions may not be practical
 - Book Value (or Cost to Replace) may understate value
 - Aggregate cost exceeds income approach
- Problems with Market Approach:
 - Comparable data limited or non-existent
 - May include transactions between parties in a position to refer to one another
 - May include transactions involving strategic value

Valuation of Physician Practices

- Problems with Income Approach:
 - Income/Revenue may consider the income from referrals
 - Medical practices “zero out” every year – no earnings for owners without adjustments
 - Impact of future compensation

Determining FMV for Intangible Assets Absent Positive Cash Flow

- The primary issue lies within the concept of total enterprise value versus the value of individual assets
 - Sum of the parts or greater than value of whole
 - Economic benefit equivalent to costs avoided
 - Cost to assemble assets
- Workforce in-place considerations
 - Time and effort to recruit workforce
 - Ramp-up to full productivity
 - Include or exclude clinicians?

Determining FMV for Intangible Assets Absent Positive Cash Flow

- Patient charts
 - Cost to reproduce
 - HIPAA guidance
 - Labor for copying the PHI, whether in paper or electronic form
 - Supplies for creating the paper copy or electronic media (e.g., CD-ROM or flash drive)
 - Postage

Considerations in Time Shares and Real Property Leases

- “Local market” impact to value versus value for proximity to referral sources
 - Information regarding market comparable, industry/specialty specific leases may be limited
- Rates must be consistent with the specific terms of the agreement and condition of the space being leased
 - Class A, B, C space
 - NNN versus gross, common area maintenance, leasehold improvements, duration of the lease, etc.
 - Time share arrangements must factor any furniture, fixtures, equipment, staff, supplies, or other services provided into determination of fair market value

Personal Property (Equipment) Leases

- Market comparable data for most types of equipment, furniture, etc. is available through industry-specific sources
- Renewal of existing leases of equipment, furniture, etc. can be problematic
 - The one-time cost to purchase each leased asset versus the total historical lease payments for each specific asset should be factored into the decision to renew the lease.
 - The cumulative term of the lease versus the estimated useful lives for each specific asset should be factored into the decision to renew the lease.
 - Fair market value should have some basis in the current appraised value of the assets

Value-Based Clinician Compensation

- Allows for an objective method for moving some risk to employed clinicians
 - Shift from fee-for-service to episodic care
- Medicare adjustments under MACRA provide a means to measure applicable physician compensation adjustments
- Physician compensation impact
 - Incentives for improving quality, practice operations, and use of technology (or penalties for failing to do so)
 - Resource use (cost) will become the largest contributing factor for Medicare adjustments, and will provide challenges to traditional productivity-based compensation and traditional methods of evaluating fair market value

Ethical Quandary #2

Your VP of Business Development has negotiated a deal with a key orthopedic group to joint venture a new ambulatory care facility and provide various management and medical director services to the new facility.

- He gives you a term sheet and tells you to draft up the documents.
- When you raise concerns regarding the FMV of the “contributed assets” and compensation rate, as well as the high number of hours of service projected, he acknowledges the above FMV rates and that the physicians aren’t really going to provide the number of hours of service called for by the term sheet.
- Nonetheless, he says “Just get the document done – we need to do this deal to avoid losing this group’s admissions to our competitor. I’ll take responsibility if we are ever challenged.”

What Should You Do?

- A. Just get the documents done – if the deal blows up, you can produce a memo to file indicating you raised concerns and the VP assumed the risk.
- B. Refuse to paper deal terms that violate the AKS and will expose the organization to FCA risk.
- C. Counsel the VP on the risks to the organization and to him personally in light of Yates memo.
- D. Inform the CEO of your concerns.

Government and the Courts

- Key cases:
 - Bradford
 - Tuomey
 - Halifax
- What are the takeaways?

Bradford: Fixed Payment Can Take into Account Volume or Value

“A fixed payment compensation arrangement such as the one in this case may be considered as taking into account the volume or value of referrals — if that fixed payment is in excess of fair market value.”

