Vanderbilt Law Review

Volume 67
Issue 7 *En Banc*

Article 2

2014

Common and Uncommon Families and the American Constitutional Order

Linda C. McClain

Reviving *Hanlester Network*: A Safe Harbor for Harmless Remunerations Under the Anti-Kickback Statute

I. INTRODUCTION

Consider two hypothetical doctors, Smith and Jones. Dr. Smith is a cardiologist and a savvy businessman. He negotiates a special deal with SmartTick Inc., a manufacturer of cardiac stints. SmartTick will pay a $1,000 "incentive fee" to Dr. Smith every time he implants one of their stints in a patient. Within months, Dr. Smith is performing more cardiac stint procedures than any other cardiologist in the area, even though some of his patients do not need them. One

day, an elderly man (who never needed a stint in the first place) dies due to a complication from one of Dr. Smith's surgeries.[1]

Dr. Jones, on the other hand, is an OB/GYN with a passion for underserved populations. A hospital in Seymour—an impoverished, rural city—wants to hire Dr. Jones to relocate there. The women in Seymour currently have no access to an OB/GYN. The hospital will pay Dr. Jones an above-market salary for moving to Seymour and for the increased business that she will generate. Dr. Jones agrees. However, Dr. Jones's former patients like her so much that they are willing to drive an extra hour to Seymour to continue seeing her. At the hospital, Dr. Jones spends half of her time seeing old patients and half of her time seeing new patients from Seymour. Dr. Jones, unlike Dr. Smith, never orders any medically unnecessary services for her patients.[2]

To the average observer, Dr. Smith's conduct is abhorrent, while Dr. Jones's actions are commendable. Nevertheless, under current federal law, both doctors have likely committed a felony. The federal Anti-Kickback Statute ("AKS")[3] criminalizes the giving and receiving of remunerations in exchange for patient referrals. The AKS is incredibly broad and applies to both Smith's blatant fraud and Jones's seemingly innocuous behavior. The sweeping nature of the AKS discourages health care providers from entering into arrangements that could provide patients with better, more affordable care. The Ninth Circuit acknowledged this reality in *Hanlester Network v. Shalala*[4] when it attempted to narrow the scope of the AKS. Unfortunately, the courts legal analysis was ultimately unsound. Nevertheless, *Hanlester Network* remains significant because it suggests a useful framework for reforming the AKS.

This Comment proceeds in four parts. Part II provides the basic framework of the Anti-Kickback Statute and summarizes the Ninth Circuit's decision in *Hanlester Network*. Part III explains why the Ninth Circuit's reasoning in *Hanlester Network* was motivated by

---

1. This hypothetical was borrowed from an example given by Professors Matt Curley and Brian Roark in their Fall 2013 Health Care Fraud and Abuse course at Vanderbilt Law School.

2. This hypothetical is based on a technical violation of the regulatory safe harbor for physician recruitment under the Anti-Kickback Statute. *See* (2007). Unfortunately, the lack of OB/GYN services for women in rural locales is not a hypothetical problem, but rather a growing public health concern. *See Ob-Gyns Urged to Help Reduce Health Disparities for Rural Women*, AM. CONG. OBSTETR. & GYNECOL. (Feb. 20, 2009), http://www.acog.org/About_ACOG/News_Room/News_Releases/2009/Ob-Gyns_Urged_to_Help_Reduce_Health_Disparities_for_Rural_Women (explaining the lack of OB/GYN services in rural communities, the preventable diseases that this causes, and the need for physician recruitment to these areas).

3. 42 U.S.C. § 1320a-7b(b) (2012).

4. 51 F.3d 1390, 1394 (9th Cir. 1995).

laudable policy goals, even though its legal reasoning left something to be desired. Part IV uses *Hanlester Network* as the inspiration for a new regulatory safe harbor that could meaningfully narrow the AKS. Part V briefly concludes. Ultimately, this Comment argues that the U.S. Department of Health and Human Services ("HHS") should create a safe harbor that immunizes health care providers from AKS liability when they (1) cause no harm to federal health care programs and (2) receive the informed consent of their patients.

II. BACKGROUND

Before discussing any proposals for reform, some background information is in order. Section A of this Part provides an overview of the AKS, and Section B explores how the Ninth Circuit interpreted the AKS in *Hanlester Network*.

A. The Anti-Kickback Statute

Federal health care programs like Medicare and Medicaid pay out enormous sums to health care providers each year. In 2012, for instance, the federal government spent over $500 billion on Medicare benefit payments—sixteen percent of the entire federal budget.[5] Unsurprisingly, health care providers often try to game this lucrative system. Health care fraud costs the federal government between $80 and $100 billion each year.[6] This statistic can best be understood as *lost* care: the money that the government pays to fraudsters could be used to provide care for Americans who need it.

Congress enacted the AKS to combat one particular form of health care fraud: pay-for-patient, or "kickback," schemes. A kickback is essentially a payment from one health care provider to another in exchange for patient referrals. Congress decided to prohibit remuneration schemes for two primary reasons. First, kickbacks can lead to overutilization of health care services, which drains the federal budget. Kickbacks often encourage health care providers to prescribe more services than they would otherwise, and the federal government must then reimburse those expenses.[7] (Some have suggested that the

5. *Medicare Spending and Financing Fact Sheet*, KAISER FAMILY FOUND. (Nov. 14, 2012), http://kff.org/medicare/fact-sheet/medicare-spending-and-financing-fact-sheet/ [hereinafter KFF].

6. *Health Care Fraud*, FED. BUREAU INVESTIGATION, http://www.fbi.gov/about-us/investigate/white_collar/health-care-fraud (last visited Oct. 15, 2013); Parija Kavilanz, *Health Care: A "Goldmine" for Fraudsters*, CNN MONEY (Jan. 13, 2010, 3:07 PM), http://money.cnn.com/2010/01/13/news/economy/health_care_fraud/.

