

MEMORANDUM

TO: Infectious Diseases Society of America
FROM: King & Spalding

DATE: April 11, 2012

RE: **Legality of Gainsharing Arrangements Between Infectious Diseases
Physicians and Hospitals**

Gainsharing arrangements are agreements between hospitals and physicians where hospitals agree to share cost savings in patient care with physicians, provided those savings are attributable to physician decision-making and these arrangements are carefully developed and executed in a manner that ensures patient quality of care. These gainsharing arrangements have achieved increasing acceptance among federal agencies charged with enforcing anti-kickback and physician self-referral laws.

While these arrangements are not devoid of any risk at all, several recent developments indicate that these hospital-physician shared savings arrangements are worth pursuing and could be win-win propositions for hospitals and physicians alike. Recently, over a dozen favorable Advisory Opinions by the Office of the Inspector General (“OIG”) have been issued along with an OIG 2011 announcement that it is considering a new safe harbor protecting shared savings programs and gainsharing arrangements. As well as a regulatory gainsharing exception under the Stark self-referral law has been proposed and there has been an increasing number of government-sponsored pilot projects implementing similar incentive payment plans.

The numerous publically available OIG Advisory Opinions on gainsharing, described further below, offer a very detailed road map as to what features these arrangements should include to be in compliance with current laws and provide a high degree of assurance to hospitals and physicians of the legality of similar propositions. If a hospital or physician group is in doubt about the appropriateness of a proposed arrangement, the parties should request an OIG Advisory Opinion.

I. What Is Gainsharing?

The term “gainsharing” refers to a variety of arrangements by which hospitals encourage physicians to practice more efficiently in the hospital by sharing some portion (typically measured by a percentage) of the hospital’s cost savings attributable to changes in physician behavior. The OIG has in the past expressed concerns that gainsharing arrangements could violate the civil monetary penalty (“CMP”) law prohibiting hospitals from paying physicians to induce them to limit or reduce items or services furnished to Medicare or Medicare beneficiaries,¹ and could violate the anti-kickback statute if one purpose of the gainsharing arrangement is to influence referrals for federal health program reimbursable business.²

In addition, the Centers for Medicare and Medicaid Services (“CMS”) in the past has expressed concern that gainsharing arrangements might violate the Stark self-referral prohibition. Unless an exception applies, the Stark statute prohibits (1) a physician or his immediate family member, who has any kind of “financial relationship” with an entity, from making a referral to that entity to furnish one or more of 11 categories of “designated health services” payable by the Medicare program, and (2) the entity from presenting a claim for reimbursement for a designated health service resulting from a prohibited referral.³ This is a “bright line” statute; if a physician makes a referral for such a service to an entity with which he or she has a financial relationship, then presenting that item or service to Medicare or Medicaid for payment would be illegal in the absence of an applicable exception. The Stark law has been an ongoing concern with respect to gainsharing, because the OIG Advisory Opinion process does not address the lawfulness of the proposed facts under Stark -- that is left to CMS.

II. History of the Growing Acceptance by Both OIG and CMS of Gainsharing

The OIG issued a Special Advisory Bulletin in 1999 declaring that any incentive plan whereby a hospital compensated physicians directly or indirectly based on cost savings on items or services furnished to patients under the physicians’ care was prohibited by the CMP statute, unless Congress enacted clarifying legislation. In the Special Advisory Bulletin, the OIG noted that under the anti-kickback statute and CMP law, gainsharing arrangements did not fall within any safe harbor or exception and involved a high risk of potential abuse. The OIG concluded that it had no authority under current law to allow such gainsharing arrangements and would not be issuing any more advisory opinions in this area. The Bulletin warned hospitals to expeditiously unwind any of these programs currently in existence. However, within just two

¹ 42 USC 1320a-7a.

² 42 USC 1320a-7b.