“We conclude that the compensation arrangement between BRMC and the doctors is inflated to compensate for the [doctors] ability to generate other revenues. Specifically, we find that the amount of the compensation arrangement was arrived at by taking into account the anticipated referrals from the doctors. We therefore conclude that the compensation arrangement between BRMC and the doctors is not — fair market value under the Stark Act.”

Tuomey: Anticipating Volume or Value Can Run Afoul of FMV

“Our analysis of these sources, set forth below, yields the conclusion that compensation arrangements that take into account anticipated referrals do implicate the volume or value standard.”

“It stands to reason that if a hospital provides fixed compensation to a physician that is not based solely on the value of the services the physician is expected to perform, but also takes into account additional revenue the hospital anticipates will result from the physician's referrals, that such compensation by necessity takes into account the volume or value of such referrals.”

“Thus, it is for the jury to determine whether the contracts violated the fair market value standard by taking into account anticipated referrals in computing the physicians' compensation.”

Halifax: Source of Funds – Varies Based on Volume or Value

“The Incentive Bonus was not a ‘bonus **based on** services personally performed’ by the Medical Oncologists, as the exception requires. Rather, as described by the Defendants themselves, this was a bonus that was **divided up** based on services personally performed by the Medical Oncologists. The bonus itself was based on factors in addition to personally performed services -- including revenue from referrals made by the Medical Oncologists for DHS. The fact that each oncologist could increase his or her share of the bonus pool by personally performing more services cannot alter the fact that the size of the pool (and thus the size of each oncologist’s bonus) could be increased by making more referrals.” (emphasis original)

Safeguards for FMV Compliance

- Consider adoption of a physician compensation plan for employed physicians with a process for validating FMV compensation, including committee and/or outside review of all compensation prior to payment that would push physicians over predetermined thresholds and documentation of the rationale for such payment.
 - Include a mechanism for validating that the compensation methodology does not take into account the volume or value of DHS referrals.
- Contract management databases
- Time sheet requirements to ensure services actually rendered.
- Auto adjustments based on productivity reductions beyond pre-defined productivity corridor.

Ethical Quandary #3

- You are working with physician group representatives to develop a medical director and call coverage arrangement. The group is very frugal and has declined to have its own legal counsel. They request your advice on structuring certain specific aspects of the arrangement to comply with the Stark Law and AKS, including the compensation formula, length of term and hours expectation. How should you handle?

Employment v. In-Office: Differences

- Scope of productivity bonuses
- Profit-sharing bonuses
- Fair market value
- Commercial reasonableness

In-Office Ancillary Services Exception

Applies to DHS provided by a ***physician group practice*** if the following three tests are satisfied:

Location

- Same building as a physician office (part-time occupancy permissible only if minimum office hour standards satisfied); or
- Centralized location occupied by group on full-time basis.

Provider

- By referring physician;
- By another physician in the group (including independent contractors); or
- By a non-physician supervised by physician in group.

Billing

- By group, wholly owned subsidiary or agent
- Under billing number assigned to group or subsidiary.

Minimum Office Hour Standards

If DHS are offered in an office that is occupied on less than a full-time basis, there must be a physician office in the same building in accordance with one of the following three tests:

- The physician office is normally open at least 35 hours per week and one or more members of the group provide physician services at the office at least 30 hours per week;
- The office is open at least 8 hours per week; the individual referring physician practices at such office at least 6 hours per week; and the patient receiving the DHS ordinarily receives physician services at that location; or
- The office is occupied by the group at least 8 hours per week; one or more members of the group provides physician services there 6 hours per week; and the referring physician is present and orders the DHS during a visit on the premises or the referring physician or another member of the group is present while DHS are performed.

In each case, the services provided by the group at the office must include some physician services that are unrelated to the furnishing of DHS (although such services may lead to the ordering of DHS).