7. Richard P. Kusserow, *The Medicare and Medicaid Anti-Kickback Statute and the Safe Harbor Regulations--What's Next?*, 2 HEALTH MATRIX 49, 52 (1992).

AKS also prevents unfair competition in the health care marketplace,[8] but this rationale cannot be meaningfully separated from the government's concern with costs.[9]) Second, kickbacks compromise patient welfare by potentially corrupting a doctor's medical judgment. Instead of focusing on the best interests of the patient, doctors may order unnecessary tests and risky operations to line their own pockets with kickback payments.[10] These concerns led Congress to pass the first version of the AKS in 1972 and to strengthen the statute with a series of amendments.[11]

1. Prima Facie Case

To prove a violation of the AKS, the government must show, beyond a reasonable doubt, that the defendant (1) knowingly and willfully (2) gave, received, or solicited a remuneration (3) in return for patient referrals (or other business) (4) in connection with a federal health care program.[12] The first element—the scienter requirement—

---

8. *See* Medicare and State Health Care Programs: Fraud and Abuse; OIG Anti-Kickback Provisions, 56 Fed. Reg. 35,952, 35,954 (Jul. 29, 1991) ("[T]he [AKS] does not make increased cost to the government the sole criterion of corruption. . . . [K]ickback schemes can freeze competing suppliers from the system, can mask the possibility of government price reductions, can misdirect program funds, and . . . can erect strong temptations to order more drugs and supplies than needed." (quoting United States v. Ruttenberg, 625 F.2d 173, 177 n.9 (7th Cir. 1980)).

9. *See* James F. Blumstein, *The Fraud and Abuse Statute in an Evolving Health Care Marketplace: Life in the Health Care Speakeasy*, 22 AM. J.L. & MED. 205, 222 n.152 [hereinafter Blumstein, *Health Care Speakeasy*] (arguing that, if unfair competition is occurring, this would be impossible to prove without first demonstrating increased costs).

10. Kusserow, *supra* note 8.

11. *See* Social Security Amendments of 1972, Pub. L. No. 92-603 (1972) (original AKS statute); Medicare-Medicaid Anti-Fraud and Abuse Amendments, Pub. L. No. 95-142 (1977) (expanding the statute to cover any "remuneration," upgrading the crime to a felony, increasing the penalties); Medicare and Medicaid Amendments of 1980, Pub. L. No. 96-499 (1980) (adding a "knowingly and willfully" intent requirement); Medicare and Medicaid Patient and Program Protection Act of 1987, Pub. L. No. 100-93 (1987) (combining the Medicaid and Medicare AKS provisions into one statute, authorizing the sanction of exclusion, delegating authority to HHS to create safe harbors); Health Insurance Portability and Accountability Act of 1996, Pub. L. No. 101-191 (1996) (increasing penalties, increasing funds for enforcement, creating new exceptions, authorizing OIG advisory opinions); Patient Protection and Affordable Care Act, Pub. L. No. 111-148 (2010) (specifying that the AKS does not require specific intent).

12. 42 U.S.C. § 1320a-7b(b)(1)–(2) (2012):

> (b) Illegal remunerations
>
> (1) whoever knowingly and willfully solicits or receives any remuneration (including any kickback, bribe, or rebate) directly or indirectly, overtly or covertly, in cash or in kind--
>
> (A) 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 a Federal health care program, or
>
> (B) in return for purchasing, leasing, ordering, or arranging for or recommending purchasing, leasing, or ordering any good, facility, service, or item for which payment

was the focus of *Hanlester Network*, which will be discussed in more detail in Parts II.B and III.A. Moreover, the fourth element is self-explanatory: the AKS only safeguards *federal* health care programs from kickbacks (though many states have enacted their own anti-kickback laws[13]). The second and third elements require further elaboration.

The second element of the AKS requires the provision of some sort of "remuneration." The original AKS only prohibited schemes involving a "kickback," "bribe," or "rebate."[14] However, when federal courts began reading these terms narrowly,[15] Congress broadened the statute to cover "any remuneration."[16] This change in terminology underscores the broad scope of the AKS. Remunerations include essentially anything of value—including kickbacks, bribes, rebates, and gifts, as well as leases, equipment, employment contracts, and other arrangements that depart from fair market value.[17] Remunerations are prohibited under the AKS whether they are paid "directly or indirectly, overtly or covertly, in cash or in kind."[18] Thus, health care providers can even face AKS liability for seemingly innocent behavior like providing free donuts in the doctors' lounge.[19]

> may be made in whole or in part under a Federal health care program, shall be guilty of a felony and upon conviction thereof, shall be fined not more than $25,000 or imprisoned for not more than five years, or both.
>
> (2) whoever knowingly and willfully offers or pays any remuneration (including any kickback, bribe, or rebate) directly or indirectly, overtly or covertly, in cash or in kind to any person to induce such person--
>
> (A) to refer 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 a Federal health care program, or
>
> (B) to purchase, lease, order, or arrange for or recommend purchasing, leasing, or ordering any good, facility, service, or item for which payment may be made in whole or in part under a Federal health care program, shall be guilty of a felony and upon conviction thereof, shall be fined not more than $25,000 or imprisoned for not more than five years, or both.

13. *See generally* Kathryn Leaman, *State Anti-Kickback Statutes: Where the Action Is*, 2 HEALTH L. & POL'Y BRIEF 22 (2008) (surveying a sample of state anti-kickback statutes).

14. Social Security Amendments of 1972 § 1877(b).

15. *See, e.g.,* United States v. Porter, 591 F.2d 1049 (5th Cir. 1979) (holding that handling fees are not a "kickback"). *But see* U.S. v. Hancock, 604 F.2d 999 (7th Cir. 1979) (rejecting *Porter* and holding that handling fees are a "kickback").

