Physician Relationships in the Academic Medical Center Context: Anti-Kickback and Stark Law Issues

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2. Common AMC Organizational and Inter-Entity Financial Relationships
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Context

1. Vast majority of AMCs operate through a web of financial relationships that are significantly more complex than traditional hospital-physician arrangements.
2. Clinically-related financial relationships within AMCs are often comingled (and inadvertently "disguised") with research and medical education.
3. AMCs have actively grown their clinical enterprise through acquisitions which introduces additional risk.
4. To understand the financial relationships, it's imperative to understand organizational design and inter-entity relationships.

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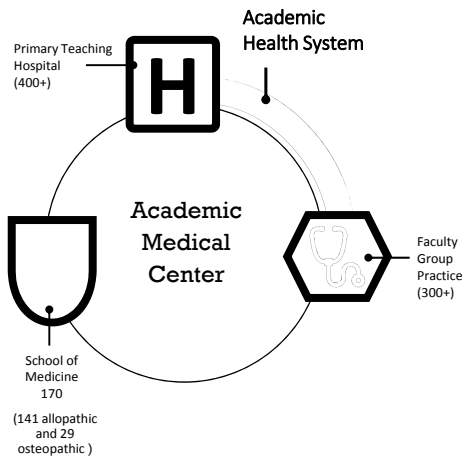
AMC vs. Academic Health System



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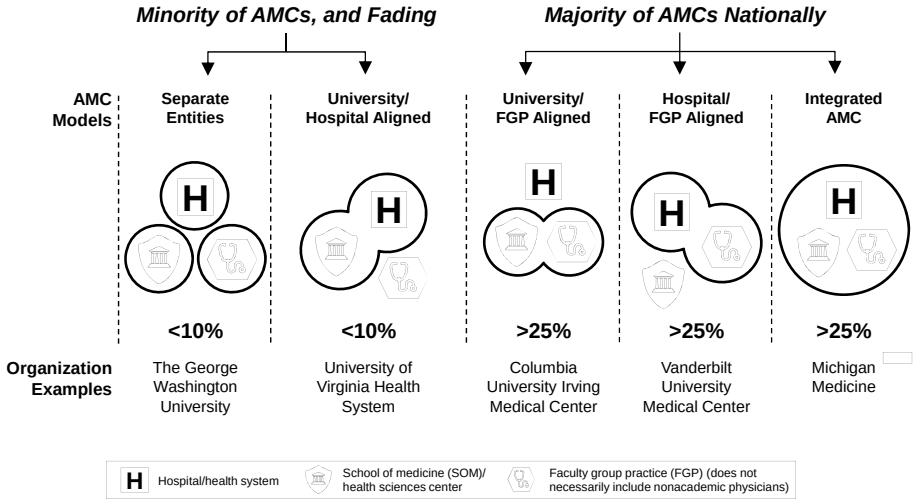
Spectrum of AMC Organizational Models



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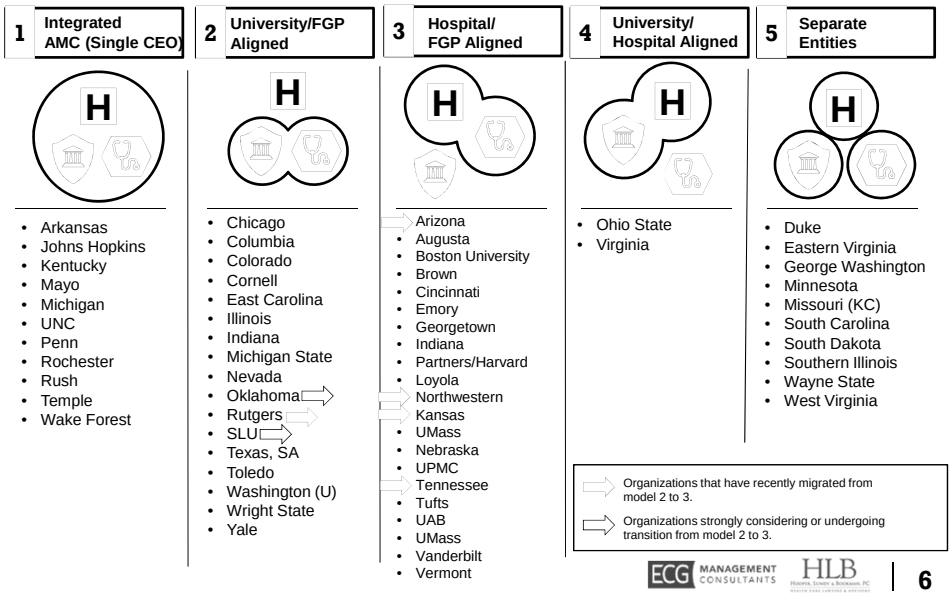
Closer Look at Patterns in Organizational Design



