Stark 101

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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.

Stark

- Only when there are DHS, but all hospital services are DHS. (See slide 8 for others.)
- Tyranny of the definitions.
- Not criminal; but the penalty is up to $15,000/claim.
- Intent doesn't matter*, (except circumvention schemes); you must meet every part of an exception.

*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 outpt. hospital services.
- Outpt. SLP services.

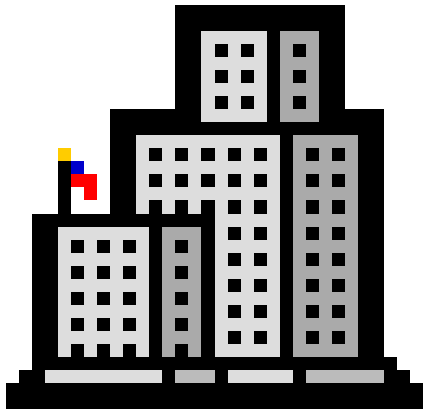
Physician

Order for DHS

like lab, x-ray, therapy, hospital services

$/services like a

lease, salary ownership, goods, service



Entity, such as clinic, hospital, etc.

Stark Quirks

- The offending financial relationship may be unrelated to the referrals. (Lawn mowing.)
- "Referral" is really "making a plan of care."
- The "entity" includes both:
  - The entity billing for the service AND

    The entity providing the service.
  - This prohibits "under arrangements" relationships if the physician who orders the service is providing it "under arrangements."
  - If a physician is leasing equipment to a hospital, and sending patients to the equipment, beware.

The Analysis

- Is there a financial arrangement between a physician and an organization that provides DHS the physician ordered?
  - No: We're done.
  - Yes: Find an exception.

Exceptions That Protect Both Ownership & Compensation

- Physician services.
- In-office ancillary services.
- Prepaid plans.
- Electronic prescribing.

Ownership Exceptions

- Investment in publicly traded securities/mutual funds.
- Hospitals in Puerto Rico.
- Rural providers.
- Hospital ownership (note the time limit).

Compensation Exceptions

- Rental of office space or equipment.
- Bona fide employment.
- Personal service arrangements.
- Remuneration unrelated to the provision of DHS.
- Physician recruitment.
- Isolated transactions.
- Certain group practice arrangements with the hospital (must pre-date 12/19/89).

Compensation Exceptions: 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."

Key Principles

- With few exceptions (employment), agreements must be written.
- Amendments must be written as well.
- Use auto-renewal terms!
- FMV is usually important.
- Usually can't change terms within a year.

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.

In-Office Ancillary Exception

- Designed to cover services furnished in the clinic.
- Service must be delivered by Dr. or group member or under the supervision of a group practice physician.
- The exception will NOT protect:
  - DME (other than crutches, walkers, manual wheelchairs, etc.)*

* Prosthetics and Orthotics are **NOT** DME

In-Office Ancillary Exception

- Services provided in the office setting, *except:*
  - DME (other than crutches, walkers, manual wheelchairs, etc.) Prosthetic/Orthotics NOT DME.
  - some infusion pumps. (external ambulatory pumps are ok, PEN pumps are not.)
- Furnished by M.D. or group member or under the supervision of a group practice physician.
- Building where:
  - group practice member furnishes physician services unrelated to designated health services as detailed below.
  - centralized offsite locale under control of the group 24/7.
- Billed by:
  - performing or supervising physician
  - physician's group practice
  - wholly-owned entity
  - billing company

"Group Practice"

- Definition of "Group Practice" complex.
- Single legal entity.
- At least 2 physicians who are group "members".
- Distribution of income and expenses determined in advance.
- Unified business, centralized decision-making.
- No compensation based on volume or value of DHS referrals (sharing overall profits or profits from a "component" of the group consisting of at least 5 physicians is o.k.).

