



New Frontiers in AMC Funding: Mission Support Alternatives Post-*Halifax*

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“For years, many AMCs have thrived financially. But financial success has required a complex mix of revenue sources that flow through cross-subsidies to achieve the tripartite mission of clinical care, research, and education. Research and education have been loss leaders, cross-subsidized by the work of hospitals and physicians. So any changes to clinical revenue directly impact an AMC’s ability to educate clinicians and scientists and to conduct research.” PricewaterhouseCoopers (PWC), 2012.¹

“[The hospital and medical school] components of an academic medical center . . . historically have shared both a common mission in training physicians for, and providing quality medical care to, the people of the State and a common heritage as public institutions. We recognize that the relationships among components of academic medical centers are often organizationally and financially complex.” U.S. Department of Health and Human Services Office of Inspector General (OIG), 2002.²

Introduction

As the introductory quotations suggest, the medical establishment and the federal government have long recognized that the revenue-generating parts of an academic medical center (AMC) must support those components that barely pay for themselves or lose money in pursuit of the tripartite mission of teaching, research, and clinical care. In its 2012 report on the future of AMCs, PWC developed an “illustrative model” of an AMC.³ In this model, clinical care represented approximately 85% of an AMC’s revenue.⁴ Grants and contracts represented another 12% of revenue, and all other sources combined (endowment income, gifts, and tuition) accounted for only 3% in

¹ PricewaterhouseCoopers Health Research Institute, *The Future Of The Academic Medical Center: Strategies To Avoid A Margin Meltdown* (Feb. 2012) (PWC Report).

² OIG Adv. Op’n No. 02-11 (Aug. 19, 2002).

³ PWC Report at 8. In its report, PricewaterhouseCoopers provided the following context about its “illustrative model”: “Published statistics on AMCs are not readily available. Rather, organizations like AAMC publish statistics on medical colleges and then other statistics about teaching hospitals. PwC created its ‘illustrative’ analysis using financial data from AMCs and national trend data available on medical schools and COTH hospitals. Although it is difficult to define a ‘typical’ AMC, we believe the final percentages are reasonably consistent with the national averages reported separately by medical colleges and teaching hospitals and our knowledge of AMCs.” *Id.* at 8 n.9.

⁴ *Id.* at 8.

funding.⁵ A recent article in *Academic Medicine* observed that although more than half of all National Institutes of Health (NIH) extramural research grant funding went to AMC faculty members in 2011, “the indirect cost reimbursement associated with grant funding does not cover the full cost of the infrastructure needed to support the research mission” and therefore “AMCs must subsidize the research mission, contributing up to 30% of its support which often amounts to hundreds of millions of dollars in cross-subsidies from clinical or other revenue streams.”⁶ The article then provided some examples demonstrating the important advances in medicine resulting from such subsidized activities: “AMC research activities contribute to the training of all M.D.-Ph.D.s and have resulted in advances such as the polio vaccine, the first pancreas transplantation, the first neonatal intensive care unit, and the first gene therapy for cystic fibrosis.”⁷

As these and many other sources have noted, the logic for cross-subsidizing the tripartite mission of an AMC is compelling: the conventional sources of funding for medical education—tuition and, where available, endowment funds—do not begin to cover the costs of the teaching personnel and research infrastructure needed for medical education, and a number of clinical specialties, such as pediatrics and family medicine, typically do not have clinical revenues sufficient to pay for the additional costs associated with education. Further, funding for research and medical education is also subject to downward pressure. NIH grants, one of the major sources of support for biomedical research conducted at AMCs, have decreased over the past decade, with the NIH budget being reduced by over 20% during that time period.⁸ There have also

⁵ *Id.*

⁶ Wartman et al., *Health Reform and Academic Health Centers: Commentary on an Evolving Paradigm*, 90 ACAD. MED. 1587, 1588 (Dec. 2015).

⁷ *Id.*

⁸ See National Public Radio, *By the Numbers: Search NIH Grant Data by Institution* (Sept. 12, 2014), available at: <http://www.npr.org/blogs/health/2014/09/09/342196432/by-the-numbers-search-nih-grant-data-by-institution>. This reported decline excludes extra amounts that were made available in 2009 and 2010 through stimulus funding. *Id.* The 21st Century Cures Act, signed into law by President Barack Obama on December 13, 2016, provides a funding boost of over \$4.8 billion over ten years to specific NIH initiatives, but the funding is subject to future appropriations and, observed in the context of the overall funding dedicated to NIH programs (its fiscal year 2015 and 2016 program level budgets were approximately \$30 and \$32 billion, respectively), this funding increase is relatively modest and does not shift the magnitude of the downward trend observed over the longer time frame. 21st Century Cures Act, Pub. L. No. 114-244, § 1001, 130 Stat. 1033, 1039-42 (Dec. 13, 2016); U.S. Department of Health and Human Services, HHS FY 2017 Budget in Brief – NIH (Feb. 16, 2016), available at <https://www.hhs.gov/about/budget/fy2017/budget-in-brief/nih/index.html#budget>.

been many recent proposals to reduce the amount of graduate medical education (GME) funding available for medical residency programs.⁹ For all of these reasons relating to the scarcity of funding, the strong taboos against “remuneration” for referrals that exist elsewhere in the health care industry have been much more loosely applied in the AMC context, as “[i]ncreased pressure on the operation margins for most teaching hospitals . . . has necessitated a shift away from the historical ‘no strings attached’ paradigm of mission support.”¹⁰

As enforcement of the Anti-Kickback Statute¹¹ and the Ethics in Patient Referrals Act of 1989 (Stark Law)¹² via the federal False Claims Act (FCA) has become more commonplace in federal health care programs, there is an increasing risk that aggressive relators and prosecutors may advance theories of liability that, taken to their logical ends, could threaten this understanding of the complex funds-flow realities in the AMC context. The most prominent example so far is the 2013 case of *United States v. Halifax Hospital Medical Center*, which suggested that when a hospital’s financial support for its referring physicians depends on hospital profitability—a form of financial relationship far from unknown in the AMC world—a violation of the Stark Law potentially could arise.¹³ While *Halifax* involved a community hospital and not an AMC, its implications for AMCs have been widely discussed and the uncertainties it has created are influencing AMC funds-flows in a way that could be detrimental to sensible financial planning.¹⁴

⁹ For example, the National Commission on Fiscal Responsibility and Reform, known popularly as the “Simpson-Bowles Commission,” which was charged with proposing policies to improve the federal fiscal situation, recommended capping direct graduate medical education (DGME) payments at 120% of the national average salary paid to residents and reducing the indirect medical education (IME) payment adjustment schedule. See *Simpson-Bowles Facts Summary*, ThePoliticalGuide.com (retrieved Feb. 3, 2016). The Medicare Payment Advisory Commission (MedPAC) has also recommended reducing the IME payment adjustment schedule. See Medicare Payment Advisory Comm’n, *Report to Congress: Aligning Incentives in Medicare* 103 (June 2010).

¹⁰ Deborah Farringer and Ted Lotchin, *Academic Medical Centers*, Chapter 31, at 8, in REPRESENTING HOSPITALS AND HEALTH SYSTEMS HANDBOOK (American Health Lawyers Association 2016).

