WHY HEALTHCARE FRAUD AND ABUSE LAWS SHOULD ALLOW APPROPRIATE HOSPITAL GAINSHARING

I. INTRODUCTION*

Several hospitals in the United States have petitioned the federal government in recent years for permission to enter into gainsharing agreements with physicians in order to reduce costs while also walking a tightrope to maintain or improve patient care.[1] Under a typical gainsharing agreement, a hospital pays participating physicians "a share of any reduction in the hospital's costs attributable" to the physicians' cost-saving efforts in providing medical services.[2] The federal government has adopted a wary attitude toward hospital gainsharing in the past.[3] However, more recently, certain parts of the government have taken a more flexible stance on the practice. Currently, the U.S. Department of Health & Human Services (HHS) Centers for Medicare and Medicaid Services (CMS) solicits hospital administrators to experiment with gainsharing.[4] Also, the U.S. Department of Justice, which enforces United States healthcare fraud and abuse statutes refuses to prosecute certain gainsharing agreements if they have been authorized by the HHS Office of Inspector General (OIG) and CMS, respectively.[5]

Departing from its previously distrustful view of hospital gainsharing agreements, OIG issued an Advisory Opinion in January 2005 promising not to impose sanctions for violations of healthcare fraud and abuse statutes

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1. *See Hospitals Vie for Gainsharing Demonstration Slots*, INSIDE CMS, Mar. 8, 2007, *available at* 2007 WLNR 4384562; *see*, *e.g.*, Op. Dep't of Health & Human Servs., OIG No. 05-01 (Jan. 28, 2005), *available at* http://oig.hhs.gov/fraud/docs/advisoryopinions/2005/ao0501.pdf [hereinafter Advisory Opinion 05-01].

2. *Hearing on Gainsharing Before the Subcomm. on Health of the H. Comm. on Ways & Means*, 109th Cong. 8 (2005) [hereinafter *Hearing*] (statement of Lewis Morris, Chief Counsel to the Inspector Gen., U.S. Dep't of Health and Human Services).

3. *See id.* (stating that the U.S. Department of Health and Human Services Office of the Inspector General has traditionally been "very wary of gainsharing arrangements" between hospitals and physicians for several reasons, including the fact that such arrangements implicate the Civil Monetary Penalty, federal anti-kickback, and physician self-referral or "Stark" laws).

4. *See*, *e.g.*, Medicare Program: Solicitation for Proposals To Participate in the Medicare Hosptial Gainsharing Demonstration Program Under Section 5007 of the Deficit Reduction Act, 71 Fed. Reg. 54,664, 54,664–65 (Sept. 18, 2006); *see also* Deficit Reduction Act of 2005, Pub. L. No. 109-171, § 5007, 120 Stat. 4, 34–36 (2006); Medicare Presciption Drug, Improvement, and Modernization Act of 2003, Pub. L. No. 108-173, § 646, 117 Stat. 2066, 2324–26.

5. *See*, *e.g.*, Advisory Opinion 05-01, *supra* note 1; *see also* Katherine Thomas, *New Gainsharing Demo Allows Participation Of Up To 72 Hospitals*, THE GRAY SHEET, Sept. 11, 2006, at 10 (on file with author).

on a hospital's gainsharing program that would pay a group of cardiac surgeons a portion of the "savings arising from the surgeons' implementation of a number of cost reduction measures."[6] Examples of the cost reduction measures include: substituting less costly cardiac products for currently-used products; "opening packaged items only as needed" in the operating room; and limiting use of certain supplies of blood cross-matching procedures.[7] Then, in early 2005, OIG issued five other Advisory Opinions approving similar gainsharing agreements between hospitals and physicians.[8] In a number of cases, OIG examined the effectiveness of safeguards that the petitioning hospital had put in place to prevent the gainsharing arrangement from defrauding Medicare, such as "measures . . . promot[ing] accountability, adequate quality controls, and controls on payments that may change referral patterns," concluding the proposed arrangements presented little risk of fraud and abuse.[9] OIG thus "exercised . . . discretion not to impose sanctions" on the arrangements.[10]

Separately, CMS has begun implementing gainsharing demonstration projects that were authorized by Congress in the Deficit Reduction Act of 2005[11] and the Medicare Prescription Drug, Improvement, and Modernization Act of 2003.[12] CMS seeks to evaluate whether gainsharing can improve a hospital's operational and financial performance while also advancing the quality and efficiency of care provided to Medicare beneficiaries.[13] Hospitals included in the gainsharing demonstration projects submitted their applications to CMS by January 9, 2007.[14]

Lewis Morris, OIG chief counsel, explained HHS's more receptive view on gainsharing in testimony before the House Committee on Ways and Means Subcommittee on Health on October 7, 2005, stating that, "[p]roperly structured, gainsharing arrangements may offer opportunities for hospitals to reduce costs without causing inappropriate reductions in medical services or rewarding referrals of federal health care program patients."[15]

Nevertheless, while some government officials may be optimistic that gainsharing can provide a needed boon to cost reduction activities and the quality and efficiency of patient care at hospitals, several healthcare industry stakeholders remain fervently opposed.[16] In their view, gainsharing has

6. *See* Advisory Opinion 05-01, *supra* note 1, at 1.
7. *See id.* at 3–4.
8. *See* Katherine Thomas, *Gainsharing On The Horizon: Hospitals Seek To Control Costs By Collaborating With Physicians*, THE GRAY SHEET, Jan. 30, 2006, at 24 (on file with author).
9. *Hearing*, *supra* note 2, at 7.
10. *Id.*
11. Deficit Reduction Act of 2005, Pub. L. No. 109-171, § 5007, 120 Stat. 4, 34–36 (2006).
12. Medicare Prescription Drug, Improvement, and Modernization Act of 2003, Pub. L. No. 108-173, § 646, 117 Stat. 2066, 2324–26.
13. Thomas, *supra* note 5.
14. *See id.*
15. *Hearing*, *supra* note 2, at 7.
16. *See* Katherine Thomas, *Gainsharing Does Not Equal Device Contracting Arrangements, CMS Says*, THE GRAY SHEET, June 19, 2006, at 3 (on file with author).

the potential "to reduce physician choice" of medical devices and diagnostic tests and, thus, "limit patient access to the most appropriate care."[17] Opponents further suggest that gainsharing could encourage physicians to "cherry pick" patients whereby healthier, less expensive patients receive hospital treatment while sicker, more expensive patients are referred elsewhere.[18] Also, some medical device and diagnostic industry companies believe gainsharing might decrease "incentives to invest in new[er], more expensive technology and treatment[]" procedures.[19]

Most vocally, U.S. Congressman Pete Stark, chairman of the House Committee on Ways and Means Subcommittee on Health, remains at best skeptical of gainsharing even as his colleagues endorse the practice. Recently, he deprecated HHS's new, open-minded approach towards gainsharing in no uncertain terms, stating:

> We should be considering ways to curb these relationships, not propagate them. I believe that gainsharing is not only misguided, it is very dangerous. . . . This idea of kickbacks—which is the only thing that you can call gainsharing—is wrong. If there is money to be saved, the hospitals should give it back to Medicare. There is no reason on God's green Earth that they should give it to the doctors.[20]

With debate raging about whether hospital gainsharing represents a superior or inferior method of cutting healthcare costs while also maintaining or improving patient services, the conditioned exceptions to healthcare fraud and abuse laws that the government granted to several hospitals to encourage gainsharing agreements with physicians[21] could vanish as quickly as they arose should initial gainsharing demonstration projects not produce positive results.