³ 42 USC § 1395nn(a).

years of this Special Advisory Bulletin, the OIG softened its position considerably by issuing an Advisory Opinion which approved a gainsharing arrangement between a hospital and a group of cardiac surgeons as the OIG believed that the cost saving arrangement included sufficient safeguards for ensuring continuing high quality patient care.⁴

CMS, for its part, in 2004 stated in the preamble to the Stark II Phase II Interim Final Rule that there was no exception in the Stark law or regulations that would permit hospital payments to physicians based on their utilization of designated health services, which include inpatient or outpatient hospital services, except for several Stark exceptions that permitted such payments when made to enrollees of certain health plans. CMS reasoned that Congress intended to limit these kinds of incentives in accordance with the CMP provision, and CMS could not create a regulatory exception for such activities.⁵

The OIG in its Supplemental Compliance Program Guidance for Hospitals issued in January 2005 cautioned about the potential dangers of gainsharing arrangements. However, later in 2005, the OIG changed its course again by issuing six Advisory Opinions in support of gainsharing proposals.⁶ Those opinions concluded that the OIG would take no enforcement action under the anti-kickback statute against the gainsharing programs in question. Further, in its March 2005 “Report to Congress on Physician-Owned Specialty Hospitals,” the Medicare Payment Advisory Committee (“MedPAC”) recommended allowing certain gainsharing arrangements between physicians and hospitals.⁷ CMS then initiated certain gainsharing demonstration projects, some of which have been mandated by Congress.⁸

In 2008-2009, the OIG issued more Advisory Opinions approving gainsharing arrangements.⁹ The OIG consistently concluded that although each proposal would constitute an improper payment to induce the reduction of services under the CMP statute and also would potentially violate the anti-kickback statute, the OIG would not impose administrative sanctions. These agreements involved hospitals with groups of cardiac surgeons, anesthesiologists, orthopedic surgeons and cardiologists. In each case, the hospital and physicians agreed upon a

⁴ OIG Advisory Opinion 01-1 at <http://oig.hhs.gov/reports-and-publications/archives/advisory-opinions/index.asp>. See APPENDIX for summary.

⁵ 69 Fed. Reg. 16054, 16088 (March 26, 2004).

⁶ OIG Advisory Opinions 05-01 through 05-06 at <http://oig.hhs.gov/reports-and-publications/archives/advisory-opinions/index.asp>. See APPENDIX for summary.

⁷ http://www.medpac.gov/publications/congressional_reports/mar05_EntireReport.pdf at p. 146.

⁸ https://www.cms.gov/DemoProjectsEvalRpts/downloads/DRA5007_Solicitation.pdf.

⁹ OIG Advisory Opinions 08-09, 08-15, 08-16, 08-21, 09-06 at <http://oig.hhs.gov/reports-and-publications/archives/advisory-opinions/index.asp>. See APPENDIX for summary.

number of specific opportunities that would present substantial cost savings without adversely affecting the quality of care.

Moreover, in its Fall 2011 Semiannual Report to Congress, the OIG stated that it is considering adopting a new safe harbor to the anti-kickback law to specifically protect shared savings and gainsharing arrangements.¹⁰ The OIG already has adopted a waiver for shared savings arrangements as part of the roll out of accountable care organizations (“ACOs”) under the new health care reform law.¹¹ Since this proposal in its Semiannual Report is listed separately from its ACO waiver, it appears that the OIG is considering even broader exceptions for gainsharing arrangements.

Yet, despite this wave of favorable OIG Advisory Opinions, stakeholders continued to be concerned with whether and how such gainsharing arrangements could comply with the Stark law. However, recent actions taken by CMS have quelled much of those concerns. In the calendar year 2009 proposed rule for the Medicare Physician Fee Schedule, CMS for the first time issued a proposed exception to the Stark law for incentive payments and shared savings programs, which includes certain pay-for-performance and gainsharing arrangements. Specifically, the proposed rule would except from the Stark law remuneration paid by a hospital to a physician as part of certain documented incentive payments or shared savings programs designed to achieve (1) improvement in the quality of hospital patient care services by changing physician clinical or administrative practices, and/or (2) actual cost 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 the quality of hospital patient care services.¹² The proposed rule incorporates the standard established by the OIG Advisory Opinions. While CMS has yet to finalize this proposed exception, the proposed exception, considered with the increasing number of CMS-approved pilot programs of shared savings arrangements, provides some assurance that CMS does not view carefully planned gainsharing arrangements that provide an objective mechanism to ensure continued quality patient care a violation of the Stark law. Indeed, the Department of Health and Human Services (“HHS”) recently announced the availability of up to \$500 million in Partnership for Patients demonstration grants through the Affordable Care Act to assist hospitals and other healthcare organizations reduce healthcare acquired conditions and unnecessary readmissions.

