

**7th Annual Illinois Chapter ACC
Practice Management Symposium**

Gainsharing – Is it Still Feasible?

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W. Kenneth Davis, Jr.

Partner

Katten Muchin Rosenman LLP

525 W. Monroe • Chicago, Illinois

312.902.5573

ken.davis@kattenlaw.com

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Introduction

- Preliminary answer to the question
- Civil Monetary Penalty
- Managed care for Medicare and Medicaid beneficiaries
- Anti-Kickback Statute
- OIG Advisory Opinions
 - What they do and don't say
 - Elements generally common to all

Introduction (cont'd)

- Stark Law and Proposed Exception
- State Laws
- Tax Exemption Laws
- Federal Health Care/Insurance Reform
- Conclusion

Preliminary Answer to the Question

- Gainsharing – Is it Still Feasible?
 - Yes, if undertaken with caution and limited expectations about what might be accomplished.
 - And keep an eye on future regulatory developments: it might become easier, with greater potential for impacting the cost of care without a sacrifice in quality.

What is “Gainsharing”?

- “Shared savings” programs
- “Incentive payment” programs (*a.k.a.*, pay for performance or “P4P” and, more recently, pay for quality or “P4Q”)

Civil Monetary Penalty (“CMP”)

- Establishes a civil monetary penalty against any hospital that knowingly makes a payment directly or indirectly to a physician (and any physician who receives such a payment) as an inducement to reduce or limit items or services to Medicare or Medicaid beneficiaries under the physician’s direct care.
- Only applies with respect to Medicare and Medicaid fee-for-service (“FFS”) beneficiaries.
- Does not matter whether the items or services are “medically necessary.”

CMP Within the Context of Gainsharing

- Any arrangements that involve payments by hospitals to physicians for cost savings generated by reductions or limitations of items or services for Medicare or Medicaid FFS beneficiaries implicate the CMP.

Managed Care for Medicare and Medicaid Beneficiaries

- CMP does not apply to Medicare or Medicaid beneficiaries.
- A separate set of laws applies.
- In the interest of time, will not be discussed today.
- However, be aware that:
 - The laws applicable to Medicare and Medicaid managed care beneficiaries are generally easier to satisfy than the CMP, and
 - Unlike the CMP, they only apply to reductions or limitations of “medically necessary” items and services.

Anti-Kickback Statute (“AKS”)

- Makes it a criminal offense knowingly and willfully to offer, pay, solicit, or receive any remuneration to induce or reward referrals of items or services reimbursable by a Federal health care program.
- Has been interpreted as requiring that only one purpose of the remuneration was to obtain money for the referral of services or to induce further referrals.
- AKS amended by health care reform law:
 - With respect to violation of the AKS, a person need not have actual knowledge of the AKS or specific intent to commit a violation of the AKS.

AKS Within the Context of Gainsharing

- Any arrangement involving remuneration paid “to induce or reward referrals of items or services reimbursable by a Federal health care program,” and for which even just one purpose was to induce or reward referrals, would violate the AKS, regardless of whether there was actual knowledge of the AKS or specific intent to commit a violation of the AKS.

AKS Safe Harbors

- Several statutory and regulatory “safe harbors” exist.
- No specific safe harbor for gainsharing.
- Some of the existing safe harbors might be available, but not for arrangements that pay compensation based on a percentage of cost savings.
- Failure to fit within a safe harbor does not by itself mean the AKS has been violated.

OIG Advisory Opinions

- Since 2005, OIG has issued 13 favorable gainsharing opinions and one favorable P4P opinion.
- These represented something of a change in position from a Special Advisory Bulletin on gainsharing that the OIG issued in 1999.

OIG Advisory Opinions: What they do and don't say

- Generally the OIG concludes in each opinion that the gainsharing arrangement could constitute a violation of the CMP, but that . . .
- The OIG would not impose sanctions based on the specific facts and circumstances of the arrangement for which the advisory opinion was requested.
 - In other words, the OIG exercises its discretion to not impose sanctions based on the safeguards put in place as part of the proposed arrangement.
 - The OIG points out that whether the items or services are “medically necessary” is not relevant under the CMP.

