# THE ACADEMIC MEDICAL CENTER EXCEPTION TO THE STARK LAW: COMPLIANCE BY TEACHING HOSPITALS



## INTRODUCTION

The Stark Law (Stark) prohibits physicians from referring Medicare or Medicaid patients for services or care to entities with which the physicians have a financial relationship.[1] Medical school faculty members typically both refer their patients to the school's affiliated academic medical center (AMC)[2] and receive a portion of their compensation from the AMC.[3] The

1. The legislation is named for its Congressional sponsor, Representative Fortney "Pete" Stark of California. Stark Law, Pub. L. No. 101-239, 103 Stat. 2236 (1989) (codified as amended at 42 U.S.C. § 1395nn(a) (2006)).

2. The exception applies to any designated health services provider component of an AMC, which usually includes a medical school, a teaching hospital affiliation, and a research program. *See* ROBERT

Stark Law presents an obvious challenge to this common and longstanding practice. Congress recognizes that applying Stark in the AMC context would not only be disruptive, but might even preclude patients from receiving care at the best available facility, as the AMC hospital is often the premier hospital in the area.[4] Congress thus created a limited exception to the law that applies exclusively to qualifying AMCs and their referring physicians.[5]

This Note addresses the current state of the AMC exception to the Stark Law, and the issues that AMCs face in complying with the law. Part I introduces the reader to the Stark Law and its requirements before discussing the AMC exception and the regulations that have interpreted it. Part I also discusses *United States* ex rel. *Villafane v. Solinger*,[6] the only case to have analyzed the AMC exception. Part II introduces issues that exist with the current state of the AMC exception, particularly in the wake of the *Villafane* decision, and suggests possible solutions to those issues. Specifically, Part II addresses five issues: insistence that the arrangement fit into the AMC exception and not be allowed to meet an easier and less complex requirement, the overlap between the AMC exception and other Stark Law exceptions, retroactive application of the AMC exception, the value–volume standard and year-to-year correlation, and the intent element hidden within a flexible approach to the requirements. Finally, Part III discusses the future implications of the exception for AMCs that attempt to comply with the Stark Law, such as the need to evaluate individual AMC compliance and the suggestion to fight for a more straightforward, simplified regulatory framework.

## I. THE STARK LAW AND THE AMC EXCEPTION

The Stark Law was first passed in 1989 when Congressman Pete Stark proposed legislation to establish a bright-line test "to determine whether impermissible conflicts of interest were present in physician arrangements, regardless of the parties' intent."[7] Congressman Stark was frustrated by

B. TAYLOR, ACADEMIC MEDICINE: A GUIDE FOR CLINICIANS 54 (2006). Famous examples on television include those hospitals portrayed in ABC's "Grey's Anatomy" and "Scrubs," CBS's "Chicago Hope," Fox's "House, M.D." and NBC's "ER." "Real life" examples include Georgetown University Hospital, Johns Hopkins Hospital, Massachusetts General Hospital (Harvard), Stanford University Medical Center, and University of Chicago Medical Center. For background information on AMCs, see TAYLOR, *supra* at 53–90.

3. *Attorneys Comment on Stark II Final Rule, Applauding Added Flexibility for Providers*, Medicare Rep. (BNA) No. 12, at 208 (Feb. 16, 2001).

4. *See* United States *ex rel.* Kosenske v. Carlisle HMA, Inc., No. 1:05-CV-2184, 2007 WL 3490537, at *6 (M.D. Pa. Nov. 14, 2007), *rev'd*, 554 F.3d 88 (3rd Cir. 2009).

5. Stark Law, 42 U.S.C. § 1395nn (2006).

6. 543 F. Supp. 2d 678 (W.D. Ky. 2008).

7. David M. Deaton, *What is "Safe" About the Government's Recent Interpretation of the Anti-Kickback Statute Safe Harbors? . . . And Since When Was Stark an Intent-Based Statute?*, 36 J.

the severe and inflexible intent element of the Anti-Kickback statute,[8] which, he contended, made it difficult for the statute to effectively "protect against fraudulent overutilization of government-reimbursed healthcare services."[9] Congressman Stark argued that, "[i]f the law is clear and the penalties are substantial, we can rely on self-enforcement. Few physicians will knowingly break the law."[10] Moreover, he thought a bright-line rule would benefit health care providers by giving them "unequivocal guidance" in determining which actions were legal and which were not, and would, at least theoretically, help to minimize administrative costs.[11]

Thus, Congress passed "Stark I," the first enactment of the Stark Law,[12] which prohibited financial relationships between physicians and the clinical laboratories to which they refer patients.[13] In 1993, Congress passed "Stark II," which expanded Stark I to prohibit referrals for a broad range of "designated health services"[14] to any entity with which the physician or an immediate family member of the physician has a financial relationship.[15]

In its primary provision, the Stark Law[16] states that if a physician or member of his immediate family has a "financial relationship"[17] with an entity that provides healthcare services, then:

> (A) [T]he physician may not make a referral to the entity for the furnishing of designated health services for which payment otherwise may be made under this subchapter, and

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HEALTH L. 549, 551 (2004).

8. *See* 42 U.S.C. § 1320a-7b(b)(2) (2006).