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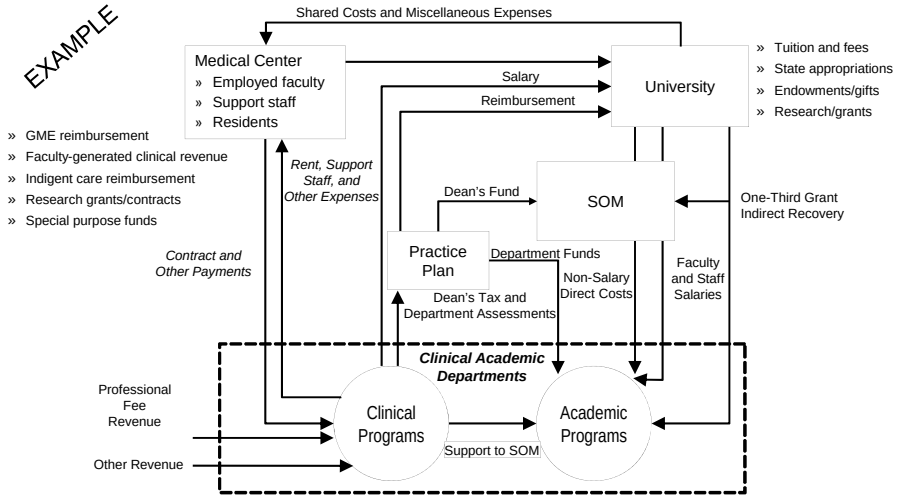
Common (and unsustainable) Funds Flow



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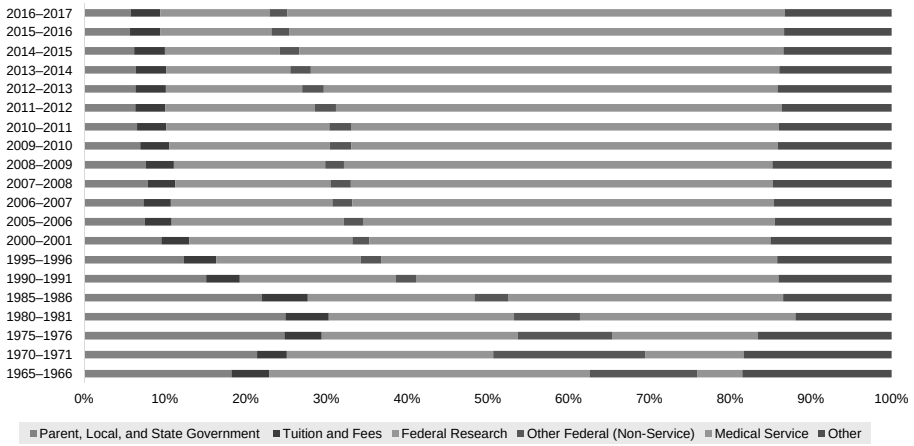
Medical Schools Are Increasingly Reliant on Funding from Partner Health System

Changes in Medical School Revenue Sources Since 1965



Source: AAMC Medical Schools Revenue by Source, 1965–2017.

