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AMC Alignment—Bold Changes, Beginning with the Clinical Enterprise

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While research and medical education differentiate an academic medical center (AMC) from a community health system, they share the common pressure to achieve a positive margin from clinical programs (across the system) to sustain their missions. As nonclinical sources of revenue flowing to research and medical education have stagnated or declined (particularly in the age of the sequester), the degree of economic dependency on the clinical enterprise has increased significantly at major AMCs. This trend has been further exacerbated by a decline in professional reimbursement to the physicians/clinical faculty, and the pressure and risk has shifted to the aligned teaching hospitals. For example, the long-standing mechanism of a “dean’s tax” on practice plan revenue (which grew in popularity not long after Medicare was established) to provide discretionary funding to the medical school has become less effective than it once was. While this remains in place for most institutions, a closer look will reveal that the practice plan’s revenue base has become more diversified with hospital contract revenue compared to years past. This in turn is causing the teaching hospitals to make greater investments in practice plans and medical schools but seeking greater clarity on the return.

Concurrently, teaching hospitals, faculty group practices, and affiliated community physicians are not immune to the wave of consolidation and integration during this era of healthcare reform. Thus, many AMCs are strongly reconsidering their level of organizational and functional integration, beginning with the clinical enterprise (collectively referring to the major teaching hospital, affiliated faculty group practices, and closely aligned community physician practices in the case of open medical staffs). A fragmented model that does not align financial and strategic interests presents significant risk for all AMCs—ranging from smaller, community-based AMCs to top-tier organizations with sizable endowments. A more-aligned AMC is a better environment for faculty and staff, learners, the community they serve, and, as suggested in a recent article in *Academic Medicine*, the local economy.[1]

Consolidating the university/medical school, teaching hospital, and affiliated physician organizations into a single entity is not necessary to achieve greater alignment, nor is it even plausible for the vast majority of institutions. However, exploring a more-integrated model between the teaching hospital and physician organizations does present an opportunity for many institutions, as their nonacademic counterparts in the provider sector have demonstrated at a unprecedented rate in recent years. Greater clinical and financial integration can present new opportunities and benefits, including but not limited to:

- Higher-performing and more cost-efficient infrastructure across the physician organizations and hospitals;
- Joint strategic planning and budgeting;
- Proactive recruitment planning (replacement and growth);
- Improved payor contracts, including both fee-for-service and risk arrangements;
- More conducive environment to build and sustain major service lines;
- Streamlined decision-making process; and
- Renewed partnership between clinical faculty/physicians and hospital administration.

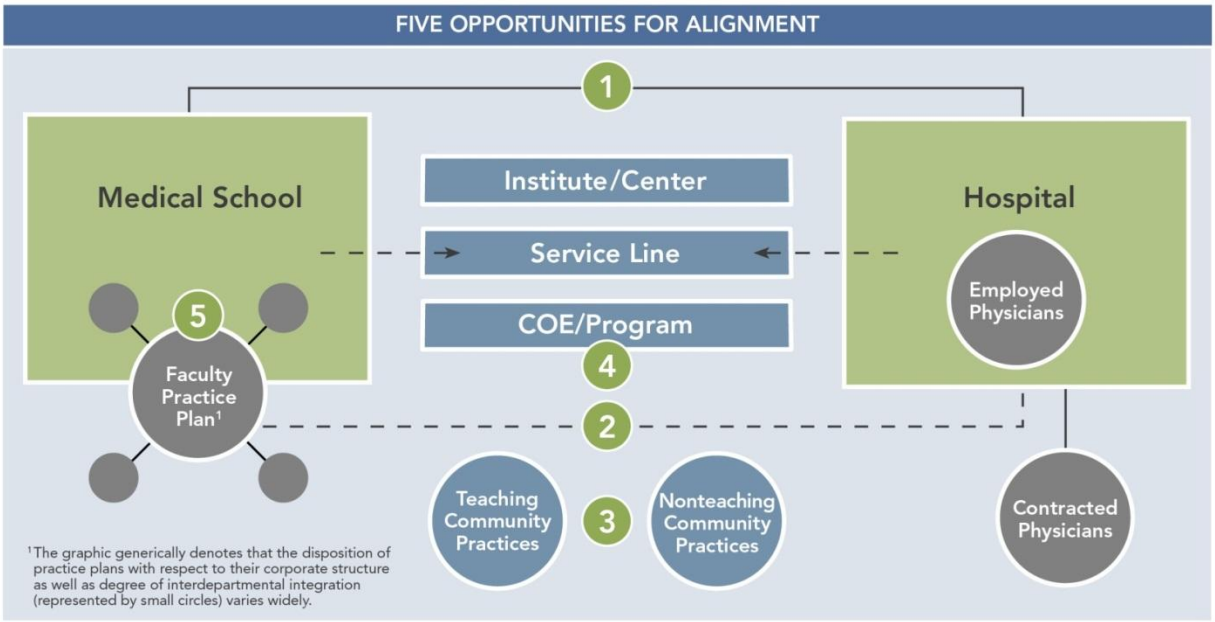
A common concern among medical school leadership nationally is that major consolidation of the clinical enterprise may yield control of clinical faculty, and that greater focus on

