

What You Can Learn from A Stark Investigation: Practical Tips

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Agenda

- Thoughts about investigations generally: relevant whether or not Stark is part of your life.
- Some quick Stark background.
- Deeper dive into lessons from an expansive Stark investigation.
- Can a health system credit physicians for work “incident to” their work?

How to Approach an Investigation

- Which platitude is best?
 - “You get more flies with honey....”
 - “Don’t give away the store.”
- Who are some of the most successful lawyers? Hint: this one may be really hard to answer.

How to Approach an Investigation

- Is your counsel bragging about how they have been involved in some of the “biggest cases ever”?
- How do you choose counsel for an investigation (or anything else for that matter!)?
- How do you choose consultants?
(Note: what you do pre-investigation matters!)

5

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How to Approach an Investigation

- Don't assume you know what they are thinking.
 - Dead bodies.
 - Are you here for the x...?
- Do you conduct a parallel investigation while the government does its thing?
- Did you consider insurance coverage?

6

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How to Approach an Investigation

- Document retention.
- Internal and external communication.
- Pros and cons of making changes during the investigation.

7

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What About the Anti-Kickback Statute?

- For employees there is the statutory employment exception: 42 USC § 1320a–7b(b)(3)(B).
- It exempts “any amount paid by an employer to an employee (who has a bona fide employment relationship with such employer).”
- Often overlooked preamble for payments within an entity.

8

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Anti-Kickback Inapplicable Internally

“Comment: Many commenters requested the OIG to clarify that payments between corporations which have common ownership are not subject to the statute. Commenters cited as examples intracorporate discounts and payments between two wholly-owned subsidiaries. Some commenters argued that referral arrangements between two related corporations do not constitute “referrals” within the meaning of the statute, and suggested that the OIG define the word “referral” to exclude such activity.

Response: We agree that much of the activity described in these comments is either not covered by the statute or deserves safe harbor protection. **We believe that the statute is not implicated when payments are transferred within a single entity, for example, from one division to another. Thus, no explicit safe harbor protection is needed for such payments.”**

- 56 F.R. 35952 (July 29, 1991)

Stark History

- Study: Owners of scanners are more likely to order scans.
- Named for Pete Stark, D-CA.
- Original Stark: 1989. Lab only.
- Stark II: Adds 11 “designated health services.”
- Stark on Stark: “It doesn’t apply to crutches”—1995. “Repeal it”—2013.

Regulatory Framework

- Statute: § 1877 of the SSA/42 USC 1395.
- Regulations: 42 CFR 411.351-389.
- Federal Register preamble.
- Annual list of Designated Health Services (DHS) in the Medicare Physician Fee Schedule.

The Big Picture

- If a physician (or immediate family member) has a financial relationship with an organization that provides DHS ordered by the physician, Stark applies. Any value will do it.
- Financial relationships can be ownership or compensation.
- 3 exceptions protect both ownership and compensation. The others only protect one or the other.
- Intent doesn't matter*

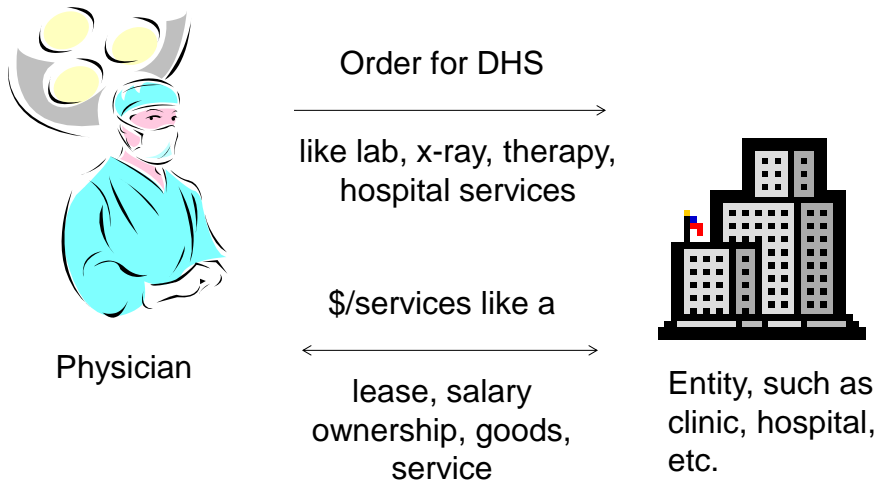
*The great reversal on intent?

