

GAINSHARING AND THE PATIENT PROTECTION AND AFFORDABLE CARE ACT

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I. INTRODUCTION

“Gainsharing” is a business practice that can reduce costs and increase efficiency while engaging and rewarding front-line workers, those who work most directly with customers or with the product a company manufactures.¹ Although the practice reportedly began as early as the nineteenth century,² it became popular in the 1930s in the steel manufacturing industry.³ While several different forms of performance incentives fall under the category of gainsharing, in the typical gainsharing arrangement employees suggest cost-saving improvements to processes and the selection of materials.⁴ They receive a previously agreed upon portion of the savings associated with the improvements as compensation.⁵

Hospitals and healthcare systems have attempted to introduce gainsharing programs in healthcare settings in order to help reduce

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¹ See V. Michel Magliore Marcoux, *Why Healthcare Fraud and Abuse Laws Should Allow Appropriate Hospital Gainsharing*, 59 ALA. L. REV. 539, 542 (2008).

² Theresa M. Welbourne & Luis R. Gomez Mejia, *Gainsharing: A Critical Review and a Future Research Agenda* 3 (Ctr. for Advanced Human Res. Studies, Working Paper No. 95-10, 1995), available at http://digitalcommons.ilr.cornell.edu/cgi/viewcontent.cgi?article=1199&context=cahrswp&sei-redir=1&referer=http%3A%2F%2Fwww.google.com%2Furl%3Fsa%3Dt%26source%3Dweb%26cd%3D4%26sqi%3D2%26ved%3D0CDQQFjAD%26url%3Dhttp%253A%252F%252Fdigitalcommons.ilr.cornell.edu%252Fcgi%252Fviewcontent.cgi%253Farticle%253D1199%2526context%253Dcahrswp%26rct%3Dj%26q%3Dhistory%2520of%2520gainsharing%26ei%3DNhqeTruSFsWw8QPEqNGKCO%26usg%3DAFQjCNEykAMn_1_ZyRYt84sMNN308_mTNw%26sig2%3D3jXbaBIq6Muypog1GOmv1A#search=%22history%20gainsharing%22.

³ Richard S. Saver, *Squandering the Gain: Gainsharing and the Continuing Dilemma of Physician Financial Incentives*, 98 NW. U. L. REV. 145, 148 (2003).

⁴ See Marcoux, *supra* note 1, at 542.

⁵ See *id.*

the increasing costs of healthcare.⁶ Unfortunately, gainsharing programs are likely to violate the federal Anti-Kickback Statute (AKS), the Stark Law, and the Civil Monetary Penalties Statute (CMP Statute).⁷ Gainsharing programs may also preclude hospitals from tax-exempt status.⁸ Consequently, gainsharing has been limited to a few Medicare demonstration programs, limited programs intended to provide data on whether to permit gainsharing on a more widespread basis. The statutes that provide for these demonstration programs allow for waivers or exemptions of the AKS, Stark Law, and CMP Statute for hospitals participating in the demonstration programs.⁹

On March 23, 2010, Congress enacted the Patient Protection and Affordable Care Act (PPACA) for the purpose of expanding health insurance coverage and reducing the cost of healthcare.¹⁰ Because gainsharing is one potential method of reducing costs while maintaining or improving performance, this Comment will analyze whether PPACA adequately removes the legal barriers associated with gainsharing.

Part II of this Comment discusses the history of gainsharing practices and attempts to institute gainsharing in healthcare settings. It also identifies potential risks for Congress to consider when enacting statutory safe harbors or amending the applicable laws to encourage the creation of gainsharing programs. Part III discusses the statutory barriers to establishing gainsharing programs in hospitals and pre-PPACA efforts to eliminate those barriers. Part IV of this Comment discusses provisions in PPACA that may help resolve the legal problems associated with gainsharing. It then analyzes the likelihood that these provisions will encourage successful gainsharing programs. Part IV also argues that the solutions adopted in PPACA

⁶ See, e.g., Deficit Reduction Act of 2005, Pub. L. No. 109-171, § 5007(c)(1), 120 Stat. 4 (2006); Medicare Prescription Drug, Improvement, and Modernization Act of 2003, Pub. L. No. 108-173, § 646, 117 Stat. 2066 (2003).

⁷ Anne B. Claiborne et al., *Legal Impediments to Implementing Value-Based Purchasing in Healthcare*, 35 AM. J.L. & MED. 442, 486-89 (2009); see 42 U.S.C. § 1320a-7b (2006) (the AKS); 42 U.S.C. § 1395nn(a)(1) (Stark); *id.* § 1320a-7a (the CMP Statute).

⁸ Gail P. Heagan & Ivan Wood, *Gainsharing: Aligning Incentives of Hospitals and Physicians*, AHLA Seminar Materials P02109911 (1999); see Treas. Reg. § 1.501(c)(3)-1(c)(2).

⁹ See, e.g., § 5007(c)(1); § 646.

¹⁰ See, e.g., The Patient Protection and Affordable Care Act, Pub. L. No. 111-148, § 2718 (2010) (entitled "Bringing down the cost of health care coverage"); The Patient Protection and Affordable Care Act, Pub. L. No. 111-148, § 2702 (2010) (entitled "Guaranteed availability of coverage").

2013]

COMMENT

1327

are not sufficient to overcome the legal hurdles that currently prevent the institution of gainsharing programs. Part V of this Comment recommends amendments to the law that will better address these issues. The recommended amendments include statutory safe harbors for qualifying gainsharing programs, so that the health care system will enjoy the benefits of gainsharing while the law protects against potential drawbacks. Part VI concludes.

II. GAINSHARING: HISTORY AND BARRIERS TO ITS APPLICATION IN THE HEALTHCARE INDUSTRY

A. *History of Gainsharing and Its Introduction into the Healthcare Setting*

Gainsharing was mainly first applied in the context of manufacturing.¹¹ One of the first gainsharing programs is attributed to Joseph Scanlon, who established a gainsharing program in the 1930s to prevent the demise of a troubled company.¹² This gainsharing model, now known as the “Scanlon Plan,” is very similar to that described *supra* in Section I. Employees were asked to provide suggestions for improving productivity.¹³ Then a “screening committee” composed of higher-level employees selected the most promising suggestions, oversaw their implementation, and evaluated their effectiveness.¹⁴ In addition to simply reducing costs, the success of the plan was attributed to “employee involvement, bonus payment, and identity with the firm.”¹⁵ The program enabled workers to provide insights on the production process and thus encouraged collaboration and teamwork.¹⁶ Because gainsharing ties rewards to processes and circumstances directly under the workers’ control—in contrast to profit sharing in which the reward may be tied to external circumstances—some commentators have argued that gainsharing programs increase employee loyalty.¹⁷ Additionally, front-line workers have access to more information about day-to-day operations than managers because front-line workers conduct these operations, so

¹¹ Saver, *supra* note 3, at 186–87.

¹² U.S. GOV’T ACCOUNTABILITY OFFICE, AFMD-81-22, PRODUCTIVITY SHARING PROGRAMS: CAN THEY CONTRIBUTE TO PRODUCTIVITY IMPROVEMENT? 7 (1981), available at <http://www.gao.gov/assets/80/79298.pdf>.

¹³ *Id.* at 8.

¹⁴ *Id.*

¹⁵ *Id.*

¹⁶ Saver, *supra* note 3, at 188.

¹⁷ *Id.* at 189.

they are likely to be able to provide novel insights on how to save money.¹⁸

Several factors have influenced the success of gainsharing initiatives in industries other than healthcare. For example, companies that did not establish a culture of “worker participation” or that did not invest the necessary time and up-front costs have not been successful in establishing gainsharing programs.¹⁹ In a 1999 study, researchers examined the likelihood of survival of 211 gainsharing programs.²⁰ Dong-One Kim, a professor of Industrial Relations and Human Resource Management at Korea University Business School, found that the programs most likely to survive were those that: employees had approved with a vote; included re-training of employees and training of new employees; involved “small bonus groups” under 100 employees; were instituted in a “labor-intensive organization[.]” and in a financially healthy organization; and involved a “major capital investment.”²¹ He also found an indirect effect related to the positive performance of the program.²² Unsurprisingly, the programs that were most successful in saving costs and compensating employees were most likely to survive.²³

Although healthcare may not be considered “labor-intensive,” the other factors that Kim identified can apply to gainsharing programs in the healthcare industry. Those instituting gainsharing in a healthcare setting can encourage the program’s success by having physicians vote on the program, ensuring proper training, and limiting the bonus groups to fewer than 100 physicians. Additionally, one must consider the financial health of the entity and the financial assets available when establishing a gainsharing program.

Healthcare providers can adopt practices from the manufacturing setting—such as gainsharing—to improve efficiency of healthcare delivery without sacrificing quality of care. Shouldice Hernia Hospital in Toronto, Canada is a well-known example of this principle. Shouldice applies strategies from manufacturing such as specialization through limiting its area of practice to only one medical condition, quality control through peer supervision, and

¹⁸ *Id.* at 186–87.

¹⁹ *Id.* at 198.

²⁰ Dong-One Kim, *Determinants of the Survival of Gainsharing Programs*, 53 *INDUS. & LAB. REL. REV.* 21, 21 (1999).

²¹ *Id.* at 34–36.

²² *Id.* at 37.

²³ *Id.*

standardization of surgical procedures.²⁴ Shouldice's success and lowered costs are also attributable to the fact that Shouldice does not operate on high-risk patients, such as those who are overweight or have other medical conditions.²⁵ But Shouldice's success illustrates that manufacturing principles are applicable to healthcare to reduce costs without compromising patient outcomes.²⁶

Legal barriers have curtailed the establishment of gainsharing arrangements in the healthcare industry.²⁷ In 1999, the Office of Inspector General (OIG) of the U.S. Department of Health and Human Services (HHS), published an advisory bulletin stating that gainsharing arrangements were in direct violation of the federal CMP Statute.²⁸ The OIG noted that "it would 'take into consideration in exercising its enforcement discretion whether a gainsharing arrangement was terminated expeditiously,'"²⁹ suggesting that active gainsharing arrangements should be shut down quickly in order to avoid penalties.

In 2001, the outlook for gainsharing in healthcare became more favorable—the OIG provided an advisory opinion indicating that it would not impose penalties on a group of cardiologists who had

²⁴ Peter Behr, *Rx for the Economy?*, WASH. POST, Apr. 10, 1986, at E1.

²⁵ *Id.*

²⁶ For example, a 2006 article reported that Shouldice's cost for disposable surgical items was less than \$20 per surgery, compared to \$200 to \$800 per surgery at other hospitals. Sharda Prasad, *A Cut Above the Rest*, TORONTO STAR, Jan. 22, 2006, at A19. The article also reported that Shouldice's complication and infection rate was under 0.5%. *Id.*

²⁷ Mary Ellen Schneider, *Legal Concerns Hinder Adoption of Gainsharing*, INTERNAL MEDICINE NEWS, May 1, 2007, at 50.