After defining hospital gainsharing, this Comment will explain the rationale for appropriate gainsharing in the context of the Medicare and Medicaid reimbursement programs. Next, statutory impediments to hospital gainsharing, which consist of certain healthcare fraud and abuse laws, are examined. Then, this Comment traces the federal government's movement from

17. *See id.*

18. Marcelo N. Corpuz III & Celestina Owusu-Sanders, *OIG Issues Advisory Opinions on Gainsharing Arrangements*, HEALTH LAW., June 2005, at 16, 18.

19. *See* Charisse Logarta, *Provider Response to Cost Containment: Fraud & Abuse Issues*, 15 ANNALS HEALTH L. 373, 377 (2006); *see also* Thomas, *supra* note 8 (stating that medical device industry trade associations oppose gainsharing "due to the potential for such arrangements to discourage medical device innovation, hurt small businesses and create anti-competitive market forces").

20. *Hearing*, *supra* note 2, at 5 (statement of Rep. Pete Stark, Member, House Comm. on Ways and Means).

21. *Id.* at 10 (statement of Lee Morris, Chief Counsel to the Inspector Gen., U.S. Dep't of Health & Human Services) (stating that OIG conditionally has approved gainsharing agreements at several hospitals despite the fact that the cost-saving programs violate the Civil Monetary Penalty and may pose a substantial risk under federal anti-kickback statutes); *see infra* pp. 27–31.

viewing hospital gainsharing warily to its present, more open-minded, neutral view of such arrangements. Finally, the future role that appropriate hospital gainsharing agreements might play in U.S. healthcare is indicated.

II. RATIONALE FOR HOSPITAL GAINSHARING UNDER THE MEDICARE PROSPECTIVE PAYMENT SYSTEM

Broadly viewed, gainsharing means a "formal reward . . . system in which [participating] workers share" in financial benefits from "productivity improvements achieved by their organization [due to] the workers' contributions."[22] In the hospital industry, the term refers to an arrangement in which a hospital gives physicians a share of any reduction in the hospital's costs that may be shown to be attributable in part to the physicians' cost-saving efforts.[23]

"[A] typical gainsharing program would establish as a baseline measurement the hospital's current annual costs for treating" a certain patient class, such as "hip replacement patients."[24] Then, after introducing physicians to "new policies and procedures" set forth in the gainsharing program for treating that group of patients, "the hospital would measure costs [related to] hip replacement patients" over the next year.[25] If the "costs for the same volume of hip replacement patients declined by $100,000 during the evaluation year compared to the baseline" year, and if that decline can be shown to be due to "the hospital . . . provid[ing] the same type [and quality] of service more efficiently," then the participating physicians would earn a group bonus based on a "previously agreed percentage amount of the cost-savings [related to] hip replacement patients during the . . . year."[26] The physicians in the gainsharing group then would divide this group bonus equally.[27]

Hospital gainsharing agreements, such as the one described above, initially appeared as a response to Congress's establishing the Medicare Prospective Payment System (PPS) for reimbursing hospital inpatient services in 1983.[28] Prior to the PPS, hospitals and physicians received Medicare and

22. Richard S. Saver, *Squandering the Gain: Gainsharing and the Continuing Dilemma of Physician Financial Incentives*, 98 NW. U. L. REV. 145, 147 (2003).

23. *Hearing*, *supra* note 2, at 8.

24. Saver, *supra* note 23, at 148.

25. *Id.*

26. *Id.*

27. *Id.*

28. Social Security Amendments of 1983, Pub. L. No. 98-21, § 601, 97 Stat. 65, 149–63 (1983). The initial PPS was for hospital inpatient services. *Id.* In 2000, the government phased in a comparable "prospective payment system for hospital outpatient services" as well. Process for Requesting Recognition of New Technologies and Certain Drugs, Biologicals, and Medical Devices for Special Payment Under the Hospital Outpatient Prospective Payment System, 65 Fed. Reg. 18,341, 18,341 (Apr. 7, 2000); *see also* Saver, *supra* note 23, at 155–57 (explaining that the "PPS provides hospitals [with] clear incentives to provide more efficient care and conserve resources [in order] to stay within a pre-determined [diagnosis-related group] payment," while "physicians face . . . opposite incentives" under the Medicare physician fee-for-service reimbursement scheme); Betsy McCubrey, Comment, *OIG Bulletin Highlights Schizophrenic Attitude in Cost-Saving Measures: Gainsharing Arrangements—Their History, Use, and*

Medicaid reimbursement "based on a fee-for-service schedule—payments were based on the reasonable costs" of each service rendered to Medicare and Medicaid beneficiaries.[29] "The greater the number of services rendered to Medicare patients, the more money the hospital [or physician] received."[30] Currently, under the Medicare PPS, hospitals receive a set payment for each beneficiary based on the beneficiary's diagnosis.[31] Thus, hospitals receive the same fee for beneficiaries with the same diagnosis regardless of what it actually costs to treat a beneficiary.[32] Meanwhile, Medicare pays physicians based on the fee-for-service model whereby a physician who provides more services to a hospitalized patient likely will receive more in reimbursement.[33]

Congress wanted the PPS to encourage hospitals to "develop more cost-effective practice patterns" to earn higher margins from fixed Medicare payments.[34] This goal soon became reality, though perhaps not as Congress intended, when hospitals realized that they would earn greater profits under the PPS if they could reduce the average patient's stay, increase the number of patient admissions, or provide fewer or less expensive services to patients.[35] Gainsharing arrangements seeking to provide less expensive services or more efficient care to patients then emerged in an effort to better align the economic interests of physicians, who control the treatment and diagnosis of patients, with the economic interests of the hospitals.[36]

III. CURRENT STATUTORY IMPEDIMENTS

Lawmakers grew concerned that hospitals were using gainsharing agreements to lower costs in a way that might reduce overall patient care quality "by rewarding physicians for withholding services [to] patients," providing cheaper, but less effective, services to patients, "discharging [sick] patients . . . sooner than medically indicated," or unnecessarily admitting relatively healthy patients who might be billed to Medicare at a profit because they require only minor treatments.[37] In 1985, Congress watched

Future, 79 N.C. L. REV. 157, 169 (2000) ("The imbalance in incentives [between hospitals and physicians] that resulted from the need for and proliferation of gainsharing programs was an unintended, though foreseeable, result of the PPS.").

29. McCubrey, *supra* note 28, at 163; *see also* U.S. GEN. ACCOUNTING OFFICE, MEDICARE: PHYSICIAN INCENTIVE PAYMENTS BY HOSPITALS COULD LEAD TO ABUSE 2 (1986), *available at* http://archive.gao.gov/d4t4/130544.pdf [hereinafter GAO REPORT].