16. Medicare-Medicaid Anti-Fraud and Abuse Amendments § 1877(b) (1977).

17. *See The Federal Anti-Kickback Statute*, AM. HEALTH CARE ASS'N, http://www.ahcancal.org/facility_operations/ComplianceProgram/Pages/RiskPoliciesProc.aspx (last visited Oct. 16, 2013).

18. 42 U.S.C. § 1320a-7b(b) (2012).

19. *See* Lisa Michelle Phelps, Note, *Calling Off the Bounty Hunters: Discrediting the Use of Alleged Anti-Kickback Violations to Support Civil False Claims Actions*, 51 VAND. L. REV. 1003, 1042 n.208 (1998) (citing a letter from the government stating that "trinkets such as doughnuts and mugs may be violating the Medicare anti-kickback law, even though the inducement seems trivial").

The third element in the AKS statute—that the remunerations were given to induce patient referrals—has been the subject of extensive litigation. Nevertheless, a strong majority of courts agree with the approach taken by the Third Circuit in *United States v. Greber*.[20] There, the Third Circuit held that the inducement element of the AKS is satisfied if soliciting patient referrals was even "one purpose" of the remuneration scheme.[21]

2. Safe Harbors & Advisory Opinions

As the preceding discussion suggests, liability under the AKS is broad, and health care providers are often surprised by the conduct that the statute prohibits. Congress acknowledged this reality when it enacted several statutory safe harbors and gave HHS the authority to create more.[22] Congress also authorized the HHS Office of Inspector General ("OIG") to issue binding advisory opinions, which function like case-by-case safe harbors.[23] Together, these safe harbors protect conduct that would otherwise violate the AKS. Examples include bona fide employment contracts,[24] group practices,[25] sales of physician practices,[26] and several others.[27]

However, the AKS safe harbors are no panacea. Courts interpret the AKS broadly and the safe harbors narrowly.[28] A health care provider's conduct must fit squarely within the four corners of a safe harbor, or it will be judged by the unforgiving "one purpose" standard from *Greber*.[29] In short, the safe harbors are a step in the right direction, but they are by no means an all-encompassing solution for health care providers who are worried about the broad reach of the AKS.

---

20. 760 F.2d 68 (3d Cir. 1985)*; see also, e.g.*, United States v. Davis, 132 F.3d 1092, 1094 (5th Cir. 1998); United States v. Kats, 871 F.2d 105, 108 (9th Cir. 1989); United States v. McClatchey, 217 F.3d 823, 835 (10th Cir. 2000).

21. *Greber*, 760 F.2d at 69.

22. Medicare and Medicaid Patient and Program Protection Act of 1987, Pub. L. No. 100-93, 101 Stat. 680, 697 (1987).

23. Health Insurance Portability and Accountability Act of 1996, Pub. L. No. 104-191; 110 Stat. 1936, 2000–02 (1996).

24. 42 C.F.R. § 1001.952(i) (2007).

25. 42 C.F.R. § 1001.952(p) (2007).

26. 42 C.F.R. § 1001.952(e) (2007).

27. *See generally* 42 U.S.C. § 1320a-7b(b)(3) (2012); 42 C.F.R. § 1001.952 (2007).

28. Blumstein, *Health Care Speakeasy*, *supra* note 9, at 205.

29. *See* HEALTH L. HANDBOOK § 7:9 (5th ed. 2009) ("[A]rrangements that do not fit squarely within an exception or safe harbor do not necessarily violate the AKS, but certainly may be subject to scrutiny and challenge.").

3. Penalties

The penalties for violating the AKS are quite severe. The AKS is a criminal statute, and a conviction amounts to a *felony*.[30] The available criminal punishments include five years in prison and fines of $25,000 per violation.[31] On the civil side, the government can seek monetary penalties of $50,000 and treble damages for each violation of the AKS.[32]

Violations of the AKS can also render a health care provider liable under the civil False Claims Act ("FCA"). Health care providers must comply with the AKS under the terms of their enrollment agreements with Medicare. Accordingly, each time a provider submits a claim for reimbursement while simultaneously violating the AKS, that claim is "false" because the provider is lying about being in compliance with federal health care laws.[33] Providers face treble damages and penalties up to $10,000 for each false claim submitted to the government.[34] Significantly, private whistleblowers can bring FCA claims as *qui tam* actions—even without the government's blessing—and recover a percentage of the ultimate recovery.[35] Thus, the FCA subjects health care providers to the threat of lawsuits from a large number of plaintiffs motivated by the prospect of a blockbuster recovery.[36]

Moreover, the AKS is closely related to the Stark law—a civil statute that prohibits physicians from referring patients to entities where the physician has a preexisting financial relationship.[37] A violation of the Stark law is a strict liability offense, which alleviates the government's burden of proving intent.[38] The AKS and the Stark law prohibit similar conduct (i.e., referring patients for financial

---

30. 42 U.S.C. § 1320a-7b(b)(1)–(2) (2012).

31. *Id.*

32. 42 U.S.C § 1320a-7a(a) (2012).

33. *See, e.g.*, United States *ex rel.* Pogue v. American Heatlhcorp, Inc., 914 F. Supp. 1507 (M.D. Tenn. 1996); United States *ex rel.* Thompson v. Columbia/HCA Healthcare Corp., 125 F.3d 899 (5th Cir. 1997).

34. 31 U.S.C. § 3729(a) (2012).

35. 31 U.S.C. §§ 3729–33 (2012).

36. *See, e.g.*, Melissa Rifai, *Department of Justice's Historic FCA and AKS Settlement*, HEALTH REFORM WATCH (Apr. 4, 2013), http://www.healthreformwatch.com/2013/04/04/department-of-justices-historic-fca-and-aks-settlement/ (discussing a $26.1 million *qui tam* settlement under the FCA against a dermatologist who received illegal kickbacks); Phelps, *supra* note 20, at 1018 n. 68 (identifying two examples of settlements under the FCA based on AKS violations of $324 million and $161 million).

