

The Government's Intensified Interest in Academic Medical Centers' and Teaching Institutions' Financial Relationships with Physicians

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Agenda

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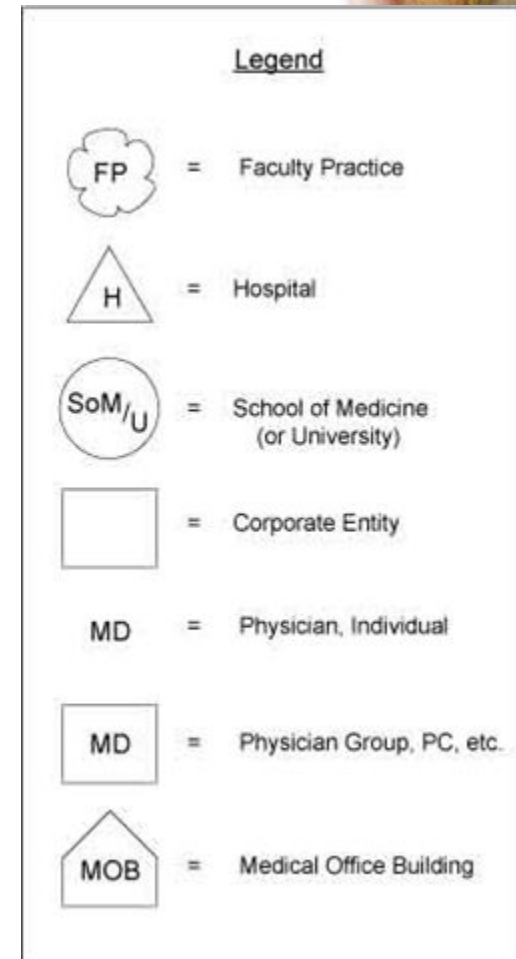
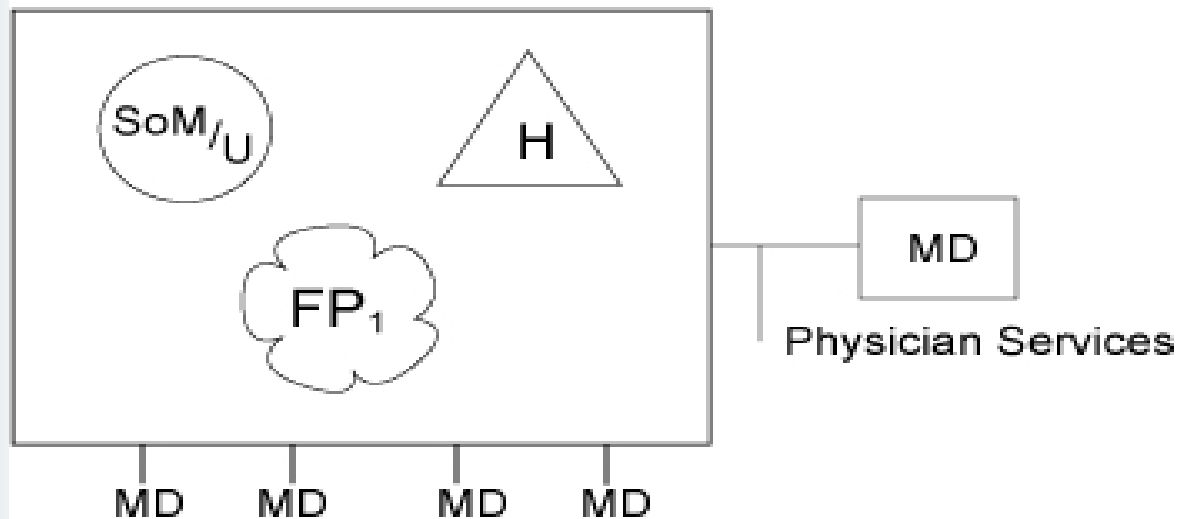
- Overview
 - The Stark Law and AMC Exception
 - The Anti-Kickback Statute and Safe Harbors
 - Other Potentially Relevant Stark Exceptions and Safe Harbors
- Recent Government Enforcement Actions
- Government Initiatives to Enhance Transparency and Disclosure
- Q&A