9. United States *ex rel.* Villafane v. Solinger, 543 F. Supp. 2d 678, 683 (W.D. Ky. 2008) (citing United States *ex rel.* Thompson v. Columbia/HCA Healthcare Corp., 20 F. Supp. 2d 1017, 1047 (S.D. Tex. 1998); United States *ex rel.* Pogue v. Am. Healthcorp, Inc., 914 F. Supp. 1507, 1513 (M.D. Tenn. 1996)). *See generally* Steven D. Wales, *The Stark Law: Boon or Boondoggle? An Analysis of the Prohibition on Physician Self-Referrals*, 27 LAW & PSYCHOL. REV. 1, 5–8 (2003) (discussing studies and statistics that suggested doctors were beginning to abuse self-referrals and government-reimbursed services).

10. Deaton, *supra* note 7, at 554 (citing 135 CONG. REC. H240-01 (daily ed. Feb. 9, 1989) (statement of Rep. Stark)).

11. *Id.*; Phase I, *infra* note 22, at 860.

12. *See generally* Wales, *supra* note 9, at 7–8 (discussing initial congressional action regarding the Stark Law).

13. Omnibus Budget Reconciliation Act of 1989, Pub. L. No. 101-239, § 6204(a), 103 Stat. 2106, 2236 (1989).

14. These services include clinical laboratory services; physical-therapy services; occupational-therapy services; radiology services; radiation-therapy services and supplies; durable medical equipment and supplies; parenteral and enteral nutrients, equipment, and supplies; prosthetics, orthotics, and prosthetic devices; home health services and supplies; outpatient prescription drugs; and inpatient and outpatient hospital services. David E. Matyas, *Fraud and Abuse, in* FUNDAMENTALS OF HEALTH LAW 138 (3d ed. 2004).

15. Omnibus Budget Reconciliation Act of 1993, Pub. L. No. 103-66, § 13562, 107 Stat. 213, 596–605 (1993) (codified as amended at 42 U.S.C. § 1395nn).

16. 42 U.S.C. § 1395nn (2006).

17. *See infra* note 25 and accompanying text.

> (B) [T]he entity may not present or cause to be presented a claim under this subchapter or bill to any individual, third party payor, or other entity for designated health services furnished pursuant to a referral prohibited under subparagraph (A).[18]

Failure to adhere to the Stark Law results in a variety of sanctions including, but not limited to, the following: denial of payment for a designated health service, requiring refunds on a timely basis for certain claims, a civil money penalty up to fifteen thousand dollars and exclusion for improper claims, and a civil money penalty of up to one hundred thousand dollars and exclusion for circumvention schemes.[19] The denial of payment and requirement of refunds are the primary sanctions. "At its core, [the] Stark [Law] is a payment statute. The primary sanction is the denial of payment or, if amounts have already been billed and collected, the timely refund of the amounts collected."[20] However, in addition to these sanctions, some courts allow the government to use Stark to bring an action under the federal False Claims Act.[21]

Because of these hefty monetary penalties and possible exclusion from participation in the Medicare and Medicaid programs, health care providers tend to have significant anxiety in their attempts to comply with the Stark Law. In an attempt to alleviate some of that anxiety and confusion, the Heath Care Financing Administration (HCFA) and the Center for Medicare and Medicaid Services (CMS), along with the Department of Health and Human Services, have issued three phases of regulations implementing the Stark Law. HCFA's "Phase I" became effective on January 4, 2002.[22] CMS's "Phase II" implemented parts of Stark II that had not been addressed in Phase I and became effective on July 26, 2004.[23] "Phase III" became effective on December 4, 2007.[24]

These regulations define a "financial relationship" to include "[a] direct or indirect compensation arrangement . . . with an entity that furnish-

18. 42 U.S.C. § 1395nn(a)(1).

19. *Id*. § 1395nn(g)(1)–(4).

20. Deaton, *supra* note 7, at 555 (citing 42 U.S.C. §§ 1395nn(g)(1), (g)(2)).

21. *Id*. (citing United States *ex rel*. Thompson v. Columbia/HCA Healthcare Corp., 125 F.3d 899, 903 (5th Cir. 1997); United States *ex rel*. Gublo v. Novacare, Inc., 62 F. Supp. 2d 347, 355 (D. Mass. 1999); United States *ex rel*. Pogue v. Am. Healthcorp, Inc., 914 F. Supp. 1507, 1513 (M.D. Tenn. 1996); United States *ex rel*. Roy v. Anthony, 914 F. Supp. 1504, 1506 (S.D. Ohio 1994)).

22. United States *ex rel*. Villafane v. Solinger, 543 F. Supp. 2d 678, 685 n.7 (W.D. Ky. 2008) (citing Physicians' Referrals to Health Care Entities With Which They Have Financial Relationships, 66 Fed. Reg. 856 (Jan. 4, 2001) [hereinafter Phase I]).

23. *Id*. (citing Physicians' Referrals to Health Care Entities With Which They Have Financial Relationships, 69 Fed. Reg. 16,054 (Mar. 6, 2004) [hereinafter Phase II]).

24. *Id*. (citing Physicians' Referrals to Health Care Entities With Which They Have Financial Relationships, 72 Fed. Reg. 51,011 (Sep. 5, 2007) (codified at 42 C.F.R. pts. 411 and 424) [hereinafter Phase III]).

es [designated health services]."[25] A "compensation arrangement" can be "any arrangement involving remuneration, direct or indirect, between a physician (or a member of a physician's immediate family) and an entity."[26] One might think that the Stark Law is an incredibly harsh requirement that would prevent all financial relationships, no matter how beneficial, between physicians and entities providing these designated health services. However, Congress has recognized that "certain business relationships between physicians and health care entities are both cost effective and beneficial to patient care,"[27] and has thus created a variety of exceptions to the Stark Law.[28] One of these exceptions must be met in order for a physician to refer to the entity, and the exceptions come in three different types: "(1) general exceptions, which are applicable to both ownership and investment interests and compensation arrangements,[29] (2) exceptions related only to ownership or investment interests,[30] and (3) exceptions related only to compensation arrangements."[31]

### *A. History of the AMC Exception*

Initially, AMCs would attempt to comply with Stark Law under the faculty practice plan exception, which stated:

> In the case of a faculty practice plan associated with a hospital, institution of higher education, or medical school with an approved medical residency training program in which physician members may provide a variety of different specialty services and provide professional services both within and outside the group, as well as perform other tasks such as research, [the definition of group

25. 42 C.F.R. § 411.354(a)(1)(ii) (2007).