¹¹ 42 U.S.C. § 1320a-7b.

¹² 42 U.S.C. § 1395nn.

¹³ No. 6:09-CV-1002-ORL-31, 2013 WL 6017329, at *11 (M.D. Fla. Nov. 13, 2013).

¹⁴ See, e.g., Douglas M. Mancino, A Guide to Complying with the Stark Physician Self-Referral Rules, ¶ 432.3 (Jul. 2015) (“Because the definition of what is based upon volume or value of referrals is not clear from the Stark Law and its regulations, the industry will need to monitor this issue to determine how CMS, OIG, DOJ, and courts are interpreting this prohibition.”); Farringer and Lotchin, *supra* note 10, at 698 (“[T]he wide variety of financial relationships that can exist among the separate components of an AMC

In the wake of the *Halifax* decision, we have encountered more frequent questions about how funds-flow structure among component parts of an AMC can best be designed to comply with federal fraud and abuse laws. Therefore, in this article we consider the implications of the legal theories advanced and, in part, adopted by the court in *Halifax* that are applicable to an analysis of AMC mission support. We begin in Part II by explaining what we mean when referring to “an AMC” and by reviewing the concept and purpose of mission support. In Part III, we discuss the potential tensions between mission support arrangements and the principal federal health care fraud and abuse laws—the Stark Law and the Anti-Kickback Statute—and then describe the historical legal exceptions that have developed to permit mission support in the AMC context. In Part IV, we discuss some typical models of mission support that have arisen in this framework. Part V summarizes the *Halifax* case, and notes the troubling implications it might have for mission support. Finally, in Part VI we consider the possible implications of legal theories advanced in *Halifax* for mission support arrangements, and explain differentiating factors between the *Halifax* setting and the AMC setting, concluding with a discussion of mitigating steps that AMCs can take against the threat of legal action based on *Halifax*-type arguments.

I. Defining Our Key Terms: Academic Medical Center and Mission Support

A. What is an AMC?

Although there is no uniform definition of “academic medical center,” the Stark Law and the American Association of Medical Colleges (AAMC) each have provided a helpful definition. Under the Stark Law, AMC means: (1) “[a]n accredited medical school (including a university, when appropriate) or an accredited academic hospital”; (2) “[o]ne or more faculty practice plans affiliated with the medical school, the affiliated hospital(s), or the accredited academic hospital”; and (3) “[o]ne or more affiliated hospitals in which a majority of the physicians on the medical staff consists of physicians who are faculty

will frequently raise new and challenging questions due to the AMC’s unique organizational structures, historical relationships, and shared mission. Mission support payments, for example, do not fit cleanly into the established exceptions to the Anti-Kickback Statute.”)

members and a majority of all hospital admissions is made by physicians who are faculty members.”¹⁵ In a 1997 guidance document, the AAMC provided a more general definition, stating that “[a]n academic medical center is the medical school and a hospital (university-based).”¹⁶ To these definitions we would add that these components—medical school, teaching hospital, and physician faculty practice plan—share a common mission: the oft-cited tripartite purpose of teaching, research, and clinical care.

B. What is Mission Support?

Although there is wide acceptance of the tripartite mission of an AMC, the term “mission support” is not as uniformly understood. Both the Centers for Medicare and Medicaid Services (CMS) and the OIG have recognized what we think of as “mission support” in describing the important and appropriate role that this component of funds-flow plays in medical education and the provision of health care services within the AMC setting. In establishing the Stark Law AMC exception, CMS implicitly endorsed mission support by requiring that all “[t]ransfers of money between components of the academic medical center must directly or indirectly support the missions of teaching, indigent care, research or community service.”¹⁷ Similarly, in advisory opinions, OIG approved of funds flowing from a hospital to a university whose employed and/or affiliated physicians provide referrals to the hospital where the hospital and university have a “shared public and charitable mission” and the funds are used to continue the organizations’ “common mission in training physicians for, and providing quality medical care to, the people of [a state.]”¹⁸

In this article, we use “Mission Support” to refer to financial support from the revenue-generating parts of an AMC (typically the hospital) to the revenue-poor parts (typically the teaching and research functions) that supports the tripartite mission, and is not tied

¹⁵ 42 C.F.R. § 411.355(e)(2).

¹⁶ See https://www.aamc.org/download/372006/data/01-97_integrated_academic_medical_center_hospitals.pdf.

¹⁷ 42 C.F.R. § 411.355(e)(1)(iii)(A).

¹⁸ OIG Adv. Op’n No. 02-11 (Aug. 19, 2002).

to deliverables or to fair market value (FMV). As we use the term, Mission Support does not include other kinds of financial support that typically are tied to deliverables, such as fee-for service payments (like medical directorships, consulting services, and product development services), federal and state funding for GME, grants for research and clinical studies, industry payments for intellectual property developed at a medical school, or tax-exempt bond financing for capital improvements.

II. Traditional Legal Constraints on Mission Support

In this part, we discuss the traditional legal restraints on Mission Support: the Anti-Kickback Statute, the Stark Law, and the FCA. As noted, while OIG and CMS have recognized that Mission Support plays an important and appropriate role in medical education and the provision of health care services, they have also recognized that because Mission Support provided by the hospital component to the university or medical school component of an AMC at least indirectly supports physician salaries, it falls within the orbit of the Anti-Kickback Statute and Stark Law. The OIG distilled the anti-kickback concern to its essence, commenting that such arrangements are “as straightforward as [they are] problematic” because they involve “a substantial [] donation by a hospital to a major referral source.”¹⁹ CMS described the issue in Stark Law terms, noting that “[a]cademic 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.”²⁰ Traditionally, the funds-flow at issue for purposes of these regulatory concerns consists of (1) payments from the hospital to the university (or university component) and (2) compensation provided by the university (or component) to its employee-physicians. When faculty physicians are employed through a faculty practice plan that is a legally separate entity from the university, the same concerns are implicated so long as the Mission Support to the

¹⁹ See OIG Advisory Op'n Nos. 05-11, 02-11, 00-06.

²⁰ 66 Fed. Reg. 856, 916 (Jan. 4, 2001) (Stark “Phase I” Rulemaking).

academic enterprise both comes from the hospital and ends up, in part, supporting physician compensation—either directly or through the faculty practice plan.²¹

Finally, these legal constraints often find their expression through the enforcement mechanisms of the FCA.

A. *Anti-Kickback Statute*

The Anti-Kickback Statute makes it a criminal offense to knowingly and willfully offer remuneration to induce a person to (1) refer an individual to a person for the furnishing or arranging for furnishing of any item or service for which payment may be made in whole or in part under a federal health care program, or (ii) to purchase, lease, order, or arrange for or recommend purchasing, leasing or ordering any good, facility, service or item for which payment may be made in whole or part under a federal health care program.²² As noted, OIG has recognized that Mission Support provided by the hospital component to the university or medical school component of an AMC may implicate the Anti-Kickback Statute because physicians employed by or affiliated with the medical school often refer patients to the hospital, and, as noted above, Mission Support payments often involve “a substantial [] donation by a hospital to a major referral source.”²³ The consequences of a conviction (or a plea) are severe, including mandatory exclusion from participation in federal health care programs, and even a civil settlement authorizes OIG to impose a discretionary exclusion.²⁴

OIG guidance, however, recognizes that within proper parameters, Mission Support is not prohibited by the Anti-Kickback Statute. Specifically, three advisory opinions have reviewed donations from the hospital entity to the academic entity serving as a source of referrals for the hospital, and all three opinions reached favorable outcomes for the AMCs. The opinions shared three factors that were essential to the OIG’s decision to

²¹ Where faculty physicians are employed by the hospital or by a hospital-controlled enterprise, the regulation of physician compensation still exists, but may not implicate Mission Support because those funds to the university no longer flow through to physician compensation.

