Analysis

Flexibility Born of Necessity: The Case for an Inclusive Academic Medical Centers Exception in an Era of Shifting Financial Realities

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"Academic Medical Centers must evolve or perish." This refrain is being echoed with increasing urgency by health care commentators and analysts warning that America's health care teaching institutions must streamline and restructure to avoid inexorable decline.

From budgetary belt-tightening and decreasing reimbursement rates to competition from community physician groups and hospitals, AMCs face a myriad of challenges in today's fiercely competitive and efficiency-seeking health care industry. Shrinking funding from traditional sources such as government, tuition, and grants is insufficient to offset academic and research expenses. No longer insulated from financial pressures, academic institutions and their affiliates increasingly rely on robust clinical programs to subsidize their research and educational missions, and simply to survive in this era of value-based medicine.

A 2012 PriceWaterhouseCoopers Health Research Institute study concluded that up to 10% of traditional AMC revenue is at risk over the next five years, projecting an 8% decrease in commercial payer reimbursement and a precipitous 23% decline in the share of AMC funding attributable to grants and contracts by 2020.[1] These trends and the sequestration cuts of 2013, which included a 2% reduction in Medicare payments, threaten each of the three elements of AMC's tripartite mission: patient care, education, and research.[2]

One of the most successful means by which AMCs have augmented clinical revenues is through acquisition of community physician groups and community hospitals. Together with increased revenue, however, such arrangements—involving referrals from both faculty and non-faculty physicians alike—generate increased compliance risks.

While AMCs have adapted by necessity with the changing health care landscape, the legal architecture governing them—most notably the Academic Medical Centers exception to the Stark Law (AMC exception)—has remained static since Phase III rulemaking in 2007, unresponsive to the shifting fiscal fundamentals of academic medicine. While authoritative expansion of the AMC exception would alleviate the compliance uncertainties faced by AMCs seeking to cross-subsidize their academic and research missions through clinical expansion, there is little evidence that the Centers for Medicare & Medicaid Services (CMS) is contemplating such action.

This article explores the breadth of the AMC exception through the lens of CMS' purpose in creating the exception, the permissive and flexible language contained in the regulatory text and preambles, and CMS' tendency over the life of the exception to broaden its inclusiveness in acknowledgment of the complex relationships and beneficial cross-subsidization arrangements among AMC components. It argues for an inclusive interpretation of the AMC exception informed by today's dynamic health care landscape and CMS' overarching goal of protecting the tripartite mission of AMCs from unnecessary regulatory burdens.

The Advantages of the AMC Exception to the Stark Law

The symbiotic nature of AMCs, often involving multiple affiliated entities (such as a faculty practice plan, university, hospitals, and outpatient clinics) engaged in the joint delivery of services, coupled with the cross-funding of various AMC components through support payments untethered from specific items or services, imposes significant hurdles to compliance under standard Stark Law exceptions.[3]

For example, although the statutory definition of "group practice" explicitly incorporates faculty practice plans that satisfy the group practice definition (not a simple feat for a complex faculty plan), the incidental benefits thereof, such as the availability of productivity bonuses and the in-office ancillary services exception, are limited to "the services provided within the faculty practice plan."[4]

However, faculty practice plan physicians frequently refer patients for ancillary services that are outside of and not wholly owned by the faculty practice entity/group practice (e.g., a teaching hospital), but with which the physician may have direct or indirect compensation arrangements (i.e., a portion of the physician's salary may come from the teaching hospital or affiliated medical school).[5] Such referrals generally would be ineligible for the in-office ancillary services exception.

It also may be difficult to structure compensation relationships for faculty practice plan physicians to fall within the personal services arrangements exception because compensation may flow directly or indirectly from several different sources.[6] Likewise, the Stark Law employment exception only protects compensation arrangements between the physician and her employer, leaving payments from other components of the AMC exposed to the self-referral prohibition.

These compliance obstacles are exacerbated by orders of magnitude when an AMC acquires a physician group or community hospital to enhance its clinical program. Such an undertaking requires integration of physicians outside of the faculty group practice in a manner that avoids prohibited referrals to and from both the faculty group practice and other AMC components.