[1] Source: Edward D. Miller, Jr., M.D., et al., "Fully Aligned Academic Health Centers: A Model for 21st-Century Job Creation and Sustainable Economic Growth," *Academic Medicine*, Vol. 87, No. 7, July 2012, pp. 1–6.

clinical programs may distract from obligations to medical education and research in the long term. However, market conditions have increasingly created a “tail wagging the dog” scenario. There is an increasing need to focus on the business of healthcare and generate a strong margin with high-quality clinical programs in order to cross-invest and sustain and/or grow the academic enterprise, including the recruitment of top-tier faculty to train tomorrow’s physicians and conduct research. Accordingly, with the changing environment in mind, major AMCs should be aggressively rethinking the organizational design of the clinical enterprise, with the appropriate incentive systems in place and safeguards to protect the academic mission.

Potential Alignment Models

While the alignment of the clinical enterprise arguably presents the most practical opportunity for most major AMCs today, Figure 1 below suggests four additional points of potential alignment.



The remainder of this article highlights these five opportunities in an AMC setting for alignment and concludes by sharing legal considerations related to the suggested concepts.

Partnership between University/Medical School and Primary Teaching Hospitals

Some affiliation agreements date back 20 years or more, and are represented in only a few pages to memorialize the relationship between a medical school and a hospital; others are 20 pages long, but fail to define tangible commitments. Opportunities exist to develop new, more contemporary affiliation arrangements that specifically describe the mutual value of the partnership and what each institution must provide to the other for their mutual success. Most importantly, there is an opportunity to overhaul the financial structure to have clear "lanes" for areas such as graduate medical education and program development. Shared risk models should be strongly considered whereby discretionary dollars are linked to performance. The days of negotiated "mission support" dollars from the hospital to the medical school, without an understanding of return on investment, are over or soon coming to an end; hospitals are seeking clear value, accountability, and transparency related to their brick-and-mortar and human capital investments.

Alignment of Clinical Enterprise between Faculty Group Practice(s) and Teaching Hospital(s)

AMCs are not immune to the consolidation occurring in the marketplace as pressure mounts to reduce costs and demonstrate quality. The business and organizational relationship between the teaching hospital and practice plan (for those not already under single ownership/governance) arguably represents the greatest potential for tighter alignment for most AMCs—ranging from community-based AMCs to large-scale, well-established institutions. Navigating a growing web of contracts between these entities to balance the economics and grow programs is not sustainable. These entities should seek to coordinate their investments and share risk more directly to more effectively align financial incentives, and in turn align strategic interests. There is a range of organizational options that can better align the clinical enterprise while addressing the common concern and misperception that a clinically driven strategy will harm the academic enterprise.