²² See Social Security Act § 1128B(b); 42 U.S.C. § 1320a-7b(b).

²³ See OIG Advisory Op’n Nos. 05-11, 02-11, 00-06.

²⁴ See 42 U.S.C. 1320a-7(b)(7).

decline to impose sanctions: (1) the components of each AMC shared a mission in medical education and delivering health care; (2) the corresponding community benefit from this mission and these services; and (3) the presence of certain safeguards to minimize the danger that the Mission Support was serving as a proxy referral fee.

The first two factors are fairly straightforward insofar as they are simply a recognition of widely supported public policy aims that would naturally be present in any bona fide AMC. Regarding the first factor, a shared mission, both the academic and clinical components of an AMC “have historically shared both a common heritage as public institutions and a common mission in training physicians for, and providing quality medical care to, the people of [State].”²⁵ Regarding the second factor, community benefit, both components of the AMCs in the three opinions supported the goals of medical education, research, and other activities providing a community benefit and/or public service, including the service of medically underserved populations.

The third factor, the presence of safeguards to minimize fraud and abuse risks, is the key element potentially affected by the *Halifax* decision discussed in greater detail below. In all three opinions, the OIG concluded that the compensation paid to the physicians was not related to the volume or value of referrals by such physicians to the hospital or other institution, and the compensation ultimately paid to the physicians was consistent with fair market value in arm’s-length transactions. This safeguard is the irreducible minimum requirement necessary to ensure a particular Mission Support arrangement is compliant with the fraud and abuse laws: simply stated, no Mission Support arrangement will be permissible if the amounts paid are based on volume or value of referrals or if the resulting physician compensation exceeds FMV.

The advisory opinions also described two additional, related safeguards that are important to the minimization of risks needed to ensure compliance. First, in each opinion, the medical school and/or faculty practice plan did not “track referrals” made by its physicians to the hospital.²⁶ In the most recent of the three advisory opinions, the OIG qualified its interpretation of this safeguard to allow such “tracking” as is reasonably

²⁵ OIG Advisory Op’n 02-11 at 7.

²⁶ See Advisory Opinion No. 05-11 at 5 n.5, 8.

required for academic purposes and is not used for purposes of determining compensation or referrals. Second, the opinions noted that the medical school and/or faculty practice plan did not require or encourage employed or affiliated physicians to refer patients to the hospital that provided the transfer of funds. We note that there is a certain artificiality in the OIG's reference to the lack of required or encouraged referrals that probably should be seen to qualify this safeguard as well. A medical school cannot function without a steady stream of patients (teaching material) admitted to the AMC hospital so that students, residents, and fellows can observe and participate in treatment. Likewise, the proximity of the teaching hospital and its facilities make the AMC hospital the natural recipient of most patient referrals. Finally, the Stark Law contains specific exceptions allowing for certain required referrals (discussed below), so long as the requirements do not apply where medical judgment, patient preference, or insurance coverage counsel otherwise. While the OIG has not gone quite as far as to acknowledge this expressly, this requirement is therefore probably best read to mean no *unreasonable* requirements for referral, consistent with the Stark Law's "special rule" for required referrals, in light of the mission of the AMC.

B. Stark Law

Mission Support payments are also subject to scrutiny under the Stark Law. Stated broadly, the Stark Law prohibits a physician who has a financial relationship with an entity that furnishes designated health services (DHS), such as a hospital, from making referrals of DHS payable by Medicare to such entity unless a statutory or regulatory exception applies.²⁷ While a Stark Law violation does not carry with it a mandatory federal health care program exclusion, it is one of the bases on which OIG may use its discretionary exclusion authority.²⁸

²⁷ See Social Security Act § 1877; 42 U.S.C. § 1395nn; 42 C.F.R. § 411.353. While practitioners have traditionally focused on the Stark Law as applying to referrals of DHS payable by Medicare, in recent years the DOJ has taken the position, which some federal district courts have accepted, that the law also applies to referrals of DHS payable by Medicaid. See, e.g., *United States v. All Children's Health Sys. Inc.*, 2013 WL 6054803, at * 5 (M.D. Fla. 2013); *United States v. Halifax Hosp. Med. Ctr.*, 2012 WL 921147, at * 4 (M.D. Fla. 2012).

²⁸ See 42 U.S.C. 1320a-7(b)(7).

The definition of DHS encompasses both inpatient and outpatient hospital services, and therefore most of the services that a physician would refer to the hospital component of an AMC constitute DHS. A “financial relationship” may consist of either an ownership/investment interest or compensation arrangement, and may be direct or indirect. Generally, Mission Support payments do not implicate physician ownership or investment interests and, therefore, the key Stark relationship at issue is whether the relationship between the hospital and the referring physician generally creates an “indirect compensation arrangement.”

An “indirect compensation arrangement” exists if the following three factors are present. First, between the referring physician and the entity furnishing DHS, there exists an unbroken chain of any number of persons or entities that have a financial relationship between them. Second, the referring physician receives aggregate compensation from the entity in the chain of relationships having a direct financial relationship with the physician that varies with, or takes into account, the volume or value of referrals generated by the referring physician for the entity furnishing the DHS. Third, the entity furnishing DHS has actual knowledge of, or acts in reckless disregard or deliberate ignorance of, the fact that the referring physician receives aggregate compensation that varies with, or takes into account, the volume or value of referrals or other business generated by the referring physician for the entity furnishing DHS.²⁹ Based on these factors, when a hospital makes a Mission Support payment to an AMC component such as a medical school or university, which in turn provides compensation to physicians who make referrals to the hospital, an “indirect financial relationship” is created between the hospital and the physician if the physician’s aggregate compensation from the medical school or university varies with the volume or value of referrals that the physician makes to the hospital. Any referrals of DHS from the physician to the hospital would therefore be prohibited unless an exception applies.³⁰

²⁹ See 42 C.F.R. § 411.354(c)(2). *Federal Register* commentary clarifies that fixed compensation may be considered to take into account “the volume or value of referrals” if “inflated” or in excess of fair market value. 69 Fed. Reg. 16054, 16059 (Mar. 26, 2004) (Stark II, Phase II interim final rule with comment period).