37. 42 U.S.C. § 1395nn (2012).

38. 1-5 HEALTH CARE LAW: A PRACTICAL GUIDE, SECOND EDITION § 5.01 (2d ed. 2013); Stephen M. Blank et al., *Health Care Fraud*, 46 AM. CRIM. L. REV. 701 (2009).

gain),[39] and they contain nearly identical safe harbors.[40] Accordingly, even though this Comment focuses on the AKS, the arguments made in Parts III and IV could apply to both statutes.

Finally, the government has powerful administrative remedies to levy against health care providers who violate the AKS. A conviction under the AKS is grounds for mandatory exclusion from federal health care programs.[41] Exclusion is known as the "death penalty" for health care providers because they cannot stay solvent without access to the nation's fifty million Medicare patients.[42]

In short, the AKS dramatically raises the stakes for health care providers. If they violate the broad terms of the statute, providers face large fines, financial ruin, and even prison time. This stark reality likely loomed large in the background of the Ninth Circuit's decision in *Hanlester Network*.

B. Hanlester Network v. Shalala

The *Hanlester Network* case involved a somewhat complicated arrangement between Hanlester Network ("Hanlester") and Smithkline BioScience Laboratories ("SKBL").[43] Hanlester and several individual employees were accused of violating the AKS for two reasons. First, Hanlester sold partnership interests in their laboratories to individual physicians, which was allegedly intended to induce the doctors to refer patients to the labs.[44] Second, Hanlester allegedly received payments from SKBL in exchange for patient referrals. Under the terms of their agreement, SKBL provided various management services for the Hanlester labs—such as staffing, billing, collection, and equipment—and Hanlester referred 85–90% of their patients to SKBL facilities.[45] Instead of bringing criminal charges, the government sought the administrative remedy of exclusion against the Hanlester defendants. The district court ultimately sided with the government, concluding that many of the defendants had violated the AKS and should be excluded from further participation in federal health care programs.[46]

---

39. *Id.*

40. *Compare* 42 U.S.C § 1320a-7b(b)(3) (2012), *with* 42 U.S.C. § 1395nn(b) (2012).

41. 42 U.S.C. § 1320a-7 (2012).

42. Pamela H. Bucy, Symposium, *The Path from Regulator to Hunter: The Exercise of Prosecutorial Discretion in the Investigation of Physicians at Teaching Hospitals*, 44 ST. LOUIS L.J. 3, 39 (2000); KFF, *supra* note 6.

43. Hanlester Network v. Shalala, 51 F.3d 1390, 1394 (9th Cir. 1995).

44. *Id.* at 1395.

45. *Id.*

46. *Id.* at 1395–96.

On appeal, the Ninth Circuit overturned most of the district court's decision.[47] According to the Court of Appeals, the misconduct at issue was solely attributable to one rogue employee—Hanlester's former vice president of marketing—so the other individuals lacked the requisite intent for an AKS violation.[48] Yet, the real value of *Hanlester Network* stems not from its facts but rather from the Ninth Circuit's extrapolation of the legal framework surrounding the AKS.

Hanlester Network stands for two interesting points of law. First, the Ninth Circuit significantly narrowed the scope of the scienter requirement in the AKS. The court interpreted the phrase "knowingly and willfully" in the statute to require that the defendant (1) knew that the AKS prohibits pay-for-patient schemes and (2) decided to participate in such a scheme anyway.[49] In other words, defendants need "specific intent" to violate the AKS; if defendants are unaware that the AKS exists, then they cannot be punished under the statute.[50] The Ninth Circuit did not derive this requirement from the text or the legislative history of the AKS, but rather from a few Supreme Court decisions that had interpreted the term "willfully" in other statutes.[51]

The second interesting holding from *Hanlester Network* dealt with the question of harm. For the defendants who violated the AKS, the Ninth Circuit held that they should not be excluded from further participation in federal health care programs. The court came to this conclusion, in part, because there was "no evidence that Hanlester [or its affiliated labs] caused *harm* to the Medicare or Medicaid programs."[52] The court refused to impose the draconian penalty of exclusion when there was no actual harm to the government because doing so would not serve the "remedial purpose" of administrative sanctions, i.e. "protect[ing] federally-funded health care programs and their beneficiaries and recipients from future conduct which is or might be harmful."[53]

Taken together, these two holdings made *Hanlester Network* stand out among the cases interpreting the AKS. When the decision was handed down, *Hanlester Network* was referred to as "dramatic,"

47. *Id.* at 1402.

48. *Id.* at 1400–01.

49. *Id.* at 1400.

50. *Id.*

51. *See id.* at 1399–1400.

52. *Id.* at 1402 (emphasis added). The court also determined that exclusion was a moot point because the rogue employee had been fired and because the joint venture was no longer in business. *Id.* at 1402 & n.21.

53. *Id.* at 1401–02.

"ground-breaking," and a "shocking defeat for the government."[54] These reactions likely stem from the fact that the Ninth Circuit's reasoning was legally questionable, despite its normative desirability.

III. *HANLESTER NETWORK* WAS BAD LAW, BUT GOOD POLICY

The Ninth Circuit had admirable intentions in *Hanlester Network*, but its legal reasoning left much to be desired. This Part explores each of the two key holdings in *Hanlester Network*, identifying both the weaknesses in the Ninth Circuit's legal reasoning and the strengths in the policy objectives that the court was trying to accomplish.