Alignment between Affiliated Community Practices and AMCs

Teaching hospitals with open medical staffs, and those that rely heavily on community physician practices for key service lines or regional coverage, are as active as their nonacademic peer hospitals with respect to direct employment or exclusive contractual arrangements with community physicians. This raises many questions, and in some cases

concerns, for the medical school and practice plan regarding the balance between nonacademic practices and clinical faculty. There are extensive organizational and strategic opportunities to better align the two groups and drive growth of the system, ranging from coordination of outreach strategies to service line development. At a minimum, AMCs should proactively consider how community practices may coexist with academic counterparts and participate in population health management (i.e., in the same "network").

Programmatic Alignment/Integration

The vast majority of the highest-ranking institutes and centers of excellence (COEs) in the country are found at AMCs. However, an overwhelming number represent only a virtual center or brand, and are not strategically and financially aligned "behind the curtain." The community-based counterpart to an AMC-based COE tends to focus on patient service, which is difficult to accomplish in a virtual environment. This places AMC-based programs at risk, because without more formal alignment, growth could be stifled, costs will be difficult to contain, and competitors with patient-centric environments may gain market share. AMCs have an opportunity to design more integrated models for institutes, COEs, and/or major service lines (including heart, cancer, neuroscience, and orthopedics) to align the financial and strategic incentives between the participating departments and divisions in a manner that does not undermine the authority of the department chair, but that effectively calls for centralized accountability of the program.

Faculty Practice Plan Integration

Departments at AMCs are notorious for wanting independence, and it is often difficult for AMC leadership to challenge or change this culture. This is very much the case with clinical departments of many faculty practice plans nationally. Understandably, chairs wish to maintain control of non-physician staff, develop their own compensation policies, retain as much of their bottom line as they can (if it is in fact positive), and in many instances take an independent approach to negotiating a contract with an affiliated hospital. The benefits of having a more integrated and empowered physician organization with practice-wide policies and aligned financial interests will likely outweigh the short term, department-centric view seen at many institutions today. There are structures that strike a balance—promoting an entrepreneurial spirit in the department while ensuring the interests and health of the physician organization are paramount. Considering the changes in the

healthcare market, finding this balance is imperative. At many AMCs, there is room for greater interdepartmental integration with tangible economic and clinical benefits.

Legal Considerations

Like community providers, AMCs must navigate the increasing complexities of healthcare law. As AMCs explore opportunities to better align the clinical enterprise, they must be mindful of the regulatory framework that will affect that relationship. The application of that framework will depend on the relationship and funding structures; for example, the employer of the clinical faculty and the types of affiliations and arrangements that connect the clinical enterprise to the school of medicine (SOM) or university. In addition, consideration will be required of academic support arrangements, donations of space or equipment, provision and compensation for rendering indigent care, and the like.[2] More specifically, because the physicians involved will be making referrals to the teaching hospital, and those referrals will inevitably involve Medicare and other federal/state healthcare program patients, consideration must be given to the Stark Law and Anti-Kickback Statute (AKS) implications of the arrangement.[3] At the same time, the faculty physicians will receive a portion of their compensation from the teaching hospital for performing a variety of administrative services, and they may also receive employment income for the provision of medical services.

As AMCs seek to branch out into systems of care and align with affiliated community physicians or nonacademic community hospitals, they will confront issues that are both more complex and directly analogous to those faced by community hospitals and their independent medical staffs.

The most direct challenge comes from the application of the Stark law to referrals of Medicare patients. That law, in summary, prohibits a physician from referring a patient to an entity for a designated health service that may be reimbursed by Medicare, unless the arrangement falls within an exception. Similarly, the entity receiving a prohibited referral cannot submit a claim to Medicare, a third-party payor, or any other third party.[4] Fortunate-

[2] The U.S. Department of Health & Human Services, Office of Inspector General has addressed a number of donation arrangements; for example, Ad. Ops. 00-6, 02-11, 03-06, 05-11, 08-09.
[3] State law will also need to be considered, but that is beyond the scope of this article.
[4] 42 U.S.C. 1395nn(a).

ly, there are a number of exceptions into which most teaching hospital/physician faculty arrangements may fall as discussed below.