26. *Id*. § 411.354(c).

27. United States *ex rel*. Kosenske v. Carlisle HMA, Inc., No. 1:05-CV-2184, 2007 WL 3490537, at *6 (M.D. Pa. Nov. 14, 2007), *rev'd*, 554 F.3d 88 (3rd Cir. 2009).

28. *See generally* Wales, *supra* note 9, at 10–12 (providing a general discussion of the exceptions to Stark).

29. Deaton, *supra* note 7, at 555 (citing 42 U.S.C. § 1395nn(b) (2003) and 42 C.F.R. § 411.355 (2002) (listing general exceptions for physician services; in-office ancillary services; services furnished by an organization to enrollees; clinical laboratory services furnished in an ambulatory surgical center or end-stage renal disease facility or by a hospice; academic medical centers; implants in an ambulatory surgery center; EPO and other dialysis-related outpatient prescription drugs furnished in or by an end-stage renal disease facility; preventative screening tests, immunizations, and vaccines; and eyeglasses and contact lenses following cataract surgery)).

30. *Id*. (citing 42 U.S.C. §§ 1395nn(c), (d) (2003) and 42 C.F.R. § 411.356 (2002) (listing exceptions for publicly traded securities, mutual funds, and specific providers)).

31. *Id*. (citing 42 U.S.C. § 1395nn(e) (2003) and 42 C.F.R. § 411.357 (2002) (listing exceptions for rental of office space, rental of equipment, bona fide employment relationship, personal service arrangements, physician recruitment, isolated transactions, arrangements with hospitals, group practice arrangements with a hospital, payments by a physician, nonmonetary compensation up to $300, fair market value compensation, medical staff incidental benefits, risk sharing arrangements, compliance training, and indirect compensation arrangements)).

> practice[32]] shall be applied only with respect to the services provided within the faculty practice plan.[33]

Essentially, this allowed a physician to refer a patient to another doctor within his faculty practice plan. However, HCFA found that "the core problem of how to treat academic medical practices . . . is [not] amenable to resolution under the [faculty practice plan exception]; the problem lies elsewhere."[34] Thus, Congress created a separate exception for "payments to faculty of academic medical centers that meet certain conditions . . . ."[35] The requirements set out in this first codification were liberalized twice in Phases II and III to make it easier for an entity to qualify as an academic medical center.[36]

There exists a lack of prior case law interpreting the AMC exception.[37] Given this lack of precedent, courts rely heavily on the overall purpose of the Stark Law,[38] the purpose of the AMC exception[39] and its regulations, and CMS's explanatory comments[40] for an interpretation of the AMC exception's many elements.[41]

### *B. The AMC Exception Generally*

The AMC exception consists of four different sets of regulations, each of which is discussed, in turn, below. A first set of requirements specifies which referring physicians are eligible to make use of the AMC exception.[42] A second set regulates the total compensation of referring physicians.[43] Third, there are requirements that concern the relationship between the component institutions of academic medical centers.[44] Finally, the terms of the financial relationships between an AMC and its referring physicians must not violate the Anti-Kickback statute.[45] An academic med-

32. 42 U.S.C. § 1395nn(h)(4)(A) (2006).
33. *Id.* § 1395nn(h)(4)(B)(ii) (internal footnotes added).
34. Phase I, *supra* note 22, at 916.
35. *Id.*
36. Phase II, *supra* note 23, at 16,109; Phase III, *supra* note 24, at 51,036.
37. United States *ex rel.* Villafane v. Solinger, 543 F. Supp. 2d 678, 687 (W.D. Ky. 2008).
38. *Id.* ("[Agencies] have focused on achieving a goal, namely prevention of healthcare fraud, more than on ensuring rigid adherence to any particular regulatory provision.").
39. Phase II, *supra* note 23, at 16,108–09 (noting that the purpose of the AMC exception is "to provide protection under [the Stark Law] for academic medical centers [which] often have complex compensation arrangements with their faculty"); Phase III, *supra* note 24, at 51,036 (seeking to "ensure that the [AMC] arrangements pose no risk of fraud or abuse").
40. *See* 42 C.F.R. §§ 411.354–355 (2007); Chevron U.S.A., Inc. v. Natural Res. Def. Council, Inc., 467 U.S. 837, 844 (1984) (discussing the Supreme Court's policy of giving considerable weight and deference to administrative interpretations).
41. *Villafane*, 543 F. Supp. 2d at 687.
42. 42 C.F.R. § 411.355(e)(1)(i)(A)–(D) (2007).
43. *Id.* § 411.355(e)(1)(ii).
44. *Id.* §§ 411.355(e)(2), 411.355(e)(1)(iii).
45. *Id.* § 411.355(e)(1)(iv).

ical center must meet each of the many complex requirements in order to qualify for the exception.

