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I. Introduction

On May 18, 2006, the Supreme Court of Florida, in *State v. Harden*, affirmed a Florida appellate court's 2004 decision that found Florida's Medicaid anti-kickback statute unconstitutional.[1] This decision is significant because it is the first time that any court has ruled that a state anti-kickback statute is federally preempted.[2] One clear impact of the decision is that certain financial arrangements that the Florida legislature sought to prohibit will now be permitted.[3] Furthermore, the Florida statute that the court preempted was stricter than its federal counterpart.[4] Therefore, the Florida legislature's decision to punish certain arrangements under the Medicaid program to a greater extent than the federal law was completely undermined.[5] Because state anti-kickback

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1. State v. Harden, 938 So. 2d 480, 495 (Fla. 2006), *cert. denied*, 127 S. Ct. 2097 (Apr. 23, 2007) (No. 06-770). Generally, a Medicaid anti-kickback statute prohibits any form of payment for referring a Medicaid-eligible individual to a provider of services reimbursed under the Medicaid program. *See id* at 485.

2. *See id.* at 492.

3. *See, e.g.*, State v. Harden, 873 So. 2d 352, 353 (Fla. Dist. Ct. App. 2004) (describing the *Harden* defendants' method of paying for patients).

4. *Compare* FLA. STAT. § 409.920(2)(e) (2000) *with* 42 U.S.C. § 1320a-7b(b) (2006).

5. Medicaid is a state-administered healthcare program generally meant to benefit the poor. *See* BARRY R. FURROW ET AL., HEALTH LAW: CASES MATERIALS AND PROBLEMS 773 (5th ed. 2004). Despite being largely questioned and criticized, the Medicaid program is currently more expensive than Medicare. *Id.* at 772.

statutes vary widely,[6] and because *Harden* represents the only case that has interpreted the preemptive power of the federal anti-kickback statute, other courts may find the Florida Supreme Court's analysis persuasive and strike down their own state's Medicaid anti-kickback statutes.[7] If a number of other states also preempt their respective state anti-kickback statutes, our already-strained healthcare system will suffer. State anti-kickback statutes help to protect our limited federal resources by harshly punishing criminal behavior to a perhaps greater extent than the federal statute.[8] Without such state enforcement, individuals who take advantage of the more lenient federal anti-kickback statute will squander limited resources.

The purpose of this Comment is to explain the Florida Supreme Court's analysis in *State v. Harden*, and to offer counterarguments that courts should consider when looking to the decision as persuasive authority. Part II of this Comment places the *Harden* decision in context by summarizing the factual background, discussing both the federal anti-kickback statute and Florida's anti-kickback statute, and describing a circuit split that has arisen regarding the interpretation of one of the federal anti-kickback statute's provisions. Part III-A examines the Florida Supreme Court's preemption analysis in detail and offers several arguments against the analysis. These arguments include the fact that the federal anti-kickback statute lacks preemption provisions and the idea that the cooperative nature of the Medicaid program should create a stronger presumption against preemption. Part III-B emphasizes the circuit split regarding the federal anti-kickback statute's scienter requirement discussed in *Harden*, and suggests a preferable uniform standard to apply to future anti-kickback statute cases. Part III-C critically examines the employer-employee safe harbor analysis in *Harden* and the case law cited by the Florida Supreme Court. Part III-D explains two recent Florida cases that have interpreted *Harden* to suggest how persuasive the *Harden* decision may become. Part IV concludes by reiterating the significance of the *Harden* decision and predicting its persuasive power.

6. *See infra* note 145.

7. One commentator has examined other state anti-kickback statutes using the *Harden* court's analytical framework, and concluded that a court would likely find the Pennsylvania anti-kickback statute unconstitutional under *Harden*. *See* Kathryn Leaman, Note, *State Anti-Kickback Statutes: Where the Action Is*, 9 J. HEALTH CARE COMPLIANCE 23, 29 (Mar.-Apr. 2007).

8. *See, e.g.*, MINN. STAT. ANN. § 62J.23 (West 2006) (noting that Minnesota's own anti-kickback rules may be more restrictive than the federal law and regulations).

II. Background

An anti-kickback statute makes it a crime to offer, pay, solicit, or receive any form of remuneration for inducing business that is reimbursed under a federal or state healthcare program.[9] Prior to the *State v. Harden* decisions from Florida's state courts discussed *infra*, only one other court had addressed the issue of whether a state anti-kickback statute was federally preempted.[10] In *Massachusetts v. Mylan Laboratories*,[11] the defendant pharmaceutical manufacturers argued that Massachusetts' anti-kickback statute was federally preempted because the statute lacked a mens rea requirement.[12] The Massachusetts district court deferred ruling on this issue, specifically noting that the case law on the mens rea requirement is evolving.[13]

The fact that only one other court has addressed the question of whether the federal anti-kickback statute preempts a state anti-kickback statute is not surprising in light of commentary by the Office of Inspector General (OIG) that accompanies the Medicare and Medicaid Patient and Program Protection Act of 1987.[14] In response to a comment requesting that the OIG "clarify the relationship between the [federal anti-kickback] statute and various State laws," the OIG broadly proclaimed that "[t]here is no federal preemption provision under the [federal anti-kickback] statute."[15] Additionally, the OIG noted that legal action under the federal anti-kickback statute could still be illegal under a state anti-kickback law, and vice versa.[16] Until the recent *Harden* decision, this statement was true.[17] The facts of the case are briefly described below.

In December 2000, the State of Florida filed a nine-count information against ten individual defendants associated with entities that provided dental services to children.[18] The State alleged that the

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9. *See, e.g.*, 42 U.S.C. § 1320a-7b(b) (2006).

10. *See* State v. Harden, 938 So. 2d 480, 492 (Fla. 2006), *cert. denied*, 127 S. Ct. 2097 (Apr. 23, 2007) (No. 06-770).

11. Mass. v. Mylan Labs., 357 F. Supp. 2d 314, 324-25 (D. Mass. 2005).

12. *Id.* at 325. *Mylan Laboratories* was decided after the Florida Court of Appeal's decision and prior to the Florida Supreme Court's decision in *State v. Harden*. In support of their argument, the defendants cited *State v. Harden*, 873 So. 2d 352 (Fla. Dist. Ct. App. 2004). *Id.* Mens rea is defined as "[t]he state of mind that the prosecution . . . must prove that a defendant had when committing a crime. . . ." BLACK'S LAW DICTIONARY 1006 (8th ed. 2004).

13. *See Mylan Labs.*, 357 F. Supp. 2d at 325.

14. *See* Medicare and State Health Care Programs: Fraud and Abuse; OIG Anti-Kickback Provisions, Pub. L. No. 100-93, §14, 56 Fed. Reg. 35,952, 35,957 (July 29, 1991) (codified at 42 C.F.R. § 1001).

15. *Id.*

16. *See id.*

17. *See* State v. Harden, 873 So. 2d 352, 353 (Fla. Dist. Ct. App. 2004).

18. *See* State v. Harden, 938 So. 2d 480, 483-84 (Fla. 2006). The defendants were

defendants paid drivers a fee for each Medicaid-eligible child that the drivers would first solicit and then transport to a Dental Express facility.[19] The first two counts charged the defendants with racketeering and conspiracy, and the remaining seven counts alleged Medicaid fraud under Florida's Medicaid anti-kickback statute.[20]

One defendant, Harden, moved to dismiss the action in October 2002, and the remaining nine defendants joined Harden's motion to dismiss shortly thereafter.[21] The defendants argued that a safe harbor listed in the federal anti-kickback statute[22] protected Dental Express' method of paying its employees to solicit and transport children to its facilities.[23] The defendants also argued that a provision of Florida's Medicaid statute[24] was unconstitutionally vague, and that soliciting patients without the intent to defraud is a protected activity under the First Amendment of the Constitution.[25] The trial court heard arguments from each side and granted the defendants' motion to dismiss in February 2003.[26]

The State of Florida appealed the trial court's ruling.[27] On appeal to Florida's Court of Appeals, the State argued that Florida's anti-kickback statute does not conflict with the federal statute and, as such, is not preempted.[28] In rejecting the State's argument, the appellate court explained two significant differences between Florida's Medicaid anti-kickback statute and the federal statute.[29] First, the court noted that

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allegedly employed by three separate corporate entities: Dental Express Dentists, Dental Express, Inc., and Express Dental, Inc. [hereinafter "Dental Express"]. *Id.*

19. *Id.* at 484.

20. *Id.*; FLA. STAT. § 409.920(2)(e) (2000).

21. *Harden*, 873 So. 2d at 353.

22. 42 U.S.C. § 1320a-7b(b)(3) (2006).

23. *Harden*, 938 So. 2d at 484. The safe harbor cited by the defendants excludes from the federal anti-kickback statute "any amount paid by an employer to an employee (who has a bona fide employment relationship with such employer) for employment in the provision of covered items or services." 42 U.S.C. § 1320a-7b(b)(3)(B). The defendants argued that Florida's attempt to prosecute an activity protected by a federal statute violates the Supremacy Clause, U.S. Const. art. VI, cl. 2 ("[the] Constitution . . . shall be the supreme Law of the Land").