In recognition of the unique compliance hurdles imposed upon AMCs, CMS promulgated the AMC exception "as a

separate compensation exception for payments to faculty of [AMCs] that takes into account . . . the symbiotic relationship among faculty, medical centers, and teaching institutions, and the educational and research roles of faculty in these settings."[7]

The most beneficial feature of the AMC exception is that "[i]t is designed to protect compensation from *all* components of the center, not only the component with the which [a physician] has an employment relationship"[8] or personal services arrangement. The AMC exception's enhanced prophylactic nature distinguishes it from the employment and personal services arrangement exceptions and is particularly attractive in light of the complex compensation relationships between physicians and AMC components. Further, the exception applies to both ownership and compensation arrangements.

AMC Exception Requirements

The exception includes five categories of requirements.[9] The first specifies which referring physicians are eligible to avail themselves of the AMC exception. A second focuses on physician compensation. A third category relates to issues of accreditation, affiliation, and staffing. A fourth governs issues of organization and financial transfers. The final category mandates compliance with the Anti-Kickback Statute.

This article addresses the first, second, and third categories of requirements, each of which present unique challenges and advantages for AMCs undergoing expansion of their clinical operations.

Referring Physician Requirements

The first category of requirements focuses on the referring physician, directing that:

- The referring physician be a *bona fide* employee of a component[10] of the [AMC] on a full-time or substantial part-time basis;
- The referring physician be licensed to practice medicine in the State;
- The referring physician have a *bone fide* faculty appointment; and
- The referring physician provide either substantial academic services (which includes both classroom and academic research services)[11] or substantial clinical teaching services for which the faculty member receives compensation as part of his or her employment relationship with the AMC.[12]

The last of these requirements is of particular significance to AMCs seeking to integrate community physicians as it precludes from the exception's scope payments to physicians who provide neither clinical teaching nor academic services.

Even with respect to physicians that do contribute to an AMC's academic or research missions, the requirement that such contribution be "substantial" introduces uncertainty. The existence of a safe harbor deeming a physician to meet the "substantial" requirement if he or she "spends at least 20 percent of his or her professional time or 8 hours per week

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providing academic services or clinical teaching services (or a combination of academic services and clinical teaching services)" does little to clarify this uncertainty because failure to meet the 20%/8-hour threshold does not preclude a physician from qualifying for protection under the exception.[13]

Suggesting an inclusive construction of the "substantial" requirement, CMS notes in its Phase II commentary that it purposefully avoided specifying what constitutes "substantial" academic or clinical teaching services "because [CMS] believe[s] it will vary with the precise duties of a given faculty member, and we wanted to provide [AMCs] with flexibility."[14]

CMS further clarified that the scope of the exception extends beyond full-time medical school faculty to include volunteer faculty members and teaching hospital employees. Somewhat circuitously, CMS explained that such individuals may qualify as protected referring physicians under the exception as long as their employment "encompasses substantial academic services or clinical teaching services."[15]

The simple fact that the employment of volunteer faculty members *could* be conceived as encompassing "substantial" academic services accommodates a broad interpretation of the "substantial" requirement. The duties of volunteer faculty members vary widely between institutions but generally a volunteer faculty appointment is a part-time role circumscribed to limited academic activities with hourly requirements—if any—that fall far short of the safe harbor threshold.[16]

On the other hand, the Phase I preamble instructs that "[t]he [AMC] exception does not apply to payments to physicians who provide only occasional academic or clinical

teaching services or who are principally community rather than [AMC] practitioners."[17] On account of CMS' cryptic pronouncements, AMCs are left with little tangible guidance as to what quantum of teaching or academic commitment short of the 20%/8 hour safe harbor threshold constitutes "substantial."

Nevertheless, it is significant that CMS has been unwilling to establish a floor with respect to the calculation of "substantial" academic services. As with the permissible and malleable language of other requirements discussed below, CMS' intent to provide AMCs with "flexibility" supports an inclusive and goal-oriented construction of the "substantial" test.

As the above discussion demonstrates, the meaning of "substantial" is far from established. It is clear, however, that the rule is intended to exclude "sham" employment agreements in which physicians purport to provide clinical services that are never performed.[18]

In one exemplary case, the University of Medicine and Dentistry of New Jersey (UMDNJ) agreed to pay $8.3 million to settle kickback and False Claims Act allegations.[19] UMDNJ officials allegedly had entered into purported part-time "clinical associate professor" employment agreements with various community cardiologists who performed little or no services for the university to secure state accreditation.