To Be A "Group Practice"

- Each member must furnish substantially the full range of patient care services he/she routinely furnishes through joint use of shared space, equipment and personnel. In short, if a physician does a type of service, s/he must do it for your patients.
- Group members must provide at least 75% of the total patient care services, and 75% of the services by your members must be billed by the group.
- Independent contractors:
  - don't count in the 75% test, *but*
  - can supervise services under in-office ancillary exception.

Comp Formula

- Stark only applies to Medicare and Medicaid revenue.
- Physicians can't get paid for referrals for DHS.
- DHS "Incident to" ok "in-office" (i.e. clinics) but not under employment/personal services (many hospitals). If it isn't a DHS, it isn't a problem!
- Don't forget state law.

Clinic Comp. Formula Options

- Pay on RVUs excluding DHS.
- Pay on RVUs and services that would be DHS but are for private pay. (Beware of state law and I am very uncomfortable with the risk of error.)
- Choose an allocation and stick with it. (i.e. spine surgeon shares more PT, but less imaging.)

Clinic Comp. Formula Options

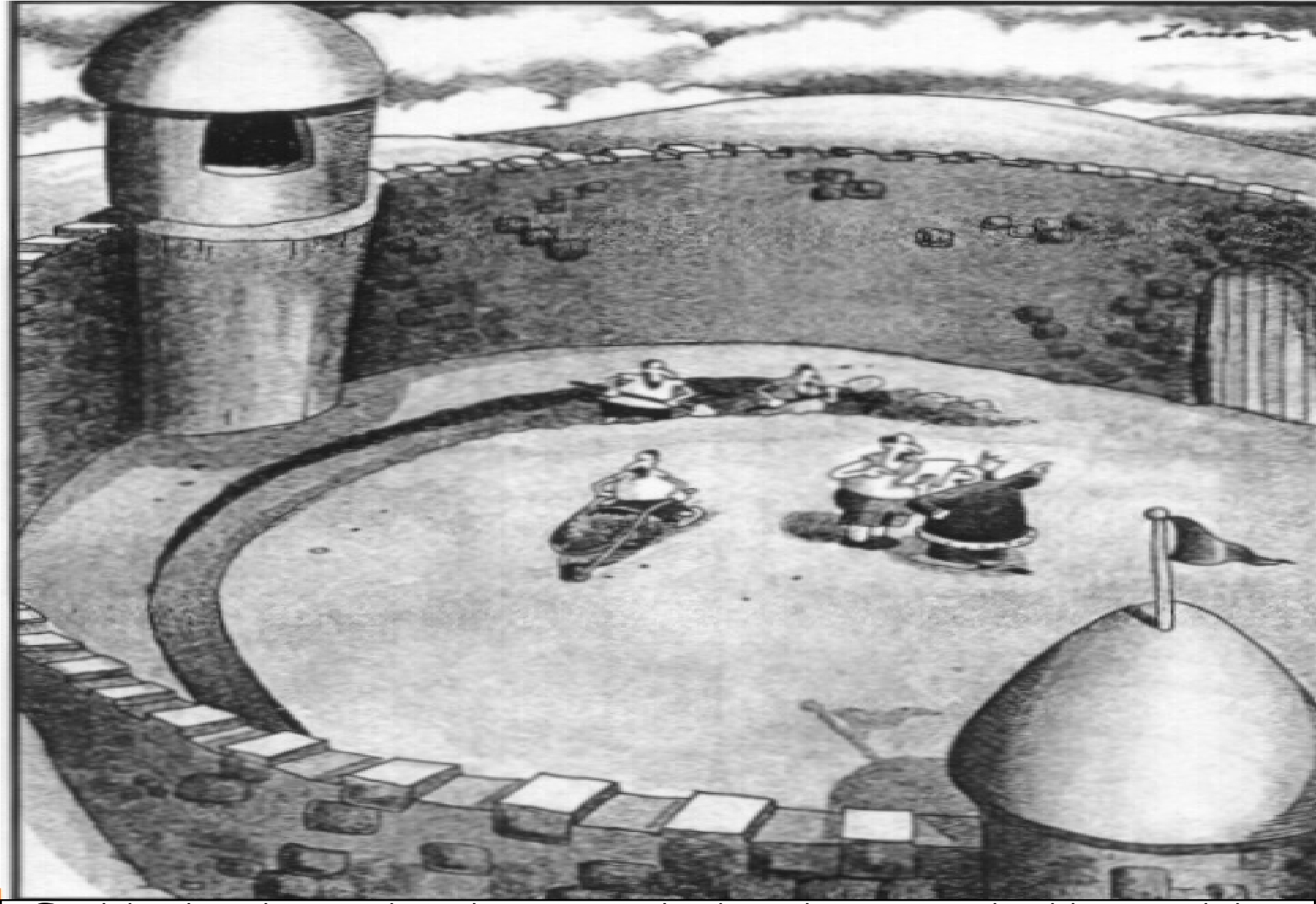
- Equal division.
- Seniority.
- Predetermined allocation.
- Subgroups with 5 or more physicians.
- Any combo of above.
- You can treat DHS differently from non-DHS.