A. The AKS Does Not Require Specific Intent, but the "One Purpose" Test Is Overly Broad

The first notable holding from *Hanlester Network*—that the scienter requirement of the AKS requires specific intent—was not the best interpretation of the AKS at the time and is a forbidden interpretation today. After *Hanlester Network*, every other federal court rejected the Ninth Circuit's interpretation.[55] As the Eleventh Circuit explained, a specific intent requirement violates the "traditional rule" of criminal law that "ignorance of the law is no excuse."[56] The only recognized exceptions to this rule are cases involving "highly technical tax or financial regulation[s]" where the law itself is so complex that it is difficult to determine what conduct is illegal.[57] This exception does not apply to the AKS because it is a relatively straightforward law that flatly prohibits pay-for-patient schemes.[58] In other words, the AKS may be broad, but its breadth is clear from the text of the statute. Indeed, federal courts outside of the Ninth Circuit interpret the AKS to require only that defendants know their conduct was "unlawful" or "wrongful," regardless of whether they knew that the AKS existed.[59]

Furthermore, even if the Ninth Circuit's interpretation was correct at the time, it is certainly untenable today. The Patient

---

54. William R. Kucera, Jr., Hanlester Network v. Shalala*: A Model Approach to the Medicare and Medicaid Kickback Problem*, 91 NW. U. L. REV. 413, 416 & nn.22–24 (1996) (collecting sources).

55. *See, e.g.*, United States v. Starks, 157 F.3d 833, 838–39 (11th Cir. 1998); United States v. Davis, 132 F.3d 1092, 1094 (5th Cir. 1998); United States v. Jain, 93 F.3d 436, 441 (8th Cir. 1996); United States v. Neufeld, 908 F. Supp. 491, 497 (S.D. Ohio 1995).

56. *Starks*, 157 F.3d at 838.

57. *Id.*

58. *See id.*

59. *See, e.g.*, *id.*; *Davis*, 132 F.3d at 1094; *Jain*, 93 F.3d at 441; *Neufeld* 908 F. Supp. at 497.

Protection and Affordable Care Act of 2010 ("PPACA") amended the AKS to overrule *Hanlester Network*.[60] The PPACA added subsection (h) to the statute, which clarifies that "a person need not have actual knowledge of this section or specific intent to commit a violation of this section."[61]

Although the Ninth Circuit ultimately lost the debate over specific intent, its desire for ratcheting up the scienter requirement in the AKS was understandable. The "one purpose" standard articulated by the Third Circuit in *Greber* is incredibly broad. In the words of two prominent health care attorneys, "The Anti-Kickback Act prohibits conduct that is engaged in every day, at all levels, throughout the health care industry."[62] Even HHS admits that the AKS reaches "many harmless or efficient arrangements."[63] The AKS bans rewards, gifts, and other incentives that are commonplace and perfectly acceptable in industries outside of the medical field.[64] Some courts have attempted to narrow the "one purpose" test by clarifying that the mere "hope or expectation" of referrals is not enough to trigger AKS liability.[65] However, health care providers cannot take much comfort in these decisions; the sweeping "one purpose" language of *Greber* is still the black letter law, and the difference between a "hope or expectation" and "one purpose" is anything but clear.[66]

The breadth of the AKS creates a very uncertain regulatory environment for health care providers. Providers face prison time and financial ruin based on metaphysical distinctions like the difference between a "purpose" and an "expectation." Health care attorneys cannot alleviate this uncertainty for their clients: it is impossible to determine whether a particular scheme is lawful under the AKS (if it

---

60. Patient Protection & Affordable Care Act, Pub. L. No. 111-148, §6402(f), 124 Stat. 119, 759 (2010).

61. 42 U.S.C. § 1320a-7b(h) (2012).

62. Michael M. Mustokoff & Robin Locke Nagele, *Health Care Providers Do Not Deserve to Be Treated as "Drug Dealers": An Analysis of the Criminal Intent Standard Under the Anti-Kickback Act*, 13 NO. 4 HEALTH LAW. 13, 17 (2001).

63. Medicare and Medicaid Programs; Fraud and Abuse OIG Anti-Kickback Provisions, 54 Fed. Reg. 3,088-01, 3,088 (Jan. 23, 1989).

64. *See also* Blank et al., *supra* note 39, at 710 ("[T]he [AKS] applies to many practices that were previously commonly accepted in business, including discount arrangements, incentives given to pharmacists, payments for services, and the practice of manufacturers giving gifts and offering business courtesies.").

65. *See, e.g.*, Hanlester, 51 F.3d at 1398 (9th Cir. 1995); McClatchey, 217 F.3d at 834 n.7 & 835 (10th Cir. 2000).

66. The Tenth Circuit candidly, albeit dismissively, acknowledged this difficulty. *See McClatchey*, 217 F.3d at 834 n. 7 ("This court recognizes that it may be difficult for a jury to distinguish between a motivating factor and a collateral hope or expectation. Making such difficult factual determinations, however, is the very role which our system of justice assigns to the finder of fact.").

does not clearly fall within a safe harbor) because the lawyer can never really know the client's intent. This confusing regulatory environment discourages health care providers from entering into relationships that could expand patients' access to affordable health care.[67] After all, health care is a market, and "markets hate uncertainty."[68]

Commentators and legislators have proposed amending the AKS to overrule the *Greber* "one purpose" test. Under these amendments, a remuneration scheme would not violate the AKS unless securing patient referrals was a "significant purpose" of the defendant's conduct.[69] However, these proposals are unsatisfactory because they still rely on complex determinations of intent. A "significant purpose" standard would require courts to weigh how much a defendant was motivated by a desire for patient referrals vis-à-vis other possible motivations—hardly an easy determination. This would inflate the costs of litigating AKS cases and actually *increase* uncertainty about how the law applies.[70] Thus, for health care providers seeking to escape the shroud of *Greber*, a "significant purpose" test does not add enough certainty to make much of a difference. Like the Ninth Circuit in *Hanlester Network*, the commentators who propose this solution are understandably bothered by the broad definition of intent under the AKS. However, something more is needed.