24. FLA. STAT. § 409.920(2)(e) (2000).

25. *Harden*, 938 So. 2d at 484. The defendants argued that "remuneration" as used in Florida's statute is vague in the employer-employee context. *Id.*

26. *Harden*, 873 So. 2d at 353. The trial court held that Florida's Medicaid fraud statute and the mens rea requirement from the statute were unconstitutional under the Supremacy Clause and were preempted by 42 U.S.C. § 1320a-7b (b)(3). *Id.* at 354. The court also held that Florida's statute was unconstitutionally vague because denying the right to solicit business absent the intent to defraud violates the First Amendment. *Harden*, 938 So. 2d at 484. Both the appellate court and Florida's Supreme Court failed to address the vagueness issue. *Id.* at 494.

27. *See Harden*, 873 So. 2d at 353.

28. *Id.* at 354.

29. *Id.* at 355.

Florida's anti-kickback statute contained no safe harbors akin to those listed in the federal anti-kickback statute.[30] Because of this difference, the Florida statute criminalized activity that the federal statute protected.[31] Next, the court noted that the federal statute's mens rea requirement was "knowingly and willfully,"[32] while the Florida statute's mens rea requirement was only "knowingly."[33] The appellate court concluded that the difference in mens rea requirements between the two statutes undermined the purpose that Congress had intended in creating the federal statute's safe harbors: to exclude certain types of payments from being considered illegal remuneration.[34]

The State of Florida appealed the decision and sought review from Florida's Supreme Court.[35] The state raised three separate arguments before the Florida Supreme Court on appeal: (1) the Florida Medicaid anti-kickback statute is not preempted by either the federal anti-kickback statute or one of the listed safe harbors; (2) the federal safe harbors do not protect a per-patient payment system like the one implemented by the defendants; and (3) the Florida statute does not violate the First Amendment and is not unconstitutionally vague.[36]

Before a closer examination of the Florida Supreme Court's decision, an introduction to both the federal anti-kickback statute and Florida's anti-kickback statute will help to better illustrate the Florida Supreme Court's analysis, discussed *infra*, and its potential ramifications. A brief description of the federal circuit split over the "knowingly and willfully" mens rea requirement will also help to explain the rather confusing scienter requirement discussed by the Florida Supreme Court. Viewing the *Harden* decision through the lens of both the state and federal anti-kickback statutes and the federal circuit split will illuminate the importance of the court's decision.

A. Overview of the Federal Anti-Kickback Statute

1. Development of 42 U.S.C. § 1320a-7b(b)

Congress enacted the federal anti-kickback statute[37] as part of the Social Security Amendments of 1972.[38] Prior to 1972, the antifraud

30. *Id.*; 42 U.S.C. § 1320a-7b(b)(3) (2006).
31. *Harden*, 873 So. 2d at 355.
32. 42 U.S.C. § 1320a-7b(b)(2).
33. *Harden*, 873 So. 2d at 355. *See infra* Part II.B.
34. *Harden*, 873 So. 2d at 355.
35. State v. Harden, 938 So. 2d 480, 485 (Fla. 2006).
36. *Id.*
37. The statute is currently codified at 42 U.S.C. § 1320a-7b(b) (2006).
38. *See* Social Security Amendments of 1972, Pub. L. No. 92-603, 86 Stat. 1329,

section of the Social Security Act[39] regulated Medicaid fraud, and was not specific to kickback activity.[40] With the Social Security Amendments of 1972, however, Congress explicitly prohibited soliciting, offering, or receiving any kickback in connection with a Medicare or Medicaid payment.[41] A mens rea requirement did not exist, and statute violators could be found guilty of a misdemeanor.[42]

Several issues regarding interpretation of the federal anti-kickback statute arose shortly after its enactment in 1972.[43] One significant issue that caused a split among circuit courts was what type of transaction constituted a kickback, bribe, or rebate.[44] In order to strengthen the government's ability to prosecute Medicare and Medicaid fraud, as well as to address certain interpretation issues, Congress passed the Medicare and Medicaid Anti-Fraud and Abuse Amendments of 1977.[45] These amendments replaced the terms kickback, bribe, and rebate with the broader phrase "any remuneration (including any kickback, bribe, or rebate)."[46] In addition, the amendments increased the maximum penalties available under the statute.[47] While expanding the remuneration terms and penalties, the 1977 amendments also narrowed the federal anti-kickback statute by excluding discounts and other price reductions disclosed to the government, as well as excluding payments made to an employee as part of a bona fide employment relationship.[48]

Congress was concerned that the increased criminal penalties could

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1419-20 (1972).

39. 42 U.S.C. § 408 (2006).

40. Tamsen Douglass Love, Note, *Toward a Fair and Practical Definition of "Willfully" in the Medicare/ Medicaid Anti-Kickback Statute*, 50 VAND. L. REV. 1029, 1035 (1997).

41. Social Security Amendments of 1972, Pub. L. No. 92-603, 86 Stat. 1329, 1419-20 (1972).

42. *Id.* The maximum penalties included a $10,000 fine, one-year imprisonment, or both. *Id.*

43. *See* Robb DeGraw, Note, *Defining "Willful" Remuneration: How Bryan v. United States Affects the Scienter Requirement of the Medicare/Medicaid Anti-Kickback Statute*, 14 J.L. & HEALTH 271, 275 (1999) (noting issues regarding the lack of mens rea requirement, the types of business ventures precluded by the statute, and the meaning of terms such as "kickback" and "bribe").

44. *See* Love, *supra* note 40, at 1035. *Compare* United States v. Porter, 591 F.2d 1048 (5th Cir. 1979) (holding that payments made to physicians who sent blood work to a certain lab were neither bribes nor kickbacks) *with* United States v. Tapert, 625 F.2d 111 (6th Cir. 1980) (holding that payments made to physicians who sent urine and blood samples to a lab were kickbacks within the meaning of the statute).

45. Medicare and Medicaid Anti-Fraud and Abuse Amendments of 1977, Pub. L. No. 95-142, § 4(b)(1), 91 Stat. 1175, 1180-82 (1977).

46. *Id.* at 1180.

47. *Id.* A violation of the statute constituted a felony with a maximum penalty of five years imprisonment and a maximum fine of $25,000. *Id.*

48. *Id.*

be imposed for inadvertent activity because a mens rea requirement did not exist, and the term "any remuneration" could be construed very broadly.[49] Therefore, in 1980, Congress amended the federal anti-kickback statute by adding a mens rea requirement.[50] In order to be convicted of violating the federal anti-kickback statute after the 1980 amendment, a person must commit the violative act "knowingly and willfully."[51] In 1987, Congress again amended the federal anti-kickback statute to provide for statutory exceptions known as "safe harbors" for specified transactions,[52] and also to give the Secretary of the Department of Health and Human Services (HHS) the power to exclude violators from federal and state health programs.[53]

In 1996, Congress amended the anti-kickback statute as part of the Health Insurance Portability and Accountability Act of 1996 (HIPAA).[54] With HIPAA, Congress extended the anti-kickback statute to all federal health programs,[55] strengthened penalties for healthcare fraud violations,[56] included an additional safe harbor,[57] and established a fraud and abuse control program through the OIG of the Department of Health and Human Services.[58] To date, the OIG has listed over twenty safe harbors in the regulation[59] that protect physicians from the statute.[60]

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49. *See* Omnibus Reconciliation Act of 1980, H.R. Rep. No. 96-1167, 96th Cong., 2nd Sess. 59, *reprinted in* 1980 U.S.C.C.A.N. 5526, 5572.

50. *See* Omnibus Reconciliation Act of 1980, Pub. L. No. 96-499, § 917, 94 Stat. 2599, 2625 (1980).

51. *Id.*

52. *See* Medicare and Medicaid Patient and Program Protection Act of 1987, Pub. L. No. 100-93, §§ 4, 14, 101 Stat. 680, 688-89, 697-98 (1987). Safe harbors protect from prosecution specific practices that would otherwise violate the anti-kickback statute. *See, e.g.*, 42 C.F.R. § 1001.952 (2005).

53. Medicare and Medicaid Patient and Program Protection Act of 1987, Pub. L. No. 100-93, § 2, 101 Stat. at 680-86. Exclusion from Medicare and Medicaid programs is often disastrous for practitioners. *See* A. Craig Eddy, *The Effect of the Health Insurance Portability and Accountability Act of 1996 (HIPAA) on Health Care Fraud in Montana*, 61 MONT. L. REV. 175, 204 (citing *Siddiqi v. United States*, 98 F.3d 1427 (2d Cir. 1996), in which an oncologist who was convicted for Medicaid fraud over a $ 640.88 billing dispute lost a $825,000 per year practice).

54. Health Insurance Portability and Accountability Act of 1996, Pub. L. No. 104-191, 110 Stat. 1936 (1996).

55. Health Insurance Portability and Accountability Act of 1996, Pub. L. No. 104-191 § 204, 110 Stat. at 1999-2000 (1996).