Although presenting not as acute a problem, the AKS must also be considered. Payments in return for referrals are prohibited, and unlike the provisions of the Stark safe harbors, the AKS contains no AMC exception. (On the other hand, the AKS is an intent-based statute, unlike the strict liability approach taken by the Stark law.) While other safe harbors may well apply, some of which are discussed below, often their boundaries do not extend to the contours of academic system relationships.

For purposes of considering models that are designed to focus the AMC's efforts on clinical alignment, however, there are several core exceptions applicable to both elements. The first series of exceptions—employment, personal services, and indirect compensation—are generally and broadly applicable in many hospital/physician settings, and they are addressed initially. Because of their limitations, however, in the Phase I Stark rules, a direct AMC exception was created, designed to supplement, not supplant, these other exceptions.[5] Over time, this exception has been amended (Phase II and Phase III), and it is vibrant today.

The three exceptions summarized below are most applicable to a potential organizational or contractual redesign of AMCs.

Employment and Personal Services Exception

The most basic arrangement is one of employment. Under Stark, bona fide employment is an exception to its prohibitions[6] if several straightforward conditions are met: (1) the employment is for identifiable services; (2) the payment made is consistent with fair market value (FMV); (3) except for a productivity bonus based on services personally performed (which is allowed), the payment cannot be based on the volume or value of referrals; and (4) the amount paid would be commercially reasonable even if no referrals were made to the employer.

[5] 72 Fed. Reg. at 51037-38.
[6] 42 C.F.R. § 411.357(c).

The reality, however, is that the faculty members increasingly are not employed by the teaching hospital. Instead, they are employed by a separate corporate entity, at times a professional corporation or some other type of physician organization.[7] For services provided to the teaching hospital in that fashion, an exception for personal services has been adopted.[8] This safe harbor addresses the situation in which, for example, a faculty practice plan might contract with the teaching hospital for administrative services (e.g., to serve as the chiefs of service).

Under the employment and personal services exception (PSE), the basic requirements are as follows: (1) services must be performed under a contract, in writing, detailing all of the services to be performed; (2) the services must be reasonable and necessary; (3) the term must be at least one year; and (4) the compensation must be FMV, set in advance, and not be reflective of the value or volume of referrals.[9] If there are separate arrangements between the teaching hospital and the physician organization, practice plans, or foundations, all the separate arrangements may incorporate or cross-reference each other. Finally, services may be furnished through employees of the organization.[10]

The PSE exception may have particular value for those AMCs that are exploring co-management arrangements with their affiliated physicians. This is likely to become more the case with the recent acknowledgment and acceptance of co-management agreements by the U.S. Department of Health and Human Services Office of Inspector General (OIG) for purposes of the AKS.[11]

Indirect Compensation and In-Office Ancillary Services Exceptions

In some arrangements, the compensation flow is not a direct one for services provided. For example, the teaching hospital may provide a support payment for the medical school,

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[7] A physician organization is defined as a physician, a physician practice, or a group practice as defined in the regulations. This would include the typical faculty practice plan; 42 C.F.R. § 411.351,352. Also to keep in mind is that the physician will "stand in the shoes" of the physician organization, and have a direct compensation arrangement if the only intervening entity is the organization itself; 42 C.F.R. § 411.354(c)(1)(ii).

[8] 42 C.F.R. § 411.357(d).

[9] *See, however*, Ad. Op. 08-09, discussing a gain-sharing arrangement between an AMC and two groups of surgeons.

[10] Analogous safe harbors exist for other arrangements between a teaching hospital and its faculty physicians related to space or equipment rentals, other compensation arrangements provided at FMV, and physician recruitments. 42 C.F.R. § 411.357 (a),(b), (l), and (e).

[11] Ad. Op. 12-22.

which is the entity that also employs the faculty. (The support payment, for example, may be in the form of a dean's tax or simply an agreed-to payment amount.) In such cases, the indirect compensation exception may be available.[12] That exception applies to situations in which an indirect compensation arrangement exists—there is an "unbroken chain of any number of persons or entities" that have financial relationships between them—but the actual physician compensation does not vary with or otherwise reflect the value or volume of referrals generated by an individual physician or the physician organization as a whole.