“In some cases, relationships clearly will not involve a transfer of remuneration and thus will not trigger [Stark]. In others, activity might involve transfer of remuneration and there may be no readily apparent exception. We expect that questions of [this] kind will arise with some frequency. Parties may submit advisory opinion requests...”

- 72 FR 51058

“Designated Health Services”

- Clinical laboratory.
- Physical therapy.
- Occupational therapy.
- Radiology services.
- Radiation therapy services and supplies.
- Durable medical equipment and supplies.
- Parenteral and enteral nutrition.
- Prosthetics and orthotics.
- Home health services.
- Outpatient prescription drugs.
- Inpatient and outpatient hospital services.
- Outpatient SLP services.





Compensation Exception: Often Overlooked

- Payments by a physician for items and services “to an entity as compensation for other items or services if the items or services are furnished at a price that is consistent with fair market value.”

Payments by a Physician

- The regulation includes language not mentioned in the statute, mainly that it does not apply to any payment that is covered by another exception.
- Can CMS do that?
- Isn't the language meaningless anyway?



In-Office Ancillary Exception

- The strongest exception: Protects ownership and compensation. A silver bullet for clinics and systems.
- Allow physicians to be compensated for work “incident to” physician work.
Health systems may want to use it!
- Has many conditions.

Advanced Imaging Notice

- Give written notice to all MR/CT/PET patients. (E-mail is ok.)
- At time of referral (i.e. NOT registration).
- Must indicate patients can go elsewhere.
- Address/phone for at least 5 “suppliers” within 25 miles. (If fewer than 5, list them. If none, no notice necessary.)
- Can say more; may wish to warn about insurance coverage.

Sharing Space and Equipment: What Is “Exclusive Use?”

- CMS says that “**in effect**, [the rules] require that space and equipment leases be for established blocks of time.”

Sharing Space and Equipment

CMS says “a physician sharing a DHS facility in the same building must control the facility and the staffing (for example, the supervision of the services) at the time the designated health service is furnished to the patient. **To satisfy the in-office ancillary services exception, an arrangement must meet all of the requirements of [the rule] not merely on paper, but in operation.** As a practical matter, this likely **necessitates a block lease arrangement** for the space and equipment used to provide the designated health services...

Sharing Space and Equipment

We note that common **per-use arrangements are unlikely to satisfy the supervision requirements** of the in-office ancillary exception and may implicate the anti-kickback statute.”

Physician Compensation in a Health System

- For more, see our May 2017 webinar:
<https://youtu.be/XEIGPiX9Kus?list=PLyjeM-paimEeqo2KRcc26MEHs5nAWhBn2>

Physician Compensation in a Health System

- Complex, and often misunderstood.
- Salary surveys are widely used, and misused.
- Can compensate physicians for personally performed work, and other things that do not “take into account” the value/volume of DHS.
- If you credit for E&M in the inpatient or outpatient setting, does that “take into account”?

27

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Hospitals and Employed Physicians

- Don't need to worry about anti-kickback.
- Stark is huge.
 - Direct or indirect compensation?

28

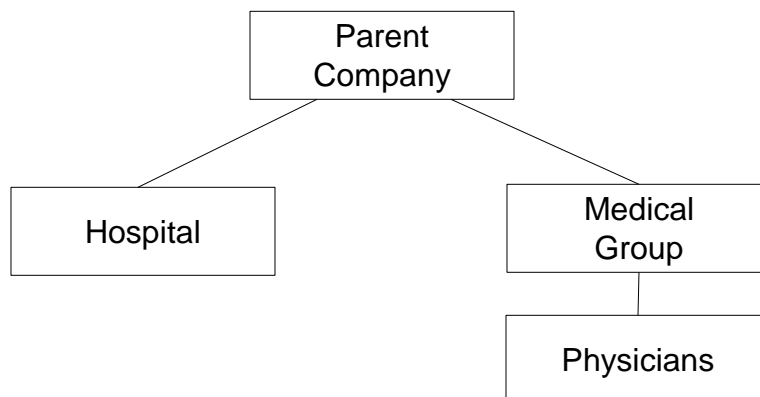
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Stark: Direct or Indirect?