30. McCubrey, *supra* note 28, at 163.

31. Saver, *supra* note 22, at 156. Under the PPS, physicians diagnose Medicare beneficiaries into a diagnosis-related group which determines what amount of prospective reimbursement the hospital will receive from the federal government for treating the beneficiary. *Id.*

32. *Id.* at 156–57.

33. *Id.* at 157.

34. *Id.* at 158.

35. McCubrey, *supra* note 28, at 169–70.

36. *See id.* at 169 (citing Mark A. Hall, *Institutional Control of Physician Behavior: Legal Barriers to Health Care Cost Containment*, 137 U. PA. L. REV. 431, 483 (1988) (stating that the "most effective motivational force is likely to be financial incentive")).

37. Saver, *supra* note 22, at 158; *see also* GAO REPORT, *supra* note 30, at 9 ("Under prospective

closely as OIG investigated Paracelsus Healthcare Corporation, which operated fourteen hospitals, to determine the legality of a gainsharing agreement under which the corporation paid physicians that reduced the length of patients' hospital stays and, thereby, maximized the profits of its hospitals.[38] OIG's investigation widened into allegations that the company had submitted "false cost reports."[39] Paracelsus entered into a $4.5 million settlement agreement with the government in 1986.[40] The investigation underscored some potential problems with gainsharing agreements.[41] Following this investigation, Congress decided to strengthen the Civil Monetary Penalty (CMP) statute as part of the Omnibus Budget Reconciliation Act of 1986.[42]

A. Civil Monetary Penalty Statute

The strengthened CMP created a major statutory obstacle for hospitals wishing to implement gainsharing arrangements. The CMP requires hospital administrators to consider the impact such cost-saving programs would have on the quality of care provided to Medicare and Medicaid beneficiaries.[43] The CMP prohibits hospitals and physicians from knowingly making or receiving payments directly or indirectly as an incentive for physicians to limit items or services provided to beneficiaries.[44] For each improper claim filed under Medicare or Medicaid, the CMP permits HHS to impose a civil

payment, the incentives could lead hospitals to underprovide services, discharge patients too early, and as under cost reimbursement, unnecessarily admit patients[.]").

38. *See* GAO REPORT, *supra* note 30, at 14–15; McCubrey, *supra* note 28, at 157–58; Abigail Trafford & Peter Dworkin, *The New World of Health Care*, U.S. NEWS & WORLD REP., Apr. 14, 1986, at 60. Hospitals, which are reimbursed under the prospective payment system on a per-patient basis, generally spend less in fixed fees on patients who stay in the hospital beds for a shorter time, resulting in greater profits for the hospitals. *See generally* Jacqueline Kosecoff et al., *Prospective Payment System and Impairment at Discharge: The "Quicker-and-Sicker" Story Revisited*, 264 JAMA 1980 (1990) (studying discharge rates after Medicare switched to the PPS and concluding that patients were discharged earlier following the change).

39. Alice G. Gosfield, *In Common Cause for Quality*, *in* HEALTH L. HANDBOOK § 5.14 (Alice G. Gosfield ed., 2006), *available at* http://www.gosfield.com/PDF/commoncausequalityCh5.pdf.

40. *See id.*

41. GAO REPORT, *supra* note 30, at 15–16 (expressing GAO's opinion that features of the Paracelsus gainsharing agreement, such as the short, one-month period of time over which the incentive operated and the decision to pay physicians based on their individual performance, "make the incentives too strong for physicians to underprovide services or admit patients to the hospital who might not need hospitalization"). *But cf.* Saver, *supra* note 22, at 159 ("Although the design of the Paracelsus incentive plans did seem questionable, all the concerns raised related to *potential* dangers. No *actual* bad patient outcomes were reported or traced to the Paracelsus incentive plans.").

42. *See* Saver, *supra* note 22, at 160 (citing Pub. L. No. 99-509, § 9313(c), 100 Stat. 1874 (1986) (codified as amended at 42 U.S.C. § 1320a-7a (2000))).

43. *See Hearing*, *supra* note 2, at 8.

44. 42 U.S.C. § 1320a-7a(b)(1) (2000) ("If a hospital or a critical access hospital knowingly makes a payment, directly or indirectly, to a physician as an inducement to reduce or limit services provided . . . the hospital or a critical access hospital shall be subject . . . to a civil money penalty of not more than $2,000 for each such individual with respect to whom the payment is made."); *id.* § 1320a-7a(b)(2) ("Any physician who knowingly accepts receipt of a payment described in paragraph (1) shall be subject . . . to a civil money penalty of not more than $2,000 for each individual described in such paragraph with respect to whom the payment is made.").

monetary penalty up to $100,000.[45] In addition, "the provider may be assessed triple the amount of damages wrongly claimed."[46]

The CMP's broad language reflects Congressional concern that hospitals must not "have an economic incentive to pay physicians to discharge patients too soon—quicker and sicker—or otherwise truncate patient care" under the Medicare PPS.[47] Thus, "any hospital gainsharing plan that encourages physicians . . . to reduce or limit clinical services violates the CMP[,]" whether or not the payment actually results in a reduction in care or in medically necessary services.[48] For example, a gainsharing agreement where a hospital provides payments to its orthopedic surgeons in exchange for the surgeons' choosing artificial hips that they implant into the hospital's patients from a limited number of less expensive artificial hip devices could violate the CMP even if the less expensive hip implants were as effective as more expensive hip implants.

B. Anti-Kickback Statute

It was felt previously[49] that gainsharing arrangements also might implicate the federal anti-kickback law.[50] That statute prohibits parties from knowingly and willfully paying, soliciting, or receiving any remuneration directly or indirectly to purchase, or recommend purchasing, any good, service, or item that is paid in whole or in part under a federal healthcare program.[51] The term "'remuneration' includes 'a kickback, bribe, or rebate.'"[52] Parties found in violation of the anti-kickback statute are "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."[53] Further, if convicted, the hospital or physician may be excluded from participation in the Medicare and Medicaid programs,[54] a penalty that could bankrupt even the most profitable medical business or practice.

While the anti-kickback statute was not intended to apply to payments made in connection with hospital cost-saving programs, the provision can apply to gainsharing programs where physicians are compensated based on

45. ROBERT FABRIKANT, PAUL E. KALB, MARK D. HOPSON & PAMELA H. BUCY, HEALTH CARE FRAUD: ENFORCEMENT AND COMPLIANCE § 5.03 (2007).

46. *Id.* "HHS derives its authority to impose this penalty from section 1128A of the Social Security Act, as supplemented by section 2105 of the Omnibus Budget Reconciliation Act of 1981, Pub. L. No. 97-35, 95 Stat. 357 (1981) and as amended by Section 137(b)(26) of the Tax Equity and Fiscal Responsibility Act of 1982, Pub. L. No. 87-248 [sic], 96 Stat. 324 (1982)." *Id.* § 5.03 n.3.

47. *Hearing*, *supra* note 2, at 8.

48. *Id.*

49. *See Survey of Recent Developments in Health Law*, 40 IND. L. REV. 931, 937 (2007). However the Deficit Reduction Act of 2005 explicitly exempts gainsharing demonstration projects from anto-kickback statutes, the Stark law. or the CMP. *Id.* (citing Pub. L. No. 109-171, § 5007(c)(1), 120 Stat. 4, 34 (codified in scattered sections of 42 U.S.C.).