56. *Id.* §§ 211-215, 110 Stat. at 2003-2007. The HIPAA of 1997 included provisions for mandatory exclusions from federal health programs (§ 211) and provided minimum periods of exclusion for certain violators (§§ 212 and 214). *Id.*

57. *Id.* § 216, 110 Stat. at 2007-08.

58. *Id.* § 201, 110 Stat. at 1992-96. Under this section, the Department of Heath and Human Services was given the responsibility of issuing advisory opinions and special fraud alerts, modifying or establishing safe harbors, and issuing guidelines to carry out the program. *Id.*

59. 42 C.F.R. § 1001.952 (2005).

Once again, in 2003, Congress added new safe harbors as part of the Medicare Prescription Drug, Improvement, and Modernization Act.[61] The OIG added the two most recent safe harbors in 2006.[62]

2. Current Federal Anti-Kickback Statute

The federal anti-kickback statute prohibits knowingly and willfully soliciting or receiving any remuneration in return for either referring an individual for any service compensated under a federal healthcare program or purchasing any item compensated under a federal program.[63] The statute also prohibits offering or paying any remuneration to any person for the same reasons.[64] Anyone who violates the statute can be charged with a felony.[65] The statute also lists a series of eight safe harbors to which the above provisions do not apply.[66]

3. Circuit Split Over the Mens Rea Requirement of "Knowingly and Willfully"

The federal courts that have interpreted the terms "knowingly and

60. Solicitation of New Safe Harbors and Special Fraud Alerts, 70 Fed. Reg. 73,186, 73,187 (Nov. 30, 2005) (to be codified at 42 C.F.R. § 1001).

61. *See* Medicare Prescription Drug, Improvement, and Modernization Act of 2003, Pub. L. No. 108-173, § 101, 117 Stat. 2066, 2150 (2003); *id.* at 2213.

62. *See* Medicare and State Health Care Programs: Fraud and Abuse; Safe Harbors for Certain Electronic Prescribing and Electronic Health Records Arrangements Under the Anti-Kickback Statute, 71 Fed. Reg. 45110 (Aug. 8, 2006) (to be codified at 42 C.F.R. § 1001).

63. Social Security Act § 1128B(b)(1), 42 U.S.C. § 1320a-7b(b) (2006).

64. *Id.* Commentators have summarized the federal anti-kickback statute as containing the following three elements: (1) knowingly and willfully, (2) soliciting or receiving remuneration, (3) to induce or in return for referrals for federally compensated healthcare services. Tracy D. Hubbell, Amy C. Mauro & Dan Moar, *Health Care Fraud*, 43 AM. CRIM. L. REV. 603, 612-13 (2006).

65. 42 U.S.C. § 1320a-7b(b) (2006).

66. *See* 42 U.S.C. §§ 1320a-7b(b)(3)(A) - 1320a-7b(b)(3)(H). The safe harbor at issue in the *Harden* case excludes from the federal anti-kickback statute "any amount paid by an employer to an employee (who has a bona fide employment relationship with such employer) for employment in the provision of covered items or services." 42 U.S.C. § 1320a-7b(b)(3)(B). The remaining safe harbors include: discounts obtained by providers so long as the discounts are properly disclosed; payments made by vendors to the authorized purchasing agent of a group furnishing services so long as there is a written contract; waiver of any coinsurance by a federally qualified health care center to an individual who qualifies for subsidized services under the Public Health Service Act; remuneration between a federally qualified health center and an MA pursuant to a written agreement; and any act specified as a safe harbor by the Secretary of HHS. *Id.* §§ 1320a-7b(b)(3)(A)-1320a-7b(b)(3)(H). These are the statutory safe harbors; there are also regulatory safe harbors promulgated by the OIG. *See, e.g.*, Medicare and State Health Care Programs: Fraud and Abuse; Safe Harbors for Certain Electronic Prescribing and Electronic Health Records Arrangements Under the Anti-Kickback Statute, 71 Fed. Reg. 45110 (Aug. 8, 2006) (to be codified at 42 C.F.R. § 1001).

willfully," both in reference to the federal anti-kickback statute and in reference to other federal criminal statutes, are split between a "heightened" mens rea standard and an intermediate, or "middle" mens rea standard.[67] A brief description of these differing standards is necessary in order to fully understand the Florida Supreme Court's mens rea discussion in *State v. Harden*.

a. Heightened Mens Rea Standard

The Supreme Court has interpreted the word "willfully" under a heightened mens rea requirement in reference to complex statutory schemes, including an anti-structuring law.[68] In *Ratzlaf*, the Court concluded that "willfully" requires both knowledge of the law itself and the specific intent to commit the crime.[69] The precedent cited by the Court involved relatively complex statutory requirements.[70]

Shortly after the Supreme Court's decision in *Ratzlaf*, the Ninth Circuit Court of Appeals applied the heightened mens rea standard to the "knowingly and willfully" requirement of the federal anti-kickback statute in *Hanlester Network v. Shalala*.[71] The Hanlester Network was a general partnership that had interests in three joint venture laboratories in California.[72] The partnership president marketed limited partnership shares in the joint ventures and, consequently, several practicing physicians working near the labs purchased these shares.[73] Smithkline

67. *See* DeGraw, *supra* note 43, at 279-87. DeGraw notes that federal courts have interpreted "willfully" in three ways: (1) as an act done "knowingly" or "purposely" (citing People v. Lee, 281 Cal. Rptr. 9, 12 (1991)); (2) as an act performed with the specific intent to commit an unlawful activity (*see, e.g.*, United States v. Muthana, 60 F.3d 1217, 1222 (7th Cir. 1995)); and (3) as violation of a known law (*see, e.g.*, Cheek v. United States, 498 U.S. 192 (1991)). DeGraw, *supra* note 43, at 279. The second and third of these interpretations are known as the "middle standard" and "heightened standard," respectively. *Id.*

68. *See* Ratzlaf v. United States, 510 U.S. 135 (1994). Structuring refers to making bank transactions that circumvent federal bank reporting requirements. *Id.* at 139-40. The statute from *Ratzlaf* criminalized actions that violated anti-structuring provisions as long as those actions were performed "willfully." *Id.* at 140.

69. *Id.* at 141.

70. *See, e.g.*, United States v. Sturman, 951 F.2d 1466, 1476 (6th Cir. 1991) (involving a statute concerning the recording and reporting of monetary transactions with foreign financial agencies). Since *Ratzlaf*, the Supreme Court has interpreted "knowingly and willfully" in reference to a federal firearms tracking law in Bryan v. United States, 524 U.S. 184 (1998). The Court in *Bryan* rejected the *Ratzlaf* standard, and held that under the willfulness requirement, "knowledge that the conduct is unlawful is all that is required." *Id.* at 196. At least one commentator has argued that the *Bryan* scienter standard will substantially affect anti-kickback statute jurisprudence, but it is arguable whether this has been the case. *See* Degraw, *supra* note 43, at 294-96.

71. *See* Hanlester Network v. Shalala, 51 F.3d 1390 (9th Cir. 1995).

72. *Id.* at 1394.

73. *Id.* at 1394-95.

BioScience Laboratories ("SKBL") also entered into a contract with the partnership through which it agreed to provide laboratory management services for all three joint venture laboratories in which the Network had ownership interests.[74] Pursuant to this agreement, eighty-five to ninety percent of tests ordered by physicians from the Hanlester laboratories were performed at SKBL facilities.[75] The Department of Health and Human Services argued that Hanlester, its limited partnerships, and various officers had violated the federal anti-kickback statute because they offered and paid remunerations to physicians who invested in the partnerships as inducement for referrals to Hanlester laboratories.[76] HHS also argued that Hanlester violated the statute by soliciting and receiving remuneration from SKBL in return for referrals of laboratory tests.[77]

The Ninth Circuit held that several of the officers did not knowingly and willfully violate the anti-kickback statute.[78] The court construed the mens rea requirement to mean that the alleged violators: (1) knew that the statute prohibits offering or paying remuneration to induce referrals, and (2) performed the prohibited conduct with the specific intent to disobey the statute.[79] Thus, as demonstrated by the Hanlester opinion, this heightened standard places a large burden on the government to obtain convictions under the federal anti-kickback statute because an alleged wrongdoer must not only know the specific statute, but must also intend to violate it.[80] The Ninth Circuit is not the only circuit that has adopted the heightened standard. More recently, the Tenth Circuit applied the heightened mens rea standard to the federal anti-kickback statute in a 2000 decision.[81] In addition, a district court within the Third Circuit applied the heightened standard to the federal anti-kickback statute in 2004.[82]

b. Intermediate Mens Rea Standard

With the exception of the Ninth and Tenth Circuits and the district court discussed *supra*, federal courts have generally rejected the heightened mens rea standard, instead applying an intermediate mens rea standard when interpreting the federal anti-kickback statute.[83] In 1996,