B. The AKS Does Not Have a Harm Requirement, but It Should

The second significant holding from *Hanlester Network* was the Ninth Circuit's refusal to exclude the defendants from further participation in federal health care programs. The Ninth Circuit justified this conclusion, in part, on the fact that the defendants did not actually cause any economic harm to the government. Of course, the appropriateness of exclusion is a different question from whether the defendants violated the AKS in the first place. Nevertheless, the court's consideration of the financial impact of the defendants' conduct

---

67. Blumstein, *Health Care Speakeasy*, *supra* note 10, at 224.

68. James Mackintosh, *The Uncertainty of Gridlock*, FIN. T. (Nov. 4, 2010, 12:06 AM), http://www.ft.com/cms/s/0/74fc990a-e79a-11df-8ade-00144feab49a.html#axzz2j54Fc4HB ("One of the few certainties in the markets is that markets hate uncertainty.").

69. *See, e.g.*, Medicare Preservation Act of 1995, H.R. 2425, 104th Cong. § 15,212 (1st Sess. 1995); James F. Blumstein, *Rationalizing the Fraud and Abuse Statute*, 15 HEALTH AFF. 118, 126 (1996).

70. Timothy S. Jost & Sharon Davies, *Perspective: The Fraud and Abuse Statute: Rationalizing or Rationalization?*, 15 HEALTH AFF. 129 (1996) (criticizing recommendations like the "significant purpose" test on these grounds).

exposes a particularly interesting feature of the AKS—the lack of a harm requirement in the government's prima facie case.

A simple reading of the text of the AKS reveals that Congress did not include a harm requirement in the statute.[71] This omission is odd, since one of the main purposes of the AKS is to prevent overutilization of federal health care (i.e., economic harm to the government).[72] The lack of a harm requirement emphasizes the expansiveness of the concept of "fraud" in the AKS. Other federal fraud statutes—including mail fraud[73] and wire fraud[74]—require the government to demonstrate harm as part of the prima facie case.[75] These harm requirements ensure that the fraud statutes remain narrow and only criminalize conduct that has some measurable negative effect.

The AKS, due to its lack of a harm requirement, may hinder innovative approaches to health care that would deliver real benefits for patients. Consider managed care organizations ("MCOs"). Medicare is traditionally a fee-for-service program, whereby health care providers are compensated for each service rendered.[76] Accordingly, providers in a fee-for-service system have an incentive to *overutilize* health care, since they get paid for each service provided (a problem that is only exacerbated when kickbacks are introduced).[77] MCOs, on the other hand, are compensated on a capitated basis; the government pays a flat fee to the MCO regardless of the volume of health care services provided.[78] Thus, MCOs have an incentive to cut costs and avoid unnecessary services, which empirically decreases the overall cost of health care.[79] As the amount of spending on medical

71. *See also* United States *ex rel.* Pogue v. American Healthcorp, Inc., 914 F. Supp. 1507, 1509 (M.D. Tenn. 1996) (concluding that a False Claims Act violation based on a violation of the AKS does not require the government to prove harm).

72. *See supra* Part II.A.

73. *See* 18 U.S.C. § 1341 (2012).

74. *See* 18 U.S.C. § 1343 (2012).

75. Of course, the government can still satisfy its burden under the mail and wire fraud statutes without demonstrating that harm *actually* occurred. It is enough that the defendant's fraud would have caused harm if it was successful. *See* Amy Zelcer, *Mail and Wire Fraud*, 49 AM. CRIM. L. REV. 985, 999 (2012). However, this requirement is still more stringent than the AKS, since remuneration schemes that have *no* potential to cause harm could still be prohibited under that statute.

76. Blumstein, *Health Care Speakeasy*, *supra* note 10, at 205.

77. *Id.* at 207.

78. *Id.* at 213.

79. *Managed Care Has Slowed Growth in Medical Spending*, NAT'L BUREAU ECON. RES. (1998), *available at* http://www.nber.org/digest/may98/w6140.html ("[F]or every 10-percentage-point increase in the HMO enrollment rate, the growth of health spending falls by 0.5 percentage points per year.").

care in the U.S. continues to rise,[80] the cost savings generated by MCOs should only be encouraged. Presently, the AKS provides only some safe-harbor protection for MCOs, subjecting them to fairly stringent conditions.[81] However, managed care arrangements—and other schemes that fall just outside of the current AKS safe harbors—are often socially beneficial and warrant more protection.

Commentators have proposed various safe harbors under the AKS that would protect health care providers who cause no economic harm, or a cost-beneficial level of economic harm, to the government.[82] For instance, William Kucera argues that the government should borrow the "rule of reason" from antitrust and exempt health care schemes from AKS liability if they do not cause overutilization of health care resources.[83]

Yet, these harm-centric proposals are necessarily incomplete. Although preventing overutilization is certainly one purpose behind the AKS, the statute also protects patient welfare. A doctor receiving kickbacks could still endanger a patient by prescribing unnecessary procedures, even if the scheme caused no economic harm to the government. For example, a doctor in an MCO could order a medically inappropriate operation because he will receive a kickback *individually*, even though the government is not injured because it pays a capitated payment to the doctor's *group*. Thus, proposals for reform that only address the economic dimension of the AKS without considering patient welfare are not completely satisfactory.

IV. A REGULATORY SAFE HARBOR INSPIRED BY *HANLESTER NETWORK*

The Ninth Circuit in *Hanlester Network* exposed some of the weaknesses in the current AKS regime. Yet, many of the proposed reforms mentioned above are either too difficult to apply or pay insignificant attention to the patient-welfare aspect of the AKS. This Comment identifies a middle ground that would reduce uncertainty for health care providers while protecting the interests of the government and individual patients. Section A of this Part outlines a

---

80. *How Does Growth in Health Care Costs Affect the American Family?*, RAND HEALTH (2009), *available at* http://www.rand.org/content/dam/rand/pubs/research_briefs/2011/RAND_RB9605.pdf ("Health care expenditures, including insurance premiums, out-of-pocket expenditures, and taxes devoted to health care, nearly doubled between 1999 and 2009.").