Group Practice Prerequisites

- Single legal entity with at least two physician members.
- Primary purpose = physician practice.
- All members furnish substantially the full range of services they routinely furnish through joint use of office space, facilities, equipment and personnel.
- Members furnish an average of 75% of their patient care services through group.
- Overhead expenses and income distributed based on prospectively determined methodology.
- Unified business with centralized decision making by a body representative of the group with effective control over groups assets/liabilities (including budgets, compensation and salaries)
- Consolidated billing, accounting and financial reporting.
- Members personally conduct at least 75% of patient encounters.
- Compensation is not based on volume or value of DHS referrals *except* in accordance with “Special Rules.”

“Special Rules” For Group Practice Profit Distributions and Productivity Bonuses

- Physicians may be paid:

- A share of the “overall profits” of the group
- A productivity bonus based on personally performed services and/or “incident to” services

as long as such profit share or bonus is not determined in a manner directly related to the volume or value of the physician’s DHS referrals.

- Overall profits means:

- Group’s entire profits derived from DHS payable by Medicare/Medicaid
- DHS profits of any component of the group consisting of 5 or more physicians

- The following profit distribution and bonus methodologies are expressly permitted:

- Per capita distribution of overall profits
- DHS profit distribution or bonus based on allocation of non-DHS revenues.
- DHS profit distribution or productivity bonus if DHS revenue \leq 5% of total group revenue and no physician receives $>$ 5% of total compensation from DHS distribution.
- Bonus based on total patient encounters or RVUs.
- Any bonus or overall profit distribution methodology that is not directly related to volume or value of DHS referrals.

What Are Incident To Requirements?

- To be covered incident to the services of a physician or other practitioner, services and supplies must be:
 - An integral, although incidental, part of the physician's professional service
 - Commonly rendered without charge or included in the physician's bill
 - Of a type that are commonly furnished in physician's offices or clinics
 - Furnished by the physician or by auxiliary personnel under the physician's ***direct supervision***
- Direct supervision requires that the supervising physician be in the ***same office suite*** and immediately available to provide assistance and direction throughout the time the "incident to" service is performed.

Profit Sharing and Bonuses Under Special Rules Based on Personally Performed and Incident To Services

	Bonus Based on Personally Performed Services	Bonus Based on Incident To Services	Profit Share
Professional Services and Other Non-DHS	Yes – Does not implicate Stark	Yes – Does not implicate Stark ¹	Yes – Does not implicate Stark
PT/OT	Yes – In accordance with Special Rules	Yes – In accordance with Special Rules	Yes – In accordance with Special Rules
Outpatient Drugs/Supplies	Yes – In accordance with Special Rules	Yes – In accordance with Special Rules	Yes – In accordance with Special Rules
DME	No – Cannot be personally performed unless physician has own DMEPOS number	No – Same issue as for personally performed DME	Yes – In accordance with Special Rules
Lab	No	No – Never considered “incident to”	Yes – In accordance with Special Rules
Imaging	No	No – Never considered “incident to”	Yes – In accordance with Special Rules

¹ This is true for all DHS except professional component of imaging services.

Legal Quandary #1

A health system client wants to form a new entity to acquire physician practices and replicate the autonomy, flexibility and compensation model that the physicians currently have in their independent practices to the greatest extent possible.

Which of the Following Features are Potentially Problematic?

- A. Forming a “Pod” for each legacy practice and splitting Pod profits equally among Pod physicians.
- B. Same as above, but allowing Pod physicians to determine how to split the profit pool at the end of each year as long as the methodology is not directly related to the volume or value of DHS referrals.
- C. Paying physicians productivity bonuses based on the “permissible DME” (canes, crutches, etc.) and outpatient prescription drugs dispensed to each physician’s patients and the imaging procedures supervised by each physician.
- D. Giving Pod physicians the right to approve the addition of new physicians to their Pod.
- E. Calculating Pod profits available for distribution without allocating centralized practice overhead.