*1. Physician Requirements*

The first category of criteria imposes four requirements on referring physicians themselves. Specifically, the law requires that:

> (i) [A] referring physician—
>
> > (A) Is a *bona fide* employee of a component[46] of the academic medical center on a full-time or substantial part-time basis. . . .
> >
> > (B) Is licensed to practice medicine in the [s]tate(s) in which he or she practices medicine;
> >
> > (C) Has a *bona fide* faculty appointment at the affiliated medical school or at one or more of the educational programs at the accredited academic hospital . . . ; and
> >
> > (D) Provides either substantial academic services or substantial clinical teaching services (or a combination [thereof]) for which the faculty member receives compensation as part of his or her employment relationship with the academic medical center. Parties should use a reasonable and consistent method for calculating a physician's academic services and clinical teaching services. A physician will be deemed to meet this requirement if he or she spends at least 20 percent of his or her professional time or 8 hours per week providing academic services or clinical teaching services (or a combination [thereof]).[47]

"The purpose of this condition is to ensure that protected physicians are truly engaged in an academic medical practice[,] . . . [not] provid[ing] only occasional academic or clinical teaching services or . . . principally

46. A "component" of an academic medical center is defined by the regulations to be "an affiliated medical school, faculty practice plan, hospital, teaching facility, institution of higher education, departmental professional corporation, or nonprofit support organization whose primary purpose is supporting the teaching mission of the academic medical center." *Id.* § 411.355(e)(1)(i)(A).

47. *Id.* § 411.355(e)(1)(i)(A)–(D) (internal footnotes added). Part (D) is often known as the "safe harbor provision." United States *ex rel.* Villafane v. Solinger, 543 F. Supp. 2d 678, 688 (W.D. Ky. 2008).

[acting as] community rather than academic medical center practitioners."[48]

*2. Requirements Concerning Compensation*

The second category of requirements under the AMC exception concerns the total compensation paid to referring physicians. The regulations mandate that the compensation of the referring physician meet all three of the following requirements:

> (A) The total compensation paid by each academic medical center component to the referring physician is set in advance.
>
> (B) In the aggregate, the compensation paid by all academic medical center components to the referring physician does not exceed fair market value for the services provided.
>
> (C) The total compensation paid by each academic medical center component is not determined in a manner that takes into account the volume or value of any referrals[49] or other business generated by the referring physician within the academic medical center.[50]

"The purpose of this requirement is to make sure that physicians are paid based on the value of their work rather than the value of their referral business to the hospitals."[51] Fair market value is defined as "the value in arm's-length transactions, consistent with the general market value."[52]

48. Phase I, *supra* note 22, at 916.

49. HCFA devoted an entire section of its preamble to clarification of this requirement, stating:

> A compensation arrangement does not take into account the volume or value of referrals . . . if the compensation is fixed in advance and will result in fair market value compensation, and the compensation does not vary over the term of the arrangement in any manner that takes into account referrals or other business generated.

Phase I, *supra* note 22, at 877–78.

50. 42 C.F.R. § 411.355(e)(1)(ii)(A)–(C) (2007) (internal footnotes added).

51. United States *ex rel.* Villafane v. Solinger, 543 F. Supp. 2d 678, 690 (W.D. Ky. 2008).

52. 42 C.F.R. § 411.351 ("'General market value' means . . . the compensation that would be included in a service agreement as the result of *bona fide* bargaining between well-informed parties to the agreement who are not otherwise in a position to generate business for the other party, . . . at the time of the service agreement."). Moreover, HCFA provided the following guidance for determining when a payment for services provided is fair market value: "[W]e intend to accept any method [for establishing fair market value] that is commercially reasonable and provides us with evidence that the compensation is comparable to what is ordinarily paid for an item or service in the location . . . ." Phase I, *supra* note 22, at 944; *see* Phase II, *supra* note 23, at 16,107.

*3. Requirements Concerning the Relationship Between the Separate Component Institutions*

The third category of requirements consists of two subcategories concerning the relationship between the components of the academic medical center: (1) issues of accreditation, affiliation, and staffing, and (2) issues of organization and internal financial transfers between the academic institution and the hospital.

Under the first subcategory, the purported AMC must consist of:

> (i) An accredited medical school (including a university, when appropriate) or an accredited academic hospital[53]. . . ;
>
> (ii) One or more faculty practice plans affiliated with the medical school, the affiliated hospital(s), or the accredited academic hospital; and
>
> (iii) 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.[54]

This subcategory of requirements is designed to guarantee that the facilities are "'sufficiently integrated into an academic medical center' and 'that the relationship between the components is sufficiently focused on the academic medical center's core mission.'"[55]

Under the second category, the Stark Law regulations require the following:

> (A) All transfers of money between components of the academic medical center must directly or indirectly support the missions of teaching, indigent care, research, or community service.
>
> (B) The relationship of the components of the academic medical center must be set forth in one or more written agreements or other written documents that have been adopted by the governing body of each component. . . .

53. An "accredited academic hospital" is defined by the regulations as "a hospital or a health system that sponsors four or more approved medical education programs." 42 C.F.R. § 411.355(e)(3).

54. *Id*. § 411.355(e)(2) (internal footnotes added).

55. *Villafane*, 543 F. Supp. 2d at 695 (quoting Phase III, *supra* note 24, at 51,037).

