In an effort to provide more efficient and less costly medical care to patients, hospitals may approach physicians (and physician practices) about gainsharing. In the health care context, gainsharing typically refers to an arrangement whereby physicians generate some measure of cost savings for a hospital and then share the savings generated with the hospital. In connection with medical items or services reimbursable by a Federal health care program, gainsharing arrangements may implicate certain federal health care laws. However, if structured to adhere with the guidance concerning such arrangements provided by the United States Department of Health and Human Services, Office of Inspector General (the “OIG”), gainsharing arrangements appear to be permissible. Indeed, in 2014, the OIG specifically represented that although “[i]t always has been, and remains, open to pursuing a gainsharing…case under appropriate facts,” “[p]rior to initiating any such case, [i]t would consider the factors set out in [its] advisory opinions [concerning gainsharing arrangements]” and “pending further notice from the OIG, gainsharing arrangements are not an enforcement priority…unless the arrangement lacks sufficient patient and program safeguards.” See the OIG’s October 3, 2014 Proposed Rule. This article is not intended to provide an exhaustive treatment of gainsharing arrangements but rather to serve as a general reference and educational guide. Physicians and physician practices are encouraged to seek advice from their own counsel to address specific legal issues that arise in their individual practices.

This article will first address the federal health care law implications of gainsharing arrangements and then examine the guidance provided by the OIG concerning such arrangements.

Federal Health Care Law Implications of Gainsharing Arrangements.

Gainsharing arrangements may implicate the federal civil monetary penalty ("CMP") statute, the Stark law and the Anti-Kickback Statute ("AKS"). We will address the potential implications of each of these federal health care laws in turn.

CMP Statute Implications.

The CMP statute includes a provision prohibiting a hospital from knowingly making payments, directly or indirectly, to a physician to induce the physician to reduce or limit medically necessary services to Medicare or Medicaid beneficiaries who are under the physician’s direct care. 42 U.S.C. § 1320a-7a(b)(1) (emphasis added) (the “Gainsharing CMP Statute”).
Stark Law Implications.

The Stark law, as amended, prohibits a physician from referring his or her Medicare or Medicaid patients for the furnishing of certain designated health services (“DHS”) to an entity with which the physician (or an immediate family member of the physician) has a financial relationship, unless an exception applies. 42 U.S.C. § 1395nn(a)(1)(A). For further information concerning the Stark law, please see our articles titled the Physician’s Guide to the Stark Law – Part I and Part II. As the provision of remuneration by a hospital to a physician pursuant to a gainsharing arrangement creates a financial relationship between the hospital and the physician, the Stark law prohibits the physician from referring Medicare and Medicaid patients to the hospital for the furnishing of certain DHS unless an exception applies. This is true even if the arrangement seeks only to reduce or limit medically unnecessary services. Although certain gainsharing arrangements may potentially take advantage of the Stark law exceptions for “personal services arrangements,” “fair market value arrangements,” or “indirect compensation arrangements,” all of these exceptions provide that the compensation involved in the arrangement cannot vary with the volume or value of referrals by the physician to the entity providing DHS. As most gainsharing arrangements provide that the cost savings generated for the hospital, a portion of which will be shared with the physician, vary with the volume or value of referrals by the participating physician, these Stark law exceptions usually do not apply to protect the arrangement. Further, an exception proposed by the Centers for Medicare & Medicaid Services in 2008 to specifically permit gainsharing arrangements, among other arrangements, has never been finalized.

AKS Implications.

The AKS, as amended, prohibits anyone from knowingly and willfully soliciting or receiving, or offering or paying, any remuneration, directly or indirectly, overtly or covertly, in cash or in kind, in return for referring, or to induce a person to refer, an individual 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. 42 U.S.C. § 1320a-7b(b)(1) and (2). For further information concerning the AKS, please see our articles titled the Physician’s Guide to the Anti-Kickback Statute – Part I and Part II. The kickback concern with gainsharing arrangements is that the payments a hospital makes to a physician for generating cost savings for the hospital may actually represent payments made to induce or reward the physician for referrals. While various safe harbors have been promulgated outlining certain arrangements that will not be prosecuted under the AKS provided certain requirements are met, none are specific to gainsharing arrangements. Further, although certain gainsharing arrangements may potentially take advantage of the “personal services and management contracts” safe harbor, this safe harbor requires, among other things, that the amount of compensation paid under the arrangement be set in advance. As most gainsharing arrangements provide for payment on a percentage basis, this requirement often cannot be met and, accordingly, this AKS safe harbor often cannot be utilized.
NOTE: Many states, including Louisiana, have analogues to federal health care laws, including the federal AKS and Stark law. By way of example, see our article titled Physician’s Guide to Louisiana’s Anti-Kickback Statutes and Stark Law. Accordingly, when structuring and/or analyzing gainsharing arrangements, applicable State health care law implications should be considered as well.