AMC Models

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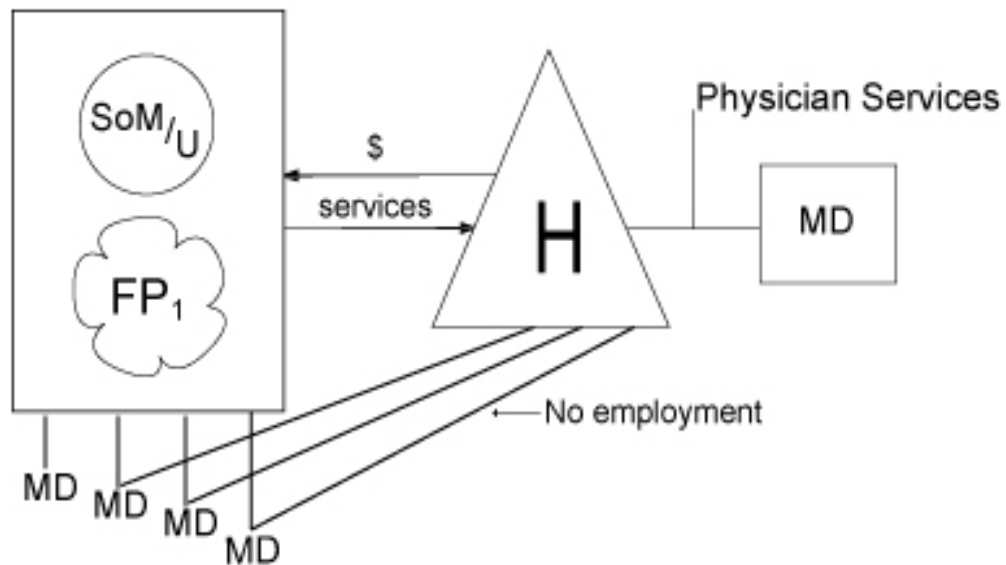
AMC in Single Corporate Entity



AMC Models

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School & Faculty Practice in a Single Entity



Legend



= Faculty Practice



= Hospital



= School of Medicine
(or University)



= Corporate Entity

MD

= Physician, Individual



= Physician Group, PC, etc.

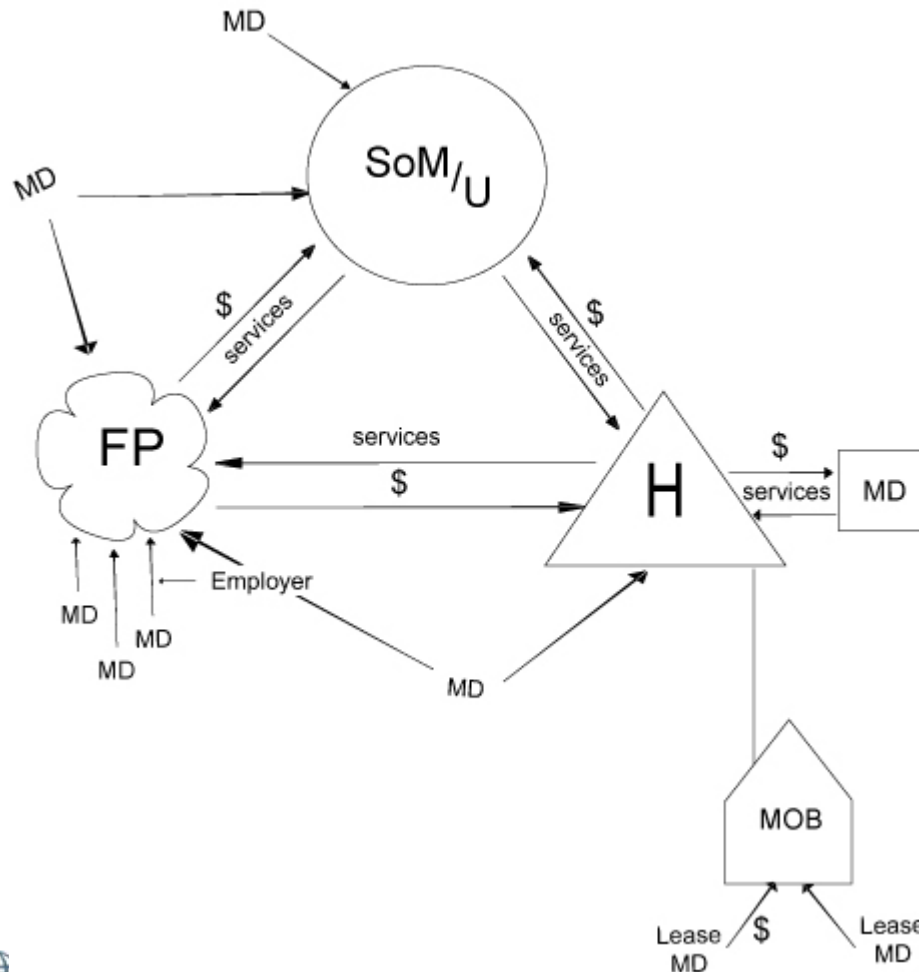


= Medical Office Building








AMC Models

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School, Hospital and Faculty Practice all Separate