²⁸ OIG Special Advisory Bulletin: Gainsharing Arrangements and CMPs for Hospital Payments to Physicians to Reduce or Limit Services to Beneficiaries (July 1999), <http://oig.hhs.gov/fraud/docs/alertsandbulletins/gainsh.htm> [hereinafter OIG Special Advisory Bulletin]. The OIG Special Advisory Bulletin stated that:

While the OIG recognizes that appropriately structured gainsharing arrangements may offer significant benefits where there is no adverse impact on the quality of care received by patients, section 1128A(b)(1) of the [Social Security] Act [which sets forth the CMP law] clearly prohibits such arrangements. Moreover, regulatory relief from the CMP prohibition will require statutory authorization.

Id.; see also D. McCarty Thorton et al., *Gainsharing: Regulatory Breakthrough, but Challenges Remain*, HEALTH CARE FRAUD REPORT (Bureau of Nat'l Affairs, D.C.), 2005 at 3–4, available at <http://www.hortyspringer.com/ACPE/HealthCareFraudReport.pdf>. The CMP Statute prohibits hospitals from paying doctors for "reduc[ing] or limit[ing] services to Medicare and Medicaid beneficiaries." OIG Special Advisory Bulletin. Both the hospitals and the doctors can be liable for penalties of up to \$2000 per patient. See *id.*

²⁹ Thorton et al., *supra* note 27, at 3 (quoting OIG Special Advisory Bulletin).

established a gainsharing program.³⁰ This opinion created renewed optimism that gainsharing programs would be permitted in the future.³¹ But the OIG identified a number of specific factors that led to this decision.³² The factors included: identifying cost-saving initiatives at the outset of the project,³³ which the OIG believed would promote “transparency”; establishing a plan for monitoring quality of patient care; setting thresholds for physician reimbursement; and disclosing to patients that the cardiologists had instituted a gainsharing program.³⁴ Some of these factors have since been used for guidance in establishing gainsharing demonstrations and proposing statutory exceptions to laws that would prevent gainsharing.³⁵ Richard Saver, a leading scholar in the field of health law, however, noted that many of the other factors that were important to the OIG in making its decision would be extremely

³⁰ *Id.* at 3–4; see Re: OIG Advisory Opinion No. 01, 2001 WL 36190940, 14 (HHSOIG Jan. 11, 2001).

³¹ Thorton et al., *supra* note 27, at 3–4.

³² Re: OIG Advisory Opinion No. 01, 2001 WL 36190940, 8–10 (HHSOIG Jan. 11, 2001). In a more recent opinion, the OIG noted that it was still concerned about possible risks of gainsharing, including:

(i) stinting on patient care, (ii) cherry-picking healthy patients and steering sicker (and more costly) patients to hospitals that do not offer gainsharing opportunities, (iii) payments in return for patient referrals, and (iv) unfair competition (as hospitals race to offer more and better gainsharing programs to foster physician loyalty and attract referrals).

2009 Health L. Handbook § 8:46 (citation omitted). These concerns are discussed *infra* Part II.D.

³³ The initiatives included nineteen measures for reducing costs, “fourteen recommendations that involve opening packaged items only as needed during a procedure.” Re: OIG Advisory Opinion No. 01, 2001 WL 36190940 (HHSOIG Jan. 11, 2001). Four of the initiatives involved using less expensive products. *Id.* One initiative involved limiting the “use of Aprotinin—a medication currently given to many surgical patients pre-operatively to prevent hemorrhaging—to patients that are at higher risk of perioperative hemorrhage as indicated by objective clinical standards.” *Id.*

³⁴ Saver, *supra* note 3, at 168.

³⁵ See *Medicare Gainsharing Demonstration: Report to Congress on Quality Improvement and Savings*, CTRS. FOR MEDICARE & MEDICAID SERVS., available at https://www.cms.gov/reports/downloads/Buczko_Gain_Sharing_Final_Report_May_2011.pdf (2011) at 2, 10 (discussing quality of care data and caps on payments to physicians at two gainsharing demonstration sites); Wilson Hayman, *Is Gainsharing Finally Here to Stay? Recent Advisory Opinions and Proposed Stark Exception Appear to Pave the Way*, THE NAT'L L. REV. 4 (2009), available at <http://www.natlawreview.com/article/gainsharing-finally-here-to-stay-recent-advisory-opinions-and-propo> (discussing a proposed exception to Stark).

difficult to replicate.³⁶ For example, the doctors involved were all part of “the same legally organized medical group,” and the cost-saving measures were already defined and supported in the literature.³⁷

The federal government has sought to examine the feasibility and effectiveness of gainsharing programs through several demonstration programs.³⁸ Section 646 of the Medicare Modernization Act (MMA), which was enacted in 2003, called for gainsharing demonstration programs in up to seventy-two hospitals as part of the Physician-Hospital Collaboration Demonstration (PHCD).³⁹ The MMA provided for a waiver of the CMP Statute for participating hospitals.⁴⁰ Indiana Health Information Exchange (IHIE) and North Carolina Community Care Networks instituted programs. But the programs focused on pay-for-performance

³⁶ Saver, *supra* note 3, at 170.

³⁷ *Id.* at 170.

³⁸ Deficit Reduction Act of 2005, Pub. L. No. 109-71, § 5007(c)(1), 120 Stat. 4 (2006); Medicare Modernization Act, Pub. L. No. 108-173, § 646, 117 Stat. 2066 (2003).

³⁹ *Medicare Health Care Quality Demonstration Programs Fact Sheet*, CTRS. FOR MEDICARE & MEDICAID SERVS., http://www.cms.gov/DemoProjectsEvalRpts/downloads/MMA646_FactSheet.pdf; *Gainsharing Gets Boost Projects Still Lack Funding*, MODERN PHYSICIAN, <http://www.modernphysician.com/article/20080609/MODERNPHYSICIAN/363294579> (June 9, 2008); Michael Romano, *Gain-sharing Demo a Go*; *CMS Details Physician-hospital Collaboration Project*, MODERN PHYSICIAN (Oct. 1, 2006) at 5, available at <http://go.galegroup.com.ezproxy.shu.edu/ps/i.do?&id=GALE%7C7CA154247530&v=2.1&u=setonhallu&it=r&p=HRCA&sw=w>. According to the MMA:

[T]he Secretary shall establish a 5-year demonstration program under which the Secretary shall approve demonstration projects that examine health delivery factors that encourage the delivery of improved quality in patient care, including— (1) the provision of incentives to improve the safety of care provided to beneficiaries; (2) the appropriate use of best practice guidelines by providers and services by beneficiaries; (3) reduced scientific uncertainty in the delivery of care through the examination of variations in the utilization and allocation of services, and outcomes measurement and research; (4) encourage shared decision making between providers and patients; (5) the provision of incentives for improving the quality and safety of care and achieving the efficient allocation of resources; (6) the appropriate use of culturally and ethnically sensitive health care delivery; and (7) the financial effects on the health care marketplace of altering the incentives for care delivery and changing the allocation of resources.

42 U.S.C. § 1395cc-3 (2006).

⁴⁰ § 1395cc-3. The MMA provides that “the Secretary may waive such requirements of titles XI and XVIII as may be necessary to carry out the purposes of the demonstration program established under this section.” *Id.*

measures in general, rather than specifically on gainsharing.⁴¹ Under the PHCD, the New Jersey Hospital Association planned to establish gainsharing programs in eight of its hospitals.⁴² Although the hospitals received CMS approval to participate in the demonstration, they did not obtain OIG approval.⁴³ Robert Wood Johnson University Hospital and St. Francis Medical Center, which were not participating in the program, sued HHS and CMS to enjoin the demonstration.⁴⁴ The U.S. District Court for the District of New Jersey found that the demonstration project was a violation of the CMP Statute and, because the hospitals had not obtained OIG approval, granted the injunction.⁴⁵

The Deficit Reduction Act of 2005 (DRA) created a demonstration program specifically for gainsharing initiatives, which required CMS to establish gainsharing programs in up to six hospitals.⁴⁶ The DRA provided a number of safe harbors for these pilot programs to ensure that they would not be in violation of sections 1128A, 1128B, and 1877 of the Social Security Act, which deal with physician inducement, remuneration, and financial relationships, respectively.⁴⁷ In order to be chosen, applicants to the

⁴¹ *Medicare Health Care Quality Demonstration Programs Fact Sheet*, *supra* note 39.

⁴² *Robert Wood Johnson Univ. Hosp., Inc. v. Thompson*, No. Civ.A.04-142(JWB), 2004 WL 3210732, at *1 (D.N.J. Apr. 15, 2004).

⁴³ *Id.* at *11-12.

⁴⁴ *Id.* at *1.

⁴⁵ *Id.* at *13.

⁴⁶ Deficit Reduction Act of 2005, Pub. L. No. 109-171, § 5007(c)(1), 120 Stat. 4 (2006); *DRA 5007 Medicare Hospital Gainsharing Demonstration Solicitation*, CTRS. FOR MEDICARE & MEDICAID SERVS, https://www.cms.gov/Medicare/DemonstrationProjects/DemoProjectsEvalRpts/downloads//DRA5007_Solicitation.pdf. The DRA provided that:

The Secretary shall establish under this section a qualified gainsharing demonstration program under which the Secretary shall approve demonstration projects by not later than November 1, 2006, to test and evaluate methodologies and arrangements between hospitals and physicians designed to govern the utilization of inpatient hospital resources and physician work to improve the quality and efficiency of care provided to Medicare beneficiaries and to develop improved operational and financial hospital performance with sharing of remuneration as specified in the project. Such projects shall be operational by not later than January 1, 2007.

Deficit Reduction Act, § 5007(a).

⁴⁷ Deficit Reduction Act, § 5007(c)(1).

An incentive payment made by a hospital to a physician under and in accordance with a demonstration project shall not constitute— (A) remuneration for purposes of section 1128B of the Social Security Act (42 U.S.C. 1320a-7b); (B) a payment intended to induce a physician to

program were required to have an organized and specific implementation plan and a method to carefully measure quality of care and efficiency.⁴⁸ The demonstrations were also required to be budget neutral in order to ensure that gainsharing actually produced savings.⁴⁹ CMS established a protocol for evaluating budget neutrality.⁵⁰ Two medical centers participated: Beth Israel Medical Center in New York and Charleston Area Medical Center in West Virginia.⁵¹ The outcome of these programs is discussed in Part II.C *infra*.

reduce or limit services to a patient entitled to benefits under Medicare or a State plan approved under title XIX of such Act in violation of section 1128A of such Act (42 U.S.C. 1320a-7a); or (C) a financial relationship for purposes of section 1877 of such Act (42 U.S.C. 1395nn).

Id.

⁴⁸ DRA 5007 Medicare Hospital Gainsharing Demonstration Solicitation, *supra* note 46.