Comp. Formula Exception

- If no physician gets more than 5% of compensation (and the group gets no more than 5% of its revenue) from Medicare and DHS, you don't need to worry about the comp formula limits.

Concerns for Group Practices

- Do you bill as a group? If box 33 lists a physician, rather than the group name, you are NOT billing under the name of a group.
- Increasing use of professional service agreements may cause group to fail to bill in its name 75% of the services provided by the group.
- Large group practices may lack unified business and centralized decision-making.
- Compensation formulas that allocate profits from components of the group that fall below 5 physicians.



Suddenly, a heated exchange took place between the king and the moat contractor.

Location, Location, Location

- Group practices can furnish services in a "centralized location. Other physicians must be in the "same building."
- "Centralized location" can be offsite BUT, if anyone else bills for any DHS at the site, it is NOT a centralized location.
- The "same building" tests are problematic unless you see patients 35 hours a week at the location/30 with a physician present.

Location, Location, Location

- The other "same building" tests only allow you to provide DHS to patients you see primarily at that location. Medicare/caid patients from other locations can't get DHS.
- The bottom line: PT or imaging can be across the street, but only if you bill for all the services there. (And you meet the supervision requirements, including physician presence for scans with contrast.)

"Same Building"

- The equipment is located in the physician's principal place of practice.

  This test is satisfied when the services are provided in a building in which the referring physician or group practice:

  A) has an office open at least 35 hours a week AND
  B) sees patients at least 30 hours a week.

“Same Building”

- The referring physician practices in the building where the services are provided is located at least 1 day a week and the building is the principal place where patients referred see the referring physician.

"Same Building"

- The three elements to this test are:

  A) The physician or group practice has an office in the building that is normally open at least 8 hours a week.

  B) The referring physician furnishes physician services in that office at least 6 hours a week. Services provided by other group members are not included in this 6 hours calculation.

  C) The building is the principal place where the referred patient sees the physician.

“Same Building”

- The services are provided in a building in which the physician or group sees patients at least one day a week and the service is ordered during a patient visit or a physician is present during the service.

"Same Building"

A) The physician or group practice has an office in the building that is open at least 8 hours a week.

B) The physician or group members regularly practice in that office at least 6 hours a week.

C) Either:

i) the physician orders the service during a patient visit; or

ii) the referring physician or a group practice member is present when the service is furnished.

Advanced Imaging Notice

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

Rural Exception

- Protects **ownership** if you are outside of a Metropolitan Statistical Area (MSA), and 75% of your patients live outside an MSA.
- **The rural exception only protects ownership, not other compensation**.
- MSAs are defined by the Census Bureau, and consist of counties.
- Note that rural areas can become urban.
- Deals that would never work in the city may be fine in rural areas.

Leases

- Written agreement, signed, specifies space.
- At least 1 year, though termination allowed.
- Rental charges set in advance and consistent with Fair Market Value (FMV).
- Amount of space is reasonable, used exclusively by the Lessee (except common areas).

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."

Sharing Space and Equipment: What is Supervision?