Legend

-  = Faculty Practice
-  = Hospital
-  = School of Medicine (or University)
-  = Corporate Entity
-  = Physician, Individual
-  = Physician Group, PC, etc.
-  = Medical Office Building

Overview of the Stark Law and the AMC Exception

The Stark Law

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The Stark Law -

- (1) *prohibits a physician from making referrals* for certain “designated health services” (DHS) payable by Medicare to an entity with which he or she (or an immediate family member) has a direct or indirect financial relationship (either ownership or compensation), unless an exception applies; and
- (2) *prohibits the entity from filing claims* with Medicare (or billing another individual, entity, or other third-party payer) for those DHS rendered as a result of a prohibited referral.



Upshot of a Stark Violation

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- If Stark applies to a financial relationship, an exception must be met
- Intent irrelevant; technical/accidental violations no defense
- Penalties include repayment of billed amounts, civil penalties and potential treble damages “bootstrapping”
- Failure to comply affects all referrals



Stark Regulations

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August 1995 - Final Stark I

January 4, 2001 - Stark II Phase I Final Regulations

March 26, 2004 - Stark II Phase II Final Regulations

September 5, 2007 - Stark II Phase III Final Rules

August 19, 2008 – 2009 IPPS Final Rule

November 19, 2008 – 2009 PFS Final Rule



AMC Exception to Stark

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- Statute itself does not provide exception for AMCs
 - Statute includes a reference to faculty practice plans in the special provisions governing payment of bonuses by group practices
- AMC exception is a regulatory exception
 - Regulatory changes over the years have affected AMC compliance requirements in potentially fundamental ways



Origin of AMC Exception

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- Industry urged CMS to create a separate exception for FPPs
 - Argued that group practice rules don't work
 - CMS rejected arguments in August 1995 final rule, based on view that personal services and employment exceptions were available
- CMS reversed its position in Phase I Final Rule
 - CMS referred to the “unique circumstances” of FPPs, including the “symbiotic relationship” among faculty, medical centers, and teaching institutions
 - Emphasized the educational and research roles of faculty in these settings



Requirements for AMC Exception

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For services to be protected, the AMC must include at least all of the following:

- Accredited medical school (including a university when applicable) or accredited academic hospital
- One or more faculty practice plans affiliated with:
 - medical school, affiliated hospital(s) or accredited academic hospital
- One or more affiliated hospitals
 - Majority of medical staff physicians are faculty members and
 - Majority of admissions are made by faculty members



Preamble from Phase I Final Rules

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“[Under the exception, a] “component” of an academic medical center means an affiliated medical school, faculty practice plan, hospital, teaching facility, institution of higher education, or departmental professional corporation. For purposes of this exception, an academic medical center may have some, but need not have all, of these components. As indicated in the preceding provision, however, the minimum requirements are a medical school, a faculty practice plan, and a hospital.”

(66 Fed. Reg at 916)



Requirements for AMC Exception

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- All transfers of money between components of the AMC must directly or indirectly support the missions of:
 - Teaching
 - Indigent care
 - Research
 - Community service



Preamble from Phase I Final Rules

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“All transfers of money between components of the academic medical center must directly or indirectly support the missions of teaching, indigent care, research, or community service. This provision ensures that the academic medical center is bona fide and that transfers of funds are not inappropriate compensation for referrals. We believe that patient care is integral to an academic medical center’s community service mission.”

(66 Fed. Reg. at 916)



AMC Exception Requirements

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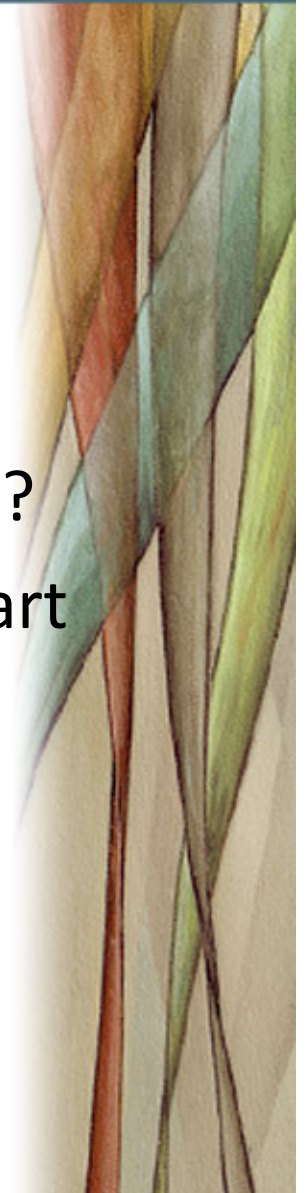
- Relationship among the components of the AMC must be set forth in one or more written agreements or other written documents
 - Adopted by governing body of each component
 - For AMC that is single legal entity, requirement is satisfied if transfers of funds between the AMC components is reflected in routine financial reports



Questions We're Being Asked

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- Are community practitioners with teaching responsibilities eligible for the AMC exception?
- Do you need to have a medical school involved?
- Can other DHS entities within the academic medical system qualify under the AMC exception?
- Do community clinics run by the FPP qualify as part of the protected AMC?