³⁰ Note that no indirect compensation arrangement is created unless the compensation paid to the physician by the medical school in the aggregate takes into account the volume or value of referrals (DHS) or other business (private pay) generated by the referring physician for the hospital. Accordingly,

Historically, the indirect compensation exception has been used to protect most properly structured Mission Support arrangements.³¹ CMS has recognized that this exception may be used by AMCs.³² Generally speaking, the exception may be used if the compensation received by the referring physician is fair market value for services and items actually provided and not determined in any manner that takes into account the volume or value of referrals or other business generated by the referring physician for the entity furnishing DHS.³³ As discussed below, it is this last element—not taking into account the volume or value of referrals—that has been most seriously stressed by the *Halifax* decision.

C. A Word on Enforcement Through the False Claims Act

Claims submitted in violation of the Stark Law or the Anti-Kickback Statute may trigger liability under the FCA and its state analogs.³⁴ The FCA provides for treble damages and civil penalties for the knowing submission or presentation of a false or fraudulent claim or a false record or statement material to a false or fraudulent claim, among other acts, including claims for health care services that are “false” by virtue of their

Mission Support payments that are fixed annually and not dependent on referrals from the faculty physicians arguably do not implicate the Stark Law prohibition at all. However, it may also be argued that if, for example, an annual block grant is arrived at based on the hospital’s prior year financial performance, then the physician’s salaries do “take into account” the volume or value of referrals or other business.

³¹ There is also a dedicated exception applicable to the referral of services furnished by an AMC, but in light of the indirect compensation exception and the byzantine requirements of this AMC exception, the exception has little practical importance and few AMCs rely on it. See 42 C.F.R. § 411.355(e).

³² See 72 Fed. Reg. 51012, 51038 (Sept. 5, 2007) (“The definition of ‘indirect compensation arrangement’ at § 411.354(c)(2) and the exception for indirect compensation arrangements in § 411.357(p) are potentially applicable to arrangements involving academic medical centers and physicians.”).

³³ Importantly, the Stark Law permits a physician’s compensation from a *bona fide* employer or under a managed care contract or other contract for personal services to be conditioned on the physician making referrals to a particular provider, practitioner, or supplier, e.g., a hospital, if certain conditions specified in the regulation are met. See 42 C.F.R. § 411.354(d)(4). However, the requirement to make referrals to a particular provider, practitioner, or supplier must not apply if the patient expresses a preference for a different provider, practitioner, or supplier, the patient’s insurer determines the provider, practitioner or supplier, or the referral is not in the patient’s best medical interests in the physician’s judgment. *Id.* The compensation arrangement must also be set out in writing, signed by the parties, and specify the services covered by the arrangement, except in the case of a bona fide employment relationship (for which no writing is required).

³⁴ 31 U.S.C. §§ 3729-3733; see, e.g., N.Y. FIN. LAW §§ 187-194.

impermissibility under the Stark Law or the Anti-Kickback Statute.³⁵ An FCA action can be initiated by a *qui tam* whistleblower such as a current or former employee (the private initiator of an FCA case is called a “relator”). The *qui tam* provisions of the FCA greatly increase the potential number of enforcers of the Anti-Kickback Statute and the Stark Law, and in the last two decades, the FCA has become the most important vehicle for enforcing cases of health care fraud.³⁶

It has long been noted that the use of the FCA to enforce cases of health care fraud and abuse may lead to adverse results in the development of the law. Because of the federal health care program exclusion consequences of being found in violation of the Anti-Kickback Statute or the Stark Law—a death sentence to most health care providers, and certainly to most AMCs—most of these enforcement cases are settled rather than tried to a judge and jury. As a prominent health policy academic noted almost fifteen years ago:

The broad contours of the Act give prosecutors the freedom to develop creative new theories of falsity and fraud, often with the assistance of *qui tam* relators. When health care FCA suits are settled rather than tried, these innovative theories are not subject to review by a court—raising the very real possibility that federal prosecutors are themselves “legislating” an expansion of the law.³⁷

The risks are compounded as more and more FCA cases initially are brought by relators, and the regional U.S. Attorney offices that evaluate the cases may lack the deep experience with health care law and policy that would allow them to reject

³⁵ See 42 U.S.C. § 1320a-7b(g) (“In addition to the penalties provided for in this section or section 1320a-7a of this title, a claim that includes items or services resulting from a violation of this section [the Anti-Kickback Statute] constitutes a false or fraudulent claim for purposes of subchapter III of chapter 37 of Title 31 [the FCA]”); *U.S. ex rel. Bartlett v. Ashcroft*, 39 F. Supp. 3d 656, 673 (W.D. Pa. 2014) (citing *U.S. ex rel. Schmidt v. Zimmer, Inc.*, 386 F.3d 235, 243 (3d Cir. 2004)) (“[B]ecause a certificate of compliance with Federal healthcare law is a prerequisite to eligibility under the Medicare program, [the hospital’s] submission of Stark-tainted claims to Medicare constitute ‘false claims’ for purposes of the FCA.”).

³⁶ For example, in its most recent semiannual report to Congress, the OIG indicated that it expected recoveries of about \$4.46 billion relating to OIG “investigative receivables” for federal fiscal year 2016. OIG, *Semiannual Report to Congress* (Apr. 1, 2016 to Sept. 30, 2016) at iv (“Investigative receivables are expected recoveries from criminal actions, civil and administrative settlements, civil judgments, or administrative actions that resulted wholly or in part from an OIG investigative activity.”).

³⁷ J. Krause, *Promises to Keep: Health Care Providers and the Civil False Claims Act*, 23 CARDOZO L. REV. 4, 1363, 1368 (2002).

questionable legal theories. Moreover, the analysis required in these cases does not lend itself to easy judgment about what is right and wrong. This point was illustrated in the unusually frank concurring opinion of a Fourth Circuit judge in a recent FCA case, who stated the Stark Law presented “[a]n impenetrably complex set of laws and regulations that will result in a likely death sentence for a community hospital in an already medically underserved area,” calling such situation a “troubling picture.”³⁸

Another troubling aspect of the use of the FCA to address the complexities of the application of the Anti-Kickback Statute and the Stark Law to the AMC world is that just dealing with allegations based on these highly fact-specific statutes has serious cost implications. For example, a report issued in 2012 stated that the average OIG subpoena or Department of Justice (DOJ) civil investigative demand (CID) can cost an institution an average of \$500,000 to \$1,500,000 before the DOJ elects to either intervene or decline to intervene in the matter.³⁹ The report then stated that since March 24, 2010, when the Attorney General of the United States issued a rule delegating the authority to issue a CID to all U.S. Attorneys, the use of CIDs has “proliferated,” with DOJ attorneys issuing over 500 CIDs in the fourth quarter of 2010, “which is more than six times the number of CIDs requested during the two preceding years combined.”⁴⁰

Wherever one stands in the debate over the use of the FCA in enforcing the Anti-Kickback Statute and the Stark Law, it should be clear that there are risks to the health care system. In light of the historic importance of AMCs to our educational and health care systems, these risks argue for especially thoughtful application, and cautious expansion, of these laws in this area.

³⁸ See *United States ex rel. Drakeford v. Tuomey Healthcare Sys.*, 675 F.3d 394, 390 (4th Cir. 2012).