¹⁰ Fall 2011 Semiannual OIG Report to Congress at <http://oig.hhs.gov/reports-and-publications/archives/semiannual/2011/fall/SAR-F11-05-Appendixes.pdf>.

¹¹ On April 10, 2012, CMS announced the selection of the first 27 ACOs to participate in the Medicare Shared Saving Program under the health care reform law. These ACOs will share in the savings to Medicare achieved through reducing costs while maintaining high quality care.

¹² 73 Fed. Reg. 38502, 38604-05.

III. Factors that the OIG and CMS Consider in Allowing Gainsharing Arrangements

From the CMS proposed gainsharing exception to the Stark law and the OIG Advisory Opinions allowing these arrangements, a pattern has emerged with respect to the characteristics these agencies look for in evaluating the legality of these incentive plans. These characteristics are:

- An incentive payment, gainsharing, or shared savings program should identify patient care quality measures or cost-saving measures, or both. It should use an objective methodology that is verifiable and supported by credible medical evidence. The measures should be individually tracked and reasonably related to the hospital's practices and patient population. The arrangement should be monitored throughout the term of the agreement to protect against inappropriate reductions or limitations in patient care services.
- The written agreement should establish baseline levels for the performance measures, using the hospital's historical and clinical data. Target levels for the performance measures should be developed by comparing historical data for the hospital's practices and patient population with national or regional data for comparable hospitals, and there should be thresholds above or below which no payments will accrue to the physicians.
- The cost savings should be clearly and separately identified, and there should be transparency and individual physician accountability for any adverse effects of the arrangement.
- The payments under the arrangement should be calculated based on actual out-of-pocket costs for all procedures, regardless of the source of reimbursement, and services should not be disproportionately performed on federal health care program beneficiaries, meaning that the services should be performed on all patients and not focus on Medicare beneficiaries for example.
- Patient admissions to the hospital should be monitored for any changes in referral patterns based on severity, age or payor.
- Physicians should have access to the same selection of items, supplies, drugs, or devices as was available at the hospital prior to the commencement of the program and should not be restricted from making medically appropriate decisions for their patients concerning the full range of tests, procedures, and supplies. An individual physician may not have an investment interest or compensation arrangement with the manufacturer or distributor that arranges for the purchase of the items, supplies or devices tracked by the program. The hospital may not limit the availability of new

technology that is linked to improved outcomes, is clinically appropriate for a particular patient, and meets regulatory standards.

- Patients should be given effective prior notice of their physicians' participation in the program, describing the paid incentives and the performance measures under the arrangement.
- The program must be set out in writing and in sufficient detail to be independently verified, must be signed by both parties, and must identify each specific performance measure and the formula for calculating the resulting payment.
- The term of the arrangement should be for no less than one year and no more than three years. The program should take into account previous payments made for performance measures already achieved to ensure that physicians do not receive duplicative payment for such cost savings.
- The formula for the calculation of payments over the term of the arrangement should be set in advance, not vary during the term of the arrangement, and not be determined in a manner that takes into consideration the volume or value of the physicians' referrals or business generated between the parties. Payments should be distributed to each set of physicians participating in each performance measure and ultimately distributed to individual physicians on a per capita basis with respect to each performance measure. There may be no increased payment based on the physicians' treatment of a greater volume of federally reimbursed patient services than during the prior payment period.
- The hospital should maintain accurate and contemporaneous documentation of the program and make such documentation available to the Secretary of HHS upon request. These records should include the following: (a) the written agreement between the parties; (b) how the performance measures were selected; (c) the selection and qualifications of the independent medical reviewer; (d) the written findings of the reviewer; (e) any corrective actions taken by the hospital based on the reviewer's written findings; (f) the amount and calculation of payments made under the program, including the hospital's projected and actual product acquisition costs; (g) the rebasing of performance measures; and (h) the written notification given to hospital patients.