50. 42 U.S.C. § 1320a-7b.

51. *See id.* §§ 1320a-7b(b)(1)–(b)(2)(B).

52. FABRIKANT ET AL., *supra* note 45, § 3.02[5] (quoting 42 U.S.C. §§ 1320a-7b(b)(1)–(b)(2)).

53. 42 U.S.C. § 1320a-7b(b)(2)(B).

54. McCubrey, *supra* note 29, at 179–80.

increased hospital profits attributable to the physicians ordering or purchasing treatments or services reimbursed by the government in a more cost-effective manner as recommended by hospital administrators.[55]

Some hospital administrators have tried to protect themselves and their incentive programs from prosecution under the anti-kickback statute by seeking refuge in the Personal Services and Management Contracts safe harbor provision.[56] Most gainsharing arrangements do not qualify, however, "[b]ecause this safe harbor requires that compensation be predetermined and volume-neutral,"[57] rather than based on the level of cost savings achieved.

C. Physician Self-Referral Statute

In addition to setting forth the risk of violating the CMP and anti-kickback statutes, Congress bolstered statutory hindrances to hospital gainsharing agreements with physician self-referral, or "Stark" laws.[58] Passed by Congress in 1989 and named after its sponsor, Rep. Forney (Pete) Stark, the initial Stark statute prohibited self-interested referrals of healthcare services under Medicare and Medicaid to clinical laboratories in which the referrer, or a member of the referrer's family, had a financial interest.[59] In 1993, Congress expanded the Stark statute's "prohibited referrals to ten categories of healthcare services in addition to clinical laborator[ies]."[60]

The Stark statute can be read to prohibit hospital gainsharing programs because a referring physician is considered to have a financial interest in a hospital offering the physician a gainsharing arrangement.[61] Thus, the physician is prohibited from referring patients to that hospital under the statute due to the remuneration the physician would receive from the hospital for the arrangement.[62] While statutory exemptions from Stark laws exist for some types of gainsharing agreements, qualifying for them while maintaining a gainsharing program is difficult and can hinder the cost reducing goal of appropriate gainsharing.[63]

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55. *Id.* at 178–79.

56. *See id.* at 179 (citing 42 C.F.R. § 1001.952(d) (1999)). "This safe harbor is also commonly known as the Personal Services Exception." *Id.* at 179 n.164.

57. *Id.* at 179.

58. 42 U.S.C. § 1395nn; *see Hearing*, *supra* note 2, at 8; FABRIKANT, ET AL., *supra* note 45, § 4.05.

59. 42 U.S.C. § 1395nn; FABRIKANT ET AL., *supra* note 45, § 4.05[1].

60. FABRIKANT ET AL., *supra* note 45, § 4.05[1].

61. See John R. Washlick, *Hospital/Physician Gainsharing Arrangements: The IRS Giveth and the OIG Taketh Away*, HEALTH LAW., Aug. 1999, at 1, 6.

62. *See id.*

63. One example of an exemption from the Stark statute is the Personal Services Exemption, which "requires that . . . compensation paid to . . . providing physician[s] be [pre-set] and [unrelated to] the 'volume or value of any referrals between the physician[] and the hospital.'" McCubrey, *supra* note 28, at 180 (quoting 42 C.F.R. § 1001.952(d)(5) (1999)). As a prerequisite for the exemption to apply, CMS, which enforces Stark violations, would require any incentive offered to physicians to be pre-determined in a manner that did not take into account increased cost reductions accruing to the hospital from the gainsharing program. *Id.* Thus, with pre-determined incentives awarded up front to physicians for their mere participation in a gainsharing program, physicians might have little motivation to alter their practice patterns to comply with the guidelines set forth in the program that would lead to cost reductions for

"The primary remedy for a Stark violation is denial of payment for [the] prohibited claim," or required refund of any amount collected on the claim.[64] Besides penalizing the entity billing as a result of the prohibited referral, the Stark statute also establishes "wrongful conduct" penalties for persons who present a prohibited bill or claim that they know or should know to be prohibited.[65] These penalties subject such persons to "a civil monetary penalty of up to $15,000 for each service provided, damages of up to three times the amount of the monetary penalty, and exclusion from the Medicare or Medicaid programs."[66]

Moreover, "[u]nlike the Anti-Kickback Statute, the Stark Law operates under strict liability and does not require proof of intent for a violation."[67] Because of the strict liability component, even physicians who want to participate in a gainsharing agreement that they believe to be legal might not do so because they want to avoid the risk of a court concluding they have violated Stark.

IV. EVOLUTION OF GOVERNMENT ATTITUDE TOWARDS HOSPITAL GAINSHARING

With such laws inhibiting hospital administrators from implementing gainsharing arrangements with physicians, health care coalitions concentrated on lobbying Congress for a change in the healthcare fraud and abuse statutes.[68] Their purpose was to improve the legal climate for gainsharing while simultaneously soliciting advisory opinions from federal agencies on how to implement legal and cost-effective gainsharing programs under existing laws.[69]

A. Shutting The Door: OIG 1999 Special Advisory Bulletin

In 1999, OIG issued a Special Advisory Bulletin (1999 OIG Report) that appeared to close the door on gainsharing as a viable method for hospitals to cut costs while also maintaining or bettering levels of patient care.[70] The 1999 OIG Report concluded that healthcare fraud and abuse statutes prohibit "any gainsharing arrangements that involve payments by or on behalf of a hospital, directly or indirectly, to induce physicians with clinical

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the hospital.

64. FABRIKANT ET AL., *supra* note 45, § 4.05[5].

65. *Id.*

66. *Id.* (citing 42 U.S.C. § 1395nn(g)(3) (2000)).

67. Logarta, *supra* note 19, at 374 (discussing the presentation of McDermott Will & Emery Partner Joan Polacheck at the Loyola University Chicago School of Law's Fifth Annual Health Law & Policy Colloquium on Nov. 10, 2005).

68. *See* McCubrey, *supra* note 28, at 198]

69. *See id.* at 197–200.

