**Annals of Health Law**

Volume 16
Issue 2 *Summer 2007*

Article 4

2007

# HPSA and the Anti-Kickback Safe Harbor: Are We Sending Doctors to the Right Neighborhoods?

Keri Tonn

# HPSA and the Anti-Kickback Safe Harbor: Are We Sending Doctors to the Right Neighborhoods?

*Keri Tonn, J.D., M.S.*[*]

## I. INTRODUCTION

The Anti-Kickback statute is aimed at preventing improper payments that might inappropriately influence healthcare decisions.[1] The statute was enacted in 1972 in an effort to protect patients and the federal healthcare programs from fraud and abuse.[2] When a hospital recruits a physician, it must be careful not to offer incentives that would violate the Anti-Kickback statute. As part of the recruitment package, hospitals frequently provide incentives that are regulated by the Anti-Kickback statute such as free or discounted office space, payment for continuing education classes and related travel, loan forgiveness, and guaranteed cash collections.[3]

Many non-medical employers easily recruit employees because they can offer competitive compensation packages, including many perks outside of the traditional salary and bonus.[4] However, hospitals are not given this luxury, and instead must contend with a wide range of federal regulations, such as the Anti-Kickback statute.[5] This limitation often unnecessarily stalls or halts the essential activity of physician recruitment to hospitals. Federal guidelines for properly recruiting physicians do not provide suitable guidance for hospitals to comply with regulations. Instead, the guidelines often force hospitals to ignore common scenarios for which physician

---

* The author graduated from the University of Houston Law Center in May 2007. She would like to thank her family and her husband, David Heard, for their support.

1. *See* 42 U.S.C. § 1320a-7(b) (2000 & Supp. III 2001–2004); *see infra* Part II. A.

2. DEP'T OF HEALTH & HUMAN SERVS., OFF. OF THE INSPECTOR GEN., FEDERAL ANTI-KICKBACK LAW AND REGULATORY SAFE HARBORS: FACT SHEET (Nov. 1999), http://oig.hhs.gov/fraud/docs/safeharborregulations/safefs.htm [hereinafter OIG FACT SHEET].

3. *See, e.g.*, MERRITT, HAWKINS, & ASSOCIATES, SUMMARY REPORT: 2005 REVIEW OF PHYSICIAN RECRUITMENT INCENTIVES, at 11, http://www.merritthawkins.com/pdf/2005_incentive_survey.pdf (last visited Feb. 16, 2007) [hereinafter MERRITT RECRUITMENT INCENTIVES] (providing a detailed summary of the types of incentives offered to physicians).

4. *See, e.g.*, M. Todd Henderson & James C. Spindler, *Corporate Heroin: A Defense of Perks, Executive Loans, and Conspicuous Consumption*, 93 GEO. L.J. 1835 (2005) (providing an overview of various perks that are offered with compensation packages in different industries). *See generally* U.S. SEC. & EXCHANGE COMM'N, EXECUTIVE COMPENSATION: A GUIDE FOR INVESTORS, http://www.counselassure.com/shared/docs/executivecompensationguide.pdf (last visited Feb. 17, 2007) (describing how to research executive compensation for publicly traded companies).

5. *See* 42 U.S.C. § 1320a-7(b).

luxury, and instead must contend with a wide range of federal regulations, such as the Anti-Kickback statute.[5] This limitation often unnecessarily stalls or halts the essential activity of physician recruitment to hospitals. Federal guidelines for properly recruiting physicians do not provide suitable guidance for hospitals to comply with regulations. Instead, the guidelines often force hospitals to ignore common scenarios for which physician recruitment is necessary for the hospital's own survival. Consider the following example:

> A small non-profit hospital ("Hospital X") has just discovered quality of care, performance, and other like issues in its orthopedics department. As a result of intense medical staff peer review, attempted administrative oversight, and frequent nurse complaints, the group of five physicians that once made up the orthopedics department has moved all of its business to a competing hospital down the road. Unfortunately for Hospital X, orthopedics was one of its most profitable service lines, with a steady stream of patients, favorable reimbursement, and top of the line equipment. Hospital X cannot mend relations with the five orthopedic physicians and it is desperately seeking to recruit some orthopedic physicians into the community. All of the proposed strategies, however, are running afoul of the Anti-Kickback statute.

The hypothetical situation described with Hospital X is not an uncommon problem for many hospitals in the country. The United States Department of Health and Human Services' (HHS) Office of Inspector General (OIG) has stated that experience indicates that physician recruitment is "an area frequently subject to abusive practices."[6] However, the OIG recognizes that particular recruitment initiatives may be necessary, especially in areas that struggle to recruit physicians.[7] Therefore, a tension exists between some of the fraud and abuse laws and the need for hospitals to attract physicians into their communities.

Hospitals across the country are becoming increasingly timid in their recruitment efforts since the recent Tenet Alvarado settlement.[8] In the spring of 2006, Tenet Healthcare Corporation settled with the OIG for $21

5. *See* 42 U.S.C. § 1320a-7(b).

6. Medicare and State Health Care Programs: Fraud and Abuse; Clarification of the Initial OIG Safe Harbor Provisions and Establishment of Additional Safe Harbor Provisions Under the Anti-Kickback Statute, 64 Fed. Reg. 63,518, 63,543 (Nov. 19, 1999) (to be codified at 42 C.F.R. pt. 1001).

7. Jeremy Fine Bollinger, *Doctoring Fraud & Abuse: Enforcement of Stark and the Anti-Kickback Law in Physician Recruitment may be Bad for Your Health*, 38 LOY. L.A. L. REV. 485, 497 (2004).