IV. Conclusion

In its recent Advisory Opinions, the OIG has indicated that carefully structured arrangements can meet hospitals' goals of incentivizing efficiencies through monetary rewards to physicians under the anti-kickback statute. Moreover, the OIG announced in 2011 that it is considering the adoption of a specific safe harbor for gainsharing arrangements. CMS also has

recently demonstrated through its proposed gainsharing exception to the Stark law and willingness to approve pilot programs with shared savings arrangements that it is open to hospital-physician incentive payment plans, provided that such plans have meaningful mechanisms in place to ensure continued patient quality of care, such as those mechanisms described above.

Gainsharing arrangements between hospitals and infectious diseases specialists are ideally suited to achieve the objectives of reducing hospital acquired infections and inappropriate antimicrobial use, and thereby avoiding unnecessary costs. Such arrangements if constructed to include adequate safeguards to ensure that no necessary services are being unduly limited should be in line with recent OIG and CMS positions allowing gainsharing plans.

However, until the OIG and CMS finalize specific gainsharing exceptions to current laws, hospitals or physician groups with concerns over whether a particular proposed gainsharing arrangement is appropriate could seek an OIG Advisory Opinion and present the proposal to CMS to ensure the legality of the arrangement.

Attachment: Appendix

APPENDIX—OIG ADVISORY OPINIONS APPROVING GAINSHARING ARRANGEMENTS

OIG Adv. Op. No.	Description of Arrangement	Cost Savings Opportunities Identified	Safeguards to Protect Against Inappropriate Reductions in Services
<p>01-01 (1/18/2001) <i>Cardiac Surgeons</i></p>	<p>Hospital will share with a group of cardiac surgeons a percentage of its cost savings arising from surgeons' implementation of cost reduction measures in certain designated cardiac surgery procedures. Payment to the physician groups will be 50% of the difference between their adjusted current year costs and base year costs, if any.</p>	<p>Hospital identified nineteen (19) specific cost-savings opportunities in three different categories:</p> <ol style="list-style-type: none"> 1. Opening packaged items only as needed during a procedure. 2. Substituting less costly items for those currently being used. 3. Limiting use of Aprotinin (preoperative anti-hemorrhage medication) to patients at higher risk of perioperative hemorrhage as indicated by objective clinical standards. 	<ol style="list-style-type: none"> 1. <u>"As Needed" Use Limitations and Substitution Recommendation:</u> "Floor" beyond which no savings would accrue to the Surgical Group would be established using objective historical and clinical baseline measures. 2. <u>Aprotinin Limitation:</u> Medical appropriateness will be determined according to specific, objective, generally accepted clinical indicators.
<p>05-01 (2/4/2005) <i>Cardiac Surgeons</i></p>	<p>Hospital will share with a group of cardiac surgeons a percentage of its cost savings arising from surgeons' implementation of cost reduction measures in certain designated cardiac surgery procedures. Payment to the physician groups will be 50% of the difference between their adjusted current year costs and base year costs, if any.</p>	<p>Hospital identified twenty-four (24) specific cost-savings opportunities in four different categories:</p> <ol style="list-style-type: none"> 1. Opening packaged items only as needed during a procedure. 2. Performing blood cross-matching only as needed. 3. Substituting less costly items for those currently being used. 4. Product standardization of certain cardiac devices where medically appropriate. 	<ol style="list-style-type: none"> 1. <u>"As Needed" Use Limitations and Substitution Recommendation:</u> "Floor" beyond which no savings would accrue to the Surgeon Group would be established using objective historical and clinical baseline measures. 2. <u>Product Standardization:</u> Surgeons will make case-by-case determinations regarding medically appropriate cardiac devices, and the full range of available devices will not be compromised as a result of product standardization.
<p>05-02 (2/17/2005) <i>Cardiologists</i></p>	<p>Hospital will share with five cardiology groups a percentage of its cost savings arising from cardiologists' implementation of cost reduction measures in certain designated cardiac catheterization laboratory procedures. Payment to each Cardiology Group will be 50% of the difference between their adjusted current year costs and base year costs, if any.</p>	<p>Hospitals identified eighteen (18) specific cost-savings opportunities that fell into two categories:</p> <ol style="list-style-type: none"> 1. Product standardization of cardiac catheterization devices where medically appropriate. 2. Limiting use of certain vascular closure devices to an "as needed" basis for inpatient coronary interventional procedures and diagnostic procedures. 	<ol style="list-style-type: none"> 1. <u>Product Standardization:</u> Cardiologists will make case-by-case determinations regarding medically appropriate cardiac devices, and the full range of available devices will not be compromised as a result of product standardization. 2. <u>"As Needed" Use Limitation:</u> "Floor" beyond which no savings would accrue to the cardiologists would be established using objective historical and clinical baseline measures.