The DRA required demonstration projects to meet the following criteria:

(1) Arrangement for remuneration as share of savings.—The demonstration project shall involve an arrangement between a hospital and a physician under which the hospital provides remuneration to the physician that represents solely a share of the savings incurred directly as a result of collaborative efforts between the hospital and the physician. (2) Written Plan Agreement.—The demonstration project shall be conducted pursuant to a written agreement that—(A) is submitted to the Secretary prior to implementation of the project; and (B) includes a plan outlining how the project will achieve improvements in quality and efficiency. (3) Patient Notification.—The demonstration project shall include a notification process to inform patients who are treated in a hospital participating in the project of the participation of the hospital in such project. (4) Monitoring Quality and Efficiency of Care.—The demonstration project shall provide measures to ensure that the quality and efficiency of care provided to patients who are treated in a hospital participating in the demonstration project is continuously monitored to ensure that such quality and efficiency is maintained or improved. (5) Independent Review.—The demonstration project shall certify, prior to implementation, that the elements of the demonstration project are reviewed by an organization that is not affiliated with the hospital or the physician participating in the project. (6) Referral Limitations.—The demonstration project shall not be structured in such a manner as to reward any physician participating in the project on the basis of the volume or value of referrals to the hospital by the physician.

Deficit Reduction Act, § 5007(b).

⁴⁹ CTRS. FOR MEDICARE & MEDICAID SERVS., MEDICARE GAINSHARING DEMONSTRATION: REPORT TO CONGRESS ON QUALITY IMPROVEMENT AND SAVINGS 12 (Mar. 28, 2011), https://www.cms.gov/reports/downloads/Buczko_Gain_Sharing_Final_Report_May_2011.pdf.

⁵⁰ *Id.*

⁵¹ Medicare Hospital Gainsharing Demonstration Fact Sheet, *supra* note 39.

B. Gainsharing Models as Applied to Healthcare

Although gainsharing can generally be described as physicians suggesting and implementing cost-saving measures and the hospital sharing the savings with the physicians, as in the Scanlon plan, there are a number of different forms that such a program may take. One factor to consider is the method of determining compensation. For example, under the “Cost Management Contracts” model, physicians may be compensated for time spent participating in a committee to determine how to implement cost savings rather than based upon the amount of money saved.⁵² If the incentive payments are tied to the amount saved, those implementing the program must decide how to distribute savings.⁵³ Under other models, a hospital might distribute savings among those physicians within the practice area in which savings were recognized—the “Cost Per DRG” model—or those responsible for savings based on procedure type grouping—the “Cost Per Aggregate ICD-9.”⁵⁴ In another model, the “Specialty Gainsharing” model, changes are implemented at the specialty level and the chair for the specialty determines how savings are distributed.⁵⁵ Another program, “Line-item Gainsharing,” involves the hospital or a manager identifying the most expensive items.⁵⁶ Physicians focus on reducing the cost and are directly paid a part of the savings.⁵⁷

Other forms of gainsharing reduce or entirely eliminate the payments to physicians. In “department management gainsharing,” a manager or group of managers is hired to reduce costs in each department and is paid a “predetermined management fee.”⁵⁸ Saver has suggested a “three-way gainsharing” model in which a percentage of savings is retained by the hospital, a percentage is distributed to participating physicians, and the remainder is either distributed to patients as refunds or placed into a fund.⁵⁹ Patient representatives

⁵² Heagan & Wood, *supra* note 8.

⁵³ *See id.*

⁵⁴ *Id.*

⁵⁵ *Id.*

⁵⁶ *Id.*

⁵⁷ *Id.*

⁵⁸ Heagan & Wood, *supra* note 8.

⁵⁹ Saver, *supra* note 3, at 229. This is also very similar to the “reinvestment of cost savings” model described by Heagan and Wood, in which a portion of the savings is placed in a fund and physicians can suggest uses for it. Heagan & Wood, *supra* note 8. This model takes a similar form as Saver’s model, but does not necessarily serve the same purpose. *Id.*

would manage the fund and use the money to directly improve patients' experiences in the hospital. For example, such funds may be used for subsidizing items that are not covered by Medicare and Medicaid for needy patients, adding patient libraries, providing internet access to patients, or upgrading family waiting rooms.⁶⁰ The goal of such projects would be to convey to patients that the hospital and doctors are not benefitting from gainsharing at their expense and that patient welfare is a priority.⁶¹

C. *Potential Benefits and Arguments for Gainsharing as Applied to the Healthcare Industry*

Commentators have identified gainsharing as one method for reducing healthcare costs while preserving quality of care.⁶² Currently, Medicare and Medicaid compensate hospitals using a set per-patient fee based on a patient's diagnosis.⁶³ The fee does not depend on the amount or type of care that the patient requires.⁶⁴ On the other hand, physicians are compensated for each service performed.⁶⁵ This creates an incentive for hospitals to reduce costs as much as possible while doctors do not have such an incentive.⁶⁶ Gainsharing aligns the hospital's incentives with the doctors' incentives under the common goal of reducing costs while maintaining quality of care.⁶⁷ Physicians are encouraged to help hospitals save money and are not as affected by the negative financial implications—and the potential compromise to patient care—associated with reducing the number of services.⁶⁸

Saver argues that obtaining physician involvement is extremely important to reducing costs because “[n]early all the hot-button areas of hospital cost escalation . . . drug costs, nursing costs, technology costs, etc.—can rise or fall depending upon the practice patterns of the hospital's staff physicians.”⁶⁹ As discussed above, those on the front lines are often those with the most insight into the best ways to

⁶⁰ Saver, *supra* note 3, at 229.

⁶¹ *Id.* at 230.

⁶² *See id.* at 147.

⁶³ Marcoux, *supra* note 1, at 543–44.

⁶⁴ *Id.*

⁶⁵ *Id.*

⁶⁶ *Id.*

⁶⁷ *See* Saver, *supra* note 3, at 154.

⁶⁸ *Id.* at 180.

⁶⁹ *Id.* at 176.

reduce costs and increase productivity.⁷⁰ This observation also calls into question the potential effectiveness of “department management gainsharing,”⁷¹ which eliminates physicians from the process. Gainsharing may be more likely to gain physician “buy-in” than other cost-saving measures because, rather than imposing changes on physicians, the hospital asks for their input and allows them to use clinical judgment.⁷²

Perhaps the most convincing evidence in favor of gainsharing is the success of pilot programs. A gainsharing program was instituted at Pinnacle Health Systems in Pennsylvania program in 2003.⁷³ It reportedly saved \$5.7 million during the three years that it ran, and attributed the savings largely to negotiating with vendors for better prices on medical supplies.⁷⁴ Also, the Center for Medicare and Medicaid Innovation (CMMI) cited the PHCD and Medicare Gainsharing demonstration favorably, noting that “preliminary results indicate the hospitals and physicians achieved improved clinical and patient outcomes on measures such as decreased length of stay for inpatient care, which may result in savings to Medicare” and that “preliminary results indicate that the hospitals achieved internal savings due to increased efficiency.”⁷⁵

Results from the pilot program at Beth Israel Medical Center show that, since its demonstration began in 2006, it has saved over \$42 million and has distributed \$8 million of the savings to participating physicians.⁷⁶ Beth Israel reports that patient outcomes have not suffered since the project began.⁷⁷ Under the program, individual physicians, either an attending physician or a surgeon, were given financial responsibility for individual patients.⁷⁸ Incentive payments were conditioned on maintaining quality standards,

⁷⁰ See *supra* note 18 and accompanying text.

⁷¹ See *supra* Part II.B.

⁷² Saver, *supra* note 3, at 215.

⁷³ See Joseph Mantone, *Gain-sharing Seems to be Working, But Research Shows Stent Savings Come From Negotiations, Not Implementations*, MODERN HEALTHCARE, June 5, 2006, at 33.

⁷⁴ *Id.*

⁷⁵ CTR. FOR MEDICARE & MEDICAID INNOVATION, BUNDLED PAYMENTS FOR CARE IMPROVEMENT INITIATIVE REQUEST FOR APPLICATION 4 (2011), available at <http://innovation.cms.gov/Files/x/Bundled-Payments-for-Care-Improvement-Request-for-Applications.pdf>.

⁷⁶ Phyllis Maguire, *Results are in: Gainsharing Works*, TODAY'S HOSPITALIST, Feb. 2011, http://todayshospitalist.com/index.php?b=articles_read&cnt=1168.

⁷⁷ *Id.*

⁷⁸ CTRS. FOR MEDICARE & MEDICAID SERVS., *supra* note 49, at 8.

including not having an increase in readmission rates, adverse events, or instances of malpractice, and meeting certain specialty-specific quality measures.⁷⁹ CMS reported on the outcome of the first year of the demonstration.⁸⁰ During the first year, Beth Israel distributed \$585,000 of the savings among the 309 participating physicians.⁸¹ The savings were largely attributable to reduced length of stay in the hospital.⁸² Although total cost of hospitalization decreased, costs in the ICU increased 32% during the pilot.⁸³ It is unclear whether this increase was related to the program.⁸⁴ Beth Israel reported that it plans to expand the program to the ICU in order to control these costs.⁸⁵

Charleston Area Medical Center (CAMC) also established a gainsharing program under the demonstration program authorized by DRA Section 5007.⁸⁶ The program focused on implementing cost-saving initiatives with cardiac diagnosis-related groups (DRGs).⁸⁷ As expected, gainsharing incentive payments to individual physicians were contingent upon actual cost savings per episode of care and quality of care outcomes that did not show a statistically significant decline after the cost-saving measures were implemented.⁸⁸ CAMC distributed about \$165,000 of the savings among approximately 100 physicians during the first year of the demonstration program.⁸⁹

Going forward, additional hospitals will begin to participate in gainsharing demonstration programs.⁹⁰ The acute care episode (ACE) demonstration project involves five hospitals within the Baptist

⁷⁹ *Id.*

⁸⁰ *Id.*

⁸¹ *Id.* at 10.

⁸² Michelle Grey Campion, *Can Gainsharing Impact Cost Savings in the ICU? Hospital-Wide Analysis Hints at Impressive Rewards*, ANESTHESIOLOGY NEWS (May 2011), available at http://www.anesthesiologynews.com/ViewArticle.aspx?d=Policy+%26+Management&d_id=3&i=May+2011&i_id=729&a_id=17116.

⁸³ *Id.*

⁸⁴ *Id.*

⁸⁵ *Id.*

⁸⁶ CTRS. FOR MEDICARE & MEDICAID SERVS., *supra* note 49, at 7.

⁸⁷ *Id.*

⁸⁸ *Id.*

⁸⁹ *Id.* at 11.

⁹⁰ Rebecca Vesely, *An ACE in the Deck? Bundled-Payment Demo Shows Returns*, MODERN HEALTHCARE, Feb. 7, 2011, at 32–33; 12 *N.J. Hospitals Paying Doctors to Save Money*, USA TODAY (Aug. 19, 2009), available at http://www.usatoday.com/news/health/2009-08-19-hospital-costs_N.htm.