8. Mark Taylor & Vince Gallor, *Recruitment Predicament: Tenet Settles with Feds for $21 Million in Kickback Case, but Hospitals Still Wait for Clear Guidance on What's Allowed,* MODERN HEALTHCARE, May 22, 2006, at 6.

million after it was accused of offering more than $10 million in physician relocation arrangements for potential referring physicians.[9] For example, Tenet offered very lucrative relocation packages to recruited physicians while simultaneously offering existing physicians compensation in the form of tenant improvements.[10] Consequently, physicians who were already located in a community with an established practice received money from Tenet's hospitals without justification.[11]

The Anti-Kickback statute provides protection for activities that might appear to violate the statute on the surface, but in practicality do not pose a large risk for fraudulent behavior.[12] These protections are provided by "safe harbors."[13] Safe harbors were developed "to limit the reach of the [Anti-Kickback] statute by permitting certain non-abusive arrangements, while encouraging beneficial and innocuous arrangements."[14] At the heart of the federal regulations that limit physician recruitment initiatives is the Anti-Kickback's safe harbor for physician recruitment in underserved areas.[15] This specific safe harbor language relies on Health Professional Shortage Area (HPSA) designations. HPSAs are areas designated by HHS's Health Resources and Services Administration (HRSA) that have shortages in certain types of medical care.[16] This paper addresses some of

9. *Id.* Kurt Mosely, Vice President of Business Development at the physician recruitment firm of Merritt, Hawkins & Associates responded to the Tenet case, stating that "[h]ospitals in America need to recruit. They need to incentivize doctors to come to their communities. A lot of times these laws are brought into effect without any consideration to the consequences. Recruiting is harder, more convoluted, and the hospitals just get scared when the federal government starts making noise." *Id. See also* Press Release, Off. Inspector Gen., OIG Executes Tenet Corporate Integrity Agreement Unprecedented Provisions Include Board of Directors Review, Sept. 28, 2006, http://oig.hhs.gov/fraud/docs/press/Tenet%20CIA%20press%20release.pdf. As a result of the settlement, Tenet was forced to divest Alvarado Hospital. *Id.*

10. Press Release, Carol C. Lam, Dep't of Justice, U.S. Attorney S. Dist. of Cal., May 17, 2006, http://www.usdoj.gov/usao/cas/press/cas60517-1.pdf.

11. *Id.*

12. *See* 42 C.F.R. § 1001.952 (2006).

13. *Id. See infra* Part II.B.

14. Medicare and State Health Care Programs: Fraud and Abuse; OIG Anti-Kickback Provisions, 56 Fed. Reg. 35,952, 35,958 (July 21, 1991).

15. *See* 42 C.F.R. § 1001.952(n) (2006); *infra* Part II. C.

16. U.S. Dep't of Health & Human Servs., Health Resources & Servs. Admin., Shortage Designation, http://bhpr.hrsa.gov/shortage [hereinafter HRSA Shortage Designation] (last visited Feb. 17, 2007). HRSA is an agency of the HHS that seeks to improve "access to health care services for people who are uninsured, isolated or medically vulnerable." U.S. Dep't of Health & Human Servs., Health Resources. & Servs. Admin., http://www.hrsa.gov/about/default.htm (last visited Feb. 17, 2007). *See infra* Part III. A.

the problems with the HPSA based requirement of the Anti-Kickback law's safe harbor.[17]

The physician recruitment safe harbor should be amended to help hospitals, physicians, and communities better meet their respective needs. Part II of this paper provides a brief overview of the Anti-Kickback statute, along with the physician recruitment safe harbor. Part III of this paper discusses the HPSA designation process and the shortcomings of using HPSA designation as a way to curb fraudulent behavior. It further focuses on the October 2006 Government Accountability Office's (GAO) report that recommended that HHS revise the HPSA designation process. In addition, Part III discusses an advisory opinion that required a hospital to demonstrate community need based on multiple factors because it was not designated as a HPSA. Part III also considers several uses of HPSA designation for other federal programs and how its use in those programs has problems similar to the use of HPSA designation in the Anti-Kickback physician recruitment safe harbor arena. Finally, Part IV of this paper provides potential alternatives to the current safe harbor language that relies on HPSA designation.

Although several changes related to the HPSA requirement were proposed when the safe harbors were published in 1999, the OIG should revisit some of these suggestions and propose new ones in light of healthcare realities and HPSA designation controversies. Indeed, the Anti-Kickback physician recruitment safe harbor should be expanded because physician shortages and recruitment barriers hurt not only healthcare providers, but also patients.[18]

## II. ANTI-KICKBACK LAW

### *A. General Overview*

The Anti-Kickback statute is a broad fraud and abuse statute that covers financial relationships between and among individual and institutional healthcare providers.[19] There are essentially five elements of the Anti-Kickback statute: 1) knowing and willful; 2) offer or payment; 3) of any remuneration; 4) to induce someone to refer patients or to purchase, order, or recommend; 5) any item or service that may be paid for under a federal

17. Although outside the scope of this paper, the Stark law also addresses physician recruitment activities. *See* 42 U.S.C. § 1395nn(e)(5) (2000); 42 U.S.C. § 1395(e)(5) (2004); *see also* Albert S. Shay, *Death of an Exception or Much Ado About Nothing*, 38 J. HEALTH L. 423 (2005) (providing an analysis of the Stark II, Phase II regulations regarding physician recruitment).

18. *See* Bollinger, *supra* note 7, at 505.

19. 42 U.S.C. § 1320a-7(b) (2000 & Supp. III 2001-2004).

healthcare program.[20] The rationale behind the Anti-Kickback statute is that decisions of people who purchase and order healthcare services involving federal funding should not be influenced by money.[21]

Anti-Kickback concerns are very real and threatening for healthcare providers. A violation of the Anti-Kickback statute may result in criminal, civil, and/or administrative penalties.[22] These penalties can range from a felony conviction to exclusion and civil monetary penalties.[23] In addition, physicians and other individuals can bring a qui tam action under the False Claims Act.[24]

One important aspect of the Anti-Kickback statute is the purpose requirement, which examines the purpose behind the remuneration. Courts are split on how exactly to interpret this purpose requirement, which creates confusion for hospitals that are trying to structure physician recruitment arrangements. For example, in *United States v. Greber*, the Third Circuit adopted the "one purpose" test, which states that if only one purpose of the remuneration is to induce referrals, despite other potential legitimate reasons, it may violate the Anti-Kickback statute.[25] This test has come under criticism, however, because almost all business transactions are entered into with the goal of increasing profit.[26] Thus, if Hospital X, mentioned above, wanted to recruit orthopedic physicians, it would essentially be attempting to rebuild its market share. Under the one purpose test then, Hospital X might be subject to an Anti-Kickback violation if the other factors of the statute were also met.

Not all jurisdictions have adopted the "one purpose" test. The Tenth Circuit in *United States v. McClatchey* stated that referrals may be "expected" or "hoped for," but motivation for the transaction must be for reasons distinct from inducing referrals in order to avoid a violation.[27]

---

20. *Id.*

21. OIG FACT SHEET, *supra* note 2.

22. 42 U.S.C. § 1320a-7 (2000 & Supp. III 2001-2004).