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<p>05-03 (2/17/2005) <i>Cardiac Surgeons</i></p>	<p>Hospital will share with a group of cardiac surgeons a percentage of its cost savings arising from surgeons' implementation of cost reduction measures in certain designated cardiac surgery procedures. Payment to the surgical group will be 50% of the difference between the adjusted current year costs and base year costs, if any.</p>	<p>Hospital identified twenty-nine (29) specific cost-savings opportunities that fell into four categories:</p> <ol style="list-style-type: none"> 1. Opening packaged items only as needed during a procedure. 2. Performing blood cross-matching only as needed. 3. Substituting less costly items for those currently being used. 4. Product standardization of certain cardiac devices where medically appropriate. 	<ol style="list-style-type: none"> 1. <u>"As Needed" Use Limitations and Substitution Recommendation:</u> "Floor" beyond which no savings would accrue to the Surgical Group would be established using objective historical and clinical baseline measures. 2. <u>Product Standardization:</u> Surgeons will make case-by-case determinations regarding medically appropriate cardiac devices, and the full range of available devices will not be compromised as a result of product standardization.
<p>05-04 (2/17/2005) <i>Cardiologists</i></p>	<p>Hospital will share with eight cardiology groups a percentage of its cost savings arising from the cardiologists' implementation cost reduction measures in certain designated cardiac catheterization laboratory procedures. Payment to each Cardiology Group will be 50% of the difference between their adjusted current year costs and base year costs, if any.</p>	<p>Hospital identified seventeen (17) specific cost-savings opportunities that fell into three categories:</p> <ol style="list-style-type: none"> 1. Product standardization of certain cardiology devices where medically appropriate. 2. Limiting use of certain vascular closure devices to an "as needed" basis for inpatient coronary interventional procedures and diagnostic procedures. 3. Substituting less costly contrast agents for those currently being used by the cardiologists. 	<ol style="list-style-type: none"> 1. <u>"As Needed" Use Limitation:</u> "Floor" beyond which no savings would accrue to the cardiologists would be established using objective historical and clinical baseline measures. 2. <u>Substitution Recommendations:</u> "Quality thresholds" beyond which no savings would accrue to the cardiologists would be established using national averages and objective historical baseline measures. 3. <u>Product Standardization:</u> Cardiologists will make case-by-case determinations regarding medically appropriate cardiac devices, and the full range of available devices will not be compromised as a result of product standardization.
<p>05-05 (2/25/2005) <i>Cardiologists</i></p>	<p>Hospital will share with a cardiology group a percentage of its cost savings arising their implementation of cost reduction measures in certain designated cardiac catheterization laboratory procedures. Payment to the Cardiology Group will be 50% of the difference between its adjusted current year costs and base year costs, if any.</p>	<p>Hospital identified twelve (12) specific cost-savings opportunities that fell into two categories:</p> <ol style="list-style-type: none"> 1. Product standardization of certain cardiac catheterization devices where medically appropriate. 2. Limiting use of certain vascular closure devices to an "as needed" basis for inpatient coronary interventional procedures and diagnostic procedures. 	<ol style="list-style-type: none"> 1. <u>Product Standardization:</u> Cardiologists will make case-by-case determinations regarding medically appropriate cardiac devices, and the full range of available devices will not be compromised as a result of product standardization. 2. <u>"As Needed" Use Limitation:</u> "Floor" beyond which no savings would accrue to the cardiologists would be established using objective historical and clinical baseline measures.