Sponsored Research Funding is Insufficient

ACADEMIC MEDICINE INVESTMENT IN MEDICAL RESEARCH

AAMC

The average medical school investment applied to externally supported research projects was **an additional $0.53 for each dollar of sponsored research received**. This amounted to an average investment of $111 million with a 95 percent confidence interval between $90 million and $132 million per medical school"

Source: AAMC: Academic Medicine, Investment in Medical Research, 2015 survey of 46 medical school institutions

Integrated AHS is Economic Engine of AMC

1. Traditional academic revenue streams into universities and medical schools are declining.
2. Professional fees in faculty physician groups have stagnated while costs continue to grow.
3. Freestanding practice plans can no longer subsidize the academic mission at historical levels (e.g., dean's tax).
4. The margins of health systems are the last place to find meaningful resources to reinvest in the academic mission.
5. Health system performance is a reflection of the combined effort of the clinical faculty and health system team.
6. Greater alignment of these parties will be imperative to succeed in the market.

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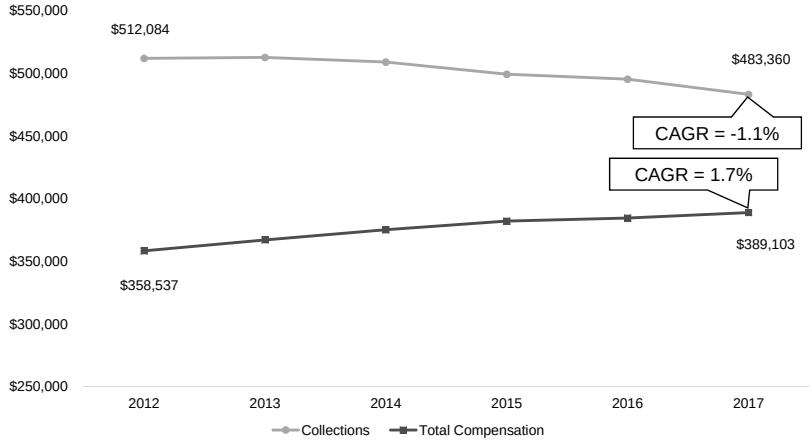
Faculty Compensation Outpacing Collections

The need for supplemental funding to support faculty continues to increase and teaching hospitals are not immune from AKS and Stark.



Source: MGMA *2018 Physician Compensation and Production Report.* Based on market basket comparison of total compensation and collections at the median for community-based physician providers. Data includes the following specialties: anesthesiology, hospitalist (IM), IM (general), orthopedic surgery (general), general pediatrics, general surgery, and diagnostic radiology.

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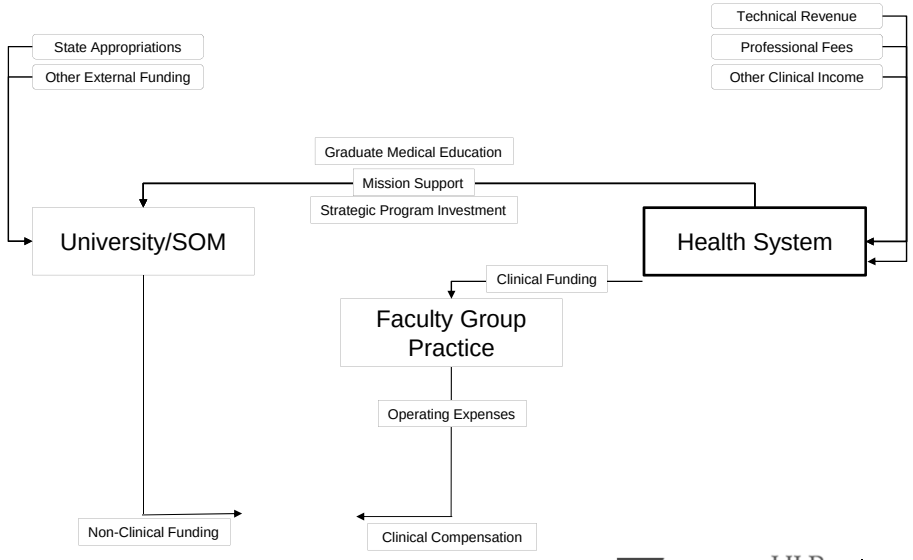
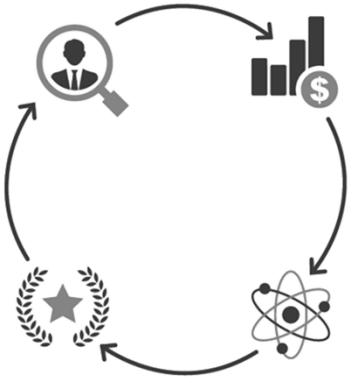
Modern AMC Funds Flow