- The diagnostic test rules (and therefore Stark) require that a physician "supervise" a diagnostic test to bill for it.
- The question: Can two consecutive tests be supervised by different entities??

Leases

- Rental charges do not take into account value/volume/other business generated by the parties or based on a percentage of revenue, billings/collections or per unit rental charges if Lessor refers.
- Agreement is commercially reasonable.
- Holdover exception if otherwise satisfies Stark.
- USE AUTO RENEW.

Per Click

- If a physician is referring patients to a service, the physician may not be compensated on a "per click/per use" or percentage basis.
  - Example: Physician owns scanner, leases it to hospital for $500/scan. That is impermissible.

Per Click

- The same lease is permissible if the payment is a flat fee per month.
- Per click/per use leases are still permissible if the owner does not refer to the lessee.
  - Example: Clinic or hospital leases scanner from a mobile imaging company where the mobile imaging company is not owned by local physicians.

Stark's Impact on Ancillary Sharing/Joint Ventures

- In rural areas, things are pretty easy.
- In urban areas, joint ventures for DHS are increasingly difficult.
- In an urban area, if a physician leases equipment and techs to a hospital, this is problematic.

Bona Fide Employment

- Identifiable services.
- Pay consistent with FMV. Except productivity bonus for personally performed services, doesn't take into account, directly or indirectly, volume or value of referrals.
- Commercially reasonable, for a legitimate business purpose.

Personal Service Arrangement

- Writing, signed, detailing services.
- Covers all services or cross-references other agreements or refers to a master list.
- One year, termination allowed.
- Compensation set in advance, does not exceed FMV, and except incentive compensation (next slide) doesn't take into account volume of value of referrals/other business generated.
- No counseling/promotion of arrangement that violates any federal or state law.
- Holdover.

Physician Incentive Plan

- No payment directly or indirectly as an inducement to reduce or limit medically necessary services with respect to a specific individual.
- Upon request provide information as to the government.
- If there is substantial financial risk, complies with the rules in § 422.208 and 422.210.

Physician Compensation In A Health System

- Complex, and often misunderstood.
- Salary surveys are widely used, and misused.
- For more, see our May 2017 webinar: https://youtu.be/XEIGPiX9Kus?list=PLyjeM-paimEeqo2KRcc26MEHs5nAWhBn2

Physician Compensation In A Health System

- Can compensate physicians for personally performed work, and other things that does 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)