74. *Id.*
75. *Id.* at 1395.
76. *Id.*
77. *Hanlester Network*, 51 F.3d at 1395.
78. *Id.* at 1400.
79. *Id.*
80. *See* DeGraw, *supra* note 43, at 282.
81. United States v. McClatchey, 217 F.3d 823, 834-35 (10th Cir. 2000).
82. *See* Robert Wood Johnson Univ. Hosp., Inc. v. Thompson, Civil Action No. 04-142, 2004 U.S. Dist. LEXIS 8498 (D. N.J. Apr. 15, 2004).
83. *See* Degraw, *supra* note 43, at 283.

the Eighth Circuit interpreted the federal statute's mens rea requirement in *United States v. Jain*.[84] Dr. Jain was a psychologist who operated an outpatient therapy clinic.[85] The government charged Dr. Jain with violating the federal anti-kickback statute because of an alleged link between payments made to him and his volume of patient referrals.[86] The Eighth Circuit explicitly rejected the *Hanlester* analysis; instead, the Eighth Circuit held that satisfying the mens rea requirement of the federal anti-kickback statute requires that the defendant knew his conduct was wrongful, rather than requiring that he knew his actions violated a known legal duty.[87]

Similarly, in *United States v. Davis*, the Fifth Circuit also applied an intermediate mens rea standard in interpreting the federal anti-kickback statute.[88] Davis was convicted, *inter alia*, of violating the federal anti-kickback statute's prohibition against offering and paying to induce Medicare referrals.[89] During his appeal, Davis argued that the statute required a heightened mens rea requirement, citing *Hanlester*.[90] The court did not decide whether the statute required the heightened mens rea requirement that Davis argued, and presumably misinterpreted the *Hanlester* holding.[91] The *Davis* court read the *Hanlester* opinion as requiring that the alleged wrongdoer know that the action was unlawful, and in doing so impliedly rejected *Hanlester*'s actual standard.[92]

Finally, in 1995, a district court within the Sixth Circuit cited *Jain* and interpreted the term willful as the "purpose to commit a wrongful act" in *United States v. Neufeld*.[93] The intermediate approach taken by the courts in *Jain, Davis*, and *Neufeld* appears to be the majority view

84. *See* United States v. Jain, 93 F.3d 436 (8th Cir. 1996).

85. *Id.* at 438.

86. *Id.*

87. *Id.* at 441. The court in *Jain* distinguished *Ratzlaf* by stating that the anti-structuring statute at issue criminalizes a willful violation of another statute, while the word willfully in the federal anti-kickback statute merely modifies a series of prohibited acts. *Id.*

88. United States v. Davis, 132 F.3d 1092 (5th Cir. 1998).

89. *Id.* at 1094.

90. *Id.*

91. *See id.* This misinterpretation stems from the *Davis* court's understanding that *Hanlester* does not require knowledge of which particular statute makes the conduct illegal. *Id.*; Douglas A. Blair, *The Knowingly and Willfully Continuum of the Anti-kickback Statute's Scienter Requirement: Its Origins, Complexities, and Most Recent Judicial Developments*, 8 ANNALS HEALTH L. 1, 32 (1999). *Hanlester* does in fact require knowledge of the specific statute in question. *See* Hanlester Network v. Shalala, 51 F.3d 1390, 1400 (9th Cir. 1995).

92. *Davis*, 132 F.3d at 1094. *See* Degraw, *supra* note 43, at 285.

93. *See* United States v. Neufeld, 908 F. Supp. 491, 497 (D. Ohio 1995). In reaching its decision, the court cited both *Ratzlaf* and *Hanlester*, and explicitly rejected the interpretations of "willful" from the two courts. *See id.* at 495-97.

concerning interpretation of the federal anti-kickback statute's mens rea requirement,[94] but the Hanlester interpretation remains good law, and may be applied not only in circuits that have followed it, but also in circuits that have yet to rule on the issue.[95]

4. Federal Anti-Kickback "Employees" Safe Harbor

Because of the extremely broad language used in the federal anti-kickback statute, the statute itself may cover relatively harmless financial arrangements.[96] To avoid criminalizing innocuous payment practices, the OIG has promulgated over twenty safe harbors that list payment arrangements treated as exceptions to the federal anti-kickback statute.[97] Although a financial arrangement must meet each element of a safe harbor to be deemed exempt from prosecution, a failure to fall entirely within a safe harbor is not an automatic breach of the anti-kickback statute.[98] In fact, commentators have suggested that most arrangements, even those specifically created to fall within an enumerated safe harbor, will not completely fall under a safe harbor and therefore will be evaluated on a case-by-case basis.[99]

One such safe harbor, which was at issue in the Harden case, is the "Employees" safe harbor.[100] According to this safe harbor, amounts paid by an employer to an employee in a bona fide employment relationship for any item or service that is reimbursed under a federal health program is not an illegal remuneration.[101] Determining what exactly constitutes a "bona fide employment relationship," however, is not necessarily a simple task.[102]

94. The United States Supreme Court interpreted willfully as done "with knowledge that the conduct is unlawful is all that is required." Bryan v. United States, 524 U.S. 184, 196 (U.S. 1998). The Eleventh Circuit applied this *Bryan* standard to the federal anti-kickback statute in *United States v. Starks*, 157 F.3d 833, 836 (11th Cir. 1998).

95. *See* Degraw, *supra* note 43, at 287.

96. *See* Medicare and Medicaid Programs; Fraud and Abuse Anti-Kickback Provision, 54 Fed. Reg. 3088 (Jan. 23, 1989) (codified at 42 C.F.R. § 1001).

97. *See* 42 C.F.R. § 1001.952 (2005).

98. Medicare and State Health Care Programs: Fraud and Abuse, 64 Fed. Reg. 63,518, 63,521 (Nov. 19, 1999) ("not . . . every arrangement that does not comply with a safe harbor is suspect under the anti-kickback statute").

99. *See* Linda A. Baumann, *Navigating the New Safe Harbors to the Anti-Kickback Statute*, 12 HEALTH L. 1, 3 (2000); Lissa Bourjolly & Erin Moak, *Health Care Fraud*, 41 AM. CRIM. L. REV. 751, 766-67 (2004).

100. 42 C.F.R. § 1001.952(i).

101. *Id.*

102. *See, e.g.*, United States v. Starks, 157 F.3d 833, 839-40 (11th Cir. 1998) (rejecting defendants' argument regarding the existence of a bona fide employment relationship).

B. *Overview of Florida's Medicaid Anti-Kickback Statute*

Florida's legislature enacted its state's anti-kickback statute in 1991.[103] The statute made it unlawful to:

> Knowingly solicit, offer, pay, or receive any remuneration, including any kickback, bribe, or rebate, directly or indirectly, overtly or covertly, in cash or in kind, in return for referring an individual to a person for the furnishing or arranging for the furnishing of any item or service for which payment may be made, in whole or in part, under the Medicaid program, or in return for obtaining, purchasing, leasing, ordering, or arranging for or recommending, obtaining, purchasing, leasing, or ordering any goods, facility, item, or service, for which payment may be made, in whole or in part, under the Medicaid program.[104]

At the time of enactment, Florida's Medicaid anti-kickback statute defined "knowingly" as an act "done by a person who is aware or should be aware of the nature of his conduct and that his conduct is substantially certain to cause the intended result."[105] Florida's anti-kickback statute contained no safe harbors akin to those listed in the federal anti-kickback statute.[106]

In response to the *State v. Harden* decision in 2004,[107] the Florida legislature amended Florida's Medicaid anti-kickback statute.[108] A mens rea requirement of both knowingly and willfully was included within the statutory definition of "knowingly."[109] The 2004 amendment still did not list any specific safe harbors.[110]

C. *Federal Preemption*

In 1824, the United States Supreme Court held that the U.S.

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103. *See* 1991 Fla. Laws ch. 282, § 50 (1991).

104. FLA. STAT. § 409.920(2)(e) (2000). A violation of the statute was punishable as a third-degree felony, which imposed a maximum penalty of five years imprisonment and a $5,000 fine. State v. Harden, 938 So. 2d 480, 491 (Fla. 2006).

105. FLA. STAT. § 409.920(1)(c).

106. *See* FLA. STAT. § 409.920.

107. *State v. Harden*, 873 So. 2d 352 (Fla. Dist. Ct. App. 2004).

108. *See* 2004 Fla. Laws 344, § 8, 2392-93.

109. *See* FLA. STAT. ANN. § 409.920(1)(d) (West Supp. 2007). "Knowingly" is defined as an act done:

> voluntarily and intentionally and not because of mistake or accident . . . 'knowingly' also includes the word 'willfully' or 'willful' which . . . means that an act was committed voluntarily and purposely, with the specific intent to do something that the law forbids, and that the act was committed . . . either to disobey or disregard the law.

Id.

110. *See* 2004 Fla. Laws 2392-93.