OIG Advisory Opinions: What they do and don't say (cont'd)

- As it relates to the AKS, generally the OIG concludes in each opinion that that gainsharing arrangement could constitute a violation of the AKS, if the requisite intent behind the remuneration is to induce or reward referrals, but that . . .
- The OIG would not impose administrative sanctions based on the specific facts and circumstances of the arrangement for which the advisory opinion was requested.

OIG Advisory Opinions: The “Concerns”

- “stinting on patient care”
- “cherry picking healthy patients”
- “steering sicker (and more costly) patients to hospitals that do not offer such [gainsharing] arrangements”
- “payments in exchange for patient referrals”
- “unfair competition (a ‘race to the bottom’) among hospitals offering cost-saving programs to foster physician loyalty and to attract more referrals”

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- Written agreement with each physician group
- Each physician has medical staff privileges
- Program administrator analyzes specific cost-saving opportunities based on historical data for the physicians
 - Recommends ways to increase cost savings
 - Reviews medical appropriateness
- Clearly articulated and easily measured recommendations:
 - Product standardization
 - Product substitution
 - “As needed” use

OIG Advisory Opinions:

“Easier” Elements (cont’d)

- Safeguards against inappropriate reductions or limitations for items or services
 - Normal, full range of items will be available if deemed medically necessary by a physician for a patient
 - Physician determines what is needed for each patient
 - For arrangements involving “as needed” use or recommended substitution, there’s a “floor” underneath which the physician group does not share in savings

OIG Advisory Opinions: “Easier” Elements (cont’d)

- Each physician group is paid 50% of the cost savings
 - Actual current costs against base year costs
 - With a reduction if there has been inappropriate reduction below target
- Cost savings calculated separately
 - For each physician group
 - For each cost saving recommendation
- Patient treatment monitored by a committee
- Patients are provided written disclosure of program

OIG Advisory Opinions: “Tougher” Elements generally common to all

- Most had only 1-year terms, with a few having 3-year terms
- For multi-year programs, cost saving targets are “re-based” at the end of each year
- Hospital makes payment to the physician group, and then any payments to the individual physicians must be on a *per capita* basis

Additional Suggestions Based on OIG Advisory Opinions

- Should have independent and credible clinical evidence that program will not adversely affect quality of patient care
 - Review on a periodic basis
- Should have objective criteria on which to measure potential changes in quality
 - And remember re-basing requirement
- Should have program reviewed by an independent reviewer before going live and, for multi-year programs, at least on an annual basis

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- “If a physician (or an immediate family member of such physician) has a financial relationship with an entity . . . then the physician may not make a referral to the entity for the furnishing of designated health services for which payment otherwise may be made” under Medicare (and to some extent Medicaid) **UNLESS AN EXCEPTION APPLIES.**
- Note that compliance with the Stark Law is waived for gainsharing demo projects.

Stark Law Within the Context of Gainsharing

- Any arrangement involving a financial relationship between a physician and a hospital to which the physician refers Medicare or Medicaid beneficiaries for the provision of inpatient or outpatient services must fit within a Stark Law exception.
- No specific exception for gainsharing.
- Some of the existing exceptions might apply, such as the exceptions for bona fide employment relationships, personal services arrangements, fair market value arrangements, indirect compensation arrangements and services involving academic medical centers.
 - As long as arrangements that pay compensation based on a percentage of cost savings or other formula are sufficiently detailed to be verified, then they should satisfy the “set in advance” requirement.
- Potentially no exception is needed at all.

Stark Law

Within the Context of Gainsharing (cont'd)

- Remember that the AKS has “safe harbors”
 - An arrangement is not necessarily illegal just because you cannot satisfy the elements of a safe harbor.
- Whereas, the Stark Law has “exceptions”
 - A physician cannot under any circumstances refer to a provider of designated health services unless the physician’s financial relationship with the provider fits within an exception.

Proposed Stark Law Exception

- In the CY 2009 Medicare Physician Fee Schedule proposed rule, CMS proposed an exception that would permit remuneration provided by a hospital to physicians on its medical staff under incentive payment and shared savings programs
- In the preamble to the CY 2009 Medicare Physician Fee Schedule final rule, CMS said it was not prepared to finalize the rule and solicited additional comments until February 17, 2009.
- Speculation is strong that the exception will not be finalized any time soon.

Proposed Stark Law Exception (cont'd)

- Specifies conditions that must be satisfied
 - Many conditions mirror those found important