This does not mean, however, that within the physician organization itself, compensation may not be allocated based on a method other than the measurement of services personally performed. Most integrated faculty practice plans will be able to take advantage of the in-office ancillary services exception applicable to group revenue. This exception applies when such groups practice together on an integrated basis for the large portion of their professional activities.[13]

AMC Exception

The difficulty with the exceptions generally available to the standard hospital and community physician relationship is that in the academic setting, a number of the requirements did not translate well to typical academic faculty and SOM relationships. The nature of the fund transfers and the subsidies that exist (for example, in the area of research and teaching, as opposed to the more straightforward payment for clinical services arena) led to the need for a special exception. This resulted in a Stark exception for AMCs.[14]

The AMC exception first defines its setting—what is an AMC?—and then creates an exception for those compensation (and potentially ownership) situations that fall within it. Thus, services provided by an AMC will not violate the Stark prohibition of referrals, within the boundaries of the exception. While not without some significant limitations, it should protect many of the arrangements that will foster alignment between the teaching hospital and its affiliated faculty physicians. Nonetheless, there are definitions and rules that an organization must fall within to enjoy this exception as previewed below.

[12] 42 C.F.R. § 411.354(c)(2);357(p).
[13] 42 C.F.R. § 411.355(b).
[14] 42 C.F.R. § 411.355(e).

AMC

The AMC consists of an accredited medical school, one or more faculty practice plans, and one or more affiliated hospitals in which a majority of the physicians are on the medical staff. For this purpose, a faculty member is on the faculty of the affiliated medical school, or on the faculty of one or more of the educational programs at the accredited academic hospital. Faculty from any affiliated medical school or accredited academic hospital education program may be aggregated.[15]

Accredited Academic Hospital

The accredited academic hospital is a hospital or a health system that sponsors four or more approved medical education programs.

Referring Physicians

For the referrals made from the AMC-affiliated physician to be excepted from the Stark prohibitions, the physician must initially be a bona fide employee of "a component" of the AMC. This means that the physician must be an employee of the medical school, faculty practice plan, hospital, teaching facility, institution of higher education, departmental professional corporation, or nonprofit support organization whose primary purpose is to support the teaching mission of the AMC. The physician must also provide "substantial" academic services or clinical teaching services as a part of the employment relationship, and will be deemed to have met this requirement if he/she spends at least 20% or eight hours per week furnishing those services (in each category or a combination).

Compensation Conditions

A number of compensation rules apply with respect to compensation paid to the AMC referring physician:

- The total compensation by each AMC component to the referring physicians must be set in advance. Thus, the aggregate compensation is set in an agreement before furnishing the services and is in "sufficient detail" so that it can be objectively verified. The formula may not be changed during the course of the agreement in any

[15] *Id.*

manner that takes into account the volume or value of referrals or other business generated;[16]

- The aggregate compensation paid does not exceed FMV for the services provided; and
- The total compensation paid by each AMC component is not determined in a manner that takes into account the value or volume of referrals.

In addition to the foregoing, transfers of money between AMC components must directly or indirectly support the AMC missions of teaching, indigent care, research, or community service.[17]

And finally, the entire relationship must be set forth in writing, and must be adopted by the governing body of each component.

The AMC provides a fair amount of flexibility, and at least one court has already determined that, perhaps unlike other Stark exceptions, CMS does not want this exception determined in a "hypertechnical manner." It does not require a formal system of keeping records to determine what is "substantial," does not require an ongoing review of compensation over time if the core requirements are met, and a formal contract (rather than a "writing") is not a necessity.[18]

On the other hand, there remain limits that may affect the full extent of potential alignment structures. For example, the "set in advance" requirement with respect to compensation does require a specific formula that may be incompatible with assessment of "contribution" to success of an integration effort determined on a discretionary basis. The limitation with respect to "value or volume" also limits compensation from the teaching hospital to services personally furnished, which may affect department- or service-line-based incentives for a chief. The limitation in the definition of an AMC itself may well affect an integration strategy between faculty and non-faculty physicians within the AMC, as the result of the limitation that the majority of all admissions must be made by physicians who are faculty members.