> (C) All money paid to a referring physician for research must be used solely to support bona fide research or teaching and must be consistent with the terms and conditions of the grant.[56]

#### *4. General Anti-Kickback Requirement*

Finally, the AMC exception requires that "[t]he referring physician's compensation arrangement does not violate the Anti-Kickback statute, . . . or any Federal or State law or regulation governing billing or claims submission."[57] For the purposes of the AMC exception, that means that physicians must avoid the inference that they "knowingly and willfully" paid or received money to induce patient referrals.[58]

Additionally, compliance with the Stark Law does not necessarily mean that a physician is not receiving illegal kickbacks[59]:

> [A]lthough many of the standards within the Stark exceptions are very similar to the standards in the Anti-Kickback safe harbors, compliance with a Stark exception does not guarantee compliance with an Anti-Kickback safe harbor. Indeed, Stark sets forth only the minimum standards for permitted financial relationships, not the full range of legally permissible activity.[60]

### *C.* Villafane v. Solinger*: The Lone Court's Decision and Approach*

The AMC exception has been analyzed only once, in *United States* ex rel. *Villafane v. Solinger*.[61] Consequently, at least for now, health care facilities must look to the court's decision in that case for primary guidance in complying with the Stark Law.

#### *1. Facts*

Plaintiff Juan Villafane (Villafane) was a pediatric cardiologist and a former professor at the University of Louisville School of Medicine (Med-

56. 42 C.F.R. § 411.355(e)(1)(iii).
57. *Id.* § 411.355(e)(1)(iv).
58. 42 U.S.C. § 1320a-7b(b)(2) (2006).
59. See Wales, *supra* note 9, at 1–2, for a hypothetical kickback scenario.
60. Deaton, *supra* note 7, at 555 (citing Phase I, *supra* note 22, at 863; Medicare and State Health Care Programs: Fraud and Abuse; Clarification of the Initial OIG Safe Harbor Provisions and Establishment of Additional Safe Harbor Provisions Under the Anti-Kickback Statute, 64 Fed. Reg. 63,518–19 (Nov. 19, 1999) (codified at 42 C.F.R. §§ 1001.951, 1001.952 (2007))).
61. 543 F. Supp. 2d 678, 688 (W.D. Ky. 2008).

ical School).[62] He sued the Medical School's research foundation (Research Foundation) and research fund; his former medical group, of which several other pediatric cardiologists employed by the Medical School were also members; and several of its individual physicians who were members of the Medical School's faculty (Physician Defendants).[63] He also sued Norton Hospitals, Inc., d/b/a/ Kosair Children's Hospital (Kosair), Kentucky's only freestanding, full-service pediatric hospital,[64] and Larry Cook, the chief of its medical staff.

The lawsuit concerned the flow of money between Kosair and the individual Physician Defendants. Physician Defendants all participated in the Medical School's faculty practice plan.[65] Under this arrangement, faculty salaries at the Medical School were funded not only by grants, donations, and contributions from various sources, but also by a portion of the revenue from the Physician Defendants' private practices.[66] Most importantly, faculty salaries were also funded by contributions from hospitals, including Kosair, where all Physician Defendants extensively practiced and to which they referred their patients.[67]

Thus, it was undisputed that faculty salaries paid from the Medical School to Physician Defendants were derived, at least in part, from funds contributed by a hospital to which Physician Defendants referred their patients—raising a clear Stark issue.

### *2. Analysis*

As an initial matter, "[a]lthough the arrangement [between Kosair and Physician Defendants] predated the adoption of the AMC exception, the court concluded that the exception still applied because it is an administrative interpretation of what Congress intended in the Stark Law."[68]

The court turned first to the requirements imposed on the referring physicians themselves. In this set of requirements, and specifically the requirement that the physician provide "'either substantial academic services or substantial clinical [teaching] services,'" the court found uncertainty in the presence of the qualifying term "substantial," stating that it created confusion as to the reach of this requirement.[69] While one would think that the rule's safe harbor provision would help to alleviate this un-

62. United States v. Solinger, 457 F. Supp. 2d 743, 747 (W.D. Ky. 2006).
63. *Id*.
64. *Id*. at 748.
65. *Id*.
66. *Id*.
67. *Id*.
68. Gerald M. Griffith, *AMCs Get New Comfort on Stark Law Compliance*, HEALTH LAW. WKLY., Apr. 18, 2008, at 1.
69. United States *ex rel*. Villafane v. Solinger, 543 F. Supp. 2d 678, 688 (W.D. Ky. 2008) (quoting 42. C.F.R. § 411.355(e)(1)(i)(D) (2007)).

certainty, the rule goes on to state that, "[a] physician who does not spend at least 20 percent of his or her professional time or 8 hours per week providing academic services or clinical teaching services (or a combination [thereof]) *is not precluded from qualifying under this paragraph* . . . ."[70] CMS noted, in Phase II of the Stark Law, that it "'wanted to provide academic medical centers with flexibility'" and that the safe harbor "'is not an absolute requirement, and . . . physicians who do not qualify under this "safe harbor" may still be providing substantial academic . . . or clinical teaching services.'"[71]

Additionally, the court paid attention to the fact that physicians are not required to keep any particular timekeeping system, and did not find determinative that the only assessment of the defendants' time was based on very general estimates by the defendant doctors themselves.[72] While the court admitted that a more accurate timekeeping system would have been more desirable, "the conclusion is inescapable that Defendants do provide substantial academic and clinical services"[73] and there was "no indication that either Congress or HCFA/CMS intended that the fate of an academic medical center would hang upon its particular timekeeping practices where its broad operations seem entirely appropriate."[74]

Second, the court addressed the requirements concerning the physicians' compensation. As an initial matter, the court held that the term "total compensation" referred only to the faculty salaries paid to defendant doctors, and throughout their analysis, referred only to such salaries.[75] The court went on to hold that the defendant doctors' faculty salaries did not exceed fair market value because they were paid at levels consistent with their abilities and responsibilities.[76] The court also held that the third requirement, the value–volume correlation, was easily met if "the faculty salary paid to the physician is initially set at fair market value and . . . does not vary once set,"[77] basing this determination on HCFA's clarifica-

70. 42 C.F.R. § 411.355(e)(1)(i)(D) (2007) (emphasis added).