Health System in San Antonio, Texas.⁹¹ The project began in 2009 and is planned to last for three years.⁹² Also in 2009, a group of twelve hospitals in New Jersey received CMS approval to begin a gainsharing demonstration program.⁹³ CMS approved the expansion of the program from twelve hospitals to thirty-three hospital sites, as part of the “Bundled Payments for Care Improvement Initiative” under PPACA.⁹⁴ Finally, the Greater New York Hospital Association will begin a gainsharing program in which Medicare would “pay hospitals and physicians at current rates” for the first six months of the program while the hospitals and doctors developed and instituted cost-saving measures.⁹⁵ Thereafter, Medicare would receive a “discount.”⁹⁶ This program is part of the “CMS Bundled Payment for Care Improvement Initiative.”⁹⁷

Even outside of healthcare settings, gainsharing programs may not be successful or long lasting, as Dong-One Kim found.⁹⁸ It largely will be left to the hospitals to ensure the success of their gainsharing programs. Previous demonstration projects have indicated that gainsharing programs can succeed in the healthcare setting.

D. Policy Concerns and Efficacy Barriers

A frequent argument against gainsharing programs is that they create a perverse incentive for doctors to use lower quality products

⁹¹ *Id.*

⁹² *Id.*

⁹³ 12 N.J. *Hospitals Paying Doctors to Save Money*, *supra* note 90. New Jersey Hospital Association (NJHA) led the effort to obtain CMS approval for the demonstration program. Richard Pizzi, *CMS Approves New Jersey Gainsharing Demonstration Project*, HEALTHCARE FINANCE NEWS, (Aug. 19, 2009), <http://www.healthcarefinancenews.com/news/cms-approves-new-jersey-gainsharing-demonstration-project>. NJHA had previously received approval to conduct a gainsharing demonstration program in 2003. *Robert Wood Johnson Univ. Hosp. Inc. v. Thompson*, No. Civ. A.04-142 (JWB), 2004 WL 3210732, at *5 (D.N.J. Apr. 15, 2004). The U.S. District Court for the District of New Jersey deemed the program to be a violation of the CMP Statute because the hospitals had not received OIG approval. *Id.* at *12. *See supra* notes 36–39 and accompanying text.

⁹⁴ *NJHA Receives Federal Approval to Expand Promising Effort to Reduce Healthcare Costs*, PR NEWSWIRE, Feb. 1, 2013, <http://www.prnewswire.com/news-releases/njha-receives-federal-approval-to-expand-promising-effort-to-reduce-healthcare-costs-189369961.html>.

⁹⁵ *CMS Unveils Bundled Payment Models*, GREATER N.Y. HOSP. ASS'N (Sept. 12, 2011), <http://www.gnyha.org/7652/Default.aspx>.

⁹⁶ *Id.*

⁹⁷ *Id.*

⁹⁸ Kim, *supra* note 20, at 34–36.

or to withhold medically necessary services in order to save money.⁹⁹ There are a number of protections to prevent this from occurring. First, gainsharing demonstration programs require physicians to meet benchmarks in terms of clinical outcomes, thus eliminating the potential for such perverse incentives.¹⁰⁰ Physicians also have other incentives to avoid a reduction in quality of care, such as concern for patient well-being, concern for professional reputation, and fear of malpractice litigation. These incentives would likely outweigh the incentive for additional financial remuneration for a large number of physicians. Finally, those programs currently approved as demonstrations require long-term measurement of cost-savings.¹⁰¹ Doctors will recognize that reducing quality of care for short-term savings will lead to increased overall cost in the long-term as patients will likely require extended hospital stays, treatment for complications, or readmissions to the hospital.¹⁰²

Opponents of gainsharing also argue that seeking to reduce services directly violates doctors' "fiduciary and ethical duties to their patients."¹⁰³ This concern is the basis for the OIG's interpretation of the Stark and CMP laws.¹⁰⁴ Clinical evidence shows that in certain instances, reducing treatment or substituting a lower cost alternative can be associated with improved clinical outcomes.¹⁰⁵ For example, the goal of disease-management programs is to treat patients more

⁹⁹ One policy paper reports negative consequences of requiring physicians to use particular devices as follows:

In Iowa, doctors constrained by a hospital's agreement have reported having to transfer patients to other hospitals in order to get them the brand of medical device that they need. In Pennsylvania, a physician has sued his hospital for using a standardization contract as a facade for receiving illegal kickbacks from a major manufacturer.

MED. DEVICE MFGS. ASS'N, CONGRESS SHOULD PROHIBIT DEVICE CONTRACT GAINSHARING TO PROTECT PERSONALIZED PATIENT CARE AND MEDICAL DEVICE INNOVATION, *available at* http://www.medicaldevices.org/system/files/Hill.LeaveBehind.Final_000_0.pdf?download=1.

¹⁰⁰ See, e.g., Sachin H. Jain & Daniel Roble, *Gainsharing in Healthcare: Meeting the Quality-of-Care Challenge*, HEALTHCARE FINANCIAL MANAGEMENT, Mar. 2008, at 78 (discussing quality measurements as a safeguard); CTRS. FOR MEDICARE & MEDICAID SERVS., *DRA 5007 Medicare Hospital Gainsharing Demonstration Solicitation*, *available at* https://www.cms.gov/DemoProjectsEvalRpts/downloads/DRA5007_Solicitation.pdf.

¹⁰¹ CTRS. FOR MEDICARE & MEDICAID SERVS. *supra* note 49; *Medicare Health Care Quality Demonstration Programs Fact Sheet*, *supra* note 39.

¹⁰² Saver, *supra* note 3, at 207.

¹⁰³ *Id.* at 199.

¹⁰⁴ *Id.*

¹⁰⁵ *Id.* at 202-03.

effectively but with fewer episodes of care.¹⁰⁶ Because of this objective, disease-management initiatives may technically violate the Stark and CMP laws.¹⁰⁷

Potential downsides to gainsharing may be avoided by adopting some of the OIG's requirements. For example, the OIG has suggested that there is an incentive for "cherry picking," keeping healthy patients while referring unhealthy patients, who are more expensive to treat, to other institutions.¹⁰⁸ The OIG requires documentation of the types of patients seen by the hospital to ensure that hospitals and doctors do not turn away sick patients in order to save money.¹⁰⁹ Also, adjusting for the severity of the patient's condition will counteract any incentive to turn away unhealthy patients because there would not be any "penalty" for providing the necessary treatments associated with caring for a higher-risk patient.¹¹⁰ There is also a concern that physicians who are already efficient will not be rewarded for efficiency, but programs can be designed to reward those who maintain efficiency goals, rather than meeting ever increasing goals.¹¹¹

The type of risks associated with a gainsharing program will depend upon the type of gainsharing initiatives that a healthcare provider adopts. For example, the favorable advisory opinion that the OIG issued in 2001 involved gainsharing initiatives in a cardiology department.¹¹² One of the measures adopted by the cardiology department involved not opening surgical supplies prior to a patient's surgery so that the instruments would not be wasted if the surgeon did not need them.¹¹³ Such a measure does not encourage physicians to withhold care or otherwise change the way that patients are treated. Similarly, cutting costs through purchasing items in bulk would not encourage physicians to "cherry-pick" patients or otherwise negatively impact the way that patients are treated.

An additional concern is that gainsharing initiatives would limit

¹⁰⁶ *Id.* at 212–13.

¹⁰⁷ *Id.*

¹⁰⁸ Thorton et al., *supra* note 28, at 3.

¹⁰⁹ Hayman, *supra* note 35.

¹¹⁰ See Method and Sys. for Evaluating a Physician's Economic Performance and Gainsharing of Physician Services, U.S. Patent No. 7,640,173 B2, at [3] (filed Dec. 29, 2009).

¹¹¹ See *id.* at [3–4].

¹¹² Re: OIG Advisory Opinion No. 01-01, 2001 WL 36190940 (HHSOIG Jan. 11, 2001).

¹¹³ *Id.*

the treatment options available to physicians, thus limiting their freedom to make clinical decisions and negatively impacting quality of care through a de facto forced standardization.¹¹⁴ In fact, this result would directly contravene the purpose of the CMP Statute. Saver argues that imposing strict limitations on gainsharing can have the same effect: “[p]hysicians often have to respond flexibly and with some degree of innovation and experimentation as to choosing different treatment paths, depending upon the particular needs and clinical circumstances of the individual patient.”¹¹⁵

Additionally, gainsharing creates the concern that excessive standardization of medical devices will allow manufacturers to increase market share and reduce competition, eventually enabling them to increase prices. There has been opposition, especially from device manufacturers, who argue that standardization will stifle innovation by destroying the market for new products.¹¹⁶ A counterargument is that, at least when each contract is expired, hospitals and physicians will continually look for ways to save costs, and perhaps will be more aggressive in renegotiating contracts as a result.¹¹⁷ Also, if the programs are limited to individual departments within hospitals, each implementing its own cost-savings measures, standardization would be limited and negative effects on competition would be less likely.

The risk that gainsharing programs will limit physicians’ freedom or stifle innovation depends upon the size of the gainsharing programs and the level of freedom that physicians retain when deciding which products to use for individual patients. If the

¹¹⁴ *Id.*

¹¹⁵ Saver, *supra* note 3, at 206.

¹¹⁶ Paula DeJohn, *Growing Popularity of Gainsharing Brings Pushback from Manufacturers*, 31 HOSP. MATERIALS MGMT. 8 (2006); *Gainsharing: Still the Wrong Answer*, BIOMET (June 9, 2010 7:07 AM), <http://www.biomet.com/corporate/ceoBlog/postDetail.cfm?postID=58>; MED. DEVICE MFGS. ASS’N, *supra* note 99.

¹¹⁷ One might argue that gainsharing presents the same risk of consolidations and reversed incentives that has occurred in the context of Group Purchasing Organizations (GPOs). Mariah Blake, *Dirty Medicine*, WASH. MONTHLY, July/Aug. 2010, *available at* <http://www.washingtonmonthly.com/features/2010/1007.blake.html>. GPOs are organizations formed to purchase medical supplies in bulk at a discounted rate. *Id.* In 1986, GPOs were granted an exemption from the AKS, which made it lawful for suppliers to pay GPOs “fees,” which were essentially a portion of their revenue. “This created an incentive to cater to the sellers rather than to the buyers.” *Id.*; Frank Pasquale, *Understanding Medicine’s Middlemen*, BALKINIZATION (July 12, 2010), <http://balkin.blogspot.com/2010/07/understanding-medicines-middlemen.html>.

programs are limited to individual departments within hospitals, each implementing its own cost-saving measures, standardization would be limited. If, however, cost-saving measures were implemented on a broader basis, standardization, and possible detrimental effects on innovation, would be possible.

III. LEGAL BARRIERS TO THE ESTABLISHMENT OF GAINSHARING PROGRAMS IN HEALTHCARE SETTINGS

A number of legal barriers, including regulations of tax-exempt entities, the AKS, the Stark Law, and the CMP Statute, have curtailed the establishment of gainsharing programs in healthcare. In recent years, the OIG's inconsistent decisions about whether it will enforce these laws against hospital gainsharing programs have compounded this problem.¹¹⁸

A. *Violations Related to Hospitals' Tax-exempt Status*

Tax-exempt organizations may not use their earnings to benefit any "person with a personal and private interest in the activities of the organization" including doctors.¹¹⁹ Tax-exempt organizations also may not serve any private interest unless the private interest is incidental to serving the public interest.¹²⁰ In order to be incidental to serving the public interest, the private interest "must be both qualitatively and quantitatively incidental."¹²¹ "Qualitatively incidental" means that the interest is a "necessary concomitant of the activity that benefits the public at large and the benefit cannot be achieved without necessarily benefiting certain private individuals."¹²² "Quantitatively incidental" means that the interest is "neither direct nor substantial in comparison to the benefit conferred on the public by the activity."¹²³ The penalty to a physician or other individual deemed a "disqualified person" for violating this law is 25% of the excess benefit and, "if the excess benefit is not corrected, an additional tax equal to 200% of the excess benefit."¹²⁴

¹¹⁸ Barry F. Rosen, *Commentary: Cleaver Guidance on Gainsharing Would Lower Costs*, DAILY RECORD, July 7, 2009.