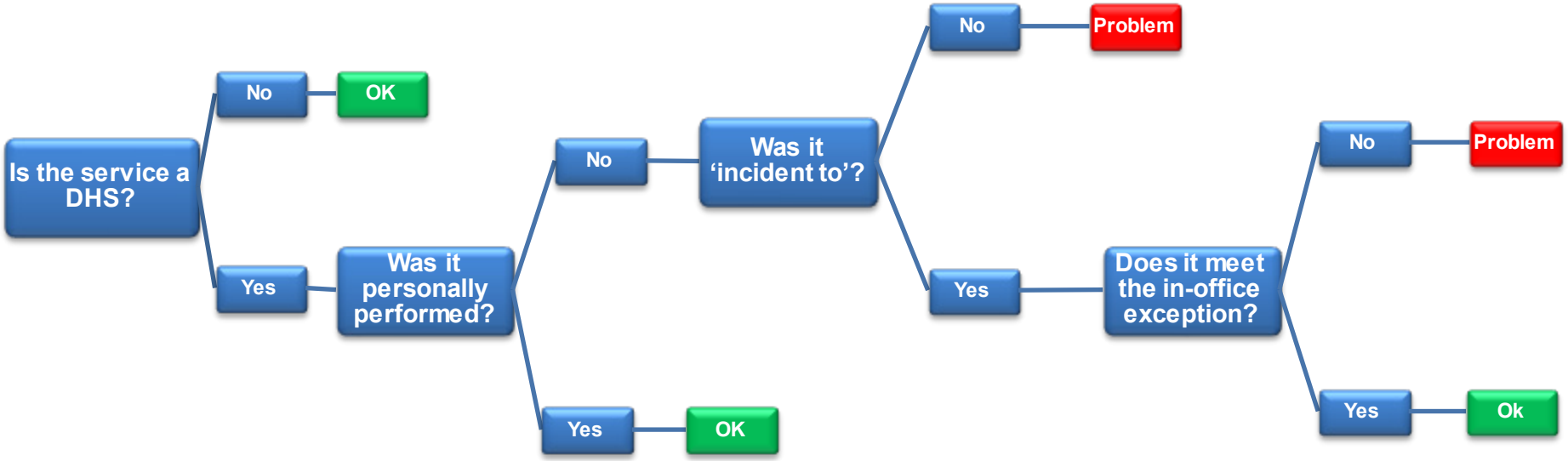
Only DHS Constitute Referrals

"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

Productivity Decision Tree



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)(ii).	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).

Physician Recruitment

- Payment by a hospital to a physician to relocate practice to the hospital's geographic area if:
  - Signed, in writing.
  - Not conditioned on physician's referral of patients to the hospital.

Physician Recruitment

- Remuneration not determined in a manner that takes into account directly or indirectly the volume per value of referrals/other business generated.
- Physician may have privileges/refer to other hospitals unless a written agreement consistent with 411.354(d)(4).

Recruitment Payment to the Group

- Also signed by a physician practice.
- Except for costs incurred by the physician practice, all payments go to the physician.
- Income guarantee can't exceed actual incremental costs (in a rural area or HPSA if replacing a departing physician may also get a lower of a per capita allocation or 20% of the practice's aggregate costs.)

Recruitment Payment to the Group

- Keep costs for 6 years.
- Does not take into account volume or value of referrals.
- Practice may not unreasonably restrict recruit's ability to practice.
- Consistent with anti-kickback statute.

Isolated Transactions

- FMV.
- Does not take into account volume or value of referrals or other business.
- Commercially reasonable.
- No additional transactions between the parties for six months except those that need a Stark exception.

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?

Miscellaneous

- Charitable donations if tax exempt, not connected to volume or value and consistent with anti-kickback statute.
- Non-monetary comp up to $407 (note the one time 50% overpayment correction) as long as it is not solicited.

FMV

- Signed, written and describes services.
- Describes timeframe and no more than one term change per year.
- Commercially reasonable.
- Compensation is specified, set in advance, consistent with FMV, doesn't take into account volume or referrals or other business. This means no formula based on earnings, billings, collections or per click if ordered by the Lessor.

Medical Staff Incidental Benefits

- Non-cash stuff from a hospital.
- Offered to all in the same specialty w/o regard to referrals/business.
- Except for ID in ads/must be while rounding/helping hospital.
- Must be on campus (pagers/medical records access still ok) & benefit delivery of services.
- Less than $34/pop.

What is Compensation?