OIG Opinions Support Certain Gainsharing Arrangements.

As explained herein, there are no specific exceptions under the CMP statute or the Stark law and no specific safe harbors under the AKS available to protect gainsharing arrangements that seek to share cost savings generated in connection with the provision of medical items or services reimbursable by a Federal health care program. However, despite the compliance risks presented by such gainsharing arrangements, the OIG has issued numerous advisory opinions indicating that certain gainsharing arrangements will not be prosecuted even though they may implicate the CMP statute and/or the AKS. While the OIG cannot opine on whether the Stark law is implicated in connection with any requested advisory opinion, presumably, the OIG would not have repeatedly blessed certain gainsharing arrangements, if they would clearly violate the Stark law. Further, although OIG advisory opinions (i) cannot be relied on by any persons other than persons requesting the opinion at issue and (ii) are limited in scope to the specific arrangement described in the opinion and technically “ha[ve] no applicability to other arrangements, even those which appear similar in nature or scope,” such opinions provide valuable insight concerning whether, and under what circumstances, particular types of health care arrangements will or will not be challenged by the OIG. Moreover, such opinions are routinely relied upon by health care providers in structuring health care arrangements. Significantly, for purposes of this article, the OIG advisory opinions concerning proposed gainsharing arrangements consistently outline various patient safeguards that, if included in, or considered in connection with, gainsharing arrangements, reduce the risk that the arrangement will be challenged by the OIG as well as certain deficiencies that, if not avoided in such arrangements, will heighten the risk of challenge by the OIG, specifically:

Gainsharing arrangement safeguards that reduce the risk of challenge by the OIG

- specifying the actions that will generate cost savings and the amount of savings each action is expected to generate;
- obtaining credible medical support that the specified cost saving actions will not adversely affect patient care;
- utilizing objective historical and clinical measures to establish a baseline threshold below which no savings will accrue to the physicians;
- basing shared savings on all procedures regardless of a patient’s insurance coverage;
- calculating savings based on the hospital’s actual acquisition costs;
limiting participation to physicians already on staff;
limiting the financial incentives offered in duration and amount;
distributing savings to physicians on a per capita basis, thus reducing the incentive for an individual doctor to generate disproportionate cost savings by, among other things, underutilizing certain items or services;
with respect to product standardization measures, requiring the physicians to make a patient-by-patient determination of the most appropriate device from a full range of devices, and ensuring that the devices the physicians used before a gainsharing arrangement is put in place are still available to them if requested by them after the gainsharing arrangement is put in place;
monitoring hospital admissions for changes in severity, age, or payor and, if it appears that one or more physicians are attempting to steer more costly patients to other hospitals, including a mechanism for discontinuing any such physician’s participation in the gainsharing arrangement;
including adequate quality controls, such as an independent review mechanism, to consistently monitor compliance with the terms of the gainsharing arrangement; and
providing written disclosure of the gainsharing arrangement to patients.

Gainsharing arrangement deficiencies that increase the risk of challenge by the OIG

- failure to identify individual cost-saving actions with specificity;
- lack of a demonstrable direct connection between physician actions and hospital cost savings;
- insufficient safeguards against other actions actually accounting for any “savings”;
- reliance on quality-of-care indicators of questionable validity and statistical significance; and
- lack of independent verification of cost savings, quality-of-care indicators, or other essential aspects of the gainsharing arrangement.

See, e.g., OIG Advisory Opinion Nos. 01-01, 05-01, 05-02, 05-03, 05-04, 05-05, 06-22, 07-22 and 17-09. To be clear, the referenced opinions do not conclude that the proposed gainsharing arrangements at issue therein comply with applicable health care law—to the contrary, the opinions specifically state that these proposed arrangements may violate applicable health care law—but only that the OIG will not seek to impose sanctions on those parties involved in the proposed arrangements. A review of these opinions also makes clear that whether a gainsharing arrangement is likely to withstand OIG scrutiny is a fact-intensive inquiry dependent on the specific structure of the agreement at issue. That said, gainsharing arrangements that are structured to include and address as many of the safeguards, and to avoid as many of the deficiencies, outlined in the referenced OIG advisory opinions, including those recited herein, are not likely to be challenged by the OIG based on (i) the guidance provided by
the OIG in its advisory opinions and (ii) the OIG’s specific representation that gainsharing arrangements “are not an enforcement priority” for the OIG “unless [such an] arrangement lacks sufficient patient and program safeguards” as enunciated in such opinions.

**Conclusion:** Although typical gainsharing arrangements may implicate federal health care laws, they should not be subject to OIG challenge if structured properly.

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