¹¹⁹ Heagan & Wood, *supra* note 8 (citing Treas. Reg. § 1.501(c)(3)-1(c)).

¹²⁰ *Id.*

¹²¹ *Id.*

¹²² *Id.*; see also I.R.S. Gen. Couns. Mem. 37,789 (Dec. 18, 1978); Rev. Rul. 70-186, 1970-1 C.B. 128; I.R.S. Gen. Couns. Mem. 39,498 (Jan. 28, 1986).

¹²³ Heagan & Wood, *supra* note 8; see also I.R.S. Gen. Couns. Mem. 37,789 (Dec. 18, 1978).

¹²⁴ Heagan & Wood, *supra* note 8.

It is unclear whether gainsharing payments to physicians would qualify as qualitatively incidental. Cost-saving initiatives could be instituted without providing the financial benefits of gainsharing to doctors, which means that the benefit to the public—reduced healthcare costs—could be achieved without benefitting private individuals. This could be accomplished under the “reinvestment of cost savings” model, or a variation on the “three-way costs savings model,” both discussed in Part II.B *supra*. If the doctors’ shares of the savings were reinvested in patient projects, hospitals and doctors could avoid any private benefit. Importantly, however, gainsharing programs may be less successful if physicians do not have financial incentives to cut costs.

According to some commentators, other forms of gainsharing can be modeled to comply with the regulations.¹²⁵ In order to avoid penalties, gainsharing programs must pay doctors a reasonable compensation, taking into account the benefit conferred and the “fair market value” of the doctors’ services.¹²⁶ The doctors’ compensation must be “the result of arm’s length bargaining . . . [and] must not be merely a device to distribute profits to insiders.”¹²⁷ The payments must also be “based on personally performed services, and tied to quality and efficiency measures monitored by an independent expert.”¹²⁸ A safe harbor also exists,¹²⁹ but it contains a number of requirements related to the governance of the hospital, and so it is unlikely to protect gainsharing programs.¹³⁰ Finally, a program may also be deemed to be in compliance with the law based

¹²⁵ *See id.*

¹²⁶ *Id.*

¹²⁷ *Id.*

¹²⁸ Claiborne et al., *supra* note 7, at 489.

¹²⁹ Rev. Proc. 97-13, 1997-1 C.B. 632 (1997); Claiborne et al., *supra* note 128, at 489.

¹³⁰ In order to satisfy this safe harbor, a hospital would have to ensure that: (a) Not more than 20 percent of the voting power of the governing body of the qualified user in the aggregate is vested in the service provider and its directors, officers, shareholders, and employees; (b) Overlapping board members do not include the chief executive officers of the service provider or its governing body or the qualified user or its governing body; and (c) The qualified user and the service provider under the contract are not related parties, as defined in § 1.150-1(b).

Rev. Proc. 97-13, 1997-1 C.B. 632 (1997). Although a hospital may fall under these exceptions, it would be unlikely that a hospital would re-organize its governance in order to satisfy the safe harbor.

on the relevant “facts and circumstances”.¹³¹

B. Anti-Kickback Statute

The federal AKS imposes criminal penalties and potential fines on:

whoever knowingly and willfully solicits or receives any remuneration (including any kickback, bribe, or rebate) directly or indirectly, overtly or covertly, in cash or in kind . . . in return for referring an individual to a person for the furnishing or arranging for the furnishing of any item or service for which payment may be made in whole or in part under a Federal health care program.¹³²

Gainsharing programs can violate this statute because gainsharing may incentivize physicians to refer patients to the hospital, including Medicare and Medicaid patients whose care will be paid for as part of a federal healthcare program.¹³³ This incentive may exist because increasing the volume of patients would increase the overall savings included in the gainsharing program.¹³⁴

As of 2009, there were no safe harbors that protected gainsharing programs from liability for violating the AKS, but hospitals could seek an advisory opinion from the OIG.¹³⁵ The statute does contain a safe harbor for “[p]ersonal services and management

¹³¹ Claiborne et al., *supra* note 7, at 489 (citing I.R.S. Private Letter Ruling 200926005 (Mar. 17, 2009)).

¹³² 42 U.S.C. § 1320a-7b(b)(1) (2012); *see also* Heagan & Wood, *supra* note 8.

¹³³ Saver, *supra* note 3, at 171 n.100.

¹³⁴ *Id.*

¹³⁵ Claiborne et al., *supra* note 128, at 489. Since 2001, the OIG has issued 13 advisory opinions regarding gainsharing programs, finding that each program would or could potentially violate the CMP Statute and AKS but stating that the OIG would not impose sanctions. Re: OIG Advisory Opinion No. 09-06, 2009 WL 2371264 (HHSOIG June 23, 2009), 1; Re: OIG Advisory Opinion No. 08-15, 2008 WL 6067525 (HHSOIG Oct. 6, 2008), 1; Re: OIG Advisory Opinion No. 08-09, 2008 WL 6067519 (HHSOIG Jul. 31, 2008), 1; Re: OIG Advisory Opinion No. 07-21, 2007 WL 6400848 (HHSOIG Dec. 28, 2007), 1; Re: OIG Advisory Opinion No. 07-22, 2007 WL 6400849 (HHSOIG Dec. 28, 2007), 1; Re: OIG Advisory Opinion No. 06-22, 2006 WL 6252293 (HHSOIG Nov. 9, 2006), 1; Re: OIG Advisory Opinion No. 05-06, 2005 WL 6289869 (HHSOIG Feb. 18, 2005), 1; Re: OIG Advisory Opinion No. 05-05, 2005 WL 6289868 (HHSOIG Feb. 18, 2005), 1; Re: OIG Advisory Opinion No. 05-04, 2005 WL 6289867 (HHSOIG Feb. 10, 2005), 1; Re: OIG Advisory Opinion No. 05-03, 2005 WL 6289866 (HHSOIG Feb. 10, 2005), 1; Re: OIG Advisory Opinion No. 05-02, 2005 WL 6289865 (HHSOIG Feb. 10, 2005), 1; Re: OIG Advisory Opinion No. 05-01, 2005 WL 6289864 (HHSOIG Jan. 28, 2005), 1; Re: OIG Advisory Opinion No. 01-01, 2001 WL 36190940 (HHSOIG Jan. 11, 2001), 1.

contracts.”¹³⁶ The safe harbor states that the term “remuneration,” as defined by the statute, does not include payments made to an agent for the agent’s services, pursuant to an agency agreement.¹³⁷ But the regulation’s requirements would preclude many gainsharing agreements. For example, the “aggregate compensation paid to the agent over the term of the agreement [must be] set in advance.”¹³⁸ Many gainsharing models determine the amount of compensation after the cost-savings initiatives have been instituted based on the amount of money saved.¹³⁹ Although the amount could be set in advance based on a different metric—e.g., the number of hours dedicated to meeting and developing ideas—or upon the projected amount of savings, setting the amount in advance could diminish the level of incentive to follow through with the cost-saving initiative. Thus, it is unlikely that any of the safe harbors sufficiently protect gainsharing programs from violating the AKS.¹⁴⁰

C. Stark Law

The federal Stark Law prohibits physicians with a financial relationship with a particular “entity” from referring patients to the entity for services that would otherwise be paid using Medicaid or Medicare funds.¹⁴¹ It also prohibits “entities” from making claims for payment under such circumstances.¹⁴² The statute defines “financial

¹³⁶ 42 C.F.R. § 1001.952(d); *see also* Heagan & Wood, *supra* note 8.

¹³⁷ 42 C.F.R. § 1001.952(d); *see also* Heagan & Wood, *supra* note 8.

¹³⁸ 42 C.F.R. § 1001.952(d).

¹³⁹ *See* Part II.B *supra*.

¹⁴⁰ Additionally, there are some state statutes that are similar to the federal AKS, and therefore hospitals must be cognizant of the risk of violating state law as well as federal law when instituting a gainsharing program. Heagan & Wood, *supra* note 8; *see, e.g.* FLA. STAT. ANN. § 456.054 (West 2006); S.C. CODE ANN. § 44-113-60 (1994); UTAH CODE ANN. § 26-20-4 (West 2007). This issue, however, is beyond the scope of this Comment.

¹⁴¹ 42 U.S.C. § 1395nn(a)(1) (2006).

¹⁴² *Id.* Entity is defined as

[a] physician’s sole practice or a practice of multiple physicians or any other person, sole proprietorship, public or private agency or trust, corporation, partnership, limited liability company, foundation, nonprofit corporation, or unincorporated association that furnishes DHS [designated health services]. An entity does not include the referring physician himself or herself, but does include his or her medical practice.

42 C.F.R. § 411.351. Designated health services includes:

(i) Clinical laboratory services. (ii) Physical therapy, occupational therapy, and outpatient speech-language pathology services. (iii) Radiology and certain other imaging services. (iv) Radiation therapy

relationship” to include: “a compensation arrangement . . . between the physician . . . and the entity.”¹⁴³ The statute carves out an exception for employment relationships in which the physician is compensated for “identifiable services.”¹⁴⁴ It also includes an exception for “personal services” under a written agreement.¹⁴⁵ There also is a “physician incentive plan exception,” but payment cannot be made as “an inducement to reduce or limit medically necessary services.”¹⁴⁶

An additional exception was proposed in 2008 that would have allowed hospitals to institute gainsharing programs for up to three years, provided the programs met certain conditions.¹⁴⁷ The finalization of the rule, however, was delayed and the American Hospital Association, Federation of American Hospitals, and the Association of American Medical Colleges recommended changes to the rule because it contained too many restrictions to “allow for innovation and the types of physician-hospital efforts to maximize quality of health care.”¹⁴⁸ This rule has not been instituted to date.

This may add to hospitals’ hesitation in establishing gainsharing programs. Currently, hospitals may run gainsharing programs that the OIG has approved via advisory opinions.¹⁴⁹ The OIG only issues opinions as to the AKS and CMP statute,¹⁵⁰ but it has generally not enforced the Stark Law against gainsharing programs that have received such approvals.¹⁵¹ But should it promulgate an exception,

services and supplies. (v) Durable medical equipment and supplies. (vi) Parenteral and enteral nutrients, equipment, and supplies. (vii) Prosthetics, orthotics, and prosthetic devices and supplies. (viii) Home health services. (ix) Outpatient prescription drugs. (x) Inpatient and outpatient hospital services.

Id.