23. *Id.* The felony conviction resides in the Anti-Kickback statute, but exclusion and civil monetary penalties can also arise from a violation of the Anti-Kickback statute. *Id.*

24. *See, e.g.*, United States *ex rel.* Thompson v. Columbia/HCA Healthcare Corp., 125 F.3d 899, 903 (5th Cir. 1997) (physician brought a claim under the False Claims Act arguing that the healthcare provider submitted claims that violated the Anti-Kickback statute). *See also* David M. Deaton, *What is "Safe" About the Government's Recent Interpretation of the Anti-Kickback Statute Safe Harbors? ... And Since When was Stark an Intent Based Statute?*, 36 J. HEALTH L. 549, 552 n.21 (2003) (providing a sample of cases similar to *Thompson*).

25. 760 F.2d 68, 69 (3d Cir. 1985).

26. United States v. McClatchey, 217 F.3d 823, 834 (10th Cir. 2000).

27. *Id.*

Thus, the court in *McClatchey* implicitly acknowledged that the "one purpose" test is unworkable.[28]

Courts have further considered physician recruitment practices in other situations. For example, in *Polk County v. Peters*, a hospital offered a physician an income guarantee, moving expenses, free office space, and paid insurance premiums.[29] In turn, the physician signed a contract stating that he would repay the income guarantee.[30] However, even though the original employment contract did not contain a clause that required the physician to refer patients to this particular hospital, the physician's staff privileges were eventually terminated because he did not use this hospital as his primary hospital.[31] Regardless, the court held that the physician's benefits were an inducement for him to refer patients to the hospital; therefore, the contract was unenforceable under the Anti-Kickback statute.[32]

As a result of the range of the Anti-Kickback penalties and the broad and varying inducement standards, hospitals that want to recruit physicians rightfully fear stretching the limits of the Anti-Kickback language. As an Anti-Kickback case can be brought by the government or via a private right of action,[33] hospitals must ensure that they fully comply with the law. Though compliance with the Anti-Kickback statute is a daunting task, hospitals have been given some latitude to maneuver through the statute via safe harbor protection.

### *B. What are Safe Harbors?*

Due to the breadth the Anti-Kickback statute and the confusion about how far it extends, Congress directed HHS to enact its own regulations that would exempt certain behaviors from Anti-Kickback liabilities and help hospitals to execute their strategic goals.[34] These permitted activities are commonly known as "safe harbors." Safe harbors have several important nuances. First, if an arrangement does not fall within a safe harbor, the arrangement is not per se illegal, but rather, it may be subject to scrutiny.[35] Second, safe harbors often have a limited application because they are very detailed, cover a narrow set of circumstances, and are frequently difficult to

28. *Id.*
29. 800 F. Supp. 1451, 1451-52 (E.D. Tex. 1992).
30. *Id.* at 1452.
31. *Id.* at 1456.
32. *Id.*
33. *See* Feldstein v. Nash Cmty. Health Servs., Inc., 51 F. Supp. 2d 673 (E.D.N.C. 1999) (physician was trying to void a contract he entered into with a hospital by arguing that the terms of the contract violated the Anti-Kickback Statute).
34. OIG FACT SHEET, *supra* note 2.
35. *Id.*

translate into proposed physician recruitment arrangements.[36] Despite these limitations, healthcare entities frequently look to safe harbors to see if a proposed arrangement is permitted under the Anti-Kickback statute. Safe harbors can be a very useful tool in brainstorming and developing proposed arrangements and recruitment packages for physicians. If the physician recruitment safe harbor language were to exclude the HPSA requirements, this particular safe harbor would be even more useful to hospitals in this process.

### *C. Physician Recruitment Safe Harbor*

The OIG proposed the physician recruitment safe harbor in response to the difficulties that rural hospitals encountered in recruiting physicians.[37] Moreover, the goal of the original proposed safe harbor was to improve rural hospital recruitment tactics and not to protect "arrangements designed to channel Medicare and Medicaid business to recruiting hospitals."[38] As part of the proposed safe harbor, the OIG sought comments on geographic criteria to limit the safe harbor,[39] suggesting that it be limited to areas that were designated HPSAs.[40] In the final rule, the OIG stated that HPSA designation was a logical geographic criterion because it would expand the protection to non-rural areas, but at the same time it would only provide protection to areas "with a demonstrated need for practitioners and only to practitioners who actually serve the residents of such areas."[41] Thus, one of the main criteria in both the proposed and final safe harbor rules was the necessity of showing community need as evidenced by HPSA designation.

The physician recruitment safe harbor allows a healthcare entity to provide something of value to induce a practitioner "who has only been practicing within his or her specialty for one year or less to locate, *or* to induce a practitioner to relocate his or her primary place of practice into a HPSA for his or her specialty area," as long as nine criteria are met.[42] One of the nine criteria also references HPSA designation. The statute states that "[a]t least 75 percent of the revenues of the new practice must be generated from patients residing in a HPSA or a Medically Underserved

36. *See id.*

37. Health Care Programs: Fraud and Abuse; Additional Safe Harbor Provisions Under the OIG Anti-Kickback Statute, 58 Fed. Reg. 49,008, 49,010 (Sept. 21, 1993).

38. *Id.*

39. *Id.*

40. Medicare and State Health Care Programs: Fraud and Abuse; Clarification of the Initial OIG Safe Harbor Provisions and Establishment of Additional Safe Harbor Provisions Under the Anti-Kickback Statute, 64 Fed. Reg. 63,518, 63,541 (Nov. 19, 1999) (to be codified at 42 C.F.R. pt. 1001).

41. *Id.*

42. 42 C.F.R. § 1001.952(n) (2006) (emphasis added).

Area (MUA) or who are part of a Medically Underserved Population (MUP)."[43]

The physician recruitment safe harbor is intended to help communities with a demonstrated need to recruit practitioners that will serve the residents of that area.[44] The ultimate question is whether the current language of the safe harbor effectively achieves this goal. Arguably, the current language does not.

The current safe harbor language is sometimes self-defeating as a result of the HPSA requirement. The OIG received many suggestions for how to determine community need instead of using HPSA designation, but all of these were refuted.[45] As a result, hospitals struggle to recruit physicians legally and communities struggle to access much needed healthcare services.