71. *Villafane*, 543 F. Supp. 2d at 689 (emphasis omitted) (quoting Phase II, *supra* note 23, at 16,109–10).

72. *Id*. at 689–90.

73. *Id*. The court focused on the defendant doctors' enormous academic responsibilities: requiring supervision of more than one hundred medical students and residents at Kosair, their continued and daily review of patient status, their annual work assignments and performance review, and their curricula vitae. *Id*.

74. *Id*. at 690.

75. *Id*. In the court's view, any other interpretation "would require the Medical School to exert control over the internal salary decisions of any private practice whose physicians were faculty members," which would not only be well outside the scope of the Stark Law but also seems utterly impractical. *Id*.

76. *Id*. at 692.

77. *Id*. at 693.

tion of this requirement and, particularly, on the language "does not vary over the term of the arrangement."[78]

Third, the court held that the arrangement met the third set of requirements. The court looked first at the requirements concerning accreditation, affiliation, and staffing, and took note of the extremely permissive language in the regulations regarding these requirements.[79] The court decided that since the defendant doctors provided evidence that the majority of the staff at Kosair were Medical School faculty members and that those faculty members generated the majority of the hospital's net revenue, this demonstrated that the arrangement was "sufficiently focused on the academic medical center's core mission" and satisfied this requirement.[80] The court then looked at the requirement concerning issues of organization and financial transfers. The court found that no authority required a specific type of documentation to authorize the relationship[81] and that the documents exchanged between Kosair and the Medical School, which included both an agreement purporting to establish an automatically continued relationship and annual documents between the two entities, were sufficient to show the relationship between Kosair and the Medical School.[82]

Fourth, the court held that the arrangement did not violate the Anti-Kickback statute.[83] After noting that the Sixth Circuit has not explicitly spoken "to the question of whether payments made partly, but not entirely, to induce referrals would satisfy the intent element,"[84] it rejected the "one purpose" test[85] and instead chose to "interpret the AMC exception's incorporation of the Anti-Kickback law's provisions so as not to effectively countermand the broader purpose of the AMC exception itself."[86] The court found it determinative that the plaintiffs asserted no specific facts to support an extremely general Anti-Kickback allegation in their complaint.[87] Instead the court focused on the defendants' "sworn assertions that no improper intent was behind Kosair's payments to the Research Foundation, as well as Defendants' observation regarding the illogic of the

78. *Id*. at 692–93 (emphasis omitted) (quoting Phase I, *supra* note 22, at 877–78). See *supra* note 49 for the full text of HCFA's clarification.
79. *Villafane*, 543 F. Supp. 2d at 695.
80. *Id*.
81. *Id*. at 697 (noting that CMS requires only "'a clearly established course of conduct that is appropriately documented'" (emphasis omitted) (quoting Phase II, *supra* note 23, at 16,110)).
82. *Id*.
83. *Id*. at 698.
84. *Id*. at 697.
85. *Id*. The one purpose test holds that the intent elements of the Anti-Kickback statute can be met if payments to physicians are to *any* extent motivated by an intent to induce referrals. *Id*. (citing United States v. Greber, 760 F.2d 68, 71 (3d Cir. 1985)).
86. *Villafane*, 543 F. Supp. 2d at 697.
87. *Id*. at 698.

suggestion that the only full-service children's hospital in Kentucky would need to induce referrals through kickbacks to physicians."[88]

## II. ISSUES WITH THE AMC EXCEPTION AND SUGGESTIONS TO RESOLVE THEM

In the wake of the *Villafane* decision, there are several issues with the AMC exception. Congress intended the Stark Law to provide a bright-line rule to guide physicians and health care providers with respect to their financial relationships, but "this objective has proven elusive."[89] Given the goal of obtaining the bright-line, strict liability rule that Congress was striving for, and the seemingly endless flexibility given to courts in interpreting the statute in the wake of the *Villafane* decision, many of these issues need to be resolved. It is important to identify the many troubling aspects to the court's analysis that "highlight the structural flaws of the AMC exception and the potential difficulties with achieving compliance even under [a flexible] reading of the exception."[90]

### *A. AMCs Are Forced to Fit into a More Complex Exception*

First, there is some evidence that AMCs are going to be forced to fit into this complex exception even when other exceptions are available to them. In *Villafane*, the court failed to make a ruling on the issue of whether the arrangement in that case created an indirect compensation arrangement.[91] Plaintiffs alleged that an indirect compensation arrangement existed between the entities.[92] This would require the defendant physicians' total compensation from the Medical School to vary with the volume or value of referrals or other business generated for the hospital.[93] However, the court's determination that the arrangement satisfied the second set of AMC exception requirements, including the value–volume correlation requirement, necessarily means that the arrangement did not meet the definition of an indirect compensation arrangement, and thus that there may have been no financial relationship with which to trigger the Stark Law in the first place.[94] Thus, the court chose to do the complex analysis and extensive fact-finding under the AMC exception when it could have "con-