AMC Exception Requirements for Referring Physicians

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- All money paid to a referring physician for research must be used solely to support *bona fide* research or teaching
 - Also must be consistent with terms of research grant
- CMS specifically declined to allow the use of research money for indigent care and community service
 - *“If an academic medical center pays a physician using research funds and the payments are used for purposes other than bona fide research or teaching, the academic medical center would not satisfy the conditions of [the AMC exception for referrals from that physician].” (72 Fed. Reg. at 51037)*



AMC Exception Requirements for Referring Physicians

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The referring physician must be:

- *Bona fide* employee of an AMC component
 - Full-time
 - Substantial part-time
- Licensed to practice medicine in the state
- *Bona fide* faculty appointment at:
 - Affiliated medical school –OR–
 - One or more educational programs at accredited academic hospital



AMC Exception Requirements for Referring Physicians

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- The referring physician must provide substantial:
 - Academic services or
 - Clinical teaching services or
 - Combination of both
- A physician is “deemed” to meet the “substantial” requirement if he/she spends:
 - At least 20% professional time OR
 - 8 hours per week



Preamble from Phase II Final Rules

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On the topic of substantial academic and clinical teaching, CMS stated:

“ . . . we are not including primary care physicians who do not perform substantial academic or clinical teaching services [within the AMC exception protection]. While we recognize that primary care services may be part of a State institution’s mission, the primary care physicians are essentially in the same circumstances as employed physicians of any health system. Arrangements with those physicians can be structured to fit other exceptions, including the fair market value exception or the personal services exception.”

(69 Fed. Reg. at 16109)



AMC Exception Requirements for Referring Physicians

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- “Total” compensation paid by each AMC component to the referring physician must be:
 - Set in advance
 - In the aggregate, not exceed FMV for the services provided
 - Not take into account volume or value of referrals or other business generated
 - Not violate the federal anti-kickback statute or any federal or state law governing billing or claims submission



Preamble from Phase III Final Rules

EPSTEINBECKERGREEN

On the issue of how to measure FMV of “total” compensation paid within the AMC exception, CMS stated:

“The commenter is incorrect, however, that the [AMC] exception requires that compensation paid by each component must satisfy a fair market value test. Rather, . . . [the exception] states that aggregate (that is, the total from all components) compensation cannot exceed fair market value for the services provided.”

(72 Fed. Reg. at 51037)



Preamble from Phase I Final Rules

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*“In determining fair market value for services in an academic medical practice, we believe the relevant comparison is aggregate compensation paid to physicians practicing in similar academic settings located in similar environments. Relevant factors include geographic location, size of the academic institutions, scope of clinical and academic programs offered, and the nature of local health care marketplace. Nothing in this regulation is intended to preclude productivity bonuses paid to academic medical center physicians on the basis of services they **personally** perform.”*

(66 Fed. Reg. at 916; emphasis in original).



Preamble from Phase II Final Rules

EPSTEINBECKERGREEN

“One commenter asked us to clarify that in establishing a referring physician’s compensation, an academic medical center is not limited to the fair market value at other academic medical centers if the fair market value for comparable private practice physicians in its area is higher The commenter is correct. An academic medical center can use either measure of fair market value.”

(69 Fed. Reg. at 16110).



Preamble from Phase II Final Rules

EPSTEINBECKERGREEN

“The result of these interpretations is that all physicians, whether independent contractors, or academic medical center physicians, can be paid productivity bonuses based on work they personally perform . . . [in addition] independent contractor and academic medical center physicians, like their group practice and employed counterparts, can be paid using certain forms of percentage compensation . . .”

(69 Fed. Reg. at 16067)



Questions We're Being Asked

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- What documentation should a hospital insist on getting to show that the other AMC components are paying faculty in a manner protected by the AMC exception?
- Can the amount of funds flow from the hospital to the other AMC components be tied to the hospital's financial performance and still protected under Stark?
- Can faculty physicians participate in service line joint ventures?