### *D. Reviewing Safe Harbor Compliance*

If a proposed arrangement does not clearly fit in a safe harbor it is reviewed on a case-by-case basis.[46] In an advisory opinion, the OIG presented multiple factors that it considers regarding a physician recruitment package that does not fit directly in the safe harbor.[47] First, the OIG evaluates "whether there is documented evidence of an objective need for the practitioner's services."[48] Although this factor might appear to be a great asset for places like Hospital X, which can demonstrate the need, the subjectivity of what objective need qualifies may haunt and potentially delay possible transactions. For example, what might be an objective need of Hospital X for orthopedic services might not exist for a nearby competitor; therefore, other hospitals or the OIG might see it as a purely subjective evidence of need. In addition, the ability to demonstrate a documented need might require historical data. For Hospital X, which recently lost its five orthopedic physicians, this could take many months to document. In the meantime, Hospital X will likely lose both patients and revenue. Furthermore, the community members that do not necessarily

43. *Id.* at § 1001.952(n)(8).

44. Medicare and State Health Care Programs: Fraud and Abuse; Clarification of the Initial OIG Safe Harbor Provisions and Establishment of Additional Safe Harbor Provisions Under the Anti-Kickback Statute, 64 Fed. Reg. at 63,541.

45. *See infra* Part III.A.

46. Medicare and State Health Care Programs: Fraud and Abuse; Clarification of the Initial OIG Safe Harbor Provisions and Establishment of Additional Safe Harbor Provisions Under the Anti-Kickback Statute, 64 Fed. Reg. at 63,545.

47. Advisory Op., Off. Inspector Gen., HHS No. 01-4, 1, 6-7 (May 3, 2001) [hereinafter Advisory Op. 01-4]. *See infra* text accompanying notes 54-57. *See also infra* Part III. D.

48. Advisory Op. 01-4, *supra* note 47, at 8.

have access to other hospitals (because of distance limitations or insurance requirements) will be harmed.

Second, the OIG will consider "whether the practitioner has an existing stream of referrals within the recruiting entity's service area."[49] This factor presents a problem for hospitals recruiting physicians with established referral patterns, especially those physicians in urban areas who "relocate their offices short distances to underserved areas."[50] For Hospital X, this factor would force it to recruit from another city. Getting a physician to relocate with his or her family often takes a considerable amount of time, especially if he or she has children in school or a working spouse or partner. Thus, the needy constituents of Hospital X's services are further deprived until relocation is completed.

Third, the OIG will assess whether the recruited physician is only receiving the minimum benefit necessary to recruit him or her.[51] This factor, like many of the other factors, is very subjective. Determining whether a benefit is the minimum necessary to recruit the physician depends on a multitude of elements that can constantly vary. Finally, the OIG will consider "whether the remuneration directly or indirectly benefits other referral sources."[52] This factor has the potential to hinder Hospital X's recruitment efforts because orthopedic physicians receive referrals from many types of physicians, and they themselves refer many patients to other physicians. Although these four factors sound like a welcome invitation for hospitals like Hospital X to begin recruitment initiatives without a HPSA designation, they are not as clear and easy to meet as they might appear to be at first blush.

How can a hospital feel comfortable knowing that there is a great deal of case-by-case analysis required within each of the aforementioned factors? Most likely, a hospital would want to get an advisory opinion on any proposed arrangement. To do so, a healthcare entity may write to the OIG, provide necessary information regarding existing regulations, and in turn possibly receive from the OIG a written assessment of whether a proposed arrangement complies with the Anti-Kickback statute.[53] An OIG advisory opinion provides a "case specific" analysis on a non-hypothetical arrangement.[54]

---

49. *Id.*

50. *Id.*

51. *Id.* at 9.

52. *Id.*

53. 42 C.F.R. § 1008.1 (2006).

54. Medicare and State Health Care Programs: Fraud and Abuse; Issuance of Advisory Opinions by the OIG, 62 Fed. Reg. 7350, 7351 (Feb. 19, 1997) (to be codified at 42 C.F.R. pt. 1008).

An advisory opinion, although helpful, is not easily obtained. First, a hospital must spend considerable time and money going through the advisory opinion process.[55] Second, once a hospital makes a request for an advisory opinion, the OIG has ten days to decide whether to accept or decline the request.[56] If the OIG accepts the request, it has sixty days to render an opinion, as long as the sixty-day window has not been tolled.[57] An advisory opinion will not be provided if the request is not related to a specific, named individual or entity.[58] Consequently, a hospital must identify the particular physician it wishes to hire before it seeks an advisory opinion. While the healthcare entity waits for the OIG's opinion, the recruited physician may be lured to another hospital, thereby causing the recruitment initiative to fail entirely.

## III. HPSA DESIGNATION

### *A. What is a HPSA?*

For many Americans, especially those in rural and inner-city areas, "obtaining [health care] is difficult because healthcare providers are in short supply."[59] The HPSA designation system was developed to combat this problem.[60] HPSA designation was originally created in 1978 as part of the HHS's attempt to "identify areas in need of physicians and other healthcare providers from HHS's National Health Service Corps programs."[61] There are three different types of HPSA designations: geographic area, specific population group, or specific healthcare facility.[62] As previously

55. The requestor of an advisory opinion is required to pay a non-refundable $250 initial deposit and is responsible for "paying a fee equal to the costs incurred by the Department in responding to the request for an advisory opinion." 42 C.F.R. § 1008.31 (2006). In 1997, the OIG stated that although it is difficult to calculate how much the fee would be, the average charge would be approximately $100 per hour. The approximate work time can range from three hours for a simple request, such as whether a court action equates to a conviction, to forty hours or more for a multiple party complex business deal. Medicare and State Health Care Programs: Fraud and Abuse; Issuance of Advisory Opinions by the OIG, 62 Fed. Reg. at 7353.

56. 42 C.F.R § 1008.41(b) (2006).

57. *Id.* at § 1008.43(c).

58. *Id.* at § 1008.15(c)(1) (requiring that the requestor of an advisory opinion provide specific facts of the arrangement that it in good faith plans to undertake).

59. U.S. GOV. ACCOUNTABILITY OFF., HEALTH PROFESSIONAL SHORTAGE AREAS: PROBLEMS REMAIN WITH PRIMARY CARE SHORTAGE AREA DESIGNATION SYSTEMS 1 (Oct. 2006), *available at* http://www.gao.gov/new.items/d0784.pdf [hereinafter GAO HPSA].