Physician Supervision of Midlevel Clinicians

- Exception for assistance to compensate midlevels
- Billing considerations
 - “Incident to” billing, shared/split services, place of service
 - Consider the billing NPI and how it may impact productivity-based compensation
- How many midlevels can one physician supervise?
- Compensation amounts typically similar to that of collaborative agreements
- Overall physician compensation should be consistent with fair market value

Pooled Productivity/Equal Share

- Example:
 - 3 physicians of the same specialty
 - All wRVUs personally performed by the physicians are pooled and multiplied by a conversion factor
 - Each physician receives an equal share of the resulting pool (*i.e.*, one-third)
- Does this comply with a Stark Law exception?

Pooled Productivity/Equal Share

- Three potentials:
 - MD #1 – paid more than the average
 - MD #2 – paid at the average
 - MD #3 – paid less than the average
- MDs #1 and #2 paid on 100% or less of their productivity, but what about MD #3?

Pooled Productivity/Equal Share

- “The amount of the remuneration . . . [e]xcept as provided in paragraph (c)(4) of this section, is not determined in a manner that takes into account (directly or indirectly) the volume or value of any referrals by the referring physician”
- Do professional services personally performed by MDs #1 and #2 take into account the volume or value of MD #3’s referrals?
- What about fair market value?

Productivity v. Profit Share

- Using a pool of funds to then pay a bonus based on productivity
- When the source of funds is DHS revenues or profits, is it a productivity bonus or is it a profit share?
- Source or funding of the pool v. allocation of the pool

Source of Funds

- Typically, arises:
 - In diversified systems/multi-corporation structures
 - Payments to physician group from entity other than employer
 - Trying to characterize as productivity bonus
- Translates to “takes into account volume or value of referrals” – thus, you should be attuned
- This is Halifax
- DOJ now thinks any funds **originating** at hospital takes into account volume or value

Group Practices: Potential Pitfalls

- Too much autonomy for PODs – insufficient centralization over decision making, particularly where budgets, physician compensation and staff salaries are concerned.
- Too many part-time employed physicians with other jobs – members don't provide 75% of their patient care services through the group.
- Too many independent contractors – members of the group do not conduct 75% of encounters.
- Failure to prospectively determine compensation methodology.
- Post hoc variations from compensation formula – actual distributions do not match predetermined methodology.
- Bonus/profit share formula that takes into account the volume/value of DHS.

Group Practices: Potential Pitfalls

- Failure to include expenses allocable to DHS in bonus/profit pool calculations, resulting in exaggerated profits.
 - Insufficient allocation of overhead for services performed by hospital affiliates can also exaggerate profits.
 - Application of practice-wide contractual allowances, bad debt ratios or other assumptions can distort POD profits.
- Subsidization of group practice by hospital affiliate based on downstream DHS revenues.
- Profit pools for pods of less than five physicians (e.g., when a physician leaves a POD).
- Different postal addresses/suite numbers for offices where physician services and DHS are delivered.
- Inadequate physician supervision to satisfy IOAS exception or to base productivity bonus on incident to services.
- Insufficient physician office hours to satisfy minimum office hour rules.

Consultation Exception to Referral Definition

- The Stark Law applies to referrals, but “referral” does not include a request by a pathologist for clinical diagnostic laboratory tests and pathological examination services, by a radiologist for diagnostic radiology services, and by a radiation oncologist for radiation therapy or ancillary services necessary for, and integral to, the provision of radiation therapy,” if:
 - The request results from a consultation initiated by another physician (whether the request for a consultation was made to a particular physician or to an entity with which the physician is affiliated); and
 - The tests or services are furnished by or under the supervision of the pathologist, radiologist, or radiation oncologist, or under the supervision of a pathologist, radiologist, or radiation oncologist, respectively, in the same group practice as the pathologist, radiologist, or radiation oncologist.