³⁹ McDermott et al., *Modern False Claims Act Practice – It Ain't the Same Since It all Changed*, American Health Lawyer's Association Health Care Compliance Association Fraud and Compliance Forum (Oct. 1-2, 2012) at 2, available at https://www.healthlawyers.org/events/programs/materials/documents/fc12/203_mcdermott.pdf.

⁴⁰ *Id.* at 8 (quoting Statement of Assistant Attorney General for the Civil Division Tony West before the Senate Committee on the Judiciary, January 26, 2011, available at <https://www.justice.gov/sites/default/files/testimonies/witnesses/attachments/2015/01/22/01-26-11-civ-west-testimony-re-protecting-american-taxpayers-significant-accomplishments-and-ongoing-challenges-in-the-fight-against-fraud.pdf>).

D. A Note on the Internal Revenue Code: Tax-Exempt Organizations

Arrangements that may trigger Stark Law or Anti-Kickback Statute concerns also may implicate the excess benefit transactions principles of the Internal Revenue Code. Simply put, tax-exempt organizations may not permit any part of their revenues to confer a private benefit or private inurement. The Internal Revenue Service has recognized that financial arrangements that violate the Stark Law or the Anti-Kickback Statute likely also implicate these principles, by conferring an excess benefit on the involved physicians.⁴¹ The consequences of an Anti-Kickback Statute or Stark Law violation thus could include a threat to an AMC's 501(c)(3) status. However, the IRS has made clear that it does not intend to become an additional enforcer of these statutes, and will limit its interest to cases where a clear violation of the Anti-Kickback Statute or the Stark Law has been established by a court or the enforcing agency.⁴² Moreover, our research has revealed no instances where the agency attempted to impose sanctions on a tax-exempt organization on such basis.

III. Common Mission Support Strategies

Broadly speaking, Mission Support agreements can involve "fixed amount" payment methodologies and/or "variable amount" payment methodologies. While the methods are enormously variable, for pedagogical purposes we attempt to provide a framework.

A. Mission Support in Fixed Amounts

One historically standard (although as we noted in our introduction, decreasingly common) method of fixed payment is a block grant, whereby the payment amount is determined for a given period, often based on the prior period's financials, and such amount is not determined based on a hospital's revenues or operating margin. Strategic

⁴¹ See G.C.M. 39,732 (1987).

⁴² *Id.* ("Where the courts and the administrative agency responsible for administering a non-tax statute have not spoken to its application to a particular arrangement, we should not rush to do so unnecessarily.").

targeted support strategies are also considered Mission Support arrangements of a fixed variety. Such strategies may include payments for faculty recruitment or retention (where there is demonstrable community or academic need), for sponsored research (with or without intellectual property or royalty rights), or for particular areas of capital investment (such as an annual commitment for research infrastructure or the medical library). The donation of capital assets (e.g., a medical office building) has been another fixed amount Mission Support strategy. Two OIG advisory opinions have declined to impose sanctions in situations where clinical components of an AMC donated capital assets to academic components.⁴³

B. Variable Amounts

Variable amount Mission Support payment methods can be grouped into several overarching types. One standard type of methodology is where the Mission Support payment is tied to the clinical enterprise's financial performance. "Financial performance" arrangements can take many forms. One such form is where the net operating margin serves as a trigger for the annual payment, and the payments made based on this trigger are set in advance by written agreement.⁴⁴ Another performance-based structure is where the academic entity receives a fixed percentage of the clinical entity's net revenue with no specific margin trigger.⁴⁵ A related structure is a payment based on net revenue but including a partial, fixed guarantee, so that the overall payment is tied to some financial metric but with a payment floor.⁴⁶ Some structures blend certain of these strategies, such as a guaranteed base payment of a certain

⁴³ See OIG Adv. Op'n No. 00-06 (Oct. 6, 2000) (academic space in hospital-owned building); OIG Adv. Op'n No. 05-11 (Aug. 16, 2005) (medical office building for use as a family medicine clinic).

⁴⁴ E.g., (i) when net operating revenues are positive and between 0-3% of net patient service revenues, a payment of 4% of net operating revenues shall be made; (ii) when net operating revenues are between 3% and 5% of net patient service revenues, a payment equal to "i" above plus 8% of the incremental net operating revenues above 3% shall be made; (iii) etc. (additional incremental tiers). A second example is where the payments increase over time.

⁴⁵ E.g., the medical school shall receive a Mission Support payment from the health system equal to 5% of system net patient service revenue of the prior fiscal year.

⁴⁶ E.g., a Mission Support payment from the health system to the dean of the medical school of 3% of the system's net patient service revenues. However, the health system guarantees an annual payment floor of \$1.1 million under this Mission Support provision.

percentage of net revenues, along with a tiered, contingent payment that depends on an operating margin or other financial performance measure.⁴⁷

Other Mission Support payment methodologies may not be focused on the financial performance of the clinical entity. For example, the ultimate goal of a Mission Support arrangement may be to have the same operating margin in each of the AMC components—the hospital and the academic enterprise. To effectuate such goal, funds are transferred from one component to the other as needed to equalize the operating margins between the hospital and university. There are also “collaborative” Mission Support payment arrangements, in which, for example, the agreement between the parties calls for them to negotiate the annual amount in good faith if the health system component determines that the existing allocated amount is overly burdensome. This tends to work best when there is a good deal of trust among the parties, such that the university or other recipient of the Mission Support payment can be confident that the hospital will not make sudden changes in the size of the payment.⁴⁸ One type of such arrangement is a “fixed amount unless” Mission Support payment, where the annual base payment is fixed at a default amount but some or all may be subject to “good faith” negotiation at a high level of responsibility, somewhat distanced from on-the-ground referrals, in the event of revenue shortfall.⁴⁹ A similar method is where the annual block payment is reviewed after an initial period of time for sustainability, but the underlying agreement ensures that the payment level following any such review and resulting dispute resolution will fall within a corridor that is fixed at the time of initial agreement.

⁴⁷ *E.g.*, a three-tiered payment system structured as follows: (i) “Dean’s Tax” of 4% of overall system net service patient revenues; (ii) modest annual fixed grant (less than 0.5% of the entire system funds flow) from the clinical enterprise to the dean of the school of medicine to be used for furthering the academic mission of the school; and (iii) net operating margin tier, where school of medicine receives no payment if the annual adjusted operating margin of the clinical enterprise is less than 5%, but if the adjusted operating margin is: (i) between 5% and 7.5%, then school receives 10% of the increment over 5%; (ii) between 7.5% and 9%, then school receives 25% of the increment over 7.5%; (iii) etc. (additional incremental tiers).

⁴⁸ This occurs most commonly where the clinical enterprise and academic components are closely aligned, such as when they are part of the same university parent and/or have identical boards.

⁴⁹ *E.g.*, “The health system shall promptly notify the university in writing in the event that it learns that existing revenues will no longer be available in amounts sufficient to permit the health system to make the supplemental payment to the university in any given fiscal year. The parties shall discuss and explore the availability of potential alternative sources of revenues.”

C. A Couple of Additional Considerations for All Payment Methodologies

In designing a Mission Support arrangement, there are certain details that must be considered regardless of the particular support type or payment methodology.