70. Publication of the OIG Special Advisory Bulletin on Gainsharing Arrangements and CMPs for Hospital Payments to Physicians to Reduce or Limit Services to Beneficiaries, 64 Fed. Reg. 37,985 (July 14, 1999) [hereinafter 1999 OIG Report]; Saver, *supra* note 22, at 162–63.

care responsibilities to reduce or limit services to Medicare or Medicaid patients."[71]

OIG analyzed the CMP, anti-kickback, and physician self-referral statutes and determined that all three statutes likely prohibited gainsharing.[72] The agency also concluded that under the very broad statutory proscription provided by the CMP, a hospital's payment to a physician "need not be tied to an actual diminution in care, so long as the hospital knows that the payment may influence the physician to reduce or limit services to his or her patients."[73] In OIG's view, any hospital incentive plan, including gainsharing arrangements, that directly or indirectly encourages physicians through payments to reduce or limit clinical services violates the CMP.[74]

The Report added that, notwithstanding the statutory prohibitions against hospital gainsharing, OIG considered granting favorable advisory opinions to certain hospitals to protect individual gainsharing arrangements from OIG administrative sanctions.[75] However, after reviewing requests from hospitals for approval of gainsharing programs, OIG decided that the high risk of abuse of such programs prevented it from using its advisory opinion power to immunize such arrangements from sanction.[76] OIG also noted that the Office of Counsel, which issues advisory opinions, did not have the "resources [or] the expertise to police a multitude of such arrangements on an ongoing basis."[77]

Finally, OIG said case-by-case determinations of gainsharing arrangements by hospitals would be "an inadequate and inequitable substitute for comprehensive and uniform regulation in this area."[78] For example, if OIG issued a favorable opinion to one provider and not another, then the former provider "would have a significant competitive advantage in recruiting and attracting physicians to admit patients to its facility," as physicians admitting patients to that provider's hospital would have the chance to earn additional income not available elsewhere.[79] The dour outlook on gainsharing presented in the 1999 OIG Report appeared to ban hospital administrators from making gainsharing agreements with physicians.[80]

71. 1999 OIG Report, 64 Fed. Reg. at 37,985.
72. *See* 64 Fed. Reg. at 37, 985 (July 14, 1999).
73. 1999 OIG Report, 64 Fed. Reg. at 37,985.
74. *Id.*
75. *Id.* at 37,987.
76. *Id.* ("In order to retain or attract high-referring physicians, hospitals will be under pressure from competitors and physicians to increase the percentage of savings shared with the physicians, manipulate the hospital accounts to generate phantom savings, or otherwise game the [gainsharing] arrangement to generate income for referring physicians.").
77. *Id.*
78. *Id.*
79. *Id.*
80. *See id.*; Saver, *supra* note 22, at 166–67.

B. Tide Turning: OIG's 2001 Advisory Opinion On Gainsharing

OIG reconsidered its hard-line approach on hospital gainsharing in 2001. Its Advisory Opinion No. 01-1 (2001 OIG Report) was more receptive to gainsharing cost savings than its 1999 OIG Report.[81] In the 2001 OIG Report, OIG exercised agency discretion by declining to sanction Atlanta-based St. Joseph's Hospital's proposed gainsharing agreement with a group of cardiac surgeons.[82] OIG did so despite concluding that the proposed arrangement would constitute an improper payment to induce reduction or limitation of services pursuant to the CMP and potentially would generate "prohibited remuneration under the anti-kickback statute, if the requisite intent to induce referrals [was] present."[83]

OIG did not immediately repeat that more favorable outlook on gainsharing by issuing additional advisory opinions declining to impose sanctions on other hospital gainsharing programs. Therefore, the agency's more hostile position on gainsharing, expressed in the 1999 OIG Report, continued to cause the majority of hospital administrators to shy away from starting gainsharing programs with physicians.[84] Federal laws on hospital gainsharing in the early 2000s barely had improved from a "complete ban" to a "near-ban" on the cost-savings practice.[85] In 2003, one health policy expert observed that "hospital gainsharing today remains fraught with legal risk, and there is a dearth of gainsharing by hospitals."[86]

C. Court Ruling Reduces Means For Hospital Gainsharing Approval

Garnering an advisory opinion endorsement from OIG is a costly, time-consuming process for hospitals that offers no guarantee of success.[87] In 2003, the eight-hospital New Jersey Hospital Association (N.J. Hospitals) decided to implement gainsharing without first securing such an OIG opinion.[88] Instead, the N.J. Hospitals simply sought and received approval from CMS for a three-year gainsharing pilot initiative.[89]

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81. *See* Op. Dep't of Health & Human Servs., OIG No. 01-1 (Jan. 11, 2001) [hereinafter 2001 OIG Report], *available at* http://oig.hhs.gov/fraud/docs/advisoryopinions/2001/ao01-01.pdf; Saver, *supra* note 22, at 167.

82. 2001 OIG Report, *supra* note 80, at 14; *see also* Richard S. Saver, *One More Setback For Gainsharing*, HEALTH LAW PERSP., Aug. 27, 2004, at 3, *available at* http://www.law.uh.edu/healthlaw/perspectives/(RiSa)GainsharingNJ.pdf.

83. 2001 OIG Report, *supra* note 82, at 14.

84. *See* Saver, *supra* note 22, at 170–71.

85. *Id.* at 150 (stating that "OIG imposed rigorous requirements and relied upon certain mitigating factors in [the 2001] instance that many other hospitals interested in gainsharing will be unable to meet or replicate").

86. *Id.*

87. Saver, *supra* note 82, at 5–6.

88. *See* Robert Wood Johnson Univ. Hosp., Inc. v. Thompson, No. Civ. A. 04-142, 2004 WL 3210732, at *12 (D.N.J. Apr. 15, 2004).

89. *Id.* at *1; Saver, *supra* note 81, at 3–4.

The N.J. Hospitals' program, also known as the "Hospital Performance-Based Incentives Demonstration" (Demonstration Project),[90] proposed to allow physicians "to earn bonuses of up to 25% more in Medicare fees if hospital operating efficiencies improved over the measurement period."[91] Four New Jersey area hospitals that were excluded from the Demonstration Project sought an injunction in federal court to strangle the N.J. Hospitals' gainsharing program in its infancy.[92] The disgruntled hospitals alleged the N.J. Hospitals' program would cause them "to suffer economic injuries through an increase in illicit referrals by participating doctors to Participating Hospitals to the detriment of the non-participating hospitals."[93] In addition to such anti-competitive concerns, they also argued that the N.J. Hospitals' program violated the CMP and anti-kickback statutes.[94]

In *Robert Wood Johnson University Hospital Inc. v. Thompson*, the U.S. District Court for the District of New Jersey decided in 2004 that the N.J. Hospitals' Demonstration Project violated the CMP statute because physicians would earn a financial bonus for treating Medicare patients with greater "cost-efficiency" which the court equated with a reduction of services to those patients.[95] The court reasoned that the Demonstration Project's objective is "to reduce services provided to patients, albeit without 'sacrificing the quality of patient care.'"[96] Thus, the court implicitly agreed with OIG's broad understanding of the CMP statute, expressed in the 1999 OIG Report, that a hospital's payment to a physician violates the law, regardless of whether it results in an actual diminution in care, as "long as the hospital knows that the payment may influence the physician to reduce or limit services to his or her patients."[97] To bolster its conclusion that the N.J. Hospitals' gainsharing project illegally paid physicians for reducing services to Medicare patients, the court noted defendants' admission that the "'[a]ltered practice patterns [under the initiative] could include shorter inpatient stays, fewer marginal but costly diagnostic tests, conversion to generic drugs, shorter operating room times, more cost effective use of intensive care units, etc.'"[98]

The decision criticized the N.J. Hospitals' failure to seek and obtain a favorable OIG advisory opinion before starting the gainsharing project, especially because the hospital group was aware of the 1999 OIG Report and