AMC Virtuous Cycle

Investments also continue in non-clinical time to fuel the growth of the academic enterprise that yields value to the AMC as a whole.

Recruitment
Recruit and retain the best faculty; offer the highest quality and specialized service lines in the regional market.



Finance
Improve collective financial position of the AHS and make smart reinvestments in academics.

Reputation
Improve stature regionally and nationally as an AMC with halo effect for university. Increase value of the brand. Compete more effectively.

Academic
Increase research productivity and footprint; strengthen teaching programs. Invest in people and technology.

Source: The Relationship Between the University of Pittsburgh School of Medicine and the University of Pittsburgh Medical Center—A Profile in Synergy, Academic Medicine, Vol. 83, No.9, September 2008.

AHSs Continue to be Attractive

AAMC Association of American Medical Colleges

"Seven out of 10 [survey respondents] believe that **teaching hospitals provide added value for patients over other types of hospitals**. The top reasons they cited are: (1) more people weighing in on diagnoses, (2) their expertise in educating and training new doctors, and (3) providing the latest information and cutting-edge techniques."[1]

[1] Darrell Kirch, MD, "What Americans Think about Medical Schools and Teaching Hospitals" (AAMCNews, July 31, 2018).

BEST HOSPITALS U.S.News HONOR ROLL 2018-19

All of the top 20 hospitals/health systems in the *U.S. News & World Report* rankings have close affiliations with or are organizationally structured within a major academic medical center (AMC).

MOODY'S INVESTORS SERVICE

"**AMCs generally have stronger overall credit** quality than do other community or teaching hospitals . . . [and] also generally have larger revenues bases and patient populations than other NFP hospitals for additional credit advantages."[2]

[2] "Academic Medical Center Hospitals Benefit from University Ties, Strong Market Positions" (Moody's Investors Service, January 14, 2014).

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Stark Law and AKS Overview

	THE ANTI-KICKBACK STATUTE (42 USC § 1320a-7b(b))	THE STARK LAW (42 USC § 1395nn)
Prohibition	Prohibits offering, paying, soliciting or receiving anything of value to induce or reward referrals or generate Federal health care program business	• Prohibits a physician from referring Medicare patients for designated health services to an entity with which the physician (or immediate family member) has a financial relationship, unless an exception applies • Prohibits the designated health services entity from submitting claims to Medicare for those services resulting from a prohibited referral
Referrals	Referrals from anyone	Referrals from a physician
Items/ Services	Any items or services	Designated health services
Intent	Intent must be proven (knowing and willful)	• No intent standard for overpayment (strict liability) • Intent required for civil monetary penalties for *knowing* violations
Penalties	Criminal: • Fines up to $25,000 per violation • Up to a 5 year prison term per violation Civil/Administrative: • False Claims Act liability • Civil monetary penalties and program exclusion • Potential $50,000 CMP per violation • Civil assessment of up to three times amount of kickback	Civil: • Overpayment/refund obligation • False Claims Act liability • Civil monetary penalties and program exclusion for *knowing* violations • Potential $15,000 CMP for each service • Civil assessment of up to three times the amount claimed
Exceptions	*Voluntary* safe harbors	*Mandatory* exceptions
Federal Health Care Programs	All	Medicare/Medicaid