- Is the entity that provides the DHS the same as the one paying the physician, or is there an “intervening entity”?

– 42 C.F.R. § 411.354(c)(1)(i)



Stark: Direct or Indirect?

- Is the entity that provides the DHS the same as the one paying the physician, or is there an “intervening entity”?
 - 42 C.F.R. § 411.354(c)(1)(i).
- Hospital in one entity, medical group is separate: Indirect compensation if hospital subsidizes doctors.
- If the medical group provides lab, x-ray, etc. may still have direct.

Possible Stark Exceptions

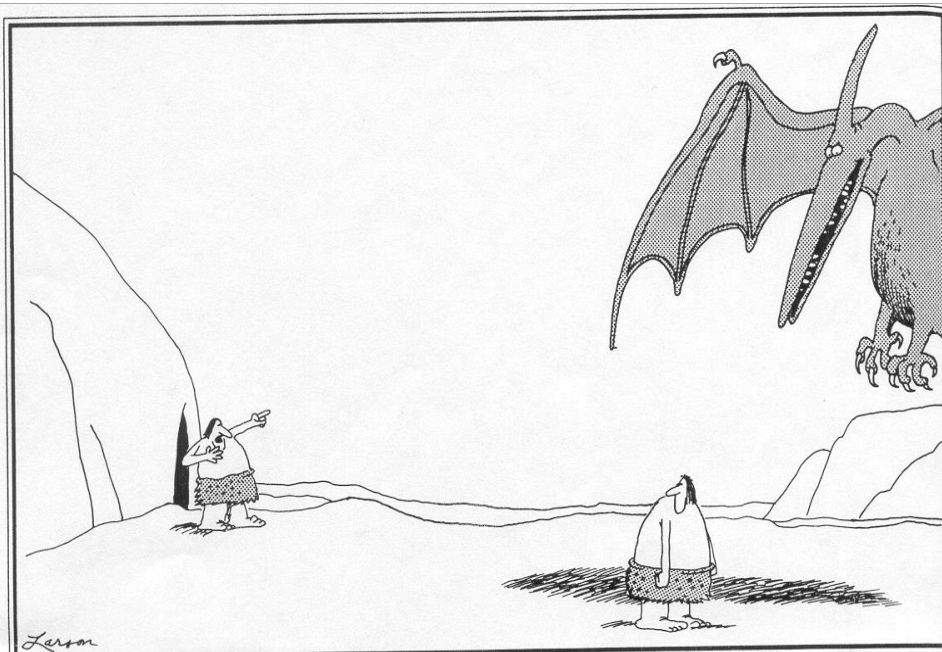
- Stark treats direct and indirect comp. differently.
- Comp. from a medical group to the physician is direct and should meet the employment exception.
- Comp. (subsidies and other payments) from other medical system entities must meet the indirect compensation exception, if it is indirect comp.

Direct: Employment Exception

- “Identifiable” services.
- Consistent with FMV and not determined in a manner that takes into account directly or indirectly the volume or value of any referrals.
- Commercially reasonable even if no referrals.
- Productivity bonus for personally-performed services okay.
- Need not be written.

33

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"Look out, Thak! It's a ... a ... dang! Never can pronounce those things!"

Indirect Compensation Requires:

- (i) Between the referring physician (or a member of his or her immediate family) and the entity furnishing DHS there exists an unbroken chain of any number (but not fewer than one) of persons or entities that have financial relationships . . . between them (that is, each link in the chain has either an ownership or investment interest or a compensation arrangement with the preceding link);
- (ii) **The referring physician (or immediate family member) receives aggregate compensation from the person or entity in the chain with which the physician (or immediate family member) has a direct financial relationship that varies with, or takes into account, the volume or value of referrals or other business generated by the referring physician for the entity furnishing the DHS . . . ; and**
- (iii) **The entity furnishing DHS has actual knowledge** of, or acts in reckless disregard or deliberate ignorance of, the fact that the referring physician (or immediate family member) receives aggregate compensation that varies with, or takes into account, the volume or value of referrals or other business generated by the referring physician for the entity furnishing the DHS.