90. *Robert Wood Johnson*, 2004 WL 3210732, at *5.
91. Saver, *supra* note 82, at 4.
92. *Robert Wood Johnson*, 2004 WL 3210732, at *1.
93. *Id.* at *2.
94. *Id.* at *3 (noting that the plaintiffs contended that "[e]njoying the [HHS] Secretary's imprimatur on the Demonstration Project, the Participating Hospitals could act more cavalierly, possibly without opprobrium or fear of investigation, in the face of both the Anti-Kickback Statute and the CMP, whereas non-participating hospitals could not maintain comparable positions.").
95. *See id.* at *9.
96. *Id.* (citation omitted).
97. 1999 OIG Report, 64 Fed. Reg. 37,985, 37,985 (July 14, 1999).
98. *Robert Wood Johnson*, 2004 WL 3210732, at *9 (alteration in original).

the problems posed by the CMP provision.[99] The court held while CMS and the HHS Secretary may waive physician self-referral laws, neither CMS nor the HHS Secretary can waive the CMP statute.[100] Thus, without a favorable OIG Advisory Opinion secured by the applying hospitals, a gainsharing demonstration project approved by CMS likely will violate the CMP facially.[101]

Besides analyzing the N.J. Hospitals' gainsharing project in the context of the CMP statute, the court considered whether the initiative violated the anti-kickback statute.[102] The court concluded the demonstration did not because the N.J. Hospitals did not seek with the requisite scienter of "knowingly and willfully" to induce patient referrals through the payment of remuneration to physicians.[103] Thus, the gainsharing project's goal to allow hospitals to provide physicians with "financial incentives *solely* for producing cost efficiencies" in their medical practices, "without sacrificing the quality of patient care," was deemed technically to comply with the anti-kickback statute, even though the result of such incentive payments might lead to more patient referrals or shorter hospital stays at participating hospitals.[104]

Following *Robert Wood Johnson*, hospitals interested in implementing gainsharing agreements realized that they must seek advance approval from OIG to assure that a given gainsharing program would not be sued by competing hospitals (asserting that the program violated the physician self-referral laws) or sanctioned by the federal government (asserting violation of the CMP statute).[105]

D. OIG Changes Tune: 2005 Advisory Opinions

Several hospitals noted the fate of the N.J. Hospitals' gainsharing demonstration project and sought advance approval from OIG for their own gainsharing projects.[106] In early 2005, OIG issued six advisory opinions approving different hospital gainsharing arrangements.[107] OIG limited each opinion to its facts, preventing other parties from relying on the opinions as

99. *Id.* at *11–12 ("The [HHS] Secretary should have required the proposed participants in the Demonstration Project to secure an Advisory Opinion from the OIG which at least assured forbearance from the imposition of sanctions as per OIG Advisory Opinion No. 01-1.").
100. *See id.* at *12.
101. *See id.*
102. *See id.* at *5–6.
103. *Id.* at *6.
104. *Id.* at *8.
105. *See id.* at *12; Saver, *supra* note 82, at 5.
106. *See* Advisory Opinion 05-01, *supra* note 1; Op. Dep't of Health & Human Servs., OIG Nos. 05-03 & 05-04 (Feb. 17, 2005); Op. Dep't of Health & Human Servs., OIG Nos. 05-05, 05-06 & 05-07 (Feb. 25, 2005); Thomas, *supra* note 8.
107. *See* Advisory Opinion 05-01, *supra* note 1; Op. Dep't of Health & Human Servs., OIG Nos. 05-03 & 05-04 (Feb. 17, 2005); Op. Dep't of Health & Human Servs., OIG Nos. 05-05, 05-06 & 05-07 (Feb. 25, 2005); Thomas, *supra* note 8.

precedent.[108] In each case, however, the agency considered these three aspects of an appropriate hospital gainsharing agreement to evaluate its legality: accountability, quality controls, and safeguards against payments for referrals.[109]

OIG Advisory Opinion 05-01, issued January 28, 2005, represents the agency's current approach toward hospital gainsharing proposals.[110] It discusses a proposed gainsharing agreement between a hospital and a group of cardiac surgeons in which the surgeons would share "a percentage of the hospital's cost savings arising from the surgeons' implementation of a [series] of cost reduction measures."[111] Under the arrangement, the hospital would pay the surgeons 50% of the first year cost savings attributable to 24 specific changes in operating room practices.[112] The hospital hired an independent program administrator to identify the changes by conducting a study of historic practices by the hospital's cardiac surgery department.[113] Examples of the cost-saving measures include: standardizing "certain cardiac devices where medically appropriate"; substituting less costly products for currently-used products; "opening packaged items only as needed"; and limiting the use of certain supplies and blood cross-matching procedures.[114]

OIG notes that, "[p]roperly structured, arrangements that share cost savings can serve legitimate business and medical purposes [and] . . . may increase efficiency and reduce waste, thereby potentially increasing a hospital's profitability."[115] However, the agency adds that poorly implemented hospital gainsharing may influence physician judgment to the detriment of patient care by encouraging "stinting on patient care . . . payments in exchange for patient referrals . . . [and] . . . cherry picking" of healthy patients.[116]

OIG deems the proposed gainsharing agreement in Advisory Opinion 05-01 to have accountability, meaning that it "clearly and separately" identifies actions that promote cost savings.[117] The agency states that the hospital's proposal plainly delineates each cost-saving method that will be used.[118] Further, the hospital promises to make full disclosure to each patient of his or her physician's participation in the gainsharing program.[119] This "transparency" to patients "permits scrutiny of the actions of physicians that are attributable to gainsharing payments, thus allowing the medi-

108. *See*, *e.g.*, Advisory Opinion 05-01, *supra* note 1, at 1.
109. Hearing, supra note 2, at 9; Mitch Dean, *The New Gainsharing—Has Anything Really Changed?*, ABA HEALTH ESOURCE, Nov. 2005, *available at* http://www.abanet.org/health/esource/vol2no3/dean.html.
110. *See* Advisory Opinion 05-01, *supra* note 1; Dean, *supra* note 108.
111. Advisory Opinion 05-01, *supra* note 1, at 1.
112. *Id.* at 4–5.
113. *Id.* at 2–3.
114. *Id.* at 3–4.
115. *Id.* at 6.
116. *Id.*
117. *See Hearing*, *supra* note 2, at 9.
118. *See* Advisory Opinion 05-01, *supra* note 1, at 3.
119. *Id.* at 6.

cal malpractice liability system" to hold physicians accountable if they provide inappropriate care.[120]

Additionally, the hospital's gainsharing agreement contains quality controls to prevent cost-saving measures from adversely affecting patient care. For example, the hospital used the program administrator as "a qualified, outside, independent party"[121] to establish baseline thresholds for cost-saving measures based on that hospital's historic use data and national data. Further, the program administrator is being used on an ongoing basis to perform expert review of the cost-saving measures to assess the potential impact on patient care.[122] Such oversight by the program administrator "allows for the detection and appropriate handling of any inappropriate variation in treatment or uses of supplies or devices."[123]

Finally, the hospital's proposal contains several safeguards to prevent gainsharing payments from inducing patient referrals or rewarding an inappropriate reduction in patient services.[124] For example, participating surgeons will not be able to share in savings accrued from procedures in excess of the volume of procedures payable to the hospital by a federal healthcare program in the current year.[125] Also, distributions to participating surgeons will be made on a per capita basis to reduce incentives for individual surgeons to generate disproportionate cost savings.[126]