81. *See generally* Douglas A. Blair, *The New Proposed Safe Harbors for Certain Managed Care Plans and Risksharing Arrangements: A History, Analysis, and Comparison with Existing Safe Harbors and Federal Regulations*, 9 HEALTH MATRIX 37 (1999).

82. *See, e.g.*, Timothy J. Aspinwall, *The Anti-Kickback Statute Standard(s) of Intent: The Case for a Rule of Reason Analysis*, 9 ANNALS HEALTH L. 155 (2000); Kucera, *supra* note 55.

83. *See* Kucera, *supra* note 55, at 448.

regulatory safe harbor inspired by *Hanlester Network*, and Sections B and C address some potential objections to this proposal.

A. A Two-Prong Safe Harbor for Harmless Remuneration Schemes

HHS should create a regulatory safe harbor that immunizes defendants from AKS liability when (1) the remuneration scheme at issue does not increase health care costs for the federal government and (2) the affected patients give their informed consent to the arrangement.

The first prong of the safe harbor essentially adds a harm requirement to the AKS. Defendants could satisfy this condition by demonstrating that their conduct did not cause the government to pay out more money than it would otherwise or did not exceed the fair market value for the services provided.[84] This element would bring the AKS in line with other federal fraud laws, such as mail and wire fraud, by making "no harm, no foul" a legitimate defense for health care providers.[85]

The second prong of the safe harbor—the informed consent requirement—is a safeguard that protects patients, thus resolving the other main purpose behind the AKS. Informed consent is a state-law doctrine that is already well-developed in most jurisdictions.[86] Essentially, informed consent requires a physician, when recommending a particular treatment to a patient, to explain the risks and the available alternatives.[87] Under the safe harbor proposed here, doctors would need to disclose the existence of any remuneration schemes and explain the nature of their financial interest in them. Doctors would also need to inform their patients about the alternative ways that they could obtain the same treatment. Armed with this information, patients would then have the option of accepting or declining the doctor's recommendation.

Informed consent is a better method to protect patients than the blunt instrument of the AKS. In fact, the patient-welfare rationale for the AKS is often explained in terms of patient *choice*. According to a former Inspector General for HHS, "[T]he [AKS] helps to ensure that patients have freedom of choice among providers . . . . [T]he patient should not be steered to a particular provider for the service because

84. This "fair market value" defense was inspired by Mark A. Hall, *Making Sense of Referral Fee Statutes*, 13 J. HEALTH POL. POL'Y & L. 623, 629 (1988).

85. *See supra* Part III.B.

86. For an overview of the law of informed consent, see generally *Malpractice: Physician's Duty to Inform Patient of Nature and Hazards of Disease or Treatment*, 79 A.L.R.2d 1028 (1961).

87. Peter H. Schuck, *Rethinking Informed Consent*, 103 YALE L.J. 899, 916 (1994).

the referrer is paid a referral fee."[88] Yet, if the AKS is intended to promote patient choice, why does it completely remove certain options from the table (i.e., options where the doctor receives some sort of remuneration)? The government would likely argue that informed consent is no solution because doctors will just convince their patients to choose whichever treatment pays the doctor a kickback. However, in the world of WebMD and myriad other sources of medical information, patients are increasingly able to make informed decisions about their own health care.[89] The assumption behind the AKS—that patients cannot be trusted to accurately assess the risks and benefits of a particular treatment—is outdated and fundamentally paternalistic. It also contradicts the practice in other professions (e.g., law) of allowing individuals to consent to potential conflicts of interest, despite the presence of informational asymmetries.[90] In much the same way, the informed consent prong of the safe harbor proposed here would better respect patient autonomy by lodging the ultimate decision about what is best for the patient where it belongs—*with the patient*.

Finally, the safe harbor recommended in this Comment addresses the flaws in many of the other proposals for reforming the AKS. First, as explained above, the proposed safe harbor adds a safeguard to protect patient welfare. Proposals focusing on cost-benefit analysis or a "rule of reason" either pay insignificant attention to patient welfare or require overly complex after-the-fact determinations about whether an arrangement benefited the patient. Second, the proposed safe harbor draws a bright line between harm/no-harm and consent/no-consent that should be relatively easy for courts to apply. Scholars who try to modify the *Greber* "one purpose" test by requiring patient referrals to be a "main purpose" or "significant purpose" force courts to get inside the heads of individual defendants and determine the relative weight of their various motives. Intent is already a complicated, multi-faceted question; adding a weighing process to this determination would be burdensome for

---

88. Kusserow, *supra* note 8 at 52.

89. Frances H. Miller, *Health Care Information Technology and Informed Consent: Computers and the Doctor-Patient Relationship*, 31 IND. L. REV. 1019, 1021 (1998) ("[P]atients are becoming increasingly assertive and confident when it comes to computerized searches for medical information. . . . [A]n estimated 10,000 to 25,000 websites are now dedicated to health care issues . . . ."). Likewise, scholars have predicted that informed consent could contribute to cost containment because patients, once informed of the costs and benefits, will often choose a less expensive treatment option. Joan H. Krause, *Reconceptualizing Informed Consent in an Era of Health Care Cost Containment*, 85 IOWA L. REV. 261, 363 (1999).

90. *See, e.g.*, MODEL RULES OF PROF'L CONDUCT R. 1.7 (1983) (allowing lawyers to represent a client despite the presence of a conflict of interest if, *inter alia*, the client gives informed, written consent).

courts and unpredictable for health care providers. The bright-line test proposed here is a preferable approach.