One important consideration is which entity should receive the Mission Support, an issue that may matter for purposes of the attenuation of physician compensation from volume/value of referrals under the Stark Law. The most common potential recipients are the university, the school of medicine, the dean of the school of medicine, or one or more particular departments (*i.e.*, to the department chair). For reasons described in the following parts, the narrowest of these recipients—a particular department—poses the most risk under the fraud and abuse laws.

Another significant factor to address is the formula for distribution. For both Anti-Kickback Statute and Stark Law purposes, the amount actually paid to the physician must be FMV and not take into account the volume or value of referrals. Our description of possible payment types has focused on the clinical entity's contribution to the academic components of an AMC. However, the formula through which the academic entity receiving the Mission Support payment compensates its physicians is equally important, in large part because it may include, or may be deemed to include, part of the clinical entity's contribution. It is commonplace to give a certain amount of incentive funding to department chairs for distribution to the physicians in their departments. Scrutiny of the formula used by the chairs is an important part of a compliance program. Not only must Mission Support payments not take into account referrals to the hospital, such payments also generally may not take into account the volume or value of the physician's referrals for DHS provided within the medical school departments (*e.g.*, clinical laboratory, imaging).

IV. Halifax

A. The Case

The 2013 federal district court opinion in *United States v. Halifax Hospital Medical Center* granting summary judgment to the government raised concerns for AMC Mission Support given its analysis of the indirect compensation exception.⁵⁰ In *Halifax*, six medical oncologists were employed by Halifax Staffing, Inc., a not-for-profit corporation that was an instrumentality of Halifax Hospital Medical Center (Halifax Hospital).⁵¹ Effectively, the doctors employed by Halifax Staffing were indirectly employed by the Hospital.⁵² A portion of the compensation paid to the medical oncologists was drawn from an “incentive compensation pool” equal to 15% of the operating margin of Halifax Hospital’s medical oncology program.⁵³ The operating margin of the Halifax Hospital’s medical oncology program consisted in part of revenue from (1) the technical component of services personally performed by the medical oncologists at Halifax Hospital, and (2) outpatient oncology drugs ordered by the medical oncologists, both of which the court concluded constitute DHS.⁵⁴ The incentive compensation pool was divided among the medical oncologists on the basis of their personal productivity.⁵⁵ According to the relator in the case, between 2005 and 2008, the six oncologists generated collective patient service revenue that ranged from \$2,801,477 to \$3,941,050 and received bonus compensation from an incentive compensation pool that ranged from \$223,940 to \$290,252.⁵⁶

⁵⁰ 2013 WL 6017329 (M.D. Fla. Nov. 13, 2013).

⁵¹ *Id.* at *1.

⁵² See *id.* (“[Halifax Staffing] is an instrumentality of Halifax Hospital. Halifax Staffing employs the individuals who work for Halifax Hospital. Halifax Hospital pays all of the expenses and obligations of Halifax Staffing, including payroll, either directly or by transfer of funds into Halifax Staffing’s payroll account.”).

⁵³ *Id.* at *2.

⁵⁴ *Id.*; see 42 C.F.R. § 411.351 (defining DHS). While a service that is personally performed by the referring physician does not constitute a “referral” under the Stark Law, see *id.*, courts have held that the *technical component* of personally performed services does constitute a referral for “hospital inpatient services” or “hospital outpatient services,” both of which are DHS under the Stark Law. See *Tuomey*, 675 F.3d at 406-407.

⁵⁵ *Halifax*, 2013 WL 6017329, at *3.

⁵⁶ See Relator Elin Baklid-Kunz’s Mot. for Partial Summ. J. and Supporting Legal Mem. at Ex. 11 (Docket No. 274), *Halifax*, 2013 WL 6017329; see also Pl. United States’ Mot. for Partial Summ. J. (Docket No. 272) ¶ 44, *Halifax*, 2013 WL 6017329. Although these annual bonus compensation numbers are taken from the relator’s and government’s briefing, the defendants appeared to agree with them for the

The *Halifax* lawsuit was brought as a *qui tam* lawsuit in which the DOJ intervened.⁵⁷ The DOJ maintained that the relationship between the medical oncologists and Halifax Hospital was an indirect compensation arrangement because Halifax Staffing, Inc. functioned as an intermediary between the physicians and the hospital.⁵⁸ The government contended that, because the operating margin from which the incentive compensation pool was drawn consisted of revenue derived in part from referrals made by the medical oncologists to Halifax Hospital, the operating margin necessarily took into account the volume or value of referrals.⁵⁹

Halifax Hospital raised several arguments in response. It insisted that the relationship between it and the medical oncologists is a direct compensation arrangement that qualifies for the Stark Law's exception for *bona fide* employment relationships.⁶⁰ It also asserted that the compensation received by an individual medical oncologist did not vary with his or her referrals to Halifax Hospital for two reasons.⁶¹ First, the amount an individual practitioner was paid was determined based on the services that he or she personally performed.⁶² Second, the relationship between the size of the incentive compensation pool and referrals made by the medical oncologists was extremely attenuated because the operating margin on which the incentive compensation pool was based included revenues other than those stemming from referrals by the medical oncologists, and such revenues were offset by a number of expenses to determine the final operating margin.

The district court's decision largely sided with the government. First, it found that analysis of the arrangement would be identical under the indirect compensation exception or the exception for *bona fide* employment relationships because to qualify for either exception, the compensation received by the physician cannot vary with or take

purposes of their briefing on summary judgment. See Defs.' Resp. to U.S. Mot. for Partial Summ. J. at 3 (Docket No. 313), *Halifax*, 2013 WL 6017329 ("The total bonus pool averaged approximately \$250,000 per year . . .") and *id.* at 3 n.4 ("A table of these payments is set out in Relator's pending motion ([Docket No. 274])").

⁵⁷ *Halifax*, 2013 WL 6017329, at *2.

⁵⁸ *Id.* at *9.

⁵⁹ *Id.* at *8.

⁶⁰ *Id.*

⁶¹ *Id.*

⁶² *Id.*

into account the volume or value of referrals to the entity furnishing DHS.⁶³ Next, the court stated that the compensation arrangement at issue failed to meet the relevant Stark Law exceptions because additional referrals of DHS by the medical oncologists to *Halifax* “would be expected to increase the size of the pool [from which bonuses were paid],” and “[a]ll other things equal, this would in turn increase the size of the [bonus] received by the referring [physician].”⁶⁴ Accordingly, the compensation received by the medical oncologists took into account the volume or value of the medical oncologists’ referrals to Halifax Hospital. Finally, the court held that “personal productivity” does not validate an incentive pool that takes into account the volume or value of referrals and, therefore, in the case before it, it did not matter that the actual bonus amounts paid to each physician were determined based on the physician’s personal productivity, because this “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.”⁶⁵

The *Halifax* case was set to go to trial on the level of damages, but settled in the spring of 2014 for \$85 million.⁶⁶

B. Implications for AMC Mission Support Payments

Although the *Halifax* case did not involve Mission Support payments between component parts of an AMC, it bears similarity to some Mission Support arrangements in that a pool of funds that was calculated based on an amount earned by the Hospital was made available to the employer of referring physicians (*i.e.*, Halifax Staffing) and used for physician compensation—the pool included revenue earned from DHS referrals by the referring physicians. As discussed above, this historically has not been an uncommon AMC Mission Support strategy. Holding all else equal, the court concluded that the referring physicians could increase the size of the pool available for their compensation by increasing their referrals of DHS to Halifax Hospital, and that this

⁶³ *Id.* at *9.