OIG online compliance resources: https://oig.hhs.gov/compliance/

Stark Law Overview

Three Questions to Ask When Analyzing Whether a Financial Relationship Complies with the Federal Physician Self-Referral Law, 42 U.S.C. § 1395nn ("Stark Law"):

1. **Is there a referral from a physician for a designated health service (DHS)?**
   - › Referral: request by a physician for an item or service payable by Medicare or Medicaid.
   - › DHS: includes inpatient and outpatient hospital services, lab services, among others
2. **Does the physician (or an immediate family member) have a financial relationship with the entity providing the DHS?**
   - › Financial relationships include ownership and investment interests, as well as compensation relationships
3. **Does the financial relationship fit in an exception?**
   - › The relationship must fit squarely into an exception. Bright line test (?)

Stark Law Overview - AMC Exception

"Academic medical settings often involve multiple affiliated entities that jointly deliver health care services to patients (for example, a faculty practice plan, medical school, teaching hospital, outpatient clinics). There are frequent referrals and monetary transfers between these various entities, and ***these relationships raise the possibility of indirect remuneration for referrals***…. [W]e believe the fundamental need of faculty practice plans is for a separate compensation exception for payments to faculty of academic medical centers that takes into account the unique circumstances of faculty practice, including the symbiotic relationship among faculty, medical centers, and teaching institutions, and the educational and research roles of faculty in these settings. Therefore, we are using our regulatory authority under section 1877(b)(4) of the Act to create a separate compensation exception for payments to faculty of academic medical centers that meet certain conditions that ensure that the arrangement poses essentially no risk of fraud or abuse."
66 Fed. Reg. 916-17 (Jan. 4, 2001) (emphasis added)

Stark Law Overview – AMC Exception

- **42 C.F.R. § 411.355(e): Prohibition on referrals does not apply to services provided by an AMC:**
  - **Referring physician:**
    - Bona fide employee of an AMC component
    - Bona fide faculty appointment at the affiliated medical school or at one or more educational programs of the accredited academic hospital
    - Substantial academic services and/or clinical teaching services (deemed met if 20% of time or 8 hours a week)
  - **Compensation:**
    - Total compensation paid by each AMC component is set in advance and does not take into account the volume or value of referrals or other business generated by the referring physician within the AMC
    - Aggregate compensation paid by all AMC components does not exceed FMV
  - **AMC requirements:**
    - All transfers between AMC components must support the mission (teaching, indigent care, research, community service)
    - Relationship between AMC components must be set forth in writing
    - All compensation to physician for research must be used solely to support bona fide research or teaching
  - **AKS:** Compensation arrangement does not violate AKS or other Federal or State law or regulation governing billing or claims submission
  - **AMC defined**: (1) accredited medical school or accredited academic hospital, (2) one or more affiliated faculty practice plans, and (3) one or more affiliated hospitals in which a majority of the medical staff consists of physician faculty members and a majority of all hospital admissions is made by physician faculty members

Stark Law Overview – Other Exceptions

- **Indirect Compensation Arrangement Exception**
  - Is there an indirect compensation arrangement (42 C.F.R. § 411.354(c)(2))?
    - chain of financial relationships between DHS entity and referring physician
    - compensation received by the physician *in the aggregate* varies with, or takes into account, the volume or value of referrals or other business generated (look to the closest compensation link to the physician)
    - DHS entity has actual knowledge of, or acts in reckless disregard or deliberate ignorance of, the above
  - If so, does it meet the indirect compensation arrangement exception (42 C.F.R. § 411.357(p))?
    - compensation is FMV and not determined in any manner that takes into account the volume or value of referrals or other business generated
    - set out in a signed writing, specifying the services covered
    - arrangement does not violate the federal anti-kickback statute or other laws or regulations governing billing or claims submission
- **Other Common Exceptions: Employment, Personal Services, FMV**