B. Why Create a Regulatory Safe Harbor Instead of Amending the Statute?

The AKS can be modified in two primary ways: (1) an amendment by Congress or (2) a regulatory safe harbor from HHS. However, the latter seems like a better approach. As a practical manner, Congress seems quite unwilling to do anything other than *increase* the scope and severity of the AKS.[91] No politician wants to be labeled "weak on fraud," and they have an incentive to take a tough stance on this issue to curry favor with their constituents.[92] Thus, action from HHS—an agency of bureaucrats who are not concerned with reelection[93]—appears to be the only realistic option for reform.

Furthermore, a safe harbor is an *affirmative defense*, so the burden of proof would be on the defendant to show that the exemption applies. Specifically, under the safe harbor proposed here, the defendant must prove that the remuneration scheme at issue did not cause harm to the government (and that any affected patients gave their informed consent). The question of whether harm occurred will often require intricate proof, which may be quite costly and time-consuming.[94] If the *government* had the burden to demonstrate harm as part of its prima facie case, the prosecution of health care fraud under the AKS may become too expensive, even for cases involving truly dangerous fraudsters. A safe harbor strikes a better balance than a statutory amendment: it informs health care providers about how to legally structure their health care services without imposing overly burdensome requirements on government prosecutors.

C. Is a Safe Harbor Really Necessary Given the Government's Prosecutorial Discretion?

Some commentators might characterize the safe harbor proposed in this Comment as wholly unnecessary given the federal

---

91. For several decades now, Congress has repeatedly broadened the scope of liability and increased the severity of the penalties under the AKS. *See supra* note 12.

92. *See* Kucera, *supra* note 55, at 449 (describing the notion of watering down the AKS as "politically unappealing" to Congress).

93. *See* Yvette M. Barksdale, *The Presidency and Administrative Value Selection*, 42 AM. U. L. REV. 273, 287 (1993) ("Congress often avoids hard political value choices by delegating that function to administrative agencies.").

94. *See* Aspinwall, *supra* note 83, at 195–96 (advocating an affirmative defense under the AKS as a more efficient strategy that would conserve government resources because defendants have "the greatest access to the data and the most control over the clinical outcomes").

government's current practice of prosecutorial discretion. Indeed, when deciding whether to prosecute an AKS violation, OIG already considers the extent to which the remuneration scheme at issue "increases Medicare or Medicaid program costs" or "results in unnecessary utilization."[95]

However, prosecutorial discretion does not resolve the uncertainty that the AKS creates for health care providers. OIG refuses to specify a complete list of factors that it will consider when deciding whether to prosecute.[96] Accordingly, even if the government does not go after borderline cases *in practice*, the AKS still allows them to *in theory*. The mere possibility of prosecution may be enough to deter health care providers from engaging in innovative and beneficial arrangements in the first place.[97] Furthermore, some zealous prosecutors have shown a willingness to go after health care providers even in borderline cases. For example, a management company for a psychiatric hospital was prosecuted under the AKS for paying the airfare of patients who came to their facility, even though the arrangement was medically appropriate and did not increase costs to the government.[98] Thus, health care providers can never be sure whether the government will choose to make an example out of them.

Most significantly, the FCA allows *private* whistleblowers to bring suits against health care providers based on violations of the AKS.[99] Even if the *government* exercises prosecutorial discretion, there is no reason for health care providers to think that private individuals—who are often disgruntled employees—will exercise the same restraint. Thus, without some sort of legally binding safe harbor, prosecutorial discretion is not much of a solution to the sweeping nature of the AKS. Only a safe harbor like the one proposed in this Comment can provide the type of certainty that health care providers need to forge ahead with remuneration schemes that are harmless and potentially beneficial—like Dr. Jones's OB-GYN services in the hypothetical above.

, The safe harbor proposed in this Comment would not immunize truly harmful remuneration schemes or otherwise "swallow the rule" of the AKS. The government can defeat the proposed safe harbor by demonstrating that (1) the remuneration scheme led to overutilization of federal health care services or otherwise caused

95. Medicare and State Health Care Programs: Fraud and Abuse; OIG Anti-Kickback Provisions, 56 Fed. Reg. 35,952 (Jul. 29, 1991).

96. *Id.*

97. Blumstein, *Health Care Speakeasy*, *supra* note 10, at 224.

98. *See id.* at 230 n.214.

99. *See supra* Part II.A.3.

economic harm to the federal budget or (2) the defendant did not obtain the informed consent of the affected patients. One or both of these conditions is almost always present in the most egregious, high-profile kickback schemes. To the extent that these conditions are not present, the government has no interest in prosecution anyway. At the very least, the government's prosecutorial interest in such cases would be outweighed by the negative consequences that an overly broad AKS imposes on the health care marketplace.

Furthermore, the notion that the safe harbor proposed here would overly hamper the government seems disingenuous. HHS already considers economic harm and patient welfare when deciding whether to prosecute AKS violators.[100] The proposed safe harbor merely codifies those criteria into a legally binding affirmative defense that health care providers can rely on, rather than leaving the determination up to the unfettered discretion of federal prosecutors.

V. CONCLUSION

Today, *Hanlester Network* has lost much of its legal relevance. The Ninth Circuit's holdings have since been rejected, overruled, or marginalized. Nevertheless, *Hanlester Network* is still an interesting case because it both exposes the breadth of the AKS and presents a model for reforming it. This Comment proposed a regulatory safe harbor that would immunize remuneration schemes that do not threaten the federal budget or patient welfare. This safe harbor would ensure that the federal government and private whistleblowers do not prosecute AKS violations unless the purposes behind the statute are truly implicated. A safe harbor of this nature would decrease the uncertainty that health care providers currently face and allow them to explore innovative arrangements that could benefit patients and society as a whole.

*Cameron T. Norris**

100. *See supra* note 96 and surrounding text.

* J.D. Candidate, Vanderbilt University Law School, Class of 2014. I would like to thank Professors Brian Roark and Matt Curley and the staff of Vanderbilt Law Review *En Banc* for their helpful insights and edits.