OIG contrasts the appropriate safeguards proposed by the hospital in Advisory Opinion 05-01 to other proposals with features increasing the risk that payments to physicians will lead to limited or reduced services.[127] Such inappropriate features include: "no demonstrable direct connection between individual actions and a reduction in the hospital's out-of-pocket costs"; failure to identify specific individual actions giving rise to the savings; "insufficient safeguards against the risk that other, unidentified actions, such as premature hospital discharges, [in fact] might . . . account for any 'savings'"; "quality of care indicators . . . of questionable validity and statistical significance"; and "no independent verification of cost savings, quality of care indicators, or other essential aspects of the arrangement."[128]

120. *Hearing*, *supra* note 2, at 9.
121. *Id.*
122. Advisory Opinion 05-01, *supra* note 1, at 8–9 ("[T]he Proposed Arrangement protects against inappropriate reductions in services by utilizing objective historical and clinical measures to establish baseline thresholds beyond which no savings accrue to the Surgeon Group.").
123. *Hearing*, *supra* note 2, at 9.
124. *See* Advisory Opinion 05-01, *supra* note 1, at 4.
125. *Id.* at 5.
126. *See id.*; *see also Hearing*, *supra* note 2, at 9 (stating that other safeguards commonly used in hospital gainsharing agreements to minimize the risk of Medicare fraud and abuse include: "calculating savings based on the hospital's actual acquisition costs; limiting participation to physicians already on the hospital's medical staff (to prevent enticing other physicians to change referral patterns); limiting the amount, duration, and scope of the payments (there is less incentive for a physician to switch referral patterns for short-term dollars)").
127. Advisory Opinion 05-01, *supra* note 1, at 10.
128. *Id.*

With respect to the CMP and anti-kickback statutes that confounded OIG in the 1999 OIG Report,[129] due to the safeguards and payment limitations, the agency will refrain from imposing sanctions on either the hospital or participating surgeons, even though the proposed gainsharing arrangement likely violates both laws.[130] Following Advisory Opinion 05-01, hospitals that are willing to commit the resources to secure OIG approval appear to have a more reliable way to implement gainsharing.

However, a system that requires all hospitals interested in pursuing gainsharing programs to request a favorable advisory opinion from OIG can be viewed as inconvenient and unnecessarily expensive for hospitals, as well as a waste of OIG resources. Further, even with OIG advisory opinion approval, hospital gainsharing arrangements entered into under the current statutory framework have no predictably lawful status because all such agreements technically violate the CMP statute. Private parties, such as the four hospitals in *Roberts Wood Johnson* that complained of their economic injuries from the competing hospitals' gainsharing agreement, also might sue to enjoin an OIG-approved gainsharing program alleging violation of antitrust laws. Finally, nothing prevents OIG from reneging on a favorable opinion for a specific gainsharing program if that program fails to perform as expected or other problems arise.

The uncertainty that a gainsharing program might not remain lawful long enough for a hospital to recoup its investment in implementing the cost-saving measure should give pause to any hospital considering such an arrangement. Rather, for a truly reliable and cost efficient mechanism of allowing hospitals to implement gainsharing, Congress needs to effect permanent, statutory changes to permit gainsharing between hospitals and physicians. The potential benefits of increased profitability and better medical services offered by widespread use of gainsharing by hospitals appear to outweigh risks associated with the practice. Believing that to be the case, many health policy experts are urging Congress to modify the healthcare fraud and abuse laws in favor of gainsharing.[131]

E. MedPAC Recommendation Sparks Gainsharing Legislative Initiative

In a March 2005 report to Congress, the Medicare Payment Advisory Commission (MedPAC) recommended that Congress enact legislation permitting appropriate forms of gainsharing, provided that HHS regulates such arrangements.[132] Criticizing current application of healthcare fraud and abuse laws to hospital gainsharing, MedPAC stated:

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129. *See* 1999 OIG Report, 64 Fed. Reg. 37,985, 37,986–87 (July 14, 1999).

130. Advisory Opinion 05-01, *supra* note 109, at 13; *see also* Sean M. McGlone, *OIG Approves Gainsharing Arrangement—More Opinions On the Way*, HEALTH CARE CLIENT BULL., Feb. 2005, at 2, *available at* http://www.bricker.com/publications/articles/821.pdf.

131. *See, e.g.*, Saver, *supra* note 22, at 238 (arguing that "the law should instead adopt a more neutral stance and allow greater experimentation with the practice").

132. MEDICARE PAYMENT ADVISORY COMM'N, REPORT TO CONGRESS: MEDICARE PAYMENT

> Currently the civil monetary penalty provision . . . prohibits gainsharing, a practice that allows physicians to share in the savings they generate for hospitals under Medicare prospective payment. Although this provision is intended to protect beneficiaries from the possibility of physicians stinting on care to benefit financially, it can undermine the incentive for hospitals and physicians to cooperate in efforts to reengineer clinical care and change physician practice patterns in the hospital.[133]

MedPAC contended that "[i]f gainsharing were permitted with appropriate safeguards, hospitals and physicians could be expected to use resource measurement to address variation in physician care patterns for hospitalized patients."[134]

Shortly after the MedPAC report, Senators Charles Grassley (R-IA) and Max Baucus (D-MT) of the Senate Finance Committee introduced the Hospital Fair Competition Act (HFCA) which proposes that HHS establish criteria to allow gainsharing arrangements to better align hospital and physician incentives to undertake cost containment measures.[135] However, the HFCA encountered strong opposition because the bill also aimed to reinstate a moratorium against certain physician self-referrals to specialty hospitals in which the physicians have investment stakes.[136] The HFCA was referred to the Senate Finance Committee on May 11, 2005, where it expired at the conclusion of the 109th Congress.[137]

F. HHS Urges Gainsharing Demonstration Projects

While Congress allowed the HFCA to languish, CMS has jumped back into the hospital gainsharing fray by soliciting proposals from hospitals interested in undertaking gainsharing demonstration projects authorized under the 2005 Deficit Act[138] and 2003 Medicare Act.[139]

The gainsharing provisions authorized by the 2005 Deficit Act require CMS to approve six demonstration projects, at least two of which must be from a rural area.[140] The goal of the demonstration projects is to evaluate whether hospital gainsharing arrangements with physicians can enhance

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POLICY 153 (Mar. 2005), *available at* http://www.medpac.gov/publications/congressional_reports/Mar05_EntireReport.pdf.

133. *Id.*

134. *Id.*

135. Hospital Fair Competition Act of 2005, S. 1002, 109th Cong. § 4 (2005); *see also Gainsharing Could Gain Momentum Under Senate's Specialty Hospital Bill*, THE GRAY SHEET, May 16, 2005, at 6 [hereinafter HFCA Article] (on file with author).

136. Dean, *supra* note 109, at 3; *see also* HFCA Article, *supra* note 136.

137. *See* Dean, *supra* note 109.