The case serves as a cautionary tale and reflects the need for AMCs to keep track of the academic and research activities performed by its faculty members in order to maintain compliance under the AMC exception,[20] as well as state and federal anti-kickback laws.

Compensation Requirements

The requirements governing physician compensation reflect CMS' concern regarding the structural complexity of AMCs and grant flexibility absent from other Stark Law exceptions. They direct that:

- Total compensation paid by each AMC component to the referring physician be set in advance;
- In the aggregate, the compensation paid by all AMC components must not exceed fair market value for the services provided; and
- The total compensation paid by each AMC component is not determined in a manner that takes into account the volume or value of referrals or other business generated by the referring physician.[21]

The requirements that total compensation by each AMC component be "set in advance" and that each AMC component not take into account the volume or value of referrals are essentially identical to that of the personal services arrangement exception.[22] However, substantially more leeway is provided to AMC components with respect to fair market valuation.

Specifically, the AMC exception only requires that that the *aggregate* compensation from *all* AMC components not exceed fair market value, dispensing the necessity of ensuring fair market value compensation by each individual AMC component. This greatly simplifies compliance and permits cross-subsidization of physician research or teaching services to better achieve the AMC's missions. Additionally, in calculating fair market value, an AMC has the option of utilizing a comparison to similarly situated academic physicians *or* comparable private practice physicians, and may adopt the higher of the two valuations.[23] These provisions, coupled with the protection of all AMC payments to a referring physician, are the foundation from which the AMC exception derives its key advantages.

An authoritative pronouncement from CMS relaxing the two majority tests would allay the fears of a great number of AMCs anxious that their continued eligibility for the AMC exception may be undermined by the addition of community-based physicians to their clinical programs.

Accreditation, Affiliation, and Staffing Requirements

In stark contrast to the propitious attributes of the compensation requirements, the accreditation, affiliation, and staffing requirements—if rigidly enforced—impose onerous hurdles to AMCs seeking to qualify for the exception.

To be eligible for the AMC exception, the AMC components must consist of:

- An accredited medical school or an accredited academic hospital;
- One or more faculty practice plans affiliated with the medical school, the affiliated hospital(s), or the accredited academic hospital; and
- One or more affiliated hospitals in which a majority of the physicians on the medical staff consists of physicians who are faculty members and a majority of all hospital admissions is made by physicians who are faculty members.[24]

It is the "two majority" element of the last of these requirements that potentially places the AMC exception out of reach for many AMCs, and, if strictly construed, would deprive

many institutions of cross-subsidized funding for meeting their tripartite mission of patient care, education, and research without running afoul of Stark Law prohibitions.

If applied inflexibly, AMCs that integrate community physicians (through acquisition of groups, community hospitals, or through mergers) to generate increased clinical revenue to support research and teaching missions will more often than not be ineligible for the exception. By their very nature, such transactions result in an influx of community physicians, diluting the faculty composition of affected medical staffs and decreasing the percentage of admissions by faculty members. In light of industry trends favoring consolidation and efficiency, strict imposition of the two majority tests would be counterproductive, undermining the academic and research functions of AMCs that are most in need of cross-subsidized support.

In apparent acknowledgment of the burden imposed by the two majority tests, the regulatory text grants AMCs significant flexibility when counting faculty members for purposes of satisfying these requirements. First, "faculty from any affiliated medical school or accredited academic hospital education program may be aggregated."[25] Second, "residents and non-physician professionals need not be counted."[26] Most significantly, "[a]ny faculty member may be counted, including courtesy and volunteer faculty."[27] Affiliated hospitals are further empowered to exclude or include physicians with certain classes of privileges from the majority calculation, but must be consistent and "include or exclude all individual physicians with the same class of privileges . . . ."[28]

This language can be interpreted as permitting the academic component of AMCs to grant volunteer and courtesy faculty appointments to community physicians for the purpose of meeting the two majority test. Indeed, the divergence between the referring physician and two majority requirements invite such a construction. Unlike the referring physician requirement, a physician is not required to be a "*bona fide*" employee, have a "*bona fide*" faculty appointment, or provide "substantial" academic or teaching services to qualify as a faculty member for purposes of calculating the two majorities. As a result, a physician may count towards a faculty majority—qualifying the AMC for the exception—even though her referrals would not be protected under the AMC exception (e.g., because she does not meet the "substantial" requirement). In this scenario, the AMC should ensure that referrals by such a physician either are outside the scope of Stark Law prohibitions or are protected through another exception.