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<p>05-06 (2/25/2005)</p> <p><i>Cardiac Surgeons</i></p>	<p>Hospital will share with a group of cardiac surgeons a percentage of the hospital's cost savings arising from surgeons' implementation of cost reduction measures in designated cardiac surgery procedures. Payment to the surgical group will be 50% of the difference between the adjusted current year costs and base year costs, if any.</p>	<p>Hospital identified twenty-seven (27) specific cost-savings opportunities that fell into four categories:</p> <ol style="list-style-type: none"> 1. Opening packaged items only as needed during a procedure. 2. Limiting use of certain surgical supplies to an "as needed" basis. 3. Substituting less costly items for those currently being used. 4. Product standardization of certain cardiac devices where medically appropriate. 	<ol style="list-style-type: none"> 1. <u>"As Needed" Use Limitations and Substitution Recommendation:</u> "Floor" beyond which no savings would accrue to the Surgical Group would be established using objective historical and clinical baseline measures. 2. <u>Product Standardization:</u> Surgeons will make case-by-case determinations regarding medically appropriate cardiac devices, and the full range of available devices will not be compromised as a result of product standardization.
<p>08-09 (8/7/2008)</p> <p><i>Orthopedic Surgeons and Neurosurgeons</i></p>	<p>Medical Center will share with a groups of orthopedic surgeons and neurosurgeons a percentage of its cost savings arising from their implementation of cost reduction measures in certain designated spine fusion surgery procedures. Payment to each group will be 50% of the difference between its adjusted current year costs and base year costs, less 50% of the Medical Center's costs to administer the arrangement.</p>	<p>The Medical Center identified thirty-six (36) specific cost-savings opportunities that fell into two categories:</p> <ol style="list-style-type: none"> 1. Limiting use of Bone Morphogenetic Protein ("BMP") to an "as needed" basis. 2. Product standardization of certain spine fusion devices and supplies where medically appropriate. 	<ol style="list-style-type: none"> 1. <u>"As Needed" Use Limitation:</u> "Floor" beyond which no savings would accrue to the Orthopedic Surgeons or Neurosurgeons would be established using specific, objective, generally accepted clinical baseline measures. 2. <u>Product Standardization:</u> Surgeons will make case-by-case determinations regarding medically appropriate spine fusion devices and supplies, and the full range of available devices and supplies will not be compromised as a result of product standardization.

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<p>08-15 (10/14/2008) <i>Cardiologists</i></p>	<p>Hospital will share with groups of cardiologists a percentage of the hospital's cost savings arising from their implementation of cost reduction measures in certain designated cardiac catheterization laboratory procedures. Payment to each Cardiology Group will be 50% of the difference between their adjusted current year costs and base year costs, if any. Base year costs are subject to annual rebasing to prevent duplicate payments for savings achieved in prior years.</p>	<p>Hospital identified thirty specific cost-savings opportunities that fell into three categories:</p> <ol style="list-style-type: none"> 1. Product standardization of cardiac catheterization devices where medically appropriate. 2. Limiting use of certain vascular closure devices to an "as needed" basis for inpatient coronary and peripheral interventional procedures and diagnostic procedures. 3. Substituting less costly anti-thrombotic medication for other products currently being used. 	<ol style="list-style-type: none"> 1. <u>Product Standardization:</u> Cardiologists will make case-by-case determinations regarding medically appropriate cardiac devices, and the full range of available devices will not be compromised as a result of product standardization. 2. <u>"As Needed" Use Limitation:</u> "Floor" beyond which no savings would accrue to the cardiologists would be established using objective historical and clinical baseline measures. 3. <u>Substitution Recommendations:</u> No "floors" were set because substituting usage of the anti-thrombotic medication comported with national guidelines and other quality indicators; quality monitoring is ongoing.
<p>08-16 (10/14/2008) <i>Physician-Owned Entity</i></p>	<p>Hospital will share with a Physician-Owned Entity a percentage of certain performance-based compensation available to the Hospital under a Quality and Efficiency Agreement (a pay-for-performance program) with a Private Insurer whereby the Private Insurer gives the Hospital an additional percentage of its annual Base Compensation amount as a bonus payment for meeting certain Quality Targets. The hospital will pay the Physician-Owned Entity up to 50% of the amount the Hospital earns from the Private Insurer as a result of achieving the Quality Targets. Compensation will be FMV and will not be determined in a manner that takes into account the volume or value of referrals.</p>	<p><i>Quality Measures:</i> The Quality and Efficiency Agreement relates to six (6) conditions or procedures. For two of them, the Private Insurer will give credit simply for reporting data. For the remaining four, Bonus Compensation requires meeting certain Quality Targets, which are among the measures described in the Specifications Manual for National Hospital Quality Measures published by the Joint Commission. In determining compliance with the Quality Targets, all of the Hospital's inpatients having a designated condition or procedure are counted, not only those insured by the Private Insurer. In order for the Hospital to receive credit with regard to a particular patient, every standard for the designated condition or procedure must be met, except where a specific standard is contraindicated for that patient.</p>	<p>If the Hospital's inflation-adjusted Base Compensation amount increases from the base year to the current year, the Physician Entity's compensation will be calculated on the basis of adjusted base year amount so that any subsequent increase in patient referrals to the hospital would not cause an increase in payments to the physician entity. The Hospital will monitor the Quality Targets and their implementation to protect against inappropriate reductions or limitations in patient care services. It will terminate the application of any Quality Target that has an adverse effect on the quality of care. Any physician who exhibits a significant change in referral patterns (including changes in patient mix) in a manner beneficial to the Hospital, due in any part to the financial awards available to the physician, will be terminated from the Physician Entity.</p>