138. Deficit Reduction Act of 2005, Pub. L. No. 109-171, 120 Stat. 4 (2006).

139. Medicare Prescription Drug, Improvement, and Modernization Act of 2003, Pub. L. No. 108-173, 117 Stat. 2066; *see also Gainsharing Demo Program, Medicare Imaging Cuts Included In Budget Bill*, THE GRAY SHEET, Jan. 2, 2006, at 10 (on file with author).

140. Deficit Reduction Act § 5007(d)(2).

operational and financial hospital performance while also helping physicians to "improve the quality and efficiency of care provided to Medicare beneficiaries."[141] The start date for the projects, which initially were to run from January 1, 2007, until December 31, 2009, [142] has been expanded to allow other hospitals time to apply.[143] During operation of the gainsharing projects, the 2005 Deficit Act stipulates that CMS report periodically to Congress on the quality improvement and savings achieved as a result of the qualified gainsharing demonstration projects.[144]

The 2005 Deficit Act imposes several requirements on the gainsharing programs. For instance, all approved programs must contain a process to notify patients of hospital and physician participation in the gainsharing project.[145] Also, each gainsharing project must receive independent review by an organization not affiliated with the participating hospital or physician.[146]

Finally, the 2005 Deficit Act provides that a hospital's payment to a physician under the demonstration projects shall not violate the CMP, anti-kickback, or physician self-referral statutes.[147] Then, in order not to provide participating hospitals with complete immunity from the healthcare fraud and abuse laws, the 2005 Deficit Act adds that the gainsharing arrangements and physician payments under the demonstration projects must not "induce a physician to reduce or limit services to a patient entitled to benefits under [the] Medicare [program]."[148] Further, physician payments under the 2005 Deficit Act cannot exceed 25% of the amount normally paid to physicians for cases included in the gainsharing demonstration.[149]

Besides pursuing the six gainsharing demonstration projects urged under the 2005 Deficit Act, CMS also plans to allow up to 72 hospitals to implement gainsharing programs authorized by the 2003 Medicare Act.[150] Section 646 of the 2003 Medicare Act sets up the Physician-Hospital Collaboration Demonstration program to test the ability of gainsharing proposals to increase health quality while reducing costs.[151] The program, expected to begin in 2007, will last three years.[152]

In a September 6, 2006, press release announcing the demonstration program, CMS said that it would give preference to proposals submitted by a healthcare group consortium, composed of up to 12 affiliated hospitals

141. *See id.* § 5007(a).
142. *Id.* § 5007(d)(3).
143. *See* Solicitation for Proposals from Rural Hospitals to Participate in the Medicare Hospital Gainsharing Demonstration Program Under Section 5007 of the Deficit Reduction Act, 72 Fed. Reg. 36,710 (July 5, 2007).
144. Deficit Reduction Act §§ 5007(e)(1)–(3).
145. *Id.* § 5007(b)(3).
146. *Id.* § 5007(b)(5).
147. *See id.* § 5007(c).
148. *Id.* § 5007(c)(1)(B).
149. Thomas, *supra* note 5.
150. *See id.*
151. *Id.*
152. *Id.*

located in a single state.[153] The agency explained that by using larger demonstration groups the resulting data could provide more accurate measure of the impact of hospital gainsharing on "longer-term patient results and overall Medicare costs."[154]

V. THE FUTURE OF APPROPRIATE HOSPITAL GAINSHARING IN U.S. HEALTHCARE

Gainsharing can be beneficial. The practice can help hospitals and physicians work together to achieve legitimate business purposes to reduce costs as well as legitimate medical purposes to maintain or improve the quality and efficiency of patient care. To remain beneficial in the long-term, gainsharing programs must be managed appropriately to meet these specific goals.

The gainsharing program approved in OIG Advisory Opinion 05-01 in early 2005 should be beneficial in the long-term. The program is managed continually by an independent entity that objectively identifies any practice changes to the possible detriment of patients.[155] Further, the goals of the gainsharing program, including both the specific actions that will promote cost savings and the quality controls and safeguards aimed at preventing Medicare fraud and abuse, have been stated transparently by the participating hospital.[156]

Hospital gainsharing will not succeed if the federal government continues to force parties interested in implementing it as a cost-saving measure to first receive OIG advisory opinion approval on a case-by-case basis. Such a time-consuming, expensive, piecemeal approach to gainsharing poses a debilitating dilemma for hospital administrators who must decide whether the commitment of resources required to start a gainsharing program by garnering a favorable OIG advisory opinion is outweighed by the cost reduction benefits the program eventually might yield to the hospital's earnings. Further, the current mechanism for implementing hospital gainsharing consumes scarce government resources in reviewing applications and enforcing decisions. Litigation strategies like *Robert Wood Johnson*, where the plaintiff alleged the government's approval of competitor hospital's gainsharing program resulted in unfair competition,[157] could be repeated if the federal government continues to follow such current policy.

If gainsharing opponents, such as Congressman Stark, chair important healthcare committees, Congress is much less likely to take action on hospi-

153. Press Release, CMS Office of Public Affairs, CMS Demonstration Program Supports Physician-Hospital Collaborations to Improve Quality of Care While Getting Better Value (Sept. 6, 2006), *available at* http://www.cms.hhs.gov/apps/media/press/release.asp?Counter=1957.

154. *Id.* (quoting Dr. Mark B. McClellan, CMS Administrator).

155. *See* Advisory Opinion 05-01, *supra* note 1, at 2.

156. *See id.* at 9; *see also Hearing*, *supra* note 2, at 9.

157. Robert Wood Johnson Univ. Hosp., Inc. v. Thompson, No. Civ. A. 04-142, 2004 WL 3210732, at *2 (D.N.J. Apr. 15, 2004).

tal gainsharing in the immediate future. Instead, lawmakers that support gainsharing will wait for CMS's reports on whether the hospitals participating in the demonstration projects authorized under the 2005 Deficit Act and 2003 Medicare Act successfully have improved quality of care and generated savings for themselves and the healthcare system as a whole. As these reports are analyzed by healthcare policy makers over the next three years, Congress could act. Thus, government agencies may not be permitted to take the status quo approach to hospital gainsharing indefinitely.

If the demonstration projects harm patient care by causing inappropriate referral patterns or a reduction in necessary services, Congress would be much more likely to follow the advice of gainsharing critics and settle for a gainsharing ban. However, if gainsharing works as hospitals expect, changing physician practice patterns in ways that result in lower costs, greater profitability, and equivalent or improved patient care, then Congress could pass a bill, along the lines of the HFCA, exempting certain types of gainsharing from the healthcare fraud and abuse statutes. Gainsharing agreements bringing physician practice patterns more in line with hospital cost-saving goals could become standard U.S. healthcare practice.

The federal government's present, measured approach toward hospital gainsharing is appropriate. Data must be collected and analyzed carefully to learn what type of gainsharing most effectively lowers costs while also improving or sustaining levels of patient care. Systematic weaknesses allowing hospital administrators and physicians to defraud Medicare need to be identified and eliminated. With the substantial amount of government and private sector analysis currently devoted to learning how to implement gainsharing efficiently, healthcare fraud and abuse laws are ripe for modification to make some form of gainsharing legal between hospitals and physicians. If this is done appropriately, hospital gainsharing will translate to better patient care at a lower cost to the healthcare system.

V. Michel Magloire Marcoux