Potentially Not Protected under AMC Exception

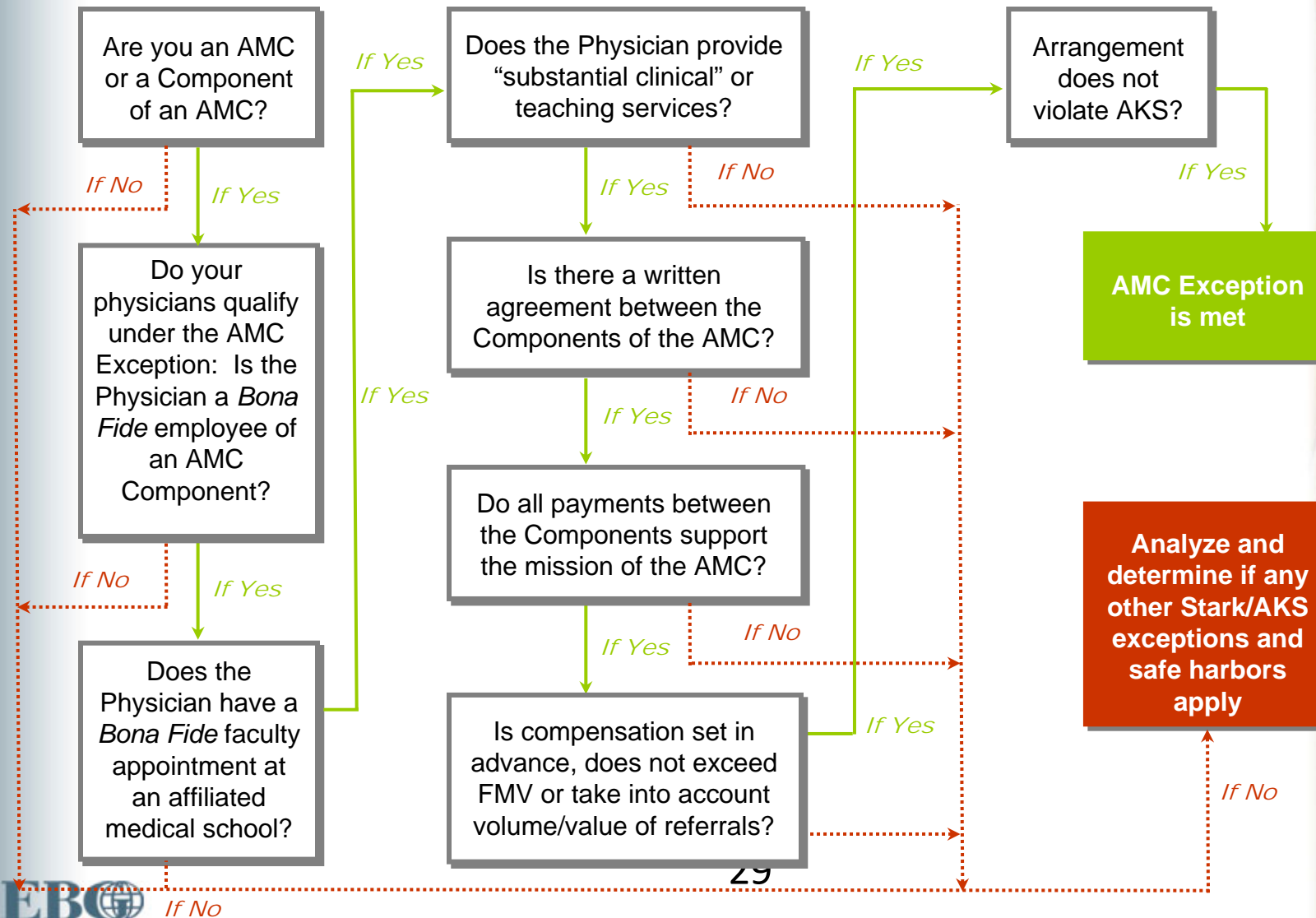
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- Independent contractor physicians
- Employed physicians who do not provide substantial academic and clinical teaching functions, *i.e.*, employed physicians with primarily clinical practices only
- Physicians employed by an entity that is not an AMC “component”
- Mission support or research arrangements involving unaffiliated hospitals
- Support arrangements with affiliated hospitals that fail to meet the faculty staff composition or faculty admissions requirements



AMC Analysis

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Other Possible Exceptions

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- Indirect compensation arrangements
- Bona fide employment
- Physician recruitment
- FMV arrangements
- In-office ancillary services/group practices
- Space Leases and Equipment Leases
- Others?



Preamble from Phase III Final Rules

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“The academic medical center exception is designed to supplement – not supplant – other exceptions, such as the exception for bona fide employment relationships . . . or the exception for personal services arrangements . . . To the extent that a hospital or other entity cannot take advantage of the academic medical centers exception, it should structure its legitimate compensation arrangements with physicians to meet another exception.”