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<p>08-21 (12/8/2008) <i>Cardiologists and Radiologists</i></p>	<p>Hospital will share with four cardiology groups and one radiology group a percentage of its cost savings arising from their implementation over two years of cost reduction measures in certain designated cardiac catheterization procedures. Payment to each Group will be 50% of the difference between their adjusted current year costs and base year costs, if any. Base year costs are subject to annual rebasing to prevent duplicate payments for savings achieved in prior years.</p>	<p>Hospital identified twenty-seven (27) specific cost-savings opportunities that fell into three categories:</p> <ol style="list-style-type: none"> 1. Product standardization of cardiac catheterization devices where medically appropriate. 2. Limiting use of certain vascular closure devices to an “as needed” basis for inpatient coronary interventional and diagnostic procedures. 3. Substituting less costly contrast agents and anti-thrombotic medications for other products currently being used. 	<ol style="list-style-type: none"> 1. <u>Product Standardization:</u> Physicians will make case-by-case determinations regarding medically appropriate device or supply, and the full range of available devices will not be compromised as a result of product standardization. 2. <u>"As Needed" Use Limitation and Substitution Recommendation:</u> “Floor” beyond which no savings would accrue to the Groups would be established using objective historical and clinical baseline measures. 3. <u>Substitution Recommendations:</u> “Quality thresholds” beyond which no savings would accrue to the cardiologists would be established using national averages and objective historical baseline measures; and/or substitutions comported with national guidelines and other quality indicators.
<p>09-06 (6/30/2009) <i>Cardiologists, Vascular Surgeons, and Interventional Radiologists</i></p>	<p>Hospital will share with a cardiology group, a vascular surgical group, and an interventional radiology group a percentage of its cost savings arising from their implementation of a number of cost reduction measures in designated cardiac catheterization procedures. Payment to each Group will be 50% of the difference between their adjusted current year costs and base year costs, if any.</p>	<p>Hospital’s study of the historic practices of the Groups with respect to cardiac catheterization procedures performed at the hospital identified twenty-one (21) specific cost-savings recommendations related to product standardization of cardiac catheterization devices and supplies where medically appropriate.</p>	<ol style="list-style-type: none"> 1. <u>Product Standardization:</u> Physicians will make case-by-case determinations regarding medically appropriate device or supply, and the full range of available devices will not be compromised as a result of product standardization. 2. No cost-savings amount will be allocated to the Groups if cardiac catheterization procedures performed by the groups involve reductions in the Hospital’s quality as measured against the ACC quality indicators.

Each of these gainsharing arrangements that formed the basis for the OIG Advisory Opinions listed in the chart above (with the exception of Opinion No. 08-16, which involves a different sort of gainsharing arrangement) also contained the following additional payment limitations:

1. No cost savings payment will be made for additional procedures performed in the event that the volume of procedures in the current year increases over the volume of like procedures performed in the base year.

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2. Case severity, patient ages, and payer mix will be monitored. Physicians whose cases exhibit significant changes from historical measures will be terminated from participation in the shared savings arrangement.
3. Aggregate payments to each Physician Group will not exceed 50% of the cost savings projected at the outset of the Arrangement. Each Group will be compensated solely for its own savings.