42 C.F.R. § 411.354(c)(2)

Indirect Comp: Plain English

- Does the payment “take into account” the volume or value of referrals?
- Mathematical question, but also a metaphysical one.

Stark: Burden of Proof

- The government will have the burden of proving that the compensation meets the definition of indirect compensation.
- “Once the government has established the proof of each element of a violation under the Act, the burden shifts to the defendant to establish that the conduct was protected by an exception.” *U.S. ex rel. Kosenske v. Carlisle HMA, Inc.*, 554 F.3d 88, 95 (3d Cir. 2009).

Things to Note

- Government must prove all three.
- “Referral” very specific: “a request by a physician for, or ordering of, DHS” 42 CFR § 411.351. Note “operating” vs. “attending.”
- Only referrals/business (i.e. in/ outpatient services) from physicians to hospitals matter. Professional services irrelevant.
- “Fair market value” does not appear.

Indirect Compensation: *Tuomey* Instruction

“An indirect compensation arrangement means that the referring physician receives aggregate compensation from the entity in the chain with which the physician has a direct financial relationship that varies with, or otherwise takes into account, the volume or value of referrals or other business generated by the referring physician for the entity furnishing services.”

Indirect Compensation Exception

- Consistent with FMV and **not determined in a manner that takes into account directly or indirectly the volume or value of any referrals.**
- Commercially reasonable even if no referrals are made to the hospital.
- In writing, signed by the parties, specifying the services covered by the arrangement.
 - Except *bona fide* employment relationship (must be for identifiable services and commercially reasonable if no referrals, but need not be written).
- Does not violate Anti-Kickback Statute.

Indirect Compensation Exception

- (1) (i)** The compensation received by the referring physician (or immediate family member) described in § 411.354(c)(2)(ii) is fair market value for services and items actually provided and **not determined in any manner that takes into account the volume or value of referrals or other business generated by the referring physician for the entity furnishing DHS.**
- (ii)** Compensation for the rental of office space or equipment may not be determined using a formula based on—
- (A)** A percentage of the revenue raised, earned, billed, collected, or otherwise attributable to the services performed or business generated in the office space or to the services performed on or business generated through the use of the equipment; or

Indirect Compensation Exception

- (B)** Per-unit of service rental charges, to the extent that such charges reflect services provided to patients referred by the lessor to the lessee.
- (2)** The compensation arrangement described in § 411.354(c)(2)(ii) is set out in writing, signed by the parties, and specifies the services covered by the arrangement, except in the case of a bona fide employment relationship between an employer and an employee, in which case the arrangement need not be set out in writing, but must be for identifiable services and be commercially reasonable even if no referrals are made to the employer.
- (3)** The compensation arrangement does not violate the anti-kickback statute (section 1128B(b) of the Act), or any Federal or State law or regulation governing billing or claims submission.

- 42 CFR § 411.357(p)

“Takes Into Account”

“Accordingly, the question, which should properly be put to a jury, is whether the contracts, on their face, took into account the value or volume of anticipated referrals. As the Stark Regulations and the agency commentary indicate, compensation arrangements that take into account anticipated referrals do not meet the fair market value standard. 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.” *Tuomey I*, 675 F.3d 394, 409 (4th Cir. 2009), underlining added.

How Is Compensation Sliced?

- 42 CFR § 411.354(c)(2)(ii) states that indirect compensation arrangements examine “**aggregate** compensation from the person or entity in the chain with which the physician (or immediate family member) has a direct financial relationship.”
- Compensation is considered in its entirety (aggregate).
- There is no temporal demarcation.

FMV: Aggregate Comp at Time of Agreement

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. With respect to rentals and leases

- 42 C.F.R. § 411.351

Government Must Show

- A violation of Stark by a preponderance of the evidence.
- Knowledge:
 - “Substantial risk that the contracts violated the Stark law, and was deliberately ignorant of, or recklessly disregarded risk.” *U.S. ex rel. Drakeford v. Tuomey*, 792 F.3d 364, 376 (4th Cir. 2015) (*Tuomey II*).
- Related to a claim:
 - Stark violations taint every single claim made as a result of a referral for DHS by physician with a prohibited financial relationship.