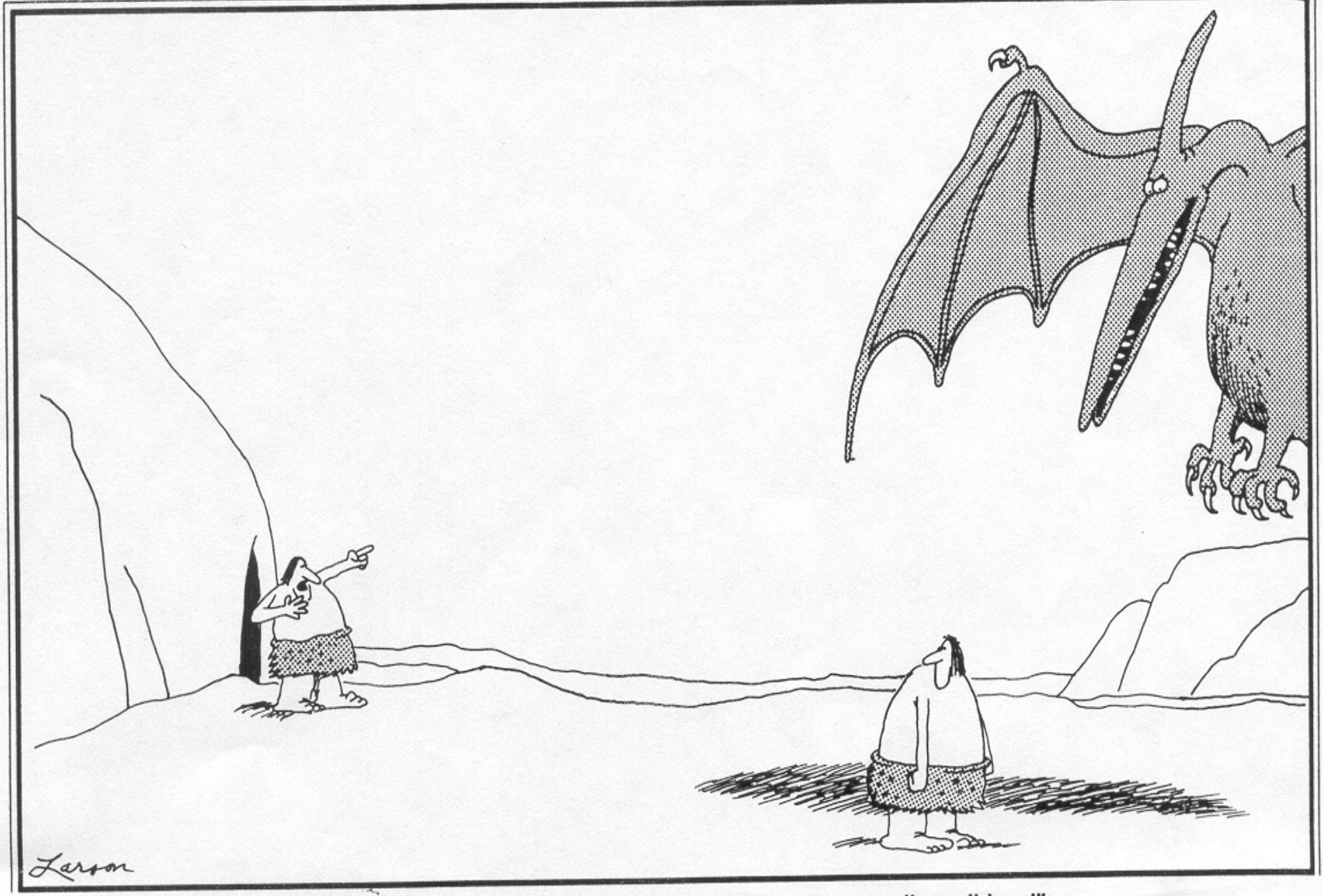
- The preamble is not always logical or consistent.
- A hospital providing internet access to a physician with such access is inappropriate. Providing new internet access may be ok.
- Transcription of hospital records does not provide compensation to the physician, transcription of office records does.

Professional Courtesy

- Must be provided to all without regard to referrals.
- Must be in writing and approved by governing board.
- Not to federal program beneficiaries.
- Must notify insurer of copay/deduct waivers.

Malpractice

- There is protection for OB.
- Other physicians would need to rely on another exception.
- Best approach is to make it part of a broader compensation package.
- Beware of FMV arguments.



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

Antikickback v. Stark

Antikickback.

- Criminal.
- Civil monetary penalties/exclusion.
- Intent is everything.

Stark.

- Civil.
- $15,000 per claim/$100,000 for circumvention scheme (fines apply only if bills are submitted).
- Intent is irrelevant.

Antikickback v. Stark

- If you meet a safe harbor, you win. If you do not meet a safe harbor, analyze intent.
- Only applies to relationships outside the corporation.

- Must meet an exception, or else.
- Applies to both transactions with others and intraorganization relations, including your compensation formula.

Antikickback v. Stark

- Covers everything paid for by a federal health care program (beware of state law extensions).
- Can get advisory opinion.

- Covers only designated health services paid by Medicare or Medicaid (but note definition of group practice).
- Can get advisory opinion.

QUESTIONS?

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