88. *Id*.
89. *Id*. at 685.
90. Eric B. Gordon, Solinger *and the Stark Law's AMC Exception: A Cautionary Message for AMCs*, HEALTH LAW. WKLY., May 16, 2008, at 1.
91. *Villafane*, 543 F. Supp. 2d at 700.
92. *Id*. at 699.
93. 42 C.F.R. § 411.354(c)(2) (2007).
94. *See supra* note 77 and accompanying text; *see also* Gerald M. Griffith, *Pros, Cons and Further Questions on the AMC Exception*, HEALTH LAW. WKLY., May 23, 2008, at 5.

ducted a much more streamlined analysis of the compensation only using an indirect compensation analysis."[95]

Instead, courts would be wise to conduct the easier analysis first, before delving into the harder exceptions, specifically those with as many different prongs and fact-finding determinations as the AMC exception contains. Not only will this make it easier for courts to analyze, determine, and make rulings on these types of issues, but it will also make it easier for the types of beneficial financial arrangements that Congress intended to exempt from Stark Law to comply with its requirements. Only if an arrangement fails to satisfy one of the less complex requirements should the courts look to the AMC exception to determine compliance.

### *B. Overlap with Other Exceptions*

There is also overlap between the AMC exception and other exceptions, and there is some question as to why the AMC exception is necessary given the availability of those other exceptions, such as the indirect compensation arrangement exception and, as earlier discussed, the faculty practice plan exception.[96]

However, there is some benefit to the AMC exception over a broader exception like the indirect compensation arrangement exception. For example, the indirect compensation exception protects only compensation arrangements,[97] whereas the AMC exception protects both ownership and compensation arrangements and protects arrangements for a variety of mission purposes.[98] Additionally, the "built-in limits on the use of funds for mission purposes and [the] fair market value limitation on referring physician compensation" may be enough to make a de facto safe harbor within the AMC exception.[99] Thus, it is beneficial for the regulations to include an exception that is specifically tailored to those things that make AMCs unique.

### *C. Retroactive Application*

As previously mentioned,[100] the *Villafane* court held that, although the arrangement between Kosair and the Medical School was created prior to the creation of the AMC exception, the expression applied retroactively as

95. Gordon, *supra* note 90, at 2.
96. *See supra* Part II.A (discussing the faculty practice plan exception).
97. *See* 42 C.F.R. § 411.354(c)(2) (2007).
98. *See id*. § 411.355(e).
99. Griffith, *supra* note 94, at 5.
100. *See supra* note 68 and accompanying text (noting the court's retroactive application of the AMC exception).

an expression of Congress's intent.[101] This retroactivity was reiterated from the prior decision in the case.[102]

Combining this retroactive application with the court's failure to rule on the indirect financial arrangement issue, this decision suggests not only that an AMC must be prepared to defend itself under the AMC exception, even if it is easier to defend itself in other ways,[103] but also that an AMC may be forced to comply retroactively with future regulations. However, there is evidence that the arrangement in *Villafane* continued well past the enactment of the Stark Law and the AMC exception,[104] and it is only fair that arrangements be required to comply with evolving law. Thus, when an arrangement already in existence continues and a new law or a new set of regulations is enacted, the arrangement should necessarily be held to the new standard. Moreover, this retroactive holding may be helpful in defense of Stark allegations in the future.[105]

### *D. Value–Volume Standard and Year-to-Year Correlation*

The *Villafane* court held that the value–volume standard was met because the physicians' salaries were fixed in advance prior to the start of the year and were consistent with fair market value since they were paid at levels consistent with their abilities and responsibilities.[106] However, the court also noted in dicta that the value–volume standard would be implicated if a correlation could be established between the inpatient revenue generated and the faculty's salary levels.[107]

This analysis and reasoning "may have serious implications in other common AMC situations."[108] AMCs commonly provide incentive to their physicians based on personal productivity at the hospital and work relative value units.[109] Thus, the availability of these incentives may change over time based on the system's overall profitability or the hospital's total net income.[110] Changes of this type could implicate a correlation in a future year without suggesting one in a single academic year, which would, under the current analysis, implicate the value–volume standard.[111]

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101. United States *ex rel.* Villafane v. Solinger, 543 F. Supp. 2d 678, 687 n.9 (W.D. Ky. 2008); Griffith, *supra* note 68, at 1.

102. *See* United States v. Solinger, 457 F. Supp. 2d 743, 756 (W.D. Ky. 2006).

103. *See* Gordon, *supra* note 90, at 2.

104. *See Solinger*, 457 F. Supp. 2d at 750 n.4 (showing evidence that the arrangements continued at least into 2002 when the most recent contracts were signed).

105. Griffith, *supra* note 68, at 1.

106. *Villafane*, 543 F. Supp. 2d at 692–94.

107. *Id.* at 694.

108. Gordon, *supra* note 90, at 3.

109. *Id.*

110. *Id.*

111. *Id.*

Perhaps courts would do better to look at the totality of the AMC's compensation system and take into account those legitimate incentive systems that AMCs commonly use to boost productivity amongst their doctors.

### *E. The Intent Element Hidden Within a Flexible Approach*

The *Villafane* court continually took a flexible approach to both Stark and the AMC exception's requirements. Instead of establishing the bright-line rule that Congress intended to create in the Stark Law,[112] the court makes compliance with the requirements increasingly confusing.