Bottom Line

- FMV relevant only if there is indirect comp.
- Indirect comp exists only if pay is linked to physician referrals to the hospitals.

Reasonable Interpretation Prevails

- Even if the government's reading is correct, the conflicting guidance eliminates the ability to impose FCA liability.
- “[I]mprecise statements or differences in interpretation growing out of a disputed legal question are . . . not false under the FCA.” *United States ex rel. Lamers v. City of Green Bay*, 168 F.3d 1013, 1018 (7th Cir. 1999)

Case Law and Settlements

- Cases very rarely go to trial.
- If a motion to dismiss or summary judgment motion is unsuccessful, defendants almost always settle.
- Examples:
 - Tuomey: \$247m verdict/\$72.4m settlement (19 physicians).
 - Adventist Health Systems: \$118.7m settlement (many).
 - North Broward Hospital: \$69.5m settlement (9).
 - Halifax Health: \$85m settlement (9).
 - Columbus Regional Health: \$35m settlement (1).
 - Covenant Medical Center: \$4.5m settlement (2009) (5).

Case Law and Settlements

- *U.S. ex rel. Schubert v. All Children's Health System, Inc.*, Case No. 8:11-cv-01687-T-27EAJ (M.D. Fla. 2013) (Order, Docket Entry 68).
- Eventually settled for \$7m.
 - “Relator endeavored to create a fair market value benchmark by drawing from the median of three nationwide salary surveys and creating a competitive salary range ...She then uses that information to allege a fair market value benchmark for all subspecialists identified in the complaint, and alleges that the salaries identified in the complaint exceed that benchmark. Assuming these allegations to be true, as required at this stage, they are sufficiently particular to satisfy Rule 9(b).”

Death of Common Sense (and Math)?

- Survey says?
 - Is 50th percentile a ceiling? What about 75th? 90th?
- Conventional wisdom in this area is awful.
- True analysis seems rare.
- FMV is supposed to ignore presence of referrals. Is that even possible?

Surveying the Environment

- Meghan Wong at MGMA has explained “the data are not intended to be used as an academic data set for extrapolating to the U.S. population of physicians,” and are not a “one-to-one representation of the universe of medical practices that are in the country.”*
- High and low responses are thrown out.

*Thanks to Tim Smith, Ankura Consulting, and Forthcoming BVR/AHLA Guide to Valuing Physician Compensation and Healthcare Service Arrangements

Surveying the Environment

- Do respondents agree on “total compensation?”
- Is there an inverse relationship between productivity and per RVU compensation? How do most professional firms allocate overhead? Who gets paid the most per hour?
- Do groups comply with the “professional data only, no technical fees” request?
- Who replies to surveys? What is the N?





Analyze This

- 90th Percentile Interventional Cardiology
2012:
 AMGA: \$102.06 MGMA: \$86.47
- 90th Percentile RVU:

2009	16,758
2010	18,316
2011	16,136
2012	15,208 (20% swing from 2010!)

“We Lose Money on Every Physician.”

- If true, is this a problem?
- Is it true?
 - How is overhead calculated and allocated?
 - How is revenue allocated?
- What about ancillaries?

Beware of Bad Lawyering!

- 4 cases discuss Medicare Manual language from 1992 that was “written with Stark in mind.”
- The discussion relates to hospital services.
- Stark I (1989) only applied to laboratories. Hospital services were added in Stark II. Stark II was passed in?

Can a Hospital Credit Physicians for Work by Extenders?

- YES!! Can compensate physicians for personally performed work, and other things that do not “take into account” the value/volume of DHS.
- If you credit for E&M in the inpatient or outpatient setting, does that “take into account”?

Why So Many Get this Wrong: Misleading Preamble

“In other words, ‘productivity,’ as used in the statute, refers to the quantity and intensity of a physician’s own work, but does not include the physician’s fruitfulness in generating DHS performed by others (that is, the fruits of passive activity). ‘Incident to’ services are not included in productivity bonuses under the statute unless the services are incident to services personally performed by a referring physician who is in a bona fide group practice.”