60. *Id.*

61. *Id. See also* HRSA Shortage Designation, *supra* note 16 (providing information the Shortage Designation Branch of HHS).

62. GAO HPSA, *supra* note 59, at 2.

mentioned, the HPSA designation in the Anti-Kickback safe harbor is the geographic area designation. Moreover, there are three key criteria for geographic HPSA designation. First, there "must be a rational service area for the delivery of primary medical care services."[63] Second, the "ratio of population to primary care physicians must be at least 3,500 to 1."[64] And third, HRSA will consider whether the "provider resources in adjoining areas are overused, excessively distant, or otherwise inaccessible."[65]

As of September 2005, there were 1,646 geographic area HPSAs[66] out of the more than 3,000 counties in the United States.[67] Therefore, the HPSA language in the safe harbor impacts a large percentage of the population, both in terms of residing in or being excluded from a HPSA region.

### *B. Why is HPSA Designation Used?*

The physician recruitment safe harbor was originally only intended to apply to healthcare entities located in rural areas.[68] However, after reviewing comments from interested parties, the OIG decided to expand the recruitment safe harbor.[69] Despite many suggestions that the proposed physician recruitment safe harbor should determine need instead of relying on HPSA designation, HHS found that HPSA designation had several advantages over other types of need-based designations.[70] For example, HHS commented that HPSA designation allows underserved urban areas to be afforded possible safe harbor protection and has the ability to target "areas that have demonstrated a shortage of practitioners in particular specialties."[71] Also, HPSA was chosen because it can encompass underserved urban areas that face many of the same recruitment challenges as rural areas.[72] Many commentators suggested other alternatives to determine community need, but HPSA designation was ultimately selected as the best way to help communities recruit physicians while minimizing the risk for fraudulent behavior.[73]

---

63. *Id.* at 10.
64. *Id.*
65. *Id.*
66. *Id.* at 15. *See also id.* at 16 (providing a map of the HPSA areas).
67. Nat'l Ass'n. of Counties, http://www.naco.org/Template.cfm?Section=About NACo (last visited Feb. 17, 2007).
68. Clarification of the Initial OIG Safe Harbor Provisions and Establishment of Additional Safe Harbor Provisions Under the Anti-Kickback Statute, 64 Fed. Reg. 63.518, 63,541 (Nov. 19, 1999) (to be codified at 42 C.F.R. pt. 1001).
69. *Id.*
70. *Id.* at 63,542.
71. *Id.*
72. *Id.*
73. *See id.* at 63,530-34.

### C. *Shortcomings of HPSA Designation*

A recent GAO report called for HHS to revise the HPSA designation process.[74] One reason was that the methodology and criteria used to determine HPSA designation had not been changed since October 1, 1993.[75] Although the formula's age does not necessarily mean it needs changing, its history must be considered. HHS proposed revising the designation process in 1998, but after receiving over 800 comments, it withdrew its proposal.[76] Therefore, the methodology and criteria from 1993 were essentially used as one of the main criteria in the 1999 safe harbor for physician recruitment under the Anti-Kickback statute.

Given the large number of comments submitted to the HHS and the historical and current debate regarding HPSA designation, the healthcare community should not have to use antiquated methodology when trying to structure modern physician recruitment arrangements. Some goals of the proposed changes in 1998 included making the HPSA designation process more proactive and "better able to identify new, currently undesignated areas of need and areas no longer in need," automating the scoring process and unnecessary time-consuming measures to gain designation, and including designations such as the percentage of elderly or uninsured individuals in an area.[77] Many of these goals and the corresponding discussion of them in the Federal Register illustrate that the HPSA designation process should be revisited. Even if all of the proposed changes from 1998 are not adopted, the proposal from nearly ten years ago and the static state of the law illustrate the need for additional evaluation of the process.

A second reason the GAO advised HHS to revise the HPSA designation process is that HRSA does not provide a timely review of HPSA designations in order to remove them from the Federal Register.[78] Consequently, some HPSAs might continue to receive federal money despite the fact that the area no longer meets the HPSA requirements.[79] HRSA stated that the reason it has not published a list of HPSAs in the Federal Register for more than four years stems from problems with computer programming.[80] Surprisingly, some HPSAs might have remained

74. GAO HPSA, *supra* note 59, at 7.

75. *Id.* at 3.

76. *Id.* at 3; *see also id.* at n.8 (proposing that the HPSA designation process be combined with HRSA's other designation processes for MUAs and MUPs).

77. Designation of Medically Underserved Populations and Health Professional Shortage Areas, 63 Fed. Reg. 46,538 46,539 (Sept. 1, 1998).

78. GAO HPSA, *supra* note 59, at 6.

79. *Id.*

80. *Id.* at 28. Although an extensive search could not provide any additional information about what types of computer programming issues exist, when the GAO asked HRSA about

within the Anti-Kickback safe harbor simply because of outdated information and the federal government's apparent lack of computer resources.

The safe harbor states, "If the HPSA ceases to be a HPSA during the term of the written agreement, the recruitment arrangement will not lose its safe harbor protection."[81] Although this type of finality may be needed to avoid changing existing arrangements, the end goal of HPSA is not necessarily served, especially considering the delays in updating HPSA designation. For example, if several physicians move to another area or change their referral patterns, a hospital could be in desperate need to recruit new physicians, or the hospital's market share could shift and the majority of patients could be drawn from new areas. Most likely though, only the originally designated area would be the HPSA. The safe harbor does not address the problem with areas remaining designated HPSAs despite no longer meeting the HPSA designation requirements.

Additionally, relying on HPSA designation can be problematic for hospitals because geographic service areas vary dramatically depending on the service line, the hospital's location within a county, and the hospital's payor mix. For example, the service area as defined by a hospital for specialists might be much larger than the service area for primary care services. A recent GAO report noted that the geographical boundaries defined by HRSA counties "may not always provide a realistic reflection of an area's healthcare needs."[82]

### *D. A Look at How the OIG will Address a Hospital that Does Not Fit in the Physician Recruitment Safe Harbor: Advisory Opinion 01-4*

The OIG's view of physician recruitment by hospitals in non-HPSAs is illustrated in a 2001 advisory opinion.[83] Although an advisory opinion is binding only on the requesting parties, other parties often look to advisory opinions to gain insight regarding how the government might view a particular arrangement.[84] Advisory Opinion 01-4 dealt with a tax-exempt rural acute-care hospital that wanted to recruit a physician for

---

the effect of not publishing a list in the Federal Register, the GAO was told that it might be minimal because HRSA currently makes public a real time account of HPSA designations via a web-based application. *Id.* at n.59.