In practice, however, medical schools are loathe to grant faculty appointments (even volunteer appointments) on such a large scale, and community physicians may face time constraints that preclude them from performing academic duties.

Further guidance regarding interpretation of the two majority tests can be drawn from the remarkably liberal approach adopted by the sole court that has addressed the AMC exception. In *United States ex rel. Vilafane v. Solinger*, a U.S. district court in Kentucky inferred, in the absence of specific evidence, that the majority of admissions at a teaching hospital were ordered by faculty physicians based on data indicating that a majority of hospital staff were faculty members.[29] In justifying this inference, the court noted "*CMS's extremely permissive language regarding [the two majorities] requirement*, which indicates *that CMS did not want the regulations applied in a hyper-technical manner. CMS seemed more concerned with the 'core mission' of the AMC then with a strict and unforgiving application of any single requirement*."[30]

The court expounded upon this theme throughout its opinion, focusing on CMS' proclivity towards "paring back the regulatory structure" of the AMC exception throughout the rulemaking process in response "to actual or potential regulatory overbreadth . . . ."[31] The court also found instructive CMS' (then the Health Care Financing Administration (HCFA)) conservative stance on Stark Law construction, noting CMS' stated intention to "be cautious in interpreting [the Stark Law's] reach so broadly as to prohibit potentially beneficial arrangements."[32]

After surveying the relevant statutory text, regulatory text, and interpretive guidance, the court observed that "[s]ince Phase I, HCFA and CMS have stated that Congress intended to permit the 'complex organizational arrangements' that so often are a hallmark of AMCs so long as those arrangements pose little risk of fraud or abuse."[33] This, according to the court, clearly evidenced the rulemakers' "desire that the AMC exception be interpreted and applied using a goal- and purpose-oriented perspective rather than a hyper-technical one" and their recognition of "the important relationships between physicians, hospitals, and medical instruction."[34] The court concluded that in creating the AMC exception:

> [CMS] want[ed] to create space within which true AMCs can operate without interference from the Stark law. *The Stark regulations are attempting to prohibit only those outlier arrangements that are nothing more than illegal schemes*.[35]

This author submits that the *Solinger* court's inclusive approach to interpretation of the AMC exception is reasonable, particularly in light of the societal benefits generated by cross-funding arrangements between AMC components.

Notably though, CMS in 2007 considered comments critiquing the application of the majority admission requirement to community and newly affiliated hospitals and expressly declined to relax the two majority tests in favor of a more inclusive test.[36]

However, today's health care landscape is dramatically different than when CMS promulgated the latest revisions to the AMC exception in 2007 with the enactment of the Affordable Care Act, substantial budget cuts, and other trends ushering in a new era of consolidation, enhanced efficiency, and value-based medicine.

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AMCs anxious that their continued eligibility for the AMC exception may be undermined by the addition of community-based physicians to their clinical programs. AMCs can take some comfort in the *Solinger* court's general adoption of a goal- and purpose-oriented construction of the AMC exception, and, in particular, its refusal to apply the two majority tests in a hyper-technical manner. Although the *Solinger* decision only serves as controlling precedent in a single judicial district, the opinion rests on a strong foundation, grounded in regulatory text, guidance, and the malleable language of the two majority tests.

In the event it seeks to avail itself of the exception, an AMC uncertain of its strict compliance with the two majority tests should be prepared to demonstrate that revenue derived from expanded clinical operations is, in fact, being used to cross-subsidize its educational and/or research missions. Such a showing would evidence a nexus between the AMC's enhanced clinical program and its academic mission, and may satisfy a court or regulators that the AMC's growth strategy comports with the goals and purpose of both the AMC exception and the Stark Law.

Conclusion

With traditional sources of AMC funding dissipating and a marked shift towards consolidation, strict application of AMC exception requirements must yield to a more inclusive construction, acknowledging that revenue from robust clinical programs is the lifeblood for AMC's education and research missions. In the absence of affirmative regulatory action, the exception as currently structured, coupled with the past pronouncements of CMS and the *Solinger* court, lend considerable flexibility to the AMC exception. Although AMCs should approach the exception with due caution, it remains an important tool in AMC compliance efforts.

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Endnotes

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