

Compensation Arrangements, Anti-Kickback Statute, Stark, and Fair Market Value

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What is Fair Market Value and Why is it Important in Healthcare Transactions?

- Healthcare entities must be careful in business transactions to make sure that all remuneration is at Fair Market Value "FMV" and is "commercially reasonable"
- Risks:
 - Federal law violations
 - Exclusion from federal payor programs
 - Fines under civil and criminal laws

Why is Fair Market Value Relevant?

- Government payor programs want to ensure that the price paid to those in a position to refer business represents the actual value of such services and not the value of referrals

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What are the Applicable Laws?

- **Anti-Kickback Statute** (42 U.S.C. § 1320a-7b): prohibits remuneration as an inducement for referrals of goods or services paid for by the government
- **Stark Law** (42 U.S.C. § 1395nn): prohibits a physician from referring to an entity with which the physician has a financial relationship when the referral is for designated health services
- **Private Inurement Rule** (26 C.F.R. 1.501(c)(3)-1(c)(2)): prohibits private individuals or entities from receiving excess benefit

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Fair Market Value

- None of these laws prevent bona fide business transactions so long as they are within the definition of "Fair Market Value"
- However, providers feel financial pressure to engage in transactions outside FMV in order to circumvent the objective of these laws, which is to eliminate money from influencing medical decisions
- Many states have similar laws which should not be overlooked

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Anti-Kickback Statute

- The Anti-Kickback Statute prohibits the knowing and willful offer, payment, solicitation, or receipt of any remuneration, in cash or in kind, to induce or in return for referring an individual for the furnishing or arranging of any item or service for which payment may be made under a federal health care program
- According to the Office of the Inspector General, the main purpose of the Anti-Kickback Statute is "to protect patients and the federal health care programs from fraud and abuse by curtailing the corrupting influence of money on health care decisions"
- This influence usually involves one provider giving something of value to another provider for less than or more than FMV to induce the referral of Medicare or Medicaid patients

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Stark Law

- Like the Anti-Kickback Statute, the Stark law was enacted to prevent economic incentives from having an impact on referrals – this time involving physicians and Designated Health Services (“DHS”)
- Stark is not intent-based, so if the remuneration is not both FMV and “commercially reasonable,” you have violated the law if there is a referral for one of the DHS
- Stark applies only to physicians who refer Medicare and Medicaid patients for DHS to entities which they have a financial relationship
- Unless the transaction meets all of the specific requirements of one or more closely-defined exceptions, it is prohibited

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Designated Health Services

- DHS include many ancillary physician services, such as:
 - clinical laboratory services
 - outpatient prescription drugs
 - physical and occupational therapy services
 - imaging services (e.g., MRI, CT, ultrasound)
 - durable medical equipment and supplies
 - home health services
 - inpatient and outpatient hospital services
 - radiation therapy services and supplies
 - parenteral and enteral nutrients, equipment, and supplies
 - prosthetics, orthotics, and prosthetic devices and supplies

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Stark Law Penalties

- Under Stark, the person who caused the illegal claim is subject to civil monetary penalties of up to \$15,000 per service billed and exclusion from Medicare and Medicaid participation
- Any physician or entity entering into a scheme to circumvent the law could face civil penalties of up to \$100,000 and exclusion from Medicare and Medicaid
- So, if a physician referred 1,000 DHS, the penalty would be up to \$15 million (1,000 services x \$15,000 per service) and exclusion from Medicare and Medicaid. In addition, the physician could also face penalties under the Anti-Kickback Statute as well as the False Claims Act

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FMV and Nonprofit Organizations

- In addition to the Anti-Kickback Statute and the Stark Law, nonprofit organizations can have other problems if they violate FMV
- Internal Revenue Code (IRC) section 501(c)(3) grants a tax exemption to nonprofits only if “no part of the net earnings of [the organization] inures to the benefit of any private shareholder or individual”
- A nonprofit that violates this prohibition can have its exempt status revoked. Loss of nonprofit status would cause the hospital to pay taxes on its earnings and lose its ability to issue tax-exempt bonds

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FMV and Nonprofit Organizations

- Because revocation of nonprofit status might be excessive punishment and not in the public interest, Congress passed IRC Section 4958, the Excess Benefit Transaction Rule, also frequently referred to as “intermediate sanctions” since the ultimate sanction is revocation of nonprofit status
- Civil penalties for violators of Section 4958 are imposed on the manager involved in the decision and the person who benefited from the decision. An excise tax equal to 25 percent of the surplus benefit (in excess of FMV) is imposed on the person who benefited. If the excess is not corrected (repaid), an additional excise tax equal to 200 percent of the excess benefit is imposed. In addition, an excise tax of 10 percent, up to \$10,000, can be imposed on the nonprofit manager involved

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The Relevance of Fair Market Value

- Any exchange of value between health care providers receiving payments under federally funded programs and others may require a FMV determination. These transactions may include:
 - Joint venture arrangements
 - Payments to physicians for clinical or administrative services
 - Business acquisitions or dispositions
 - Call coverage arrangements
 - Space rental agreements
 - Equipment leases

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The Relevance of Fair Market Value

- Management services agreements
- Income guarantees
- Payments to physicians for presenting on continuing medical education topics
- Leasing arrangements
- Providing anything of value at no cost (staff, space, computers, etc.)