81. Medicare and State Health Care Programs: Fraud and Abuse; Clarification of the Initial OIG Safe Harbor Provisions and Establishment of Additional Safe Harbor Provisions Under the Anti-Kickback Statute, 64 Fed. Reg. 63,518, 63,542 (Nov. 19, 1999) (to be codified at 42 C.F.R. pt. 1001).

82. GAO HPSA, *supra* note 59, at 26.

83. Advisory Op. 01-4, *supra* note 47.

84. *See* OIG FACT SHEET, *supra* note 2.

otolaryngology and head and neck surgery.[85] As part of the arrangement, the hospital would loan the physician money during his residency training, some of which the physician would be required to pay back.[86] The physician in turn would be obligated to do things such as create and maintain a full-time private practice within a small radius of the hospital's locale, provide emergency room on-call services, assist the hospital in fund-raising efforts, and maintain active staff privileges in otolaryngology and head and neck surgery at the hospital.[87] The advisory opinion held that the proposed arrangement would not pose much fraud and abuse risk and that the OIG would not enforce administrative sanctions.[88]

This advisory opinion demonstrates several reasons why the Anti-Kickback safe harbor regarding physician recruitment should eliminate the HPSA requirements. First, the OIG stated that it recognizes that an area can easily have a shortage of specialists even though it is not designated as a HPSA.[89] In a footnote, the OIG specified that a HPSA can only be designated for certain "primary medical care, dental, mental health, vision care, podiatric, and veterinary care."[90] The OIG further stated that the county in which a hospital is located could be in "dire shortage of physicians practicing the Specialties" and still not have HPSA designation.[91] This dichotomy, acknowledged by the OIG multiple times in the advisory opinion, clearly illustrates one of the main problems with the HPSA requirements in the safe harbor language. The HPSA requirement is problematic for hospitals, like the one in the advisory opinion, that are trying to recruit specialists. The OIG's acknowledgment and recognition of this shortcoming calls for a change.

One of the reasons the OIG approved the proposed arrangement was that the hospital was located in a rural area, with a service area that encompasses only a MUA.[92] This does not, however, provide any clear guidance to hospitals that need to recruit specialists. In fact, the OIG states that the use of MUA designation is "not determinative and is only one of many factors" that are considered.[93] Irrespective of whether a hospital's service area

85. Advisory Op. 01-4, *supra* note 47, at 2-3.

86. *Id.* at 3.

87. *Id.*

88. *Id.* at 2.

89. *Id.* at 8.

90. *Id.* at n.3. (explaining that primary medical care refers to "doctors of medicine or osteopathy who practice primarily in one of four primary care specialties." These four specialties include "general or family practice, general internal medicine, pediatrics, and obstetrics and gynecology.").

91. Advisory Op. 01-4, *supra* note 47, at n.6.

92. *Id.* at n.7.

93. *Id.*

encompasses only MUAs, if that hospital is not a HPSA, it still has a difficult time allocating resources and planning recruitment activities because MUA designation is only "one of many factors."[94] Furthermore, what if a hospital's service area for one specialty only includes sixty percent of MUAs? What if the referral patterns from the recruited specialty typically fall into another specialty that has a service area that does encompass MUAs? Overall, this advisory opinion, along with other OIG guidance, fails to provide a realistic and practical direction for the recruitment activities of a hospital not located in a HPSA.[95]

### *E. Examples of Problems with HPSA Designation in Other Contexts*

Many federal programs use HPSA and MUA designations to determine eligibility for grants, scholarships, and other benefits.[96] HPSA designation problems arise in other areas besides the Anti-Kickback safe harbor area. Studies about the effectiveness of the HPSA designation in some of the federal programs that rely on HPSA designation help illustrate similar problems that might arise from having a HPSA requirement as part of the safe harbor language. Although these other programs have goals that often differ from the goal of the Anti-Kickback statute, the problems illuminate HPSA-related problems in the Anti-Kickback safe harbor language.

#### 1. Medicare Incentive Payment Program

The Medicare Incentive Payment Program provides "bonus payments for physicians who treat Medicare patients" in HPSAs.[97] The goal behind this program is to "improve the health status of residents of areas with shortages of physicians" by helping to recruit new physicians and retain already existing physicians in HPSAs.[98] However, an OIG Management Advisory Report identified several shortcomings in the program's structure due to its pure reliance on HPSA designation, some of which are analogous to the problem of the HPSA requirement in the Anti-Kickback safe harbor. The OIG report stated that the "instability of HPSA designation over time means that the incentive payments cannot be counted on to retain physicians in

94. *Id.*

95. *See* Bollinger, *supra* note 7, at 512.

96. GAO HPSA, *supra* note 59, at 49. Some of these programs include: Federally Qualified Health Center look-alike program, Indian Health Scholarship Program, J-1 Visa Waivers, Medicare Incentive Payment program, National Health Service Corps, Rural Health Clinic Program, Scholarships for Disadvantaged Students, and Title VIII nursing education programs. *Id.* at 49-52.

97. OFF. OF THE INSPECTOR GEN., MANAGEMENT ADVISORY REPORT: DESIGN FLAWS IN THE MEDICARE INCENTIVE PAYMENT PROGRAM 1, 1 (June 1994) (explaining that in 1992, over $68 million in bonus payments were made to close to 22,000 physicians).

98. *Id.* at 4, 9.

particular areas for the long term."[99] This reference to HPSA instability is is comparable to HPSA's application in the hospital arena; if a hospital sought to engage in long-range strategic planning, it would be unable to budget resources for physician recruitment and it would lack the ability to determine growth of future service lines. The inability to engage in these types of activities will hinder access to healthcare services and waste resources in the long term.