(72 Fed. Reg. at 51037-51038)



Preamble from Phase III Final Rules

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“The definition of “indirect compensation arrangement” . . . and the exception for indirect compensation arrangements . . . are potentially applicable to arrangements involving academic medical centers and physicians. As we have stated previously, . . . parties generally may utilize any exception that the arrangement between them satisfies.”

(72 Fed. Reg. at 51038)



Stark Indirect Compensation Exception

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Defining Indirect Compensation

- “Unbroken chain” of entities with financial relationships between the referring physician and DHS entity;
- Referring physician’s aggregate compensation from the entity with which she has a direct financial relationship “varies with, or otherwise reflects, the volume or value of referrals or other business generated by the referring physician” for the DHS entity; *and*
- The DHS entity has “actual knowledge” or acts in “reckless disregard” that the referring physician’s aggregate compensation varies with, or otherwise reflects, the value or volume of referrals or other business generated



Indirect Compensation Exception Requirements

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- The compensation received by the physician
 - Is fair market value
 - Not determined in any manner that takes into account volume or value of referrals or other business generated
 - Is set out in writing, signed by parties, and specifies services covered by arrangement
- The arrangement does not otherwise violate AKS



Preamble from Phase III Final Rules

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“To the extent that a hospital, including one affiliated with an academic medical center, wishes to provide remuneration to a physician for recruitment purposes, the arrangement, depending on the facts and circumstances, may be structured to satisfy one or more exceptions, such as the exception for bona fide employment relationships . . . , the academic medical centers exception . . . , or the physician recruitment exception”

(72 Fed. Reg. at 51054)



Overview of the Anti-Kickback Statute and Safe Harbors

Anti-Kickback Statute

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42 U.S.C. § 1320a-7b(b)

“Whoever knowingly and willfully solicits or receives [or offers or pays] any remuneration (including any kickback, bribe, or rebate) directly or indirectly, overtly or covertly, in cash or in kind . . . in return for referring [or to induce a referral] . . . for which payment may be made in whole or in part under a Federal health care program . . . shall be guilty of a felony and upon conviction thereof, shall be fined not more than \$25,000 or imprisoned for not more than five years, or both”



AKS: Practical Considerations

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- AKS applies to all manner of medical services that touch Medicare – not just physician services and DHS
- Intent based – but “one purpose”/intent inferred from facts and circumstances
- Meeting a safe harbor may not be wholly “voluntary” because of prosecutorial discretion
- Felony/jail time, exclusion possible, plus “bootstrapping” treble damages



OIG AMC Advisory Opinions

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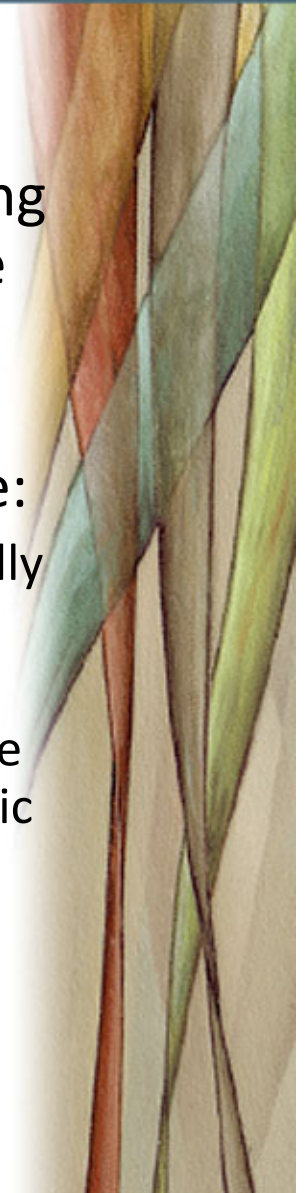
- Advisory Opinion 00-6 addressed the donation of a portion of ownership in a medical office building to an agency of the state for use by a medical school.
- Arrangement did not result in significant risks to government health care programs because:
 - The transaction is between components of an academic medical center that historically have shared the common mission of training physicians and providing quality medical care to the people of the state and a common heritage as a public institutions
 - The entity certified that it would take steps to insulate physician judgment and income from the pressure to make referrals
 - The proposed donation conferred a community benefit on the residents of the city and state



OIG AMC Advisory Opinions cont.