⁶⁴ *Id.* at *8.

⁶⁵ *Id.* at *9.

⁶⁶ See <http://www.modernhealthcare.com/article/20140303/NEWS/303039970>.

was sufficient to cause their compensation impermissibly to take into account volume or value of referrals under the Stark Law.

Further, although the district court's reasoning that "the fact that each oncologist could increase his or her share of the bonus pool by personally performing more services 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" is only addressed toward the Stark Law, the absence in the court's discussion of any consideration of attenuation between compensation and the value or volume of referrals by the court suggests that, if presented with an alleged Anti-Kickback Statute violation, the *Halifax* court would not have had trouble concluding that one purpose of the bonus arrangement was to induce referrals for services reimbursed under a federal health care program, thus also leading to a violation of the Anti-Kickback Statute under the "one purpose" test.⁶⁷ In other words, the *Halifax* court's reasoning suggests that it may have also reached an outcome favorable to the government relating to this key element of an Anti-Kickback Statute claim, had an Anti-Kickback Statute claim been raised in the motion before the court. Thus, to the extent that *Halifax* creates a dangerous precedent with respect to the Stark Law, one could argue that it is also persuasive authority for a future Anti-Kickback Statute claim.

However, there are several potentially significant distinctions between the facts in *Halifax* and Mission Support arrangements.

- First, the funds from which the incentive pool were drawn were in essence a percent of profits, or revenues net of expenses, both triggered by and calculated based on the department's profitability. The case did not consider whether an incentive pool would avoid the volume or value prohibition if it were triggered by profitability, but calculated based on some other non-volume measure, such as reduced cost per case.

⁶⁷ See *id.* at *9; *United States v. Greber*, 760 F.2d 68, 72 (3d Cir. 1985) (holding that the Anti-Kickback Statute is violated if "one purpose" of a payment is to induce referrals).

- Second, the *Halifax* case does not speak at all to arrangements that are not based on a hospital's financial performance, for example, annual block grants based on medical school expenses, or payments based on patient outcomes or patient satisfaction.
- Third, in *Halifax*, the arrangement under scrutiny involved an incentive compensation pool for a single department consisting of only six physicians who, based on the relators' briefing on summary judgment, themselves appear to have generated almost 10% of the hospital medical oncology program's gross revenues over the 2005-2008 timeframe.⁶⁸ Although the *Halifax* court rejected arguments that the relationship between the oncologist referrals and their compensation was sufficiently attenuated to avoid taking into account volume or value of referrals, the court was not presented with facts involving many more revenues from many more sources divided over many more uses.
- Fourth, the court was not presented with Mission Support having broader uses than just physician salaries. Most Mission Support payments are used for many purposes beyond physician compensation. For example, funds may be used to cover research expenses or to provide indigent care, two purposes that CMS has recognized as being an appropriate use of a Mission Support payment, in support of the tripartite mission.⁶⁹

These distinctions could lead even a court applying the *Halifax* analysis to a different conclusion if presented with common AMC Mission Support facts. However, it is not implausible that an aggressive *qui tam* relator, or even U.S. Attorney's office, could attempt to bring a case against an AMC based on Mission Support arrangements that, as discussed above, are not uncommon. At this time, *Halifax* applies only in one federal district court jurisdiction, and only relates to the Stark Law, but relators' counsel and DOJ likely will advance the arguments made in the *Halifax* case in other jurisdictions

⁶⁸ This percentage is calculated based on the annual gross revenue generated by the physicians over this five-year timeframe (an average of \$3,815,067 per year), divided by the annual gross revenue generated by the entire medical oncology program over the same timeframe (an average of \$42,299,814 per year). See Relator Elin Baklid-Kunz's Mot. for Partial Summ. J. and Supporting Legal Mem., *supra* note 56, at Ex. 11 (providing annual revenue tables from which we derived these amounts and percentage).

⁶⁹ See 42 C.F.R. § 411.355(e).

and could advance the reasoning demonstrated in *Halifax* in support of an Anti-Kickback Statute claim as well. The possibility of future case law developments to the Stark Law that are similar to the reasoning offered in *Halifax* is problematic—a threat to the existing operations of AMCs. Thus, the next part discusses what might be the implications were such a case to be brought.

V. Implications and Alternatives for Future Mission Support Strategies

As noted above, the complexity of the Stark Law and Anti-Kickback Statute jurisprudence, and the risks inherent in the development of the law through the FCA, conspire to create a situation where a recognized health care public policy acceptance of supporting AMC operations could fall victim to laws designed to address altogether different situations. This part attempts to create a framework for protecting AMC Mission Support from such results.

A. Identifying AMC Mission Support That Should Be Easily Defended Against *Halifax*

Mission Support payments based on fixed amount and “collaborative” methodologies are unlikely to be affected by the *Halifax* decision. Block grant payments do not vary with the amount of DHS referrals made by university or school of medicine-employed or affiliated physicians, although the block grant payment rationale and calculation should be clearly documented to demonstrate that such payment is truly not a proxy or pure quid pro quo for past or anticipated referrals. Donations of capital assets is another Mission Support vehicle unlikely to be affected by *Halifax* based upon the analysis provided by the OIG in the pertinent advisory opinions, assuming that the risk-mitigating features described in the opinions are adhered to as much as possible to mitigate Anti-Kickback Statute risk.

Mission Support payments made under the collaboration model arrangements described in Part IV are most likely outside of *Halifax*'s holding and, in large part, even outside of its reasoning, as there is no necessary tie between payment level and the

volume of referrals when employing this structure. Nonetheless, as with block grants or any other Mission Support methodology, it is important to document the rationale and calculations made in determining a payment made under the collaboration model, as one could envision a scenario in which the adjustments could appear to be a proxy for referrals.

B. Defending AMC Mission Support That Is More Vulnerable To Halifax

1. Legal Arguments That Distinguish Halifax from AMCs

In contrast to the fixed payment methodologies, virtually all of variable payment methodologies have some theoretical degree of vulnerability under *Halifax*, although the degree of vulnerability depends on how closely the facts adhere to those presented in *Halifax*. Payments based on a percentage of net operating margin of a *single department* and used for physician compensation are the type of payments described in *Halifax* and are therefore most vulnerable to attack under the reasoning offered in that opinion. Each of the five examples of variable funding methodologies described in Part IV would fall into this category if the payments are calculated on the basis of a single department.⁷⁰

By contrast, the *Halifax* holding arguably should not apply to variable funding methodologies based on a system- or hospital-wide operating margin metric, as opposed to a department-based or other designation of similar specificity. The difference between the limited number of participants involved in the *Halifax* scenario—six physicians generating 10% of the operating margin of a department in which they were directly involved—and an agreement in which Mission Support payments are based on an aggregate operating margin metric at the hospital or health system level (probably a more common operating margin-based Mission Support arrangement) is a significant basis for distinction. Nonetheless, while all of the five variations of variable

⁷⁰ The five variations of variable payment models that we described in Part IV are as follows: (1) tiered payments set at a percentage of net operating revenues, where the tier is triggered on the basis of an operating margin; (2) payments calculated as a percentage of net patient service revenues in which the percentage payment increases over time; (3) payments calculated as a straight percentage of revenue; (4) payments calculated as a straight percentage of revenue with a partial guarantee provided; and (5) guaranteed base payment and a contingent payment tied to a financial performance measure.

payment models that we described could be justified if this distinction is valid, it must be noted that the *Halifax* court's dicta rejected the attenuation argument and focused on the simple reasoning that if the bonus pool included revenues from referring doctors, it caused the size of the pool (and therefore the ultimate amounts of bonus) to take into account volume or value of referrals.