### 2. J-1 Visa Program

The J-1 visa wavier program is designed in part to "attract foreign physicians who have just completed their graduate medical education in the United States to practice in underserved areas."[100] A foreign physician can agree to practice for "at least three years at a facility located in, or treating residents of, a HPSA, a MUA, or a medically underserved population (MUP)" in return for "receiv[ing] the benefit of a waiver of a [two]-year foreign residency requirement."[101] During a recent hearing at which it attempted to make appropriations for the Departments of Labor, Health and Human Services, and Education for the fiscal year ending on September 30, 2006, the Committee of Appropriations stated that it had concerns with the use of the HPSA scoring process in the J-1 visa program because it might limit access to J-1 physicians in underserved communities.[102] Instead, the Committee encouraged HHS to employ an alternative method to deem J-1 visa physician placements.[103] The Committee, however, did not provide for what this alternative methodology might be.[104]

The reliance on HPSA designation is obviously problematic in many domains, notably where it negatively impacts the allocation of federal resources in programs such as the Medicare Incentive Program and the J-1 Visa Program. The HPSA language in the safe harbor also negatively impacts the allocation of healthcare resources, many of which stem from federal resources. Because recruiting hospitals have unnecessary barriers under the safe harbor language, they are forced to spend time and money on advisory opinions, possibly stall recruitment efforts, or altogether forego recruitment activities. In addition, the OIG might unnecessarily spend resources to prosecute a hospital for a violation of the Anti-Kickback statute when it simply does not meet the HPSA requirements in the safe harbor

99. *Id.*

100. GAO HPSA, *supra* note 59, at 23.

101. *Id.*

102. DEP'TS OF LABOR, HEALTH & HUMAN SERVS., AND EDUC., AND RELATED AGENCIES APPROPRIATION BILL 2006, S. REP. NO. 109-103, at 33 (2005).

103. *Id.*

104. *Id.*

language. Such prosecution is ridiculous because the HPSA designation is filled with problems itself. A change is necessary to avoid further waste of resources and federal money.

## IV. SOLUTION: AN ALTERNATIVE TO HPSA

Although the October 2006 GAO report recommended to HHS that it "complete and publish" a proposal that would address some of the HPSA designation problems,[105] such a proposal will not likely provide the best solution for the physician recruitment safe harbor. As long as the HPSA designation requirement remains in place, the following will remain true about the government: "[i]n its fervent attempt to punish and deter inappropriate financial relationships, . . . the government's actions have produced many of the results its efforts were designed to eliminate."[106] Alternative solutions may account for the realities of recruitment needs while also acknowledging the risk of fraudulent behavior. Some of the options suggested by commentators in response to the proposed HPSA designation criteria in the safe harbor may be reevaluated. Second, it will explore an analysis of the benefits of utilizing the IRS tax-exemption criteria is a possible alternative to HPSA designation, providing many benefits. Finally, it will discuss an alternative solution that does not require any showing of community need.

### *A. Other Options Suggested by Commentators in 1999*

Many of the shortcomings associated with HPSA designation as a main criteria for safe harbor protection are evidenced by the comments that were submitted in response to the proposed safe harbor language in 1999.[107] Commentators proposed disproportionate share hospital (DSH) designation, demonstrated community need, and MUA criteria as alternative designations.[108] All of the proposed alternatives, in some way, measure access to healthcare services. However, the OIG found problems with these suggested designations and instead favored its original suggestion of relying on HPSA designation.[109] The DSH designation was rejected because it does not demonstrate practitioner recruitment needs, but instead

105. GAO HPSA, *supra* note 59, at 7.

106. Bollinger, *supra* note 7, at 505.

107. *See* Medicare and State Health Care Programs: Fraud and Abuse; Clarification of the Initial OIG Safe Harbor Provisions and Establishment of Additional Safe Harbor Provisions Under the Anti-Kickback Statute, 64 Fed. Reg. 63,518, 63,542 (Nov. 19, 1999) (to be codified at 42 C.F.R. pt. 1001).

108. *Id.*

109. *Id.*

demonstrates the "number of low-income patients a hospital treats."[110] Likewise, the demonstrated community need standard was rejected because it would be cumbersome to develop as a "consistent and predictable safe harbor protection."[111]

MUAs and MUPs are HRSA's way of designating areas that have a shortage of healthcare services.[112] Although the MUA standard was suggested in response to the proposed physician recruitment safe harbor, the government felt that it would make the safe harbor protection too broad because MUAs "measure shortages of healthcare services generally."[113] Furthermore, the MUA standard is not ideal because its requirements are not regularly updated.[114]

These three proposed alternatives—DSH, community need, and MUA/MUP designation—all evaluate community need for healthcare services. As the HHS pointed out in responding to each of these suggestions, none are perfect. However, these imperfections do not necessarily render such designations useless. For example, although DSH designation demonstrates the number of low-income patients a hospital treats, it is often difficult to recruit physicians into areas where there are a large number of low-income patients. Even though hospitals in many large urban areas have an abundant supply of physicians, this "does not translate into an adequate supply of physicians within inner cities, particularly those with poor, minority populations."[115] Rather, some hospitals in urban areas, with segregated minority populations, might face an increased Medicaid and non-paying base of patients, encounter high administrative costs in dealing with Medicaid and collection agencies, or see more patients who lack access to preventive primary care, which may thereby increase the need for hospital-based care.[116] A hospital in this situation might have more difficulties recruiting than its competitors. Overall, DSH designation only applies to a specific hospital; if a hospital did have DSH designation, this might signal that it potentially has problems recruiting physicians.

---

110. *Id.*

111. *Id.*

112. GAO HPSA, *supra* note 59, at 41 (noting that as of September 2005, there were 3,443 geographic areas designations as MUAs and 488 populations groups designated as MUPs).

113. Medicare and State Health Care Programs: Fraud and Abuse; Clarification of the Initial OIG Safe Harbor Provisions and Establishment of Additional Safe Harbor Provisions Under the Anti-Kickback Statute, 64 Fed. Reg. 63,518, 63,542 (Nov. 19, 1999) (to be codified at 42 C.F.R. pt. 1001).

114. GAO HPSA, *supra* note 59, at 42.

115. Robyn Whipple Diaz, *Unequal Access: The Crisis of Health Care Inequality for Low-Income African-American Residents of the District of Columbia*, 7 J. HEALTH CARE L. & POL'Y 120, 126 (2004).

116. *Id.* at 126-27.

The MUA and MUP standards also carry some weight as valid alternatives. Although broad, they paint a picture of the adequacy of healthcare services in a particular area. However, if the OIG had chosen MUA or DSH designation as sole criteria, in place of HPSA designation, hospitals would not be substantially better off. A single designation such as a HPSA, DSH, MUA, or MUP will, on its face, may try to limit recruitment activities to areas that only really need a physician, but in reality, the designation can do more harm than good by limiting a hospital's ability to serve its community. It is then necessary to consider several other models that would more appropriately and effectively restrict improper physician recruitment activities.