- 66 Fed. Reg. 856, 876 (Jan. 4, 2001)

Problematic Preamble

“After careful consideration of the comments and the issues raised, we are adhering to our original determination that ‘incident to’ services performed by others, as well as services performed by a physician’s employees, are referrals within the meaning of section 1877 of the Act.

Problematic Preamble

As discussed in the Phase I preamble (66 FR 871–872), this interpretation is consistent with the statute as a whole. A blanket exclusion for services that are ‘incident to’ a physician’s services or are performed by a physician’s employees would, for example, substantially swallow the in-office ancillary services exception.”

- 69 Fed. Reg. 16054, 16063 (Mar. 26, 2004)

It's Misleading

- This portion of the preamble text can be read as suggesting a physician requesting an 'incident to' service is a referral. However, that is careless drafting. The text SHOULD say 'incident to' services CAN be referrals.
- The statement is true when the services are DHS. It is wrong when the services are not.

How Do We Know the Preamble Is Misleading?

- That position would be inconsistent with:
 - the statutory employment exception;
 - the regulatory definition of referral;
 - a veritable plethora of other preamble text; and
 - speeches by Kevin McAnaney, formerly Chief of the Industry Guidance Branch of the OCIG.

Stark Allows Physicians Credit for NPs and PAs They Supervise

- Stark prohibits compensation that is based on 'referrals.'
- A service is a 'referral' under Stark only when it is a DHS.
- Services by NPs and PAs are professional services, not DHS.

Stark Employment Exception

- Allows any FMV compensation that does not 'take into account' the volume and value of referrals.
- Only DHS are considered 'referrals.'

Statutory Employment Exception

(2) Bona fide employment relationships.—Any amount paid by an employer to a physician (or an immediate family member of such physician) who has a bona fide employment relationship with the employer for the provision of services if—

(A) the employment is for identifiable services,

(B) the amount of the remuneration under the employment—

(i) is consistent with the fair market value of the services, and

(ii) **is not determined in a manner that takes into account (directly or indirectly) the volume or value of any referrals by the referring physician....**

- SSA § 1877(e)(2)

Only DHS Constitute Referrals

“Referral (1) Means either of the following:

(i) Except as provided in paragraph (2) of this definition, the request by a physician for, or ordering of, or the certifying or recertifying of the need for, any designated health service for which payment may be made under Medicare Part B, including a request for a consultation with another physician and any test or procedure ordered by or to be performed by (or under the supervision of) that other physician, but not including any designated health service personally performed or provided by the referring physician. **A designated health service is not personally performed or provided by the referring physician if it is performed or provided by any other person, including, but not limited to, the referring physician's employees, independent contractors, or group practice members.**

Only DHS Constitute Referrals

(ii) Except as provided in paragraph (2) of this definition, a request by a physician that includes the provision of any designated health service for which payment may be made under Medicare, the establishment of a plan of care by a physician that includes the provision of such a designated health service, or the certifying or recertifying of the need for such a designated health service, but not including any designated health service personally performed or provided by the referring physician. **A designated health service is not personally performed or provided by the referring physician if it is performed or provided by any other person including, but not limited to, the referring physician's employees, independent contractors, or group practice members."**

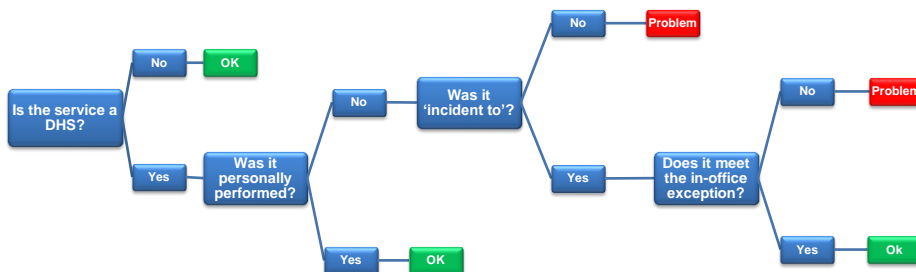
- 42 C.F.R. § 411.351

69

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Productivity Decision Tree



70

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Preamble Language

- Several preamble sections indicate physicians can be compensated in any way that isn't based on DHS.
- Prohibitions on credit for services that are 'incident to' are really for DHS that are 'incident to.' For example, PT and chemotherapy are DHS that can be delivered 'incident to' a physician's services.