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- Advisory Opinion 02-11 involved a state chartered hospital authority, which owns and operates a large teaching hospital affiliated with a state university, making a contribution to an endowment fund affiliated with the University to support research at the University's school of medicine.
- The OIG said that it would not impose penalties because:
 - Grant would be between components of an AMC that historically shared a common mission in training physicians and providing quality medical care
 - Grant would be consistent with state legislation establishing the hospital authority to support the education, research and public services of the AMC
 - Considered certifications made by the University to insulate physician judgment and income from pressure to refer to the hospital



OIG AMC Advisory Opinions cont.

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- Advisory opinion 05-11 involved a private for-profit hospital's donation building on the hospital's campus to a State medical school for use as an outpatient clinic
- The OIG said that it would not impose penalties because:
 - The proposed donation would confer a community benefit on the clinic's patients
 - The proposed donation continues a common mission that the medical school and the hospital have shared for thirty years
 - The proposed donation included steps to insulate physician judgment and income from pressure to refer patients to the hospital
 - The hospital would not be involved in any decision making related to the building



Side-by-Side Comparison

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Stark Law

- Regulated by CMS
- Prohibits referrals where a financial relationship exists
- Civil penalties only
- Strict liability
- Applies only to physicians and DHS entities
- Mandatory Exceptions
- Specific AMC Exception

Anti-Kickback Statute

- Regulated by the OIG
- Prohibits payments intended to induce referrals
- Criminal + Civil penalties
- “Intent”
- Applies to anyone who attempts, accepts or gives remuneration as inducement
- “Voluntary” Safe Harbors
- No Specific AMC Exception

**Recent Government Enforcement
Actions Under Stark and Anti-
Kickback Statutes**

Current OIG Investigations: Northwestern Memorial

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- Northwestern Memorial Hospital publicly acknowledged Dec. 15, 2008 that it is the subject of a review by OIG regarding arrangements with its FPP
- Subpoenas were issued requesting information regarding the structuring of arrangements between Northwestern Memorial and its affiliated physician practice, the Northwestern Medical Faculty Foundation
 - Approximately 600 physicians
 - Over \$400 million in annual revenue
- Northwestern Memorial defends that its physician contracts are compliant and that it intends to fully cooperate with the OIG during the inquiry
- OIG spokesman confirmed in press reports that subpoenas were issued to the hospital's corporate entities in August and that they became public through a hospital bond filing

Northwestern Memorial investigation cont.

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- Inquiry possibly triggered by a relator
- Published reports say that some doctors complained about grants to medical staff and faculty practice plan, although not verified as cause of current action
- Northwestern says grants made to the faculty foundation are lawful and generally used to support the mission of the academic medical center, which includes the doctors ability to conduct research and train the next generation of physicians

Source: Bruce Japsen. Chicago Tribune "Relationship between hospital and physicians group said to be the focus of U.S. investigating Northwestern Memorial." Dec. 14, 2008.



U.S. v. Solinger (a/k/a “Villafane Case”)

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- Two reported federal cases [Villafane I and Villafane II]
- Whistleblower action by disgruntled physician
- Government declined, whistleblower pursued
- Funds flow case
 - Hospital and physician practices contributed to research fund
 - Research fund redistributed funds to pay faculty salaries
 - Whistleblower did not get any of the funds



Villafane I

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- *U.S. v. Solinger*, 457 F. Supp. 2d 743 (W.D. Ky. 2006) [*Villafane I*]
- Stark/Anti-Kickback Intersection: Satisfying Stark's AMC exception requirements means no Anti-Kickback violation

"Although as a matter of law the AMC exception does not apply to the Anti-kickback statute, as a practical matter satisfaction of the former will indicate there has been no violation of the latter. Payments made between the components of an AMC necessarily "support the missions of teaching, indigent care, research, or community service" and may not exceed the fair market value of the academic and clinical teaching services provided . . . As such, they are not made "to induce" referrals and thus cannot be characterized as kickbacks that would violate [the AKS]."

U.S. v. Solinger, 457 F. Supp. 2d at 758.



Villafane I

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- Court denied summary judgment on AMC exception
- Defendants had burden to show AMC exception met
- Court had insufficient information to determine
- No trial; early hearing opportunity



Villafane II

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- *U.S. ex rel. Villafane v. Solinger*, 543 F. Supp. 2d 678 (W.D. Ky. 2008) [*Villafane II*]
 - Court stated that the AMC exception was “flexible, purpose oriented, and not hyper-technical”
- Substantial Academic or Clinical Services Requirement
 - The substantial services requirement serves “to ensure that protected physicians are truly engaged in academic medical practice.” 66 Fed. Reg. 56,916
 - Court found defendants met this requirement without time records
 - Requirement deemed to be satisfied without meeting technical parameters of exception’s safe harbor