### *B. Solution #1: IRS model*

The IRS model applied to tax-exempt hospitals trying to recruit physicians might be a viable alternative to the current HPSA designation requirement. For example, Revenue Ruling 97-21 establishes the limits on physician recruitment for tax-exempt hospitals.[117] If Hospital X tried to comply with the IRS guidelines, it would be able to offer recruitment incentives so long as three criteria were met. First, the incentive would have to be reasonably related to the hospital's tax-exempt purpose.[118] Second, the public purpose of the recruitment activity should outweigh the private benefits that a recruited physician would gain from the incentive package.[119] Finally, the amount of the incentive offered to the physician must be reasonable.[120]

The IRS test differs from the current safe harbor protection guidelines as it utilizes a much broader balancing test that "take[s] into account the hospital and the community's real circumstances."[121] However, if the IRS approach were adopted as a way to address physician recruitment activities, in essence, the purpose tests of *Greber* or *McClatchey* would be unnecessary.[122]

Additionally, the IRS approach is similar in many respects to the OIG's approach in Advisory Opinion 01-4, but it differs in one important way.[123] The OIG approach in Advisory Opinion 01-4 only considered an IRS-like

117. Rev. Ruling 97-21, 1997-1 C.B. 121.
118. *Id.*
119. *Id.*
120. *Id.*
121. Bollinger, *supra* note 7, at 510.
122. *Id.* at 512; *see supra* Part II. A.
123. Bollinger, *supra* note 7, at 512.

analysis as one of several factors;[124] therefore, hospitals still face the uphill battle of wondering what other factors might trump their demonstrated need.

The IRS solution might be too hasty in completely eliminating the purpose requirement despite the criticisms surrounding the "one purpose" test. When presented with the IRS test as an option in place of the HPSA requirement, the OIG definitively refused to make the physician recruitment safe harbor mirror Revenue Ruling 97-21 because such an approach would not adequately protect against fraud and abuse.[125]

Thus, a *modified* version of the IRS approach might be both useful and effective as an alternative to the limiting nature of the HPSA designation requirement. For example, assume that Hospital X is a for-profit hospital in the same predicament as the facts described above. Under a modified IRS approach, if the hospital could meet the requirements discussed in Revenue Ruling 97-21, *and* if the proposed recruitment arrangement failed either the *Greber* or *McClatchey* purpose test (depending on the jurisdiction), then it would not be in violation of the Anti-Kickback statute. If a modified version of the IRS approach were adopted, hospitals would still face the subjective balancing of the test, but they would no longer be hindered by unnecessary HPSA requirements.

### *C. Solution #2: No Community Need Standard*

Aside from the modified IRS model discussed above, another potential solution to the problems caused by the HPSA requirement would be to remove the need-based analysis from the physician recruitment safe harbor. Such a solution proposes that all references to HPSA requirements in the safe harbor be removed and nothing put in their place. Although this solution might be met with fear of fraudulent or abusive behavior, there still will be limiting criteria in the safe harbor language. For example, the safe harbor language limits offers of unrestricted staff privileges at other hospitals, disallows remuneration based on the volume or value of referrals, and bars renegotiation of a proposed arrangement.[126] As a result, hospitals still are limited in their negotiations with recruited physicians; however, those hospitals are simultaneously liberated from bureaucratic processes

124. *Id.*

125. Medicare and State Health Care Programs: Fraud and Abuse; Clarification of the Initial OIG Safe Harbor Provisions and Establishment of Additional Safe Harbor Provisions Under the Anti-Kickback Statute, 64 Fed. Reg. 63,518, 63,544-45 (Nov. 19, 1999) (to be codified at 42 C.F.R. pt. 1001).

126. 42 C.F.R. § 1001.952(n).

surrounding HPSA, DSH, or MUA designation. Additionally, even if the community need standard were eliminated, hospitals still must comply with the other requirements in the safe harbor, such as length of contract with the physician and no tie to referrals.[127] Additionally, for-profit hospitals would avoid the guessing game of the IRS three-part test.[128]

If this solution were adopted, certain other steps would have to follow. First, protections would be needed to prevent the floodgates from opening for only the hospitals with the most financial resources to attract the best physicians. Indeed, the non-HPSA safe harbor elements, which serve to check the reach of recruitment packages and to keep hospitals honest, would still need to be strictly enforced.

Second, some existing programs, such as the Medicare Incentive Program and the J-1 Visa program, should continue to emphasize attracting physicians to certain areas and populations. Removing the community need requirement from the safe harbor connotes confidence in the ability of these pre-existing programs to spread the supply of physicians across communities. Moreover, most hospitals that put forth the effort to recruit physicians do so because they have an actual need. The other requirements in the safe harbor will appropriately limit the extent of recruitment efforts.

The Anti-Kickback statute should help curb fraudulent activities rather than serve as an allocation gate. The HPSA designation has taken on a life of its own and the solutions offered by this paper adequately address hospitals' need to both recruit physicians and to comply with the overall goals of the Anti-Kickback statute.

## V. CONCLUSION

As the healthcare industry continues to change, hospitals face many hurdles in ensuring the legality of their recruitment initiatives and compliance with the Anti-Kickback statute. The current Anti-Kickback language relies on the arbitrary use of HPSA designation too heavily. The HPSA designation only serves to stall hospitals' efforts by forcing them to seek advisory opinions or forego recruitment initiatives to reduce the risk of an Anti-Kickback violation. Moreover, the HPSA designation process has several documented problems. Consequently, the HPSA language in the Anti-Kickback statute should be removed. Although some of the criteria such as DSH designation or an IRS approach mirroring Revenue Ruling 97-21 provide better alternatives to the HPSA requirement, the best approach is to no longer require a showing of community need. Furthermore, all references to HPSA designation should be removed from the physician

127. *See id.*

128. *See* Rev. Ruling 97-21, 1997-1 C.B. 121 (tax exempt hospitals, however, would still be required to follow the Revenue Ruling).

recruitment safe harbor. This will not open the floodgates to fraudulent activities because the other requirements of the safe harbor remain intact. This new solution would better serve the Anti-Kickback statute's goal of preventing fraud and abuse and would allow for bona fide activities to occur, thereby allowing hospitals to better serve their communities.