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FMV Definition – Anti-Kickback Statute

- FMV is an element of certain Anti-Kickback Statute safe harbors
 - **Personal Services and Management Contracts:** "(5) The aggregate compensation paid to the agent over the term of the agreement is set in advance, *is consistent with fair market value in arms-length transactions and is not determined in a manner that takes into account the volume or value of any referrals or business otherwise generated between the parties* for which payment may be made in whole or in part under Medicare, Medicaid or other Federal health care programs. . . . (7) The aggregate services contracted for *do not exceed those which are reasonably necessary to accomplish the commercially reasonable business purpose of the services.*" 42 C.F.R. § 1001.952(d)
 - **Space & Equipment Leases:** "(5) The aggregate rental charge is set in advance, *is consistent with fair market value in arms-length transactions and is not determined in a manner that takes into account the volume or value of any referrals or business otherwise generated between the parties* for which payment may be made in whole or in part under Medicare, Medicaid or other Federal health care programs. (6) The aggregate space rented (or equipment rental) *does not exceed that which is reasonably necessary to accomplish the commercially reasonable business purpose of the rental.*" 42 C.F.R. § 1001.952(b)–(c)
- **"Fair Market Value":** "the value of the rental property for general commercial purposes (or the equipment when obtained from a manufacturer or professional distributor), but shall not be adjusted to reflect the additional value that one party (either the prospective lessee or lessor) would attribute to the property (or equipment) as a result of its proximity or convenience to sources of referrals or business otherwise generated for which payment may be made in whole or in part under Medicare, Medicaid and all other Federal health care programs." 42 C.F.R. § 1001.952(b)(6); 42 C.F.R. § 1001.952(c)(6)

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FMV Definition – Stark Law

- The price that an asset would bring 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 the 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. See 42 C.F.R. 411.351

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FMV Definition – Tax Law

- The price, expressed in terms of cash equivalents, at which a property would change hands between a hypothetical willing and able buyer and a hypothetical willing and able seller, acting at arm's length in an open and unrestricted market, when neither is under compulsion to buy nor to sell, and when both have reasonable knowledge of the relevant facts*

*See The International Glossary of Business Valuation Terms, jointly developed by the American Institute of CPAs, the American Society of Appraisers, the Canadian Institute of Business Appraisers, the Institute of Business Appraisers, and the National Association of Certified Valuation Analysts, Business Valuation Resources, 2001

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Determining Fair Market Value

- In order to determine FMV, an investigation, analysis and valuation must be performed
 - Investigation involves interviews, reviewing actual and historical data, and understanding the actual opportunity
 - Analysis involves looking at payor mix, revenues, staffing, costs, working capital requirements, competitive factors or overall market positions
 - Valuation is either income approach (discounted cash flow), cost approach (tangible and intangible assets) or market approach (similar market transaction)

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Determining Fair Market Value

- Sometimes you need to look at the actual arrangement and cannot rely upon another arrangement-you may have to get a FMV opinion
- Look at all the facts and circumstances (e.g., necessity of services)
- Document specifically and explicitly
- Periodically evaluate
- Is it economically and operationally reasonable?
- Do not go opinion shopping
- Do not consider volume or value of business

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Commercially Reasonable

The Department of Health and Human Services (HHS) defines commercial reasonableness as a "sensible, prudent business arrangement, from the perspective of the particular parties involved, even in the absence of any potential referrals"

- Is the service necessary?
- Do you need a physician to perform the service?
- Is this arrangement prevalent and is there market data to support?
- Are there specific duties to be performed and documentation to support the service?

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Valuation Mistakes

- Nonqualified opinions
- Not updated with recent assumptions
- Stacking issues have to look at entire transaction
- Sham medical director positions
- Overpaying or paying for services that are not provided
- What are the physicians getting paid for? Is there specificity? Are they getting paid to do something that they are already required to perform?
- Are physicians making more than they are generating (e.g., salary is reasonable but not if the physician is not doing anything)?