Villafane II

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- Physician academic responsibilities "enormous"
 - Supervision of hundreds of medical students and residents
 - Rounds
 - Annual work assignments
 - Performance reviews
 - Curriculum vitae



Villafane II

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- Aggregate Compensation Must be FMV
 - The court determined that compensation is FMV if it is “in line with national salary data”
 - Includes high end of range (over 75th percentile) where physicians are highly qualified and at or near top of profession
- Volume or Value of Referrals
 - The court concluded that compensation does not take into account volume or value of referrals if the compensation is set at FMV and does not vary once set



Villafane II

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- Staff Composition and Admission Source Requirement
 - “[D]esigned to ensure that facilities are ‘sufficiently integrated into an [AMC]’ and ‘that the relationship between the components is sufficiently focused on the [AMC’s] core mission’” 72 Fed. Reg. 51,037
 - A showing that the majority of the staff are medical school faculty and the majority of the revenue is derived from the faculty is sufficient to meet this requirement
- Writing Requirement
 - The requirement is satisfied so long as there is an “established course of conduct that is appropriately documented”



UMDNJ: Background

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- In 2002, UMDNJ faced possible state ordered shut-down of cardiac surgery program because it was performing less than required number of surgeries and mortality rate was too high
- Loss of cardiology surgery certification could have threatened UMDNJ's certification as Level I trauma Center
- Agreements with community cardiologists beginning in 2003



UMDNJ: Allegations of Fraud

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- Already under deferred prosecution agreement for double billing by hospital and FPP
- Monitor Report: “Community cardiologists” hired as part-time employed faculty
 - *“These payments were disguised as “salaries,” and were not paid for medical services. They were nothing more than referral fees paid to doctors in order to induce them to bring their patients to UMDNJ. These payments were and are illegal under federal law.”*



UMDNJ: Employment Contracts

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- Employment Contracts
 - \$50,000 - \$180,000 per physician
 - Part time work as Clinical Assistant Professors
 - Teaching at medical school
 - On-call coverage
 - Weekly conferences
 - Lecturing
 - Supporting UMDNJ research efforts
- Monitor Report: \$5.7 million paid to 18 physicians since 2002; \$80 million in potential fines and penalties under Stark and Kickback



UMDNJ: Employment Contracts

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- Many of the “community cardiologists” had no research or teaching experience
- During the investigation many of these cardiologists admitted to not teaching a single lecture while being paid as part-time faculty members



UMDNJ: Liability

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- Retaliation Claim
 - UMDNJ settled a retaliation claim with the former head of the cardiology department for \$2.2M
- Stark Law/AKS Violations
 - While no longer under the deferred prosecution agreement, the U.S. Attorney’s office is continuing to investigate these allegations
- “Community Cardiologists”
 - Many of the physicians have settled the allegations with the U.S. Attorney’s office by entering criminal pleas for embezzlement; paying fines equivalent to multiples of their salaries as “part-time faculty members” and amounts referred to hospital



Government Initiatives Designed to Enhance Transparency and Disclosure

The Form 990

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- New IRS Form – especially Schedule H
- CMS Disclosure of Financial Relationships Report (“DFRR”)



The Form 990

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- The new IRS Form 990 is designed to:
 - Increase “transparency”
 - PDFs of each organization’s Form 990s are readily and publicly available at www.guidestar.com
 - Schedule H for 2009 includes disclosures of joint venture arrangements between exempt hospitals and specifically calls for disclosure of the information with respect to physician joint ventures



The Form 990--

Schedule H:

Part IV Management Companies and Joint Ventures <i>(Optional for 2008)</i>				
(a) Name of entity	(b) Description of primary activity of entity	(c) Organization's profit % or stock ownership %	(d) Officers, directors, trustees, or key employees' profit % or stock ownership %	(e) Physicians' profit % or stock ownership %
1				
2				
3				
4				
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13				
14				

Schedule H (Form 990) 2008

The DFRR

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- THE DFRR
 - A comprehensive questionnaire regarding physician/hospital relationships
 - Comments were due to OMB by January 20th
 - EBG Client Alert on the subject available at: <http://www.ebglaw.com> under News and Publications and a copy of EBG's comments to OMB can be found at <http://www.ebglaw.com/healthcare.aspx>



The DFRR—Contents of the Survey

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- Ownership interests
- Compensation arrangements
 - Personal service arrangements
 - Rentals
 - Recruitment arrangements
 - Numerous other questions, e.g.,
 - were there any charitable contributions by the physician?
 - Were there medical staff incidental benefits exceeding the published limit, etc.



From the DFRR

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“include a copy of the written agreement between the physician(s) and the hospital in force.....”





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Q&A

EBC 

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