Consultation Exception to Referral Definition *cont'd*

- “Consultation” means a professional service furnished to a patient by a physician if the following conditions are satisfied:
 - (1) The physician's opinion or advice regarding evaluation or management or both of a specific medical problem is requested by another physician.
 - (2) The request and need for the consultation are documented in the patient's medical record.
 - (3) After the consultation is provided, the physician prepares a written report of his or her findings, which is provided to the physician who requested the consultation.
 - (4) With respect to radiation therapy services provided by a radiation oncologist, a course of radiation treatments over a period of time will be considered to be pursuant to a consultation, provided that the radiation oncologist communicates with the referring physician on a regular basis about the patient's course of treatment and progress.”

Consultation Exception to Referral Definition *cont'd*

- Exception only applies to certain type of services ordered by certain types of physician specialists.
- Must result from a consultation initiated by another physician.
- Consultation definition requires a lot of things to occur:
 - Documentation.
 - Written report to physician who requested the consultation.

Ethical Quandary #4

- You advise the executive team that the current structure of the physician group/practice subsidiary does not comport with the Stark Law “group practice” definition and that your investigation indicates that the profit distribution methodology does not comply with the Special Rules. You recommend self-disclosure under the SRDP. You request information from the executive team to complete the SRDP forms, but the executive team drags its feet. After 6 months and repeated requests, you still do not have the requested information. What do you do?

What Do You Do?

- A. Continue to wait patiently until the data is produced (how long do you wait?)
- B. Counsel the client on the consequences of failure to refund known overpayments on a timely basis
- C. Go over management to the CEO/board of directors to force timely production
- D. Terminate representation

60-Day Rule: Implications for Stark Law Violations

- The ACA 60 Day Rule requires any person who has received an overpayment to report and return the overpayment to the appropriate Medicare or Medicaid agency, intermediary or contractor with written notice of the reason for the overpayment by the later of:
 - 60 days after the date the overpayment was ***identified***, or
 - The date on which any corresponding cost report is due (if applicable).
- “Overpayment” is defined by the ACA as any funds a person receives or retains under Medicare or Medicaid to which the person, “after applicable reconciliation,” is not entitled.
 - This includes payments made by Medicare for DHS rendered pursuant to an unlawful referral under the Stark Law.
- Any overpayment retained past the deadline is an “obligation” under the reverse false claims provision of the False Claims Act (“FCA”).

When is a Payment “Identified”?

- An overpayment is identified when a person has or should have, through the exercise of reasonable diligence, determined that an overpayment was received and quantified the overpayment amount.
 - The “reasonable diligence” standard gives providers an opportunity to investigate reports of potential overpayments.
 - “Reasonable diligence” is demonstrated by timely, good faith investigation, which the preamble indicated is at most 6 months from the receipt of credible information absent extraordinary circumstances.
 - An overpayment is not “identified” until it is quantified (unless a provider fails to exercise reasonable diligence).
 - Overpayments identified by a probe sample need not be returned until the full overpayment is identified.
 - The overpayment may be identified using a valid extrapolation methodology described in the disclosure.

When is a Payment “Identified”?

- Failure to exercise reasonable diligence to investigate credible information regarding a potential overpayment will result in a violation of the 60 Day Rule under the “should have known” standard if an overpayment was received.
- Thus, a provider has 6 months after receiving credible information regarding a potential Stark violation to investigate and quantify any overpayments (absent extraordinary circumstances) and 60 days thereafter to report the overpayment.
- Given the complexity of Stark Law investigations and data analyses, a provider who makes timely, good faith efforts to investigate and quantify may be able to demonstrate “extraordinary circumstances” justifying more than 6 months to identify the overpayment amount.
- Disclosures under the Self Referral Disclosure Protocol (SRDP) satisfy the 60 Day Rule reporting requirement and no refund need be issued until the case settles.
- Because the 60 Day Rule lookback period is 6 years, most SRDP disclosures voluntarily report 6 years of data even though the SRDP only requires 4 years.



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