May Credit for Supervision of any Non-DHS

“Accordingly, physicians may be paid productivity bonuses based on personally performed services, including personally performed DHS. In addition, **nothing in the [bona fide employment] exception precludes a productivity bonus based solely on personally performed supervision of services that are not DHS, since that bonus would not take into account the volume or value of DHS referrals.**”

- 69 Fed. Reg. 16054, 16087 (Mar. 26, 2004)

Stark Limits Compensation Only for DHS

“In general, a group practice can segregate its DHS revenue from its other revenues for purposes of compensating physicians: **section 1877 of the Act applies only to a practice’s DHS revenue.** Generally, this income is likely to comprise a relatively small portion of the total revenue of most practices.”

- 66 Fed. Reg. 856, 908 (Jan. 4, 2001)

Professional Services are Not DHS

“For purposes of this exception, we are defining the phrase ‘services unrelated to the furnishing of designated health services’ to mean physician services that are neither Federal nor private pay DHS, even if the services might generate orders or referrals of DHS. **Thus, for example, a cardiologist who examines a patient and thereafter orders a diagnostic radiology test has performed a service unrelated to the furnishing of DHS.**”

- 66 Fed. Reg. 856, 890 (Jan. 4, 2001)

Physician Services in the Hospital are Not DHS

“Professional services that Medicare pays independently of an inpatient or outpatient hospital service do not become DHS if they are billed by a hospital under assignment or reassignment; they remain physician services and are not considered hospital services.”

- 66 Fed. Reg. 856, 941 (Jan. 4, 2001)

‘Incident To’ is Relevant Only When There is a DHS

“We believe that the heightened supervision requirement imposed by the ‘incident to’ rules provide some assurance that the ‘incident to’ **DHS** will not be the primary incentive for the self-referral.”

- 66 Fed. Reg. 856, 909 (Jan. 4, 2001)

Only DHS Matter

“The commenters are correct. There is no ‘referral’ if a physician personally performs a **designated health service**. However, as noted above, there is a referral if the **designated health service** is provided by someone else. In many cases these referrals will qualify for an exception.”

- 69 Fed. Reg. 16054, 16063 (Mar. 26, 2004)

Only DHS Matter

“What the statute does not permit are payments for an employee’s productivity in generating referrals of **DHS** performed by others (66 FR 876). Except as permitted under the group practice definition for employees of group practices, ‘incident to’ **DHS** may not be the basis for productivity bonuses paid to employed physicians.”

- 69 Fed. Reg. 16054, 16087 (Mar. 26, 2004)

69 Fed. Reg. 16054, 16067 (Mar. 26, 2004)

Terms of exception	Group practice physicians [1877(h)(4); 411.352]	Bona Fide employment [1877(e)(2); 411.357(c)]	Personal service arrangements [1877(e)(3); 411.357(d)]	Fair market value [411.357(1)]	Academic medical centers [411.355(e)]
Must compensation be "fair market value"?	No	Yes—1877(e)(2)(B)(i) ...	Yes—1877(e)(3)(A)(v).	Yes—411.357(1)(3) ..	Yes—411.355(e)(1)(ii).
Must compensation be "set in advance"?	No	No	Yes—1877(e)(3)(A)(v).	Yes—411.357(1)(3) ..	Yes—411.355(e)(1)(ii).
Scope of "volume or value" restriction.	DHS referrals—1877(h)(4)(A)(iv).	DHS referrals—1877(e)(2)(B)(i).	DHS referrals or other business—1877(e)(3)(A)(v).	DHS referrals or other business—411.357(1)(3).	DHS referrals or other business—411.355(e)(1)(ii).
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).	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	No.
Written agreement required?	No	No	Yes, minimum 1 year term.	Yes (except for employment), no minimum term.	Yes, written agreement(s) or other document(s).

QUESTIONS?



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