[16] 42 C.F.R. § 411.354(d)(1).
[17] *See also* 42 C.F.R. § 411.355(e)(iii) for additional conditions.
[18] *U.S. ex rel. Villafane v. Solinger*, 543 F. Supp. 678 (W.D. Ky. 2008).

As an AMC seeks to prepare itself for managed care arrangements and align with the larger community, other issues may arise. For example, if there is an aligned physician group that does not provide the required "substantial" academic activity but is clinically focused, that requirement will not be met. Similarly, if the teaching hospital or faculty practice plan wishes to provide support for an unaffiliated hospital or medical group, the AMC exception may not be helpful. The same would be true with respect to hospitals that are a part of an AMC-based system but do not meet the requirements of an accredited academic hospital.

AMCs and the AKS

Payments intended to induce a flow of referrals, absent protection under the AKS safe harbors, also create regulatory issues and potential criminal exposure. The challenge in AMC arrangements is whether payments are made outside of the AKS safe harbors, most notably those for personal services arrangements where physician compensation is an issue.[19] Because support payments often fall outside of the AKS safe harbors for the same reasons they do not meet the Stark safe harbor tests, this area is also an issue.

Fortunately, OIG seems to accept that the mission of the AMC involves caring for the uninsured and training the next generation of physicians, thus requiring some latitude.[20] Therefore, where an arrangement is between AMC components with a preexisting relationship and referrals are not likely to be altered by a change; the parties share that common mission; there is no specific requirement to refer to the teaching hospital; referrals are not tracked; and compensation to the faculty is not volume or value related, but instead is at FMV for the services actually rendered, the requisites for a violation of the AKS are not likely to be met.[21]

Closing Points and Tips for Exploring Options

For an organization to explore possibilities for greater alignment, the effort must balance organizational models with financial feasibility. Too often, the process overly focuses on governance and organizational changes without being grounded in finances. In some cases, the preferred organizational model is not approved because the financial analysis is

[19] 952; personal services and management contracts. 42 CFR 1001.952(d).
[20] Ad. Op. 05-11.
[21] *Id.*

incomplete or unknown, and in other cases, discussions are short-lived because institutions resist making organizational changes (e.g., governance and leadership) without fully appreciating the financial impact and benefit to the AMC, the faculty, and the community they serve. Below are tips for a productive and well-informed planning process to explore a more-aligned AMC with a primary focus on the clinical enterprise:

1. Engage in a joint planning process with a defined timeline, and with a mutual commitment to share pertinent operational and financial information at the outset of the process. This may or may not call for outside assistance and the execution of confidentiality/nondisclosure statements.
2. Mutually agree to a set of planning parameters/boundaries before exploring options (i.e., identify what is “on or off the table” up front).
3. Seek to identify two to three viable alignment models for a given area, and allow financial information and other factors to help narrow/select the preferred option.
4. Design a model for the long term, and do not allow features to be personality dependent (i.e., the ability to pursue a model due to the current relationship among leadership).
5. Remain focused on the destination and optimal model; consider transitional issues and timing on a secondary basis.
6. It is not necessary to move immediately to the optimal solution. It may take time to address chairs or others who are in place.
7. Culture cannot be ignored, but should be recognized transparently from the outset.
8. The finance projections should be transparent to all decision makers involved.
9. Without transparency, particularly around finance matters, fact-based planning will be difficult, and there is a greater likelihood that personality or personal agendas, or historical issues that are outdated, will play a greater role.

AMCs must acknowledge that, fairly or unfairly, the clinical enterprise is its economic engine. In order to remain competitive and recruit and retain faculty, the financial arrange-

ments between the component entities and perhaps the organizational structure may need to change. If the leadership focuses on the broader, long term goals of the AMCs and keeps the political forces at bay, then new “game changing” opportunities can be identified that create a more integrated, cost efficient, and responsive organization to the benefit of the tripartite mission it serves.

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