¹⁴³ 42 U.S.C. § 1395nn(a)(2)(B) (2006).

¹⁴⁴ *Id.* § 1395nn(e).

¹⁴⁵ Heagan & Wood, *supra* note 8.

¹⁴⁶ *Id.* The term “medically necessary” is not defined in either the statute or the OIG’s decisions, but Medicare defines “medically necessary” services as: “Services or supplies that are needed for the diagnosis or treatment of [a patient’s] medical condition and meet accepted standards of medical practice.” *Home Health Agency and Home Care Glossary of Definitions*, MEDICARE, [http://www.medicare.gov/homehealthcompare/\(S\(vfj5vd55qyihdqbiikpxu4rd\)\)/Resources/Glossary.aspx?Choice=M](http://www.medicare.gov/homehealthcompare/(S(vfj5vd55qyihdqbiikpxu4rd))/Resources/Glossary.aspx?Choice=M) (last visited Apr. 24, 2012).

¹⁴⁷ Claiborne et al., *supra* note 7, at 487–88.

¹⁴⁸ *Id.* at 488 (citing *Hospital Industry Groups Urge CMS To Ease Use of Gainsharing Deals, Revisit Proposal*, HEALTH CARE FRAUD REP. (BNA) No. 13 (Feb. 25, 2009)).

¹⁴⁹ Claiborne et al., *supra* note 7, at 488.

¹⁵⁰ Rosen, *supra* note 118.

¹⁵¹ Claiborne et al., *supra* note 7, at 488.

2013]

COMMENT

1347

programs already in existence could find themselves in violation of the exception if the programs do not meet the requirements.¹⁵²

D. Civil Monetary Penalties Statute

Under the CMP Statute, hospitals may not directly or indirectly compensate doctors for “reduc[ing] or limit[ing] services provided” to Medicare or Medicaid patients.¹⁵³ The statute provides for a fine of up to \$2000 per patient for both the doctor and the hospital.¹⁵⁴ Congress passed the CMP Statute after creating the Medicare Prospective Payment System (PPS), which reimbursed hospitals for treating Medicare patients on a per-patient basis, rather than on a fee-for-service basis.¹⁵⁵ Under a per-patient payment system, a hospital receives a set amount of money for each patient treated, based on the patient’s diagnosis and regardless of the amount or type of care provided.¹⁵⁶ In contrast, payment on a fee-for-service basis means that a physician is compensated for each treatment given to the patient so that treatment costs for a particular condition will vary from patient to patient and from doctor to doctor.¹⁵⁷ Medicare continued to reimburse doctors on a fee-for-service basis even after Medicare began reimbursing hospitals on a per-patient basis.¹⁵⁸ Therefore, there was concern that hospitals would attempt to reduce the costs associated with patient care by paying doctors to reduce the services rendered.¹⁵⁹

The CMP Statute does not define the terms “reduce or limit” or “services,” and, in a Special Advisory Bulletin, the OIG adopted a broad interpretation of the statute, as applied to “any physician incentive plan that conditions hospital payments to physicians or physician groups on savings attributable to reduction in hospital costs for treatment.”¹⁶⁰ The OIG does not assume that the services must be medically necessary in order for the statute to apply: “In our view, this interpretation is plainly wrong. Simply put, the language of the statute refers to ‘services,’ not ‘medically necessary services,’ and

¹⁵² *Id.*

¹⁵³ 42 U.S.C. § 1320a-7a (2012); *see also* Saver, *supra* note 3, at 155.

¹⁵⁴ § 1320a-7a; *see also* Heagan & Wood, *supra* note 8.

¹⁵⁵ Marcoux, *supra* note 1, at 543–44.

¹⁵⁶ *Id.* at 543.

¹⁵⁷ *Id.*

¹⁵⁸ *Id.*

¹⁵⁹ *Id.* at 543–44.

¹⁶⁰ Claiborne et al., *supra* note 7, at 486–87 (internal citation and quotation marks omitted).

requires a showing of an intent to induce a reduction of services, not an actual reduction.”¹⁶¹ Claiborne recommended that Congress amend the statute to include the words “medically necessary services,” thus making it acceptable for hospitals to compensate physicians for reducing services that are not medically necessary as part of gainsharing programs.¹⁶²

By contrast, managed care organizations (MCOs) are not allowed to pay doctors to “reduce or limit *medically necessary* services to Medicare and Medicaid patients.”¹⁶³ Thus, MCOs are limited in their ability to enact gainsharing programs, but not to the same degree that hospitals are limited.¹⁶⁴ The OIG has concluded that the difference in wording signifies Congress’s desire to provide MCOs with some discretion so that they could save costs, while preventing hospitals from denying any services to Medicare and Medicaid patients.¹⁶⁵

IV. GAINSHARING IN THE CONTEXT OF THE PATIENT PROTECTION AND AFFORDABLE CARE ACT

PPACA contains several provisions that, while not addressing the laws discussed above, do aim to promote gainsharing programs. Notably, § 3022 of PPACA creates the “Medicare Shared Savings Program,” which would require accountable care organizations (ACOs) to “have a formal legal structure that would allow the organization to receive and distribute payments for shared savings.”¹⁶⁶ ACOs are “groups of doctors, hospitals, and other health care providers, who come together voluntarily to give coordinated high quality care to their Medicare patients.”¹⁶⁷ The Medicare Shared Savings Program enables Medicare to “share a percentage of the achieved savings with the ACO” provided the ACO “meet[s] both the quality performance standards and generate[s] shareable savings.”¹⁶⁸

¹⁶¹ Recent Commentary Distorts HHS OIG’s Gainsharing Bulletin, 1999 WL 34984741 (HHSOIG), 1, available at <https://oig.hhs.gov/fraud/docs/alertsandbulletins/bnagain.htm>.

¹⁶² Claiborne et al., *supra* note 7, at 492.

¹⁶³ Heagan & Wood, *supra* note 8 (emphasis added).

¹⁶⁴ Saver, *supra* note 3, at 164–66.

¹⁶⁵ *Id.*

¹⁶⁶ 42 U.S.C. § 1395jjj(b)(2)(C) (2006).

¹⁶⁷ *Accountable Care Organizations Overview*, CTRS. FOR MEDICARE & MEDICAID SERVS., <https://www.cms.gov/ACO/> (last visited Apr. 2, 2013).

¹⁶⁸ Medicare Program, Medicare Shared Savings Program: Accountable Care Organizations, 76 Fed. Reg. 67802, 67804 (Nov. 2, 2011) (to be codified at 42 C.F.R. pt. 425).

CMS and the OIG have the authority to waive the AKS, Stark Law, and the CMP for ACOs.¹⁶⁹ This program, however, does not include doctors and hospitals that are not part of an ACO.¹⁷⁰

PPACA also provides additional funding for the gainsharing demonstration and extends the program, which was set to expire in 2010, through 2014 or until the funds are exhausted.¹⁷¹ Although this was certainly a step to encourage further demonstration programs, the trouble is that it requires a very long time to collect data, and even then the amount of data collected is small.¹⁷² Also, the demonstration programs' requirement for budget neutrality may be too strict, which disallows cost-saving initiatives with high up-front costs mitigated by long-term savings.¹⁷³

PPACA does not specifically remove the legal barriers discussed above. It also does not address the concerns raised with regard to Treasury Regulation 1.501(c)(3)-1(c), under which a gainsharing program could be found to cause net earnings to "inure to the benefit of private shareholders or individuals," jeopardizing the hospital's tax-exempt status.¹⁷⁴ With regard to the AKS, PPACA § 6402 creates 42 U.S.C. § 1320a-7a(i)(6)(F), which provides that the term "remuneration" under the statute does not include "any other remuneration which promotes access to care and poses a low risk of harm to patients and Federal health care programs (as defined in section 1128B(f) and designated by the Secretary under regulations)."¹⁷⁵ This is unlikely to apply to remuneration for gainsharing programs, however, because such programs do not directly "promote access to care." PPACA also does not include any amendments to the Stark Law that would create an exception to the

¹⁶⁹ See Medicare Program; Waiver Designs in Connection with the Medicare Shared Savings Program and the Innovation Center, 76 Fed. Reg. 19655, 19656 (Apr. 7, 2011).

¹⁷⁰ See generally Frank Pasquale, *Accountable Care Organizations in the Affordable Care Act*, 42 SETON HALL L. REV. 1371, 1381 (2012) (cautioning that there are risks to pilot programs such as the influence of special interest groups, and attempting to "temper" the enthusiasm for ACOs by also discussing the challenges).

¹⁷¹ 42 U.S.C. § 18001 (2010).

¹⁷² *MedPAC Chair: CMS Has Authority to Expand Pilots but Lacks Money*, 13 INSIDE CMS 14 (July 8, 2010).

¹⁷³ Stuart Guterman & Michelle P. Serber, *Enhancing Value in Medicare: Demonstrations and Other Initiatives to Improve the Program* 23 (The Commonwealth Fund/Alliance for Health Reform Jan. 2007).

¹⁷⁴ See *supra* Part III.A.

¹⁷⁵ Patient Protection and Affordable Care Act § 6402, 42 U.S.C. § 1320a-7a(i)(6)(F) (2012).

law for gainsharing programs.¹⁷⁶ With regard to the CMP Statute, PPACA includes amendments related to correction of reporting errors and to the procedures involved in collecting civil monetary penalties; the amendments do not address gainsharing.¹⁷⁷

PPACA does give CMS the authority to waive the CMP Statute and the AKS and immunizes these waivers from judicial and administrative review—according to the chair of the Medicare Payment Advisory Commission—in order to expand the demonstration program.¹⁷⁸ This is helpful because hospitals seeking to participate in demonstration programs will no longer be required to obtain separate approval from the OIG. This provision is inadequate, however, because it does not address the potential for gainsharing programs to violate the Stark Law or the tax regulations and only applies to hospitals participating in demonstration programs. The OIG itself, in its 1999 Advisory Bulletin, stated that “case by case determinations by advisory opinions are an inadequate and inequitable substitute for comprehensive and uniform regulation.”¹⁷⁹

Additionally, PPACA makes violations of the AKS more risky. Prior to PPACA, a violation of the AKS could trigger penalties under the False Claims Act (FCA), which provides for penalties of up to \$11,000 for each fraudulent claim a party submits to the government for reimbursement, but it would not do so automatically.¹⁸⁰ PPACA added a provision explicitly stating that a violation of the AKS constitutes a “false or fraudulent claim” under the FCA.¹⁸¹

It is unlikely that Congress will permanently amend statutes until the pilot programs prove to be effective, but the pilot programs thus far have been too small to provide sufficient data.¹⁸² Although the additional authority given to CMS may encourage participation in the gainsharing demonstrations,¹⁸³ providing statutory safe harbors or

¹⁷⁶ The only amendments are related to exemptions for referrals for certain imaging and scans and “other designated health services . . . that the Secretary deems appropriate,” and mandating the establishment of procedures for reporting violations of the law. 42 U.S.C. § 18001 Sec. 6003 (2006); *see id.* § 18001 Sec. 6409.

¹⁷⁷ 42 U.S.C. § 18001 Sec. 6111 (2010).