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Hospitals and Employed Physicians

- Don't need to worry about anti-kickback

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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)

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Hospitals and Employed Physicians

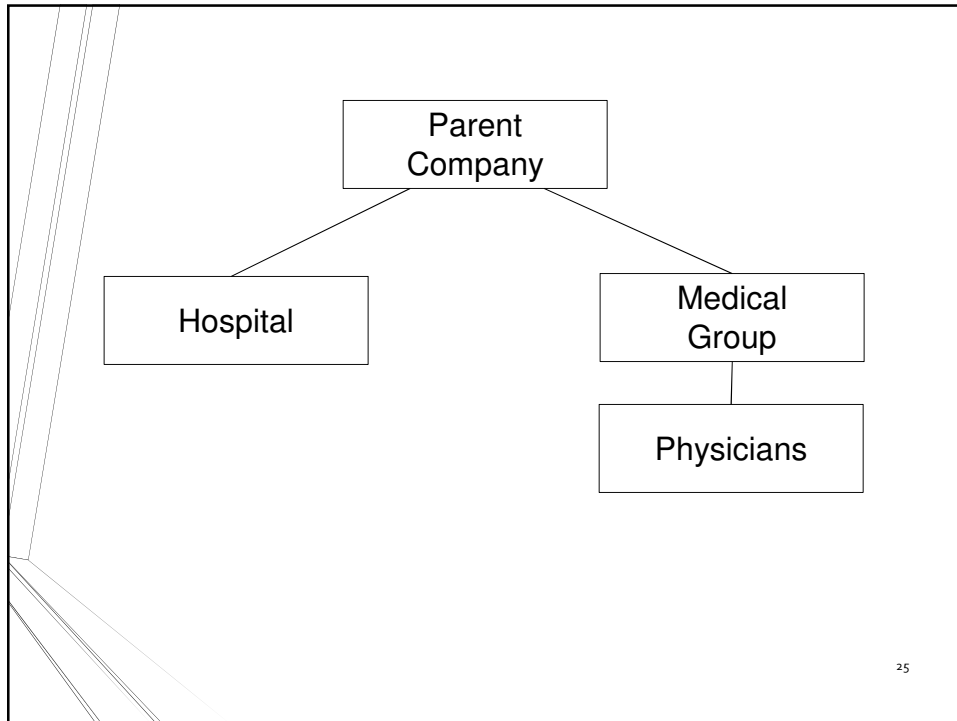
- Don't need to worry about anti-kickback
- Stark is huge
 - Direct or indirect compensation?

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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).

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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).
- Hospital in one entity, medical group is separate? Indirect compensation if hospital subsidizes Drs.
- If the medical group provides lab, x-ray, etc. may still have direct comp.

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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.

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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

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Indirect Comp: Plain English

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

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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).

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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)

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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
- Only referrals/business (i.e. in/outpatient services) from physicians to hospitals matter. Professional services irrelevant
- “Fair market value” does not appear

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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.”

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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 & commercially reasonable if no referrals, but needn't be written)
- Does not violate Anti-Kickback Statute

* But I thought indirect comp. had to take into account volume/value!!!?

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“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.

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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

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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

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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 Med. Ctr: \$4.5m settlement (2009) (5)

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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)"

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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?

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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

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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?

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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!)

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"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?

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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?

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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?”

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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)

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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.

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)

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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.

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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.

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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.

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Stark Employment Exception

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

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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)

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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.**

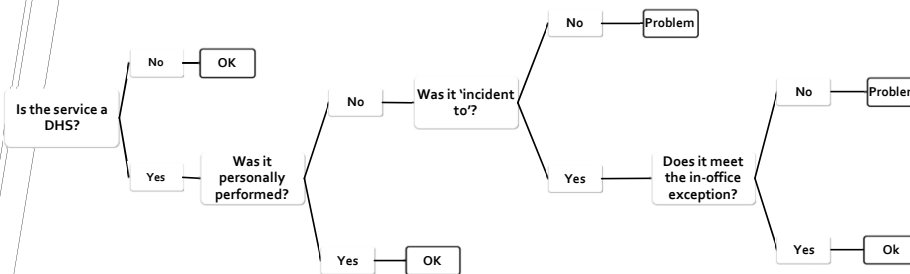
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Only DHS Constitute Referrals

(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

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Productivity Decision Tree



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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.

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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)

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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)

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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)

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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).

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Closing: Key Points to Remember

- FMV will vary by specialty, expertise, productivity, region, and other valid circumstances
- Key is that you cannot compensate a physician for the value or volume of referrals
- At the end of the day, does the compensation reflect what an arms-length transaction will bring when there is no expectation of referrals
- Careful analysis and documentation of your internal analysis and justification will be key

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