AKS Overview

- **Federal Anti-Kickback Statute, 42 USC § 1320a-7b(b)**
  - makes it illegal to knowingly and willfully offer, pay, solicit or receive remuneration to induce referrals or generate federal health care program business
  - violation may be found if one purpose is to induce referrals, even if there are other legitimate purposes for the payment
- Voluntary safe harbors similar (not identical) to Stark Law exceptions:
  - personal services and management contracts
  - employment
- Advisory Opinions 00-06, 02-11, 05-11, 08-09
  - AMC components shared mission in medical education and provision of care
  - Community benefit
  - Safeguards against payment of hidden referral fees

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Hypotheticals and Case Studies

Hypothetical #1: A faculty group practice (FGP) employs oncologists, and an affiliated hospital effectively pays the compensation through a direct or indirect transfer of funds to the FGP. The employment agreements include participation in a bonus pool equal to 15% of the operating margin (profit) of the oncology program at the affiliated hospital, including revenue from the technical component of services performed by the oncologists and outpatient oncology drugs ordered by the oncologists. The pool is divided between the oncologists based on their personal productivity and paid as a bonus.

Potential Issues? Strategies to address?

Hypotheticals and Case Studies

***United States ex rel. Baklid-Kunz v. Halifax Medical Center,* 2013 U.S. Dist. LEXIS 161718 (M.D. Fla. Nov. 13, 2013) ("Halifax")**

- Court held that the oncologists' compensation took into account the volume or value of referrals because the bonus pool was based on the profits of the hospital's oncology department, although the actual bonus paid to each physician was based on the physician's personal productivity. Basing on personal productivity "cannot alter the fact that the size of the pool (and thus the size of each oncologist's bonus) could be increased by making more referrals."
- Circumstances were not in the AMC context (oncologists were employed by an affiliated staffing entity of the hospital), but same analysis could apply.
- Can funds payable by a hospital be tied to a hospital's financial performance?

Hypotheticals and Case Studies

Hypothetical #2: A medical school's affiliated research foundation (Foundation) receives funds from various sources, including from an affiliated medical center. The Foundation then uses such funds to pay fixed, annual faculty salaries to faculty physicians. The faculty physicians are referring physicians to the medical center. Although their employment arrangement calls for academic and clinical teaching services, and as a group the faculty members train over 100 medical residents and students annually, they do not maintain a timekeeping system to track those services (e.g., a time log). On request, the physicians have provided a general estimate of hours spent providing such services.

Potential issues? Strategies to address?

Hypotheticals and Case Studies

***United States ex rel. Villafane v. Solinger,* 543 F. Supp. 2d 678 (Apr. 8, 2008)**

Qui tam action alleged FCA liability due to alleged false certification of compliance, with a focus on alleged non-compliance with the Stark Law. Defendants relied on the AMC exception, which requires "substantial" academic and/or clinical teaching services by referring physicians.

- "Though the quality or accuracy of Defendants' time reports may leave something to be desired, they are not so deficient as to actually support Plaintiff's position." The fate of an AMC does not "hang upon its particular timekeeping practices when its broad operations seem entirely appropriate."
- Stark AMC exception: "Parties should use a reasonable and consistent method for calculating a physician's academic services and clinical teaching services"

Hypotheticals and Case Studies

Hypothetical #3: Various employed physicians within a specific specialty are contractually required to provide full time services, comprised of various directorships, academic and clinical teaching services for residents, professional services, and unrestricted call coverage. The employment agreements do not provide a breakdown of time allocation between these services in exchange for compensation. On request, the physicians have provided a general estimate of hours spent providing such services. On review, it is determined that over time the physicians have provided more clinical teaching and unrestricted coverage, and less directorship or didactic services, than originally anticipated.

Potential issues?

Strategies to address management/oversight of physicians wearing multiple hats?

Questions & Discussion