¹⁷⁸ *MedPAC Chair: CMS Has Authority to Expand Pilots but Lacks Money*, *supra* note 172.

¹⁷⁹ OIG Special Advisory Bulletin, *supra* note 28.

¹⁸⁰ *See* 31 U.S.C. § 3729 (2006).

¹⁸¹ 42 U.S.C. § 1320a-7b(g) (2012).

¹⁸² *Id.*

¹⁸³ PPACA “establishes at least 35 pilot programs and demonstrations,” that test different methods of payment and forms of healthcare delivery. FURROW ET AL.,

making appropriate amendments to the applicable laws would enable gainsharing on a more widespread basis.¹⁸⁴

The chair of the Medicare Payment Advisory Commission argued that there are insufficient funds to promote gainsharing demonstrations.¹⁸⁵ The lack of funding creates a “catch-22” whereby gainsharing is only permitted on a limited basis until pilot data is available, but limiting the allowable gainsharing programs limits the amount of available pilot data.¹⁸⁶ Enacting statutory changes will make hospitals more willing to invest in gainsharing programs.¹⁸⁷ Some have argued that hospitals’ hesitation to establish gainsharing programs is due to a lack of government funding in general.¹⁸⁸ The argument may be that hospitals do not have enough incentive to incur the costs to start up such programs because they are not guaranteed a benefit.¹⁸⁹ This argument, however, disregards the fact that the nature of gainsharing makes the largest costs, the payment to the doctors, contingent upon savings to the hospital. Removing legal barriers will reduce the risks associated with establishing a gainsharing program and will make hospitals more willing to invest financial resources.

V. PROPOSED SOLUTIONS

Advisory opinions have been insufficient in promoting

HEALTH CARE REFORM SUPPLEMENTARY MATERIALS 176 (Thomson Reuters 2011); see also Atul Gawande, *Testing, Testing*, NEW YORKER, Dec. 14, 2009, available at http://www.newyorker.com/reporting/2009/12/14/091214fa_fact_gawande (arguing that employing trial and error via pilot programs is an important way to “curb costs and increase quality”).

¹⁸⁴ *MedPAC Chair: CMS Has Authority to Expand Pilots but Lacks Money*, *supra* note 172.

¹⁸⁵ *Id.*

¹⁸⁶ *See id.*

¹⁸⁷ See discussion *supra* Part V for recommended statutory changes; see also Peter D. Jacobson et al., *Regulating the U.S. Health Care System: Failure in Motion*, 36 J. HEALTH POL. POL’Y & L. 583, 585–86 (2011) (noting generally that OIG’s approach to the legality of gainsharing arrangements creates uncertainty, which “limits the expansion of existing economic relationships because it is difficult to predict which arrangements will satisfy regulators”); Edward Correia, *Aligning Physician Decision-Making with the Goals of Health Care Organizations: Are There Any Lessons from Law Firms?*, 28 J. CONTEMP. HEALTH L. & POL’Y 224, 246–48 (2012) (“[Health care organizations] should not have to live with the uncertainty of the statute and the burden of having to seek an advisory opinion in every case.”).

¹⁸⁸ *Gainsharing Gets Boost; Projects Still Lack Funding*, MODERN PHYSICIAN, June 9, 2008, available at <http://www.modernphysician.com/article/20080609/MODERNPHYSICIAN/363294579>.

¹⁸⁹ *See id.*

gainsharing because entities may be penalized if the law changes in a way that subsequently renders an advisory opinion void. Also, if entities establish gainsharing programs and then the law changes, conforming to changes in the law could be costly and could eliminate any savings recognized by instituting the program. Hospitals and physicians must have a sense of security that the law will not change in this manner or that, if the law changes, Congress and regulatory agencies will exempt programs that have already been established.

A. *Tax-exempt Organizations*

The Treasury Department should provide a safe harbor to the requirement in Treasury Regulation § 1.501(c)(3)-1(c)(2).¹⁹⁰ An argument against this action is that it could invite fraud. Hospitals might create purported gainsharing programs that do not institute any cost-saving or quality-improving measures, but simply serve to

¹⁹⁰ See generally IRS Notice 2011-20, <http://www.irs.gov/pub/irs-drop/n-11-20.pdf>. There are also concerns that tax-exempt ACOs will violate this regulation by participating in the Medicare Shared Savings Program. See *IRS Notice Regarding Participation in the MSSP through an ACO*, 2011 WL 1219269 (Apr. 18, 2011). The IRS issued a notice soliciting comments on whether it has provided sufficient guidance as to how ACOs can avoid violating restrictions on private inurement. See *id.* The notice states that:

[T]he IRS expects that it will not consider a tax-exempt organization's participation in the MSSP through an ACO to result in inurement or impermissible private benefit to the private party ACO participants where:

- The terms of the tax-exempt organization's participation in the MSSP through the ACO (including its share of MSSP payments or losses and expenses) are set forth in advance in a written agreement negotiated at arm's length.
- CMS has accepted the ACO into, and has not terminated the ACO from, the MSSP.
- The tax-exempt organization's share of economic benefits derived from the ACO (including its share of MSSP payments) is proportional to the benefits or contributions the tax-exempt organization provides to the ACO. If the tax-exempt organization receives an ownership interest in the ACO, the ownership interest received is proportional and equal in value to its capital contributions to the ACO and all ACO returns of capital, allocations and distributions are made in proportion to ownership interests.
- The tax-exempt organization's share of the ACO's losses (including its share of MSSP losses) does not exceed the share of ACO economic benefits to which the tax-exempt organization is entitled.
- All contracts and transactions entered into by the tax-exempt organization with the ACO and the ACO's participants, and by the ACO with the ACO's participants and any other parties, are at fair market value.

Id.

2013]

COMMENT

1353

distribute profits illegally. Although fraud is a concern, the safe harbor provision could contain many of the same requirements contained within the proposed Stark Law exception and the demonstration programs.¹⁹¹ For example, the Treasury Department could require hospitals to maintain documentation of the measures implemented, the baseline measures of performance, and ongoing measurements of quality of care and cost savings. Upon an audit, the hospital would be required to produce this documentation. Adding such a requirement to the safe harbor would not add any additional costs to the hospitals because they would already be required to take these steps in order to qualify for other safe harbor provisions.

B. Anti-Kickback Statute

The AKS should be amended to include a safe harbor for gainsharing programs. As discussed above in the context of treasury regulations, the safe harbor could include several requirements to ensure that only bona fide programs qualify for the safe harbor.¹⁹² Additionally, these requirements would not burden hospitals with any costs that they would not otherwise have to bear.¹⁹³ As with providing a safe harbor under Treasury Regulation § 1.501(c)(3)-1(c)(2), providing a safe harbor for gainsharing programs under the AKS could invite fraud. The safe harbor provision could contain requirements like those in the proposed Stark Law exception and the demonstration programs to deter fraud.¹⁹⁴

C. Stark Law

The Centers for Medicare and Medicaid proposed an exception to the Stark Law in 2008. The exception would have applied to payments made to physicians participating in:

certain documented incentive payments or shared savings programs designed to achieve (1) improvement of the quality of hospital patient care services by changing physician clinical or administrative practices, and/or (2) actual costs savings for the hospital resulting from the reduction of waste or changes in a physician's clinical or administrative practices, without an adverse effect on or

¹⁹¹ See *supra* notes 48 & 49 and accompanying text for requirements of gainsharing programs in demonstration programs; see *infra* notes 195–201 and accompanying text for a discussion of the proposed Stark exception.

¹⁹² See *supra* note 191 and accompanying text.

¹⁹³ See *supra* Part V.A.

¹⁹⁴ See *supra* note 191 and accompanying text.

diminution in the quality of hospital patient care services.¹⁹⁵

This exception would only apply to incentive programs that met certain criteria.¹⁹⁶ Programs would be required to identify cost-saving or quality-improvement measures and to track the success of these measures.¹⁹⁷ Hospitals would then set goals for performance measures and identify baseline levels.¹⁹⁸ Under the proposed exception, programs would be required to include at least five physicians and to give all physicians within the applicable specialty the opportunity to participate without regard to the physician's patient volume or level of "business generated for the hospital."¹⁹⁹ The hospital would be prohibited from limiting the products available to doctors or preventing them from adopting new technologies that are "linked to improved outcomes."²⁰⁰ The exception also required the hospital to disclose to patients that it had established a gainsharing program and would have required hospitals to maintain records of the cost-saving measures.²⁰¹

CMS did not adopt the proposed exception of a number of concerns, in particular that it was too restrictive to permit innovation.²⁰² In an advocacy letter to CMS, the American Hospital Association, Association of American Medical Colleges, and the Federation of American Hospitals stated that "[b]y regulating not only the 'what' but the 'how' of an incentive payment or shared-savings program, CMS limits hospitals' ability to incorporate the health care community's evolving understanding of what contributes to patient quality and safety."²⁰³ Also, the exception only applied to programs that did not violate other federal statutes—notably, gainsharing programs are also likely to violate the AKS and CMP statute.²⁰⁴

¹⁹⁵ Hayman, *supra* note 35.

¹⁹⁶ *Id.*

¹⁹⁷ *Id.*

¹⁹⁸ *Id.*

¹⁹⁹ *Id.*

²⁰⁰ *Id.*

²⁰¹ Hayman, *supra* note 195.

²⁰² Claiborne et al., *supra* note 128, at 488.

²⁰³ Letter from Rick Pollack, Exec. Vice President of the Am. Hosp. Ass'n, Joanne Conroy, Chief Health Care Officer of the Ass'n of Am. Med. Colleges & Charles N. Kahn III, President of the Fed'n of Am. Hosps., to Charlene Frizzera, Acting Adm'r of the Ctrs. for Medicare & Medicaid Servs. (Feb. 17, 2009), *available at* <http://www.aha.org/advocacy-issues/letter/2009/090217-cl-CMS-1403-FC.pdf>.

²⁰⁴ See Part I.B and III.D *supra* for discussion of the legal barriers posed by the AKS and CMP laws.

The proposed exception takes into account a number of the concerns that have been expressed about gainsharing and therefore should be used as a model in enacting a new exception. Specifically, the requirement that hospitals set goals and identify baseline measures and track performance will help ensure that physicians feel they are compensated fairly, thus increasing “buy-in” and motivation to participate.²⁰⁵ Prohibitions against limiting the products available and the use of new technologies protect the physicians from being excessively controlled and allow them to exercise clinical judgment. They also simultaneously protect individual patients from being denied specialized care. The requirement that hospitals disclose the establishment of the gainsharing program to patients maintains transparency and will help prevent patients from thinking they are being shortchanged.²⁰⁶ According to the OIG’s 2005 opinions, hospitals must disclose the gainsharing program to patients in writing, preferably before patients are admitted, but otherwise prior to surgery.²⁰⁷

The proposed exception, however, demands that hospitals identify the cost-saving or quality improvement measures up front.²⁰⁸ As Saver noted, part of the gainsharing process is to solicit suggestions for cost-saving measures.²⁰⁹ By requiring hospitals to identify the cost-saving measures up-front, the law may indirectly require them to solicit suggestions from physicians before there is any guarantee that the suggestions can legally be implemented. Although this may not seem prohibitive, it would involve using physicians’ time to discuss the suggestions and the likelihood of success of cost-saving measures. Depending on the type of measures suggested, involvement of administrative personnel and other staff

²⁰⁵ See Part II.C *supra*, stating that gainsharing programs in general may be more likely than other cost-saving measures to encourage physician “buy-in.”