Constitution's Supremacy Clause[111] invalidates any state law that either interferes with or is contrary to any law passed by Congress.[112] In analyzing a federal preemption claim, the Supreme Court historically started with the assumption that the police powers of the states were not to be superseded by a federal law "unless that was the clear and manifest purpose of Congress."[113] Since the *Rice* decision in 1947, however, the preemption doctrine has undergone frequent changes and has been the subject of significant confusion.[114]

Federal preemption may be either express or implied, and is required "whether Congress' command is explicitly stated in the statute's language or implicitly contained in its structure and purpose."[115] The Supreme Court has recognized the following three ways in which federal laws may preempt state laws:[116] (1) through express preemption, where Congress' preemptive purpose is stated within the statutory language itself;[117] (2) through implied field preemption, where the federal regulation scheme is sufficiently all-encompassing that it may be inferred that Congress did not leave any room for state regulation;[118] and (3) through implied conflict preemption,[119] where either compliance with both the federal and state regulations is physically impossible[120] or where

111. U.S. Const. art. VI, cl. 2. (Federal law "shall be the supreme law of the Land; and the Judges in every State shall be bound thereby, any Thing in the Constitution or Laws of any State to the Contrary notwithstanding.").

112. *See* Gibbons v. Ogden, 22 U.S. 1, 210-11 (1824).

113. Rice v. Santa Fe Elevator Corp., 331 U.S. 218, 230 (1947). *But see* Mary J. Davis, *Unmasking the Presumption in Favor of Preemption*, 53 S.C. L. REV. 967, 968 (2002) (arguing that while historically the Supreme Court has said that there is a presumption against preemption, there is actually a presumption in favor of preemption).

114. *See* Davis, *supra* note 113, at 972-1013; Jennifer S. Hendricks, *Preemption of Common Law Claims and the Prospects for FIFRA: Justice Stevens Puts the Genie Back in the Bottle*, 15 DUKE ENVTL. L. & POL'Y. F. 65, 69-79 (2004).

115. Gade v. Nat'l Solid Wastes Mgmt. Ass'n, 505 U.S. 88, 98 (1992) (citing Jones v. Rath Packing Co., 430 U.S. 519, 525 (1977)).

116. *See id.*

117. *See, e.g.*, Egelhoff v. Egelhoff, 532 U.S. 141, 146-52 (2001) (holding a Washington statute that revoked the designation of a spouse as the beneficiary of a nonprobate asset upon divorce was expressly preempted by the language of ERISA).

118. *See, e.g.*, Pa. R.R. Co. v. Pub. Serv. Comm'n, 250 U.S. 566, 569 (1919) (holding that through the Safety Appliance Act and regulations of the Interstate Commerce Commission, Congress had taken over the field of railcar construction to such an extent that a Pennsylvania statute, which conflicted with the Act, was impliedly preempted).

119. Some commentators have broken this implied conflict preemption category into two separate designations, impossibility preemption and obstacle preemption, but the principles remain the same. *See* Hendricks, *supra* note 114, at 69-70.

120. *See, e.g.*, Bibb v. Navajo Freight Lines, Inc., 359 U.S. 520, 523 (1959) (holding that an Illinois statute requiring a certain type of mudguard on trucks was preempted by the Commerce Clause because the statute made it physically impossible to comply with statutes in many other states).

the state regulation blocks the purposes and objectives of Congress.[121] In each of these preemption analyses, a court's objective is "to determine whether state regulation is consistent with the structure and purpose of the statute as a whole."[122]

III. Analysis

The trilogy of Florida courts that handled the *Harden* case were the first courts to hold that the federal anti-kickback statute preempted a state anti-kickback statute.[123] The most important sections of the decisions are the preemption analysis used by the courts, the lack of consensus regarding the federal anti-kickback statute's mens rea requirement, and the Florida Supreme Court's interpretation of the employer-employee safe harbor. Since the *Harden* decision from the appellate court, several Florida courts have interpreted the appellate court's decision.[124] Two decisions in particular may help to better explain the *Harden* analysis and show how influential the preemption analysis used in *Harden* may become.

A. The Preemption Analysis Used by the Florida Courts in Harden Could Influence Other Courts to Preempt State Anti-Kickback Statutes as Unconstitutional

In 2004, Florida's Court of Appeals affirmed a trial court's holding that Florida's anti-kickback statute was conflict preempted and, therefore, unconstitutional.[125] The appellate court based its finding on two significant differences between the federal statute and Florida's anti-kickback statute.[126] First, the appellate court recognized that Florida's anti-kickback statute lacked any safe harbors, and thus criminalized activity that the federal anti-kickback statute protected.[127] Second, the appellate court focused on each anti-kickback statute's mens rea

121. *See, e.g.*, Felder v. Casey, 487 U.S. 131, 138 (1988) (holding that a Wisconsin notice of claims statute was federally preempted by 42 U.S.C. § 1983 because the Wisconsin statute conflicted with the purpose and effects of § 1983's remedial measures and because the state law would produce different outcomes in § 1983 litigation).

122. Gade v. Nat'l Solid Wastes Mgmt. Ass'n, 505 U.S. 88, 98 (1992). A thorough review of federal preemption jurisprudence is beyond the scope of this Comment. Recent preemption jurisprudence has been quite puzzling, but the general background provided above will help explain the *Harden* decision. *See* Davis, *supra* note 113 at 968-72.

123. *See* State v. Harden, 938 So. 2d 480, 491 (Fla. 2006).

124. *See, e.g.*, State v. Wolland, 902 So. 2d 278, 280 (Fla. Dist. Ct. App. 2005); State v. Rubio, 917 So. 2d 383 (Fla. Dist. Ct. App. 2005), *aff'd in part, rev'd in part, and remanded*, 34 Fla. L. Weekly S 464 (Fla. July 12, 2007).

125. State v. Harden, 873 So. 2d 352, 355 (Fla. Dist. Ct. App. 2004).

126. *Id.*

127. *Id.*

requirement and noted that Florida's "knowingly" statutory requirement could criminalize negligent activity.[128] Because of these two differences, the appellate court found that Florida's anti-kickback statute stood as an "obstacle to the accomplishment and execution of the full purposes and objectives of Congress."[129]

In affirming the appellate court's decision, Florida's Supreme Court explained its preemption analysis in more depth than the lower court. At the outset, the court noted that the "federal anti-kickback statute does not contain explicit preemptive language, nor does it contain such a pervasive scheme of federal regulation so as to indicate field preemption."[130] This conclusion was relatively straightforward considering the OIG's statement that "[t]here is no federal preemption provision under the [federal anti-kickback] statute"[131] and the fact that the Medicaid system itself is implemented in large part by the states.[132] The court then began its analysis under the implied conflict preemption category, recognizing that its task was to determine whether Florida's anti-kickback statute "is consistent with the structure and purpose of the [federal] statute as a whole."[133] This task involved "looking to the provisions of the whole law, and to its object and policy."[134]

After discussing the federal anti-kickback statute and its history, the court concluded that neither the statute nor the legislative history reveals its effect on either state anti-kickback statutes or state regulatory schemes.[135] Like the appellate court, the Florida Supreme Court instead examined statutory differences to determine whether the state and federal laws conflicted.[136] First, the court examined the state law's mens rea requirement.[137] The court noted that there remains a question regarding the use of the intermediate or heightened mens rea standard as applied to an anti-kickback statute,[138] but concluded that no federal court has yet to apply a negligence standard akin to the standard from the Florida anti-

128. *Id.*
129. *Id.* (citation omitted).
130. State v. Harden, 938 So. 2d 480, 486 (Fla. 2006).
131. Medicare and State Health Care Programs: Fraud and Abuse; OIG Anti-Kickback Provisions, 56 Fed. Reg. 35,952, 35,957 (July 29, 1991) (codified at 42 C.F.R. § 1001).
132. *See* Harris v. McRae, 448 U.S. 297, 308 (1980) (referring to the Medicaid program as a "cooperative endeavor" and "cooperative federalism").
133. *Harden*, 938 So. 2d at 486 (citing Gade v. Nat'l Solid Wastes Mgmt. Ass'n, 505 U.S. 88, 98 (1992)).
134. *Id.* (citations omitted). The court also seemed to begin its analysis with a presumption against federal preemption. *See id.*
135. *Id.* at 486-90.
136. *Id.* at 490.
137. *Id.* at 491.
138. *See supra* Part II.A.3.

kickback statute.[139]

The court then discussed the state statute's lack of safe harbors.[140] In concluding that the federal anti-kickback statute preempted the state statute, the court cited congressional concern over the fact that the federal anti-kickback statute was broad enough to cover relatively harmless arrangements, which led to the federal safe harbors' enactment.[141] Because the federal safe harbors protected specified conduct that the state statute did not, the court reasoned that the Florida Medicaid statute's lack of safe harbors stood as an obstacle to Congress' purposes.[142]

Although the Harden decision only affects Florida's Medicaid anti-kickback statute, it could become quite influential because it remains the only decision that has held a state anti-kickback statute was federally preempted. Future defendants will no doubt argue that Harden's preemption analysis should be applied to other state anti-kickback statutes under which those defendants are charged.[143] Although the Harden court noted that many state anti-kickback statutes were drafted to closely follow the federal statute,[144] state anti-kickback statutes may vary considerably.[145] State statutes that either do not contain any safe harbors or that are broad enough to criminalize negligent conduct are particularly vulnerable to the Harden court's preemption analysis.[146] Despite this vulnerability, arguments exist against the Harden preemption analysis that could diminish its persuasiveness in other courts.