Stark was intended to be a strict liability statute and does not include any explicit mention of intent throughout its provisions. The regulations that accompany Stark's primary provisions also fail to include any intent element. Nevertheless, the court focused throughout its analysis on the AMC's intent in complying with the law. First, it allowed general estimates by the physicians themselves to satisfy the timekeeping requirement[113] and required no real documentation authorizing the relationship between the two entities.[114] The court also held that the Anti-Kickback prohibition was satisfied based solely on the doctors' sworn assertions that no improper intent was behind Kosair's payments to the Research Foundation and the illogic of the suggestion that the only full-service children's hospital in the area would need to induce referrals.[115]

Nothing about these three decisions shows that this is a bright-line rule. Instead, it suggests that the best approach is some sort of trial-and-error method in which AMCs attempt to meet the requirements and hope their efforts are sufficient. While the court's approach may make it easier for beneficial medical relationships to be exempted from the Stark Law, it would certainly be easier for AMCs to comply with the statute, if it was, as Congress intended, a true strict liability, bright-line test for compliance.

## III. TAKING A FLEXIBLE APPROACH: FUTURE IMPLICATIONS

If courts begin following the *Villafane* decision in taking a flexible approach to Stark Law compliance under this exception, the complexity of the exception will raise issues for AMCs attempting to comply with the law. Legal counsel at each AMC should read the lengthy and complex regulations and the minimal case law to help determine what steps should be taken to ensure that the organization is not in violation of the law.

112. *See supra* notes 7–11 and accompanying text (discussing Congress's intention and hopes to create a bright-line rule in Stark).

113. United States *ex rel.* Villafane v. Solinger, 543 F. Supp. 2d 678, 689–90 (W.D. Ky. 2008).

114. *Id.* at 697.

115. *Id.* at 698.

Technically, good faith efforts to obey the law mean very little—the Stark Law is meant to be a strict liability statute. Thus, physicians and health care entities have no choice but to take continual precautions and make checks to ensure that they are fitting within these requirements.

However, the flexibility of the approach and the complexity of the exception allow courts significant leeway in making their compliancy determination. This leaves AMCs to guess what is actually required—one court might hold that a certain practice plan complies with the Stark Law while another court might not. This type of approach presents a dichotomy:

> One lesson surely is that AMCs should evaluate their ability to demonstrate compliance with the AMC exception. Of equal importance, however, is the evidence of the complexity and unwieldy set of requirements contained in the AMC exception, such that [courts are] . . . required . . . to adopt a flexible approach to reach [the] conclusion that . . . arrangement[s] [are] in compliance.[116]

Some commentators think this flexible approach is a good thing, reasoning that AMCs will be able to better comply with the exception because of the approach courts take regarding compliance. Others take the position that the current regulatory framework is unworkable and believe the onus falls upon the AMCs to fight for regulations that make it easier to determine what relationships do and do not comply with the Stark Law. For example, Gordon "argue[s] that it is incumbent on the AMC community to seek a better resolution to the problems with the exception as currently constituted. [*Villafane*] should serve as a warning and a rallying cry for a more straightforward, simplified regulatory framework."[117] But is it really the health care facilities' job to fight for a more straightforward law?

A third group of commentators take a neutral position that the opinion is just as notable for what it does to "highlight the structural flaws of the AMC exception and the potential difficulties with achieving compliance even under the [*Villafane*] court's reading of the exception as it is for its flexible approach to the exception."[118]

## CONCLUSION

Even in taking a flexible approach and rendering a decision that appears to allow a broad reading of the AMC exception, the *Villafane* court, perhaps in an attempt to help AMCs comply with the statute, included in dicta examples of the type of AMC arrangements that would fall outside of

116. Gordon, *supra* note 90, at 4.
117. *Id*.
118. *Id*. at 1.

the AMC exception. Two examples are (1) paying part-time faculty close to full-time salaries for performance of minimal or no services[119] and (2) paying for referrals concealed as salaries and expenses above market value, purported loans without repayment requirements, and directorship contracts paying even when the doctor does not show for work.[120] Congress intended to prevent physicians from making referrals solely for personal gain,[121] and the court felt that the above arrangements were precisely of the prohibited type. This may help provide some guidance for AMCs in determining at least a few courses of conduct that will likely be found to be illegal financial relationships.

No current court decisions can be appealed, however, so at least for now, health care facilities will not be able to get real answers through the legal system. If they are finding it difficult to navigate the complexities of the Stark Law and its miles of regulatory framework, these entities will have to find an alternative way to have their voice heard. AMCs may wish to consider informing CMS of any portions of the AMC exception that it finds difficult to meet in practice.[122] As CMS makes future changes to its regulatory framework and passes further phases of regulations, it may take these specific examples into account in taking a position on support payments.[123]

While it may be important to keep the flexible standard within AMCs requirements to allow beneficial AMCs to meet the requirements of the Stark Law, the AMC exception, as it stands now and after the *Villafane* decision, is an incredibly complex rule that provides little guidance for AMC compliance. Ultimately, it will be necessary for CMS and Congress to make changes to the Stark Law and its regulations in order to obtain the bright-line rule that Congress originally intended.

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119. United States *ex rel.* Villafane v. Solinger, 543 F. Supp. 2d 678, 699 (W.D. Ky. 2008) (citing *Kickbacks: U.S. Monitor Alleges Illegal Patient Referral Scheme at N.J. Medical School*, Medicare Rep. (BNA) No. 17, at 1421 (Nov. 17, 2006)).

120. *Id.* (citing *Ohio Hospitals Settle Kickback, Fraud Case, Will Pay $13.8 Million*, Andrews Health Care Fraud Litig. Rep. No. 3, at 8 (Sept. 13, 2006)).

121. *Id.* (citing United States *ex rel.* Kosenske v. Carlisle HMA, Inc., No. 1:05-CV-2184, at *11 (M.D. Pa. Nov. 14, 2007), *rev'd*, 554 F.3d 88 (3rd Cir. 2009)).

122. Griffith, *supra* note 94, at 4.

123. *Id.*