²⁰⁶ According to one longitudinal study, there was no statistically significant difference between overall patient satisfaction before and after the institution of a gainsharing program. Charles Foster & Lynn Godkin, “Gainsharing” and Patient Satisfaction, HEALTH PROGRESS, July/Aug. 2000, at 47–48, available at http://www.google.com/url?sa=t&rct=j&q=&esrc=s&frm=1&source=web&cd=5&ved=0CEAQFjAE&url=http%3A%2F%2Fwww.chausa.org%2Fworkarea%2FDownloadAsset.aspx%3Fid%3D2147483964&ei=dZe1Tt3LEKjg2AXLxNDMDQ&usg=AFQjCNHd3-0yr_wuVAQSV7-IQljW8PF_eg&sig2=W4mdptcp5rpEmMjrX6TpRA. The article, however, states that all non-management employees were included in the program and does not describe the nature of the cost-saving measures taken. *Id.* at 43.

²⁰⁷ Barry F. Rosen & Jacy D’Aiotolo, *Commentary: Doctors May Share in Hospitals’ Cost Cuts, Sometimes*, DAILY RECORD, Sept. 9, 2005.

²⁰⁸ Hayman, *supra* note 35.

²⁰⁹ Saver, *supra* note 3, at 170–71.

members may be required to assess the feasibility of the suggestions. This amounts to an investment on the part of the hospital without any guarantee that the measures could legally be implemented. To avoid this problem, the exception could include a grace period during which the hospital and physicians, having already committed to a gainsharing arrangement, could identify cost-saving measures and establish the necessary benchmarks.

Saver and others have proposed an alternative interpretation for the restriction against paying doctors to “limit or reduce services” for Medicare and Medicaid patients.²¹⁰ The OIG has interpreted these statutes to apply to any services, whether or not the services are medically necessary.²¹¹ Medicare’s reimbursement rules, however, state that Medicare will only reimburse for services that are “reasonable and necessary.”²¹² Therefore, one could argue that the words “medically necessary” are inherently implied in the Stark Law and CMP Statute.²¹³ A reversal of opinion by the OIG, however, might not provide hospitals with the sense of security needed to incentivize them to institute gainsharing programs. There could be an ongoing concern that the OIG will revisit the decision and return to its former interpretation.

D. *CMP Statute*

As discussed above, under the CMP Statute, the OIG may seek civil monetary penalties from hospitals that pay physicians to reduce or limit services for Medicare and Medicaid patients and on physicians who accept such payments.²¹⁴ The OIG has interpreted this statute to include all services, even those that are not medically necessary.²¹⁵ Saver suggested that the OIG’s interpretation of the statute was incorrect, and that the statute, by its nature, would only apply to situations in which a physician limited or reduced services

²¹⁰ *Id.* at 165 n.71.

²¹¹ Claiborne et al., *supra* note 7, at 486–87.

²¹² Saver, *supra* note 3, at 165 n.71. The term “reasonable and necessary” has not been defined by statute; its meaning has been debated. Timothy P. Blanchard, *Medical Necessity Determinations—A Continuing Healthcare Policy Problem*, 37 J. HEALTH L. 599, 604 (2004). Blanchard suggests that the term “reasonable” and “necessary” may take cost into account as well as the patient’s health: “What ‘necessary’ services are ‘reasonable’ for taxpayers or members of an insurance risk pool to shoulder?” *Id.*

²¹³ *Id.*

²¹⁴ 42 U.S.C. § 1320a-7a (2006).

²¹⁵ Claiborne et al., *supra* note 7, at 486–87.

2013]

COMMENT

1357

that were medically necessary.²¹⁶ Although this is a compelling argument, a change in the OIG's interpretation may not be sufficient because, without an actual change to the statute, the OIG may reverse its decision. In order to encourage hospitals to establish gainsharing programs, more certainty is needed.

Claiborne has proposed that the CMP Statute's application to gainsharing programs could be resolved by amending the statute to include the words "medically necessary" so that the statute prohibits paying doctors to reduce or limit medically necessary services.²¹⁷ It is likely that this would resolve the problem, especially considering the importance that the OIG has placed upon the words "medically necessary" in previous decisions.²¹⁸

E. The Hospital Fair Competition Act of 2005

In 2005, Senator Charles Grassley and twenty-three co-sponsors introduced a bill in the Senate that would have explicitly made gainsharing programs legal.²¹⁹ S.1002, titled the Hospital Fair Competition Act of 2005, would have created exemptions to the CMP Statute, the federal AKS, and the Stark Law for "arrangements between hospitals or critical access hospitals and physicians in which physicians share in the savings experienced by the hospital or critical access hospital by reason of cost-reduction efforts that involve the physicians."²²⁰ The bill also authorized the Secretary of Department of HHS to establish requirements for the programs to ensure that the shared-savings arrangements did not pose a risk to patient care and that "financial incentives that could affect physician referrals [would be] minimized."²²¹ The bill expired at the end of the session.²²² The record as to the bill is very limited, but it is possible that the Hospital Fair Competition Act did not progress in the Senate due to concerns about a provision that would have extended the Stark Law's prohibition on physician-owned hospitals and changes to the way that hospitals would be paid.²²³

²¹⁶ Saver, *supra* note 3, at 164–65.

²¹⁷ Claiborne et al., *supra* note 7 at 491.

²¹⁸ *Id.*

²¹⁹ Hospital Fair Competition Act, S. 1002, 109th Cong. § 4 (2005); *see* Appendix A for § 4 of the Hospital Fair Competition Act of 2005.

²²⁰ *Id.*

²²¹ *Id.*

²²² *Id.*

²²³ *See, e.g., Proposed Self-Referral Ban Casts Chill on Specialty Hospitals*, MCDERMOTT WILL & EMERY (May 18, 2005),

F. Outlier Laws

Saver suggested minimal regulation via outlier laws, which would “identify only the most problematic practices, leaving other forms of gainsharing unregulated.”²²⁴ Other problematic forms of gainsharing that were troublesome but not the most problematic would be discouraged by “publicity, market pressures, physicians’ professional ethics, and tort deterrence,” rather than regulation.²²⁵ Such a law may encourage hospitals to adopt gainsharing programs and experiment with cost-saving measures. Enacting such a law, however, would still leave hospitals with a great deal of uncertainty as to whether they risk violating the CMP, the AKS, or the Stark law, and whether they risk losing their tax-exempt status. The outlier laws could provide an exemption for gainsharing programs. In order to prevent fraud, the law would then have to define what qualifies as a gainsharing program. This could mean restricting the freedom of hospitals, which is what adopting the outlier laws would strive to avoid. An outlier law would be a promising possibility if it included minimal standards for what programs would qualify for exemptions of the problematic laws.

VI. CONCLUSION

If given the appropriate regulatory environment, gainsharing programs have the potential to reduce healthcare costs and increase efficiency without sacrificing the quality of healthcare. A number of legal barriers have prevented such programs from taking hold because hospitals and other medical entities do not want to risk facing penalties. Efforts to encourage, or at least accommodate, gainsharing programs have thus far been accomplished in a piecemeal manner, through pilot programs and advisory opinions.

Although Congress enacted a large number of changes to healthcare via PPACA, it did not resolve the legal barriers to gainsharing in this legislation in a permanent way. Although the OIG may continue to issue favorable advisory opinions, healthcare organizations will only be able to establish productive and permanent

http://www.mwe.com/index.cfm/fuseaction/publications.nldetail/object_id/e6710c2c-4070-4d10-b5f4-cea8c7a74d0d.cfm; *Congress Holds Gainsharing Hearing*, GREATER N.Y. HOSP. ASS’N, <http://www.gnyha.org/902/Default.aspx?&print=yes> (opposing changes to hospital payment methods but supporting the ban on physician-owned hospitals).

²²⁴ Saver, *supra* note 3, at 227–28.

²²⁵ *Id.* at 228.

2013]

COMMENT

1359

gainsharing programs if Congress makes permanent amendments to the relevant statutes.

APPENDIX A

THE HOSPITAL FAIR COMPETITION ACT OF 2005

SEC. 4. PERMISSIBLE COORDINATED CARE INCENTIVE ARRANGEMENTS
BETWEEN HOSPITALS AND PHYSICIANS

(a) Establishment of Requirements for Arrangements and Exemption From Imposition of Civil Monetary Penalties- Section 1128A of the Social Security Act (42 U.S.C. 1320a-7a) is amended by adding at the end the following new subsection:

o. Arrangements Between Hospitals and Physicians-

(1) IN GENERAL - Subsection (b) shall not apply to an arrangement that meet the requirements under paragraph (2).

(2) REQUIREMENTS -

(A) ESTABLISHMENT- The Secretary shall establish requirements for arrangements between hospitals or critical access hospitals and physicians in which physicians share in the savings experienced by the hospital or critical access hospital by reason of cost-reduction efforts that involve the physicians.

(B) PROTECTIONS- In establishing the requirements under subparagraph

(A), the Secretary shall ensure that—

- (i) the quality of care provided to individuals is protected under the arrangement; and
- (ii) financial incentives that could affect physician referrals are minimized.

(C) MONITOR- The Secretary shall establish procedures to monitor arrangements described in subparagraph (A) to ensure that such agreements meet the requirements under such subparagraph.

(b) Exemption From Criminal Penalties- Section 1128B(b) (3) of

2013]

COMMENT

1361

the Social Security Act (42 U.S.C. 1320a-7b(b)(3)) is amended-

- (1) in subparagraph (G), by striking ‘and’ at the end;
 - (2) in subparagraph (H), as added by section 237(d) of the Medicare Prescription Drug, Improvement, and Modernization Act of 2003 (Public Law 108-173; 117 Stat. 2213)—
 - (A) by moving such subparagraph 2 ems to the left; and
 - (B) by striking the period at the end and inserting a semicolon;
 - (3) by redesignating subparagraph (H), as added by section 431(a) of the Medicare Prescription Drug, Improvement, and Modernization Act of 2003 (Public Law 108-173; 117 Stat. 2287), as subparagraph (I);
 - (4) in subparagraph (I), as so redesignated—
 - (A) by moving such subparagraph 2 ems to the left; and
 - (B) by striking the period at the end and inserting ‘; and’;
- and
- (5) by adding at the end of the following new subparagraph:
 - (J) an arrangement that meets the requirements established under section 1128A(o).

(b) Exemption From Limitation on Certain Physician Referrals- Section 1877(e) of the Social Security Act (42 U.S.C. 1395nn(e)) is amended by adding at the end of the following new paragraph:

- (9) ARRANGEMENTS BETWEEN HOSPITALS AND PHYSICIANS- An arrangement that meets the requirements established under section 1128A(o).