The strongest argument against the Harden court's preemption analysis is the lack of preemption provisions in the federal anti-kickback statute or its history. The OIG, which has the power to promulgate safe

139. *Harden*, 938 So. 2d at 491. Unlike Florida's Supreme Court, the appellate court applied the heightened mens rea standard from *Hanlester Network*. State v. Harden, 873 So. 2d 352, 355 (Fla. Dist. Ct. App. 2004); *see* discussion *supra* Part II.A.3.

140. *Harden*, 938 So. 2d at 491-92.

141. *Id.* at 491 (citing Medicare and State Health Care Programs: Fraud and Abuse; Clarification of the Initial OIG Safe Harbor Provisions & Establishment of Additional Safe Harbor Provisions Under the Anti-Kickback Statute, 64 Fed. Reg. 63,518, 63,518 (Nov. 19, 1999) (codified at 42 C.F.R. § 1001)).

142. *Harden*, 938 So. 2d at 491-92.

143. *See, e.g.*, California, *ex rel.* Ven-A-Care of the Fla. Keys., Inc. v. Abbott Labs., Inc. (In re Pharm. Indus. Average Wholesale Price Litig.), 478 F. Supp. 2d 164, 179 (D. Mass. 2007) (rejecting defendants' argument that the Massachusetts district court should follow *Harden*).

144. *Harden*, 938 So. 2d at 491; *see, e.g.*, ALA. CODE §§ 22-1-11(b),(c) (LexisNexis 2006).

145. *See* Reply Brief of Appellant State of Florida at 7-8, State v. Harden, 938 So. 2d 480 (Fla. 2006) (No. SC04-0613), 2004 WL 2387304 (explaining that the mens rea requirement in state anti-kickback statutes varies widely); *see also* Leaman, *supra* note 7, at 24-26 (noting that state anti-kickback statutes vary).

146. *See, e.g.*, Leaman, *supra* note 7.

harbors applicable to the federal anti-kickback statute, highlights this fact in the statement "[t]here is no federal preemption provision under the [federal anti-kickback] statute."[147] If there is any doubt about the OIG's stance on this matter, one need only look to the newest safe harbors for arrangements involving electronic prescribing and electronic health records technology.[148] In response to a comment concerning the preemptive power of the newest safe harbors over conflicting state laws, the OIG reiterated the notion that federal anti-kickback law does not preempt state anti-kickback laws.[149] Furthermore, the OIG offered an Advisory Opinion where it stated that "[v]an drivers soliciting, and offering free transportation services to, Medicaid patients for health care providers who compensate the drivers on a per patient or per service basis" is an example of an abusive arrangement involving free transportation.[150] It therefore appears that not only does the federal anti-kickback statute lack any cognizable preemptive power, but also that the compensation arrangement at issue in Harden may violate the federal anti-kickback statute.

Another argument that cuts against the Harden court's analysis is that because Medicaid is a cooperative federal and state program,[151] there should be an even stronger presumption against preemption.[152] The Medicaid program is administered in large part by the states, and Congress gave the states broad latitude in enforcing state laws concerning Medicaid.[153] Because the Florida statute was to cease the abusive and costly practice of giving kickbacks for referrals just like the federal statute, the Florida Supreme Court should have applied a stronger presumption against preemption even though the Florida statute was stricter than its federal counterpart.

Furthermore, the Florida Supreme Court stated that its task was to

147. Medicare and State Health Care Programs: Fraud and Abuse; OIG Anti-Kickback Provisions, 56 Fed. Reg. 35,952, 35,957 (July 29, 1991) (codified at 42 C.F.R. § 1001).

148. *See* Medicare and State Health Care Programs: Fraud and Abuse; Safe Harbors for Certain Electronic Prescribing and Electronic Health Records Arrangements Under the Anti-Kickback Statute, 71 Fed. Reg. 45110 (Aug. 8, 2006) (to be codified at 42 C.F.R. § 1001).

149. *Id.* at 45114.

150. OIG Advisory Opinion 00-7 (Nov. 17, 2000), *available at* http://oig.hhs.gov/fraud/docs/advisory opinions/2000/ao00_7.htm.

151. *See supra* note 132.

152. *See* Pharm. Research & Mfrs. of Am. v. Walsh, 538 U.S. 644, 666 (2003) (noting that the presumption against preemption has special force when the state statute is designed to foster public health and both the federal and state statutes are pursuing common purposes).

153. *See* 42 U.S.C. § 1396b(q) (2006).

look at the federal anti-kickback statute as a whole,[154] but the court arguably focused solely on the structure and purpose of the safe harbor provisions.[155] Had Florida's Supreme Court looked to the entire federal anti-kickback statute, it may have concluded that Florida's Medicaid anti-kickback statute was merely the state's attempt to enforce its own fraud and abuse law, which could be considered consistent with the general purpose of the federal statute.

B. The Florida Supreme Court's Refusal to Adopt Either of the Federal Anti-Kickback Statute's Mens Rea Standards Emphasizes a Circuit Split that Should Be Resolved by the United States Supreme Court

There is currently a circuit split regarding the application of the mens rea requirement "knowingly and willfully" to the federal anti-kickback statute, with the majority of circuits adopting an intermediate, or "middle standard," and a minority of circuits adopting a "heightened standard."[156] This split is clearly demonstrated in the Harden case because the appellate court cited an intermediate standard from *Bryan v. United States,*[157] but arguably followed the heightened mens rea standard from *Hanlester Network v. Shalala.* Florida's Supreme Court explicitly recognized the split, but failed to follow either side in its analysis.[158] Although the Florida Supreme Court did not follow either of the mens rea standards in reaching its decision, the court's discussion of the split suggests that the time to resolve the conflict is now.

In November of 2006, the state of Florida petitioned the United States Supreme Court for a writ of certiorari regarding the Harden decision.[159] Although the Court denied certiorari,[160] the Court should conclusively resolve this split in favor of a single specific mens rea

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154. *See Harden, supra* note 133, at 486.

155. *See* State v. Harden, 938 So. 2d 480, 490-92 (Fla. 2006).

156. *See* discussion *supra* Part II.B.3. Some commentators do not recognize this split as a dichotomy between standards, but rather as a continuum with *Hanlester* on one end and *United States v. Greber*, 760 F.2d 68 (3d Cir. 1985), which was the first reported case discussing the federal anti-kickback statute's scienter requirement, on the other. *See* Blair, *supra* note 91, at 9-32.

157. Bryan v. United States, 524 U.S. 184 (1998). The appellate court cited *Bryan* for the proposition that "in order to establish a 'willful' violation of a statute, 'the Government must prove that the defendant acted with knowledge that his conduct was unlawful.'" State v. Harden, 873 So. 2d 352, 355 (Fla. Dist. Ct. App. 2004) (citing *Bryan*, 524 U.S. at 191-92 (citation omitted)). This proposition is very similar to the middle standard discussed in Part II.B.3, *supra*.

158. *See supra* notes 137-39 and accompanying text. Because the appellate court cited *Bryan* right before citing *Hanlester*, it is not clear exactly which standard the court applied. *See* State v. Harden, 873 So. 2d 352, 355 (Fla. Dist. Ct. App. 2004).

159. State v. Harden, No. 06-770 (Fla. filed Nov. 28, 2006).

160. State v. Harden, 127 S. Ct. 2097 (Apr. 23, 2007) (No. 06-770).

standard for the federal anti-kickback statute.[161] When the Court explicitly resolves the split, it should adopt the same mens rea standard that it adopted with reference to a federal firearms trafficking statute[162] in *Bryan v. United States*[163] because of its similarity to the middle standard currently followed by the majority of circuits,[164] and because the firearms statute at issue in Bryan is similar to the federal anti-kickback statute.[165] Under the *Bryan* standard, "in order to establish a 'willful' violation of a statute, 'the Government must prove that the defendant acted with knowledge that his conduct was unlawful.'"[166] While this standard requires that a defendant act with an evil-meaning mind, acting "knowingly and willfully" does not require knowledge of the specific law itself.[167] Subsequent to this decision, the Eleventh Circuit applied the Bryan standard to the federal anti-kickback statute and in doing so rejected its own prior heightened mens rea standard that required knowledge of the law itself.[168] *United States v. Starks*[169] shows that the Supreme Court's mens rea standard from *Bryan* is compatible with the federal anti-kickback statute. Therefore, the Supreme Court should resolve the circuit split by explicitly extending Bryan to the federal anti-kickback statute.

Alternatively, if the Court were to adopt the heightened mens rea standard explained in *Hanlester*, the federal anti-kickback statute's purpose could be frustrated by the increased burden on government prosecutors. Forcing the government to prove that a defendant both knew of a specific statute and intended to violate it could "contribute appreciably to the cost of the medicare and medicaid programs" by allowing practices that were meant to be criminalized persist due to prosecutorial difficulty.[170]

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161. Commentators have previously suggested that the Supreme Court grant certiorari to resolve this issue in light of the numerous conflicting opinions from the Circuit Courts of Appeals. *See* Blair, *supra* note 91, at 33-36.

162. *See* 18 U.S.C. § 924(a)(1)(d) (2006).