Another basis for distinction from *Halifax* exists if the funds under a variable payment methodology are distributed to the more general university entity without any formal mechanism by which such funds are automatically directed to a specific component of such entity, e.g., distribution of funds to the medical school without a fixed percentage of such funds earmarked for the general surgery chair within the medical school.

Finally, *Halifax's* holding also does not seem to affect the use of an operating margin, whether department or hospital-wide, only as a trigger to determine whether a fixed payment, or payment calculated in some other way, will be made at all. While a physician could theoretically make the payment of incentive compensation more likely by increasing his or her DHS referrals, it would seem to be an expansion of the court's decision to state that use of a payment trigger based on operating margin is prohibited wholesale. Again, the distinction from *Halifax* is greater if the fixed payment, with a trigger, is made to the broader entity (*i.e.*, the medical school as opposed to a department chair). Nonetheless, even though we have articulated bases for distinction from *Halifax*, we again note that the *Halifax* court's dicta rejected an attenuation argument.

2. *Policy Reasons to Differentiate AMC Mission Support from Halifax*

We have described why variable Mission Support payment methodologies have some element of risk under the fraud and abuse laws. All of the distinctions noted above between these methodologies and *Halifax* rely on a strict reading of the court's holding, and the notion that a more forgiving standard regarding when compensation takes into account volume or value of referrals should be applied when there are greater degrees of attenuation.

There are several reasons supporting the argument that a court should read *Halifax* in this fashion, so that variable payment Mission Support strategies do not violate the Stark Law (or Anti-Kickback Statute). One reason is that the AMC context is categorically different than the situation described in *Halifax*. Halifax Hospital was not an AMC, so the historic tolerance of OIG and CMS for the shared mission of medical care and education was absent. It may be argued that the standard the *Halifax* court applied is not appropriate where the government has recognized the appropriateness of complex financial relationships in support of a shared tripartite mission.

Additionally, not recognizing the unique nature of the complex financial relationships in an AMC setting could be a simply untenable result for AMCs as a matter of public policy, helping to frame an argument before a court that the Anti-Kickback Statute and Stark Law could not possibly be designed to cover good-faith Mission Support arrangements. A hospital's ability to provide Mission Support logically has to depend on its financial performance; a hospital that is losing money on its basic operations may not be able to sustain itself if its commitment to Mission Support cannot take financial performance into account through one or more of the general methodologies outlined above. The *Halifax* facts were especially easy to challenge: revenue from DHS referrals from a small number of doctors going directly to an incentive pool for those doctors. While the court was not persuaded that using operating margin as opposed to revenue was sufficient to break the take-into-account connection, it may logically be argued that the greater degrees of separation noted above—payment based on hospital or system margin rather than department, and payment to university or medical school rather than department—sufficiently reduce the impact of any one doctor, or any one department, to break that connection.

Finally, at present, it appears that *Halifax* remains the view of a single federal district court, so any legal argument made in the future should include the grounds that the *Halifax* court was simply incorrect on the Stark Law. It may be argued that the court largely ignored the language and logic of the indirect compensation exception, which looks only to the amount actually paid to a physician, and not to amounts paid between entities “up the chain.” The opportunity to argue against *Halifax*'s holding would be on

stronger ground in an AMC setting than in the *Halifax* setting, as the policy arguments associated with the tripartite mission could be used (anchored in law by the government's past recognition of the legitimacy of this mission and funding flows supporting it) to bolster an AMC defendant's arguments.

3. *Compliance Strategies to Reduce Risk*

The absence of a limiting principle in the *Halifax* decision at least makes vulnerable to challenge all of the variable compensation models that we have described. Accordingly, AMCs should always consider using as many of the following specific strategies as possible to help insulate their Mission Support payment methodology from challenge under the fraud and abuse laws.

- First, basing the amount of Mission Support payments on the AMC's documented (or reasonably projected) costs of operation will present fewer concerns, as attribution of Mission Support funds to individual physicians is less likely to be viewed as taking into account the volume or value of referrals if based on the medical school's costs than if the base amounts are tied to the hospital's profitability.
- Second, the particular measures used to calculate physician compensation within the AMC setting should always be documented in detail in writing, in order to allow for differentiation from *Halifax* on the basis that the indirect compensation exception must apply because the compensation decision accounts for the factors underlying that exception, including personal productivity, quality measures, or any other factors not tied to the volume or value of referrals generated.
- Third, as we have repeatedly noted, *Halifax* relied on a small group of physicians within a single department; thus, if operating margin is used to determine the Mission Support payment, it should be a hospital- or system-wide margin instead of a department-specific margin.

- Finally, it would be best if particular Mission Support payments were not used exclusively for physician compensation. As *Halifax* dealt with a physician incentive pool, the court’s reasoning would not seem to apply to funding—even if based on revenue or operating margin—that is specifically directed to uses other than physician compensation. Uses such as capital construction, recruitment expenses attributable to community or academic need, clinical research expenses, and physician office expenses such as nursing or staffing support—so long as such expenses are not simply vehicles for physician salary support—elucidate the favorable elements of the tripartite mission and thereby are persuasive elements in support of an argument that a particular Mission Support payment strategy is not simply a masked payment for referrals.⁷¹

VI. Conclusion

Halifax suggests that when a hospital’s financial support for its referring physicians depends on hospital profitability, the Stark Law and the Anti-Kickback Statute could be implicated. Profitability naturally underlies many Mission Support arrangements, because the level of support by an AMC of its typically revenue-poor education and teaching missions naturally depends on the financial health of the institutional clinical enterprise, where the vast majority of the AMC’s revenues are generated. Thus, it is unsurprising that *Halifax* has triggered persistent interest from AMC clients regarding how to ensure that their funds-flow transfers among its component parts do not trigger any problems under the federal fraud and abuse laws. In this article, we have provided the background on AMCs, Mission Support, and the federal fraud and abuse laws that we submit must be understood collectively to understand *Halifax*’s possible application in the AMC setting. We have noted that there are important differentiating factors between *Halifax* and most properly documented and structured Mission Support

⁷¹ Of course, one could always argue that payments for these other categories of expenses within an AMC are simply freeing up additional funding for physician compensation. However, it seems to us that such an argument would be a significant expansion of the *Halifax* court’s reasoning.

arrangements, and the points of differentiation and safeguards described in this article can serve to mitigate threat of legal action based on *Halifax*-style arguments.

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