163. Bryan v. United States, 524 U.S. 184 (1998).

164. *See supra* Part II.B.3.b.

165. *See* Degraw, *supra* note 43, at 290 (describing statutory similarities including the fact that each statute was amended to include a "willfully" mens rea requirement and each currently includes the mens rea requirement "knowingly and willfully").

166. *Bryan*, 524 U.S. at 191-92.

167. *See id.* at 191-99.

168. *See* United States v. Starks, 157 F.3d 833, 838-39 (11th Cir. 1998).

169. United States v. Starks, 157 F.3d 833 (11th Cir. 1998).

170. H.R. Rep. No. 92-231 (1971), *reprinted in* 1972 U.S.C.C.A.N. 4989, 5093.

C. *The Florida Supreme Court Misinterpreted Jurisprudence Regarding the Employer-Employee Safe Harbor by Concluding that the Defendants' Practice Fell Under the Safe Harbor*

The third significant aspect of the *Harden* decision is the way that Florida's Supreme Court analyzed the defendants' method of paying drivers on a per head basis under the federal employer-employee safe harbor.[171] The court began its analysis by explaining the employee safe harbor and by quoting an OIG statement that "an employer [may] pay an employee in whatever manner he or she [chooses] for having that employee assist in the solicitation of program business and applied to bona fide employee-employer relationships."[172] The court next recognized that there are no OIG advisory opinions that address the per head payment method used by the defendants, and that there is no case law directly on point.[173] In concluding that the defendants' payment method fell under the employee safe harbor, however, the court cited two cases that applied the employee safe harbor[174] and two cases that did not.[175] The court arguably misinterpreted the cases that it cited in reaching the conclusion that the defendants' method of paying drivers per head was protected by the employee safe harbor.

The court relied on *United States* ex rel. *Obert-Hong v. Advocate Health Care*[176] and *New Boston General Hospital, Inc. v. Texas Workforce Commission*[177] to illustrate payment arrangements in which

171. This safe harbor protects payments made by an employer to a bona fide employee. *See supra* Part II.B.4.

172. State v. Harden, 938 So. 2d 480, 492 (Fla. 2006) (citations omitted).

173. *Id.* at 493. There is, however, an OIG Advisory Opinion that the court did not cite, which seems to apply to the defendants' arrangement. *See supra* note 150 and accompanying text. In response to a request for an opinion regarding free transportation services, the OIG stated that an example of an abusive arrangement involving free transportation is: "[v]an drivers soliciting, and offering free transportation services to, Medicaid patients for health care providers who compensate the drivers on a per patient or per service basis." *Id.*

174. *See* United States *ex rel.* Obert-Hong v. Advocate Health Care, 211 F. Supp. 2d 1045 (N.D. Ill. 2002) (applying the safe harbor to physician-employees who were required to refer patients to the employer hospital and who also received varying compensation based on the value of the work performed by each individual doctor); New Boston Gen. Hosp., Inc. v. Tex. Workforce Comm'n, 47 S.W.3d 34 (Tex. App. 2001) (applying the safe harbor to an employment relationship where a recruiter marketed her employer's hospital to nursing homes for both a wage and a flat fee for each home that contracted with the hospital).

175. State v. Harden, 938 So. 2d 480, 493-94 (Fla. 2006) (citing United States v. Starks, 157 F.3d 833 (11th Cir. 1998) and United States v. Polin, 194 F.3d 863 (7th Cir. 1999)).

176. United States *ex rel.* Obert-Hong v. Advocate Health Care, 211 F. Supp. 2d 1045 (N.D. Ill. 2002).

177. New Boston Gen. Hosp., Inc. v. Tex. Workforce Comm'n, 47 S.W.3d 34 (Tex. App. 2001).

courts applied the employee safe harbor.[178] In *Obert-Hong*, the defendant hospitals, among other things, allegedly required member doctors to refer patients to the hospitals and also purportedly offered bonuses based on the volume of referrals.[179] The *Obert-Hong* court noted that the federal anti-kickback statute is "designed to remove economic incentives from medical referrals, not to regulate typical hospital-physician employment relationships" and that employee compensation, unless directly related to referrals, is exempt under the federal employee safe harbor.[180] In discussing the alleged bonuses, the court further noted that the arrangement fell within the safe harbor because the bonuses "depend[ed] on the value of work performed by the individual doctor, not the value of any referrals."[181] The *Obert-Hong* decision illustrates two types of arrangements that do not fall within the safe harbor: (1) arrangements that provide an economic incentive for medical referrals and (2) compensation based on the value of referrals.[182] Applying these principles to the *Harden* defendants should have led the *Harden* court to determine that the defendants fell outside of the employee safe harbor because the defendant drivers had a clear economic incentive to refer to the defendants. Furthermore, the employees in *Obert-Hong* were doctors who provided "covered items or services,"[183] and it is arguable whether or not soliciting and driving patients is a covered service.[184]

New Boston provides more support for the *Harden* decision than *Obert-Hong*, but the case is nevertheless distinguishable. In *New Boston*, a Texas Court of Appeals held that an employment agreement under which the employee was compensated for recruiting and marketing a hospital's services to nursing homes fell within the employee safe harbor.[185] The employee was also compensated $1,000 for each home that she recruited.[186] Although the facts of the arrangement in *New Boston* appear similar to the *Harden* arrangement, the cases are in fact distinguishable. *New Boston* was not a criminal case where the defendant was charged under the anti-kickback statute, but was rather a civil case where an employee sought back pay from her employer.[187]

178. *Harden*, 938 So. 2d at 493.
179. *Obert-Hong*, 211 F. Supp. 2d at 1048-49.
180. *Id.* at 1050.
181. *Id.*
182. *Id.*
183. 42 U.S.C. § 1320a-7b(b)(3)(B) (2006).
184. *See infra* notes 190-91 and accompanying text.
185. New Boston Gen. Hosp., Inc. v. Tex. Workforce Comm'n, 47 S.W.3d 34, 38-39 (Tex. App. 2001).
186. *Id.* at 35.
187. *Id.*

The anti-kickback issue was raised on appeal by the employer-hospital in an attempt to argue that the contract was unenforceable.[188] Furthermore, the employee was not compensated to solicit individual patients, but rather to solicit nursing homes.[189] In this context, it appears that the *New Boston* employee was merely a businesswoman who received a commission as part of her compensation, and it is debatable whether she had any economic incentive at all based on Medicaid referrals.

The compensation arrangement discussed in the *Starks* decision, which did not apply the employee safe harbor to a physician arrangement, is factually similar to the *Harden* arrangement.[190] In *Starks*, the compensation arrangement included a flat fee for each patient that was referred to defendant Siegel's chemical dependency clinic.[191] The major difference between *Starks* and *Harden* is that the purported "employees" who referred patients to the clinic in *Starks* were already employed by a support clinic for pregnant women; therefore it was very difficult to argue that they were bona fide employees of the defendant Siegel.[192] Despite this difference, the arrangement is almost identical to the *Harden* arrangement because of the per head fee given for referrals in each. In fact, the *Starks* defendants did not argue that the employee safe harbor applied to their arrangement, but argued instead that the safe harbor was constitutionally vague in reference to the anti-kickback statute.[193] In holding that the statute and the safe harbor were not unconstitutionally vague, the *Starks* court specifically noted that the referring "employees" were not even providing "covered items or services."[194] Because the *Starks* arrangement is factually similar to the *Harden* arrangement, it is not certain that the *Harden* drivers were actually performing Medicaid-covered services; this distinction is critical for falling within the employee safe harbor.[195]

A final issue that the Florida Supreme Court failed to analyze, but which could have helped guide its decision, is the fact that several circuits have adopted a "one purpose" test, holding that if one purpose of a payment was to induce referrals compensated through Medicare or Medicaid, the anti-kickback statute has been violated.[196] The facts of the

188. *Id.* at 38.
189. *Id.* at 39.
190. *See* United States v. Starks, 157 F.3d 833, 835-37 (11th Cir. 1998).
191. *Id.* at 836.
192. *Id.* at 836-37. The compensation arrangement in Starks also had a clandestine quality, further undermining any argument concerning a bona fide employer-employee relationship. *See id.* at 839.
193. *Id.* at 839-40.
194. *Id.* at 839.
195. *See id.*
196. *See* United States v. McClatchey, 217 F.3d 823, 835 (10th Cir. 2000); *see also*

Harden case support the conclusion that there was one purpose of the *Harden* arrangement: to induce referrals. Therefore, the one purpose test could have been used to argue against applying the employee safe harbor.

D. *Florida State Courts Have Interpreted* State v. Harden *Inconsistently*

Although different courts have not yet had the opportunity to interpret the *State v. Harden* decision from Florida's Supreme Court in great detail,[197] Florida courts have interpreted the appellate court's decision[198] with conflicting results. The first Florida case interpreting *Harden* was *State v. Wolland*,[199] decided in May 2005. In *Wolland*, the defendant was charged with 115 counts of Medicaid fraud/false billing under Florida's Medicaid Provider Fraud Statute.[200] In a motion to dismiss, the defendant argued that the Florida statute was unconstitutional because federal law preempted the statute.[201] Applying the appellate court's analysis explained in *Harden*, the trial court concluded that the federal false claims provision[202] preempted Florida's false claims provision.[203]

The Florida Court of Appeals (the same court that decided *Harden*), however, reversed the trial court's holding.[204] Like *Harden*, the *Wolland* court recognized that the federal false claims act did not contain any express preemptive language, and also that Congress did not intend for the federal statute to exclusively control the false claims field.[205] The *Wolland* court therefore examined the issue of whether Florida's false claims statute "stands as an obstacle to the execution and

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United States v. Kats, 871 F.2d 105, 108 (9th Cir. 1989); United States v. Greber, 760 F.2d 68, 71-72 (3d Cir. 1985).

197. *See, e.g.*, Prosper Diagnostic Ctrs. v. Allstate Ins. Co., 32 Fla. L. Weekly D 2069 (Fla. Dist. Ct. App. Aug. 29, 2007) (following *Harden* but failing to discuss the decision).

198. State v. Harden, 873 So. 2d 352, 354 (Fla. Dist. Ct. App. 2004).

199. State v. Wolland, 902 So. 2d 278, 280 (Fla. Dist. Ct. App. 2005). Note that Florida's Supreme Court has since disapproved portions of *Wolland* that conflict with its recent decision in State v. Rubio, 32 Fla. L. Weekly S 464 (Fla. July 12, 2007).

200. *Id.* at 279-80; FLA. STAT. ANN. § 409.920(2)(a) (West 2004). Florida's Medicaid Provider Fraud statute provided in pertinent part: "(2) It is unlawful to: (a) Knowingly make, cause to be made, or aid and abet in the making of any false statement or false representation of a material fact, by commission or omission, in any claim submitted to the agency or its fiscal agent for payment." *Id.*

201. *Wolland*, 902 So. 2d at 280. While the Florida statute made it a crime to knowingly make and false statement, the mens rea requirement from 42 U.S.C. § 1320a-7b(a) was knowingly and willfully. *See id.*

202. 42 U.S.C. § 1320a-7b(a) (2006).

203. *Wolland*, 902 So. 2d at 281; FLA. STAT. ANN. § 409.920(2)(a).

204. *Wolland*, 902 So. 2d at 281.

205. *Id.* at 282.

accomplishment of the objectives and goals of Congress," and found that it did not.[206]

In holding that the Florida statute was not federally preempted, the court first applied a strong presumption against preemption because the federal and Florida false claims provisions share common goals.[207] Next, the court recognized that false claims are frequently asserted under the Federal False Claims Act,[208] which does not contain a willfulness mens rea.[209] In distinguishing *Harden*, the court stated that *Harden* turned on the absence of safe harbors in the Florida anti-kickback statute, therefore the *Harden* analysis is limited to the facts of that case.[210]

The next case interpreting *Harden* was *State v. Rubio*,[211] decided in December 2005 by a Florida appellate court. In *Rubio*, five defendants were accused of, *inter alia*, violating Florida's Medicaid provider fraud statute[212] and Florida's patient brokering statute.[213] These accusations arose from an arrangement through which two of the defendants solicited and transported Medicaid-eligible children from public housing areas to the clinics of two other defendant dentists.[214] The dentists would then split the fee received for each child with the person who transported the child.[215] The defendants moved to dismiss the Medicaid provider fraud statute counts on the grounds that the statute is unconstitutional, and also moved to dismiss the patient brokering statute counts on the ground that the statute criminalizes any fee-splitting arrangement without regard to mens rea.[216] The trial court agreed with both of these arguments and held that both Florida statutes were unconstitutional.[217]

The Florida Court of Appeals affirmed the trial court's decision that Florida's Medicaid provider fraud statute was federally preempted.[218] After thoroughly reviewing the *Harden* and *Wolland* appellate decisions, the court disagreed with the *Wolland* decision, holding that one cannot

206. *Id.*
207. *Id.*
208. 18 U.S.C. § 287 (2006).
209. *Wolland*, 902 So. 2d at 282-83.
210. *Id.* at 286.
211. State v. Rubio, 917 So. 2d 383 (Fla. Dist. Ct. App. 2005), *aff'd in part, rev'd in part, and remanded,* 34 Fla. L. Weekly S 464 (Fla. July 12, 2007).
212. FLA. STAT. ANN. § 409.920(2)(a) (West 2004).
213. FLA. STAT. ANN. § 817.505 (West 2004). The patient brokering statute makes fee-splitting for inducing the referral of patients to any healthcare provider illegal (and thus is not specific to federally reimbursed healthcare providers). *Id.*
214. *Rubio*, 917 So. 2d at 387.
215. *Id.*
216. *Id.* at 388.
217. *Id.*
218. *Id.* at 392.

negligently make a false statement.[219] Instead, the *Rubio* court followed the *Harden* analysis and held that Florida's false statement statute "conflicts with federal law just as much as the anti-kickback provision."[220] Like *Harden*, the *Rubio* appellate court found that because Florida's false statement statute criminalized actions that the federal counterpart did not, the statute stood as an obstacle to the objectives and purposes of the Medicaid program.[221] The appellate court in *Rubio*, however, overturned the trial court's holding that Florida's patient brokering statute was unconstitutional.[222] The defendants argued that the patient brokering statute was in effect an anti-kickback statute and, therefore, must contain a willfulness requirement.[223] Rejecting the defendants' argument, the court cited *Wolland* and explained that *Harden* was based primarily on a lack of safe harbors in the Florida anti-kickback, but the patient brokering statute contains safe harbors.[224]

From these two Florida appellate court decisions, it is clear that Florida courts viewed the Florida anti-kickback statute's lack of safe harbors as the deciding factor in the *Harden* appellate court decision.[225] Furthermore, *Wolland* construed the *Harden* analysis very narrowly, limiting the decision to the specific facts of the *Harden* case.[226] These two decisions demonstrate that Florida courts have found it difficult to apply *Harden*'s preemption analysis to similar healthcare fraud statutes. Although the Florida Supreme Court attempted to clarify its *Harden* decision in *State v. Rubio* in July 2007, the *Rubio* and *Wolland* decisions from Florida appellate courts illustrate the difficulty that applying the *Harden* framework entails. Because state Medicaid anti-kickback statutes vary broadly, *Wolland* and *Rubio* suggest that if other courts attempt to apply *Harden*'s analysis then the results will be inconsistent.

IV. Conclusion

The Florida Supreme Court's decision in *State v. Harden* is significant because it is the only decision that has held a state anti-kickback statute unconstitutional. Furthermore, state anti-kickback laws that either criminalize broader conduct than the federal law or that lack

219. *Id.*
220. *Rubio*, 917 So. 2d at 392.
221. *Id.* This holding, however, has since been reversed. *See* State v. Rubio, 34 Fla. L. Weekly S 464 (Fla. July 12, 2007).
222. *See Rubio*, 917 So. 2d at 396.
223. *Id.* at 395.
224. *Id.*
225. *See also* State v. Rubio, 34 Fla. L. Weekly S 464 (Fla. July 12, 2007) (proclaiming "the strong medicine of preemption was necessary in *Harden* because the state statute criminalized activities expressly protected in the federal law").
226. *See supra* note 210.

specific safe harbors are susceptible to the *Harden* court's preemption analysis. While it remains to be seen exactly how persuasive other courts will find the *Harden* decision, courts may use the *Harden* framework to strike down state anti-kickback statutes in the near future. In addition, state legislatures may look to the *Harden* decision and amend their own anti-kickback statutes in an attempt to bring the statutes more in line with the federal anti-kickback law. Despite these possibilities, strong arguments against preempting state Medicaid anti-kickback statutes exist and arguably undermine the *Harden* decision. One argument against preempting state Medicaid anti-kickback statutes is that the federal anti-kickback statute lacks any preemption provisions. In addition, because the Medicaid program is implemented in large part by the states, there should be a strong presumption against preemption, particularly where a state legislature has decided to enact an anti-kickback statute that is stricter than the federal counterpart.

One significant issue discussed in the *Harden* decision is the fact that courts remain split with regard to which mens rea standard to apply to the federal anti-kickback statute. If the issue comes before the United States Supreme Court, the Court should conclusively resolve this split in favor of a uniform standard. The mens rea standard that the United States Supreme Court applied in *Bryan v. United States* should be extended to the federal anti-kickback statute because the *Bryan* standard is consistent with the intermediate standard currently applied by the majority of courts, and is compatible with the anti-kickback statute's mens rea requirement "knowingly and willfully."

The *Harden* analysis will be difficult to apply to other state anti-kickback statutes as well as to healthcare fraud statutes generally. This proposition is clearly demonstrated by examining decisions from the Florida appellate courts that have interpreted *Harden*. Because of the potential for inconsistent outcomes and the weaknesses in the Florida Supreme Court's analysis, other state courts must be cautious in either attempting to apply the *Harden* framework in preemption cases or in holding state anti-kickback statutes unconstitutional. If states cannot decide for themselves how to prosecute Medicaid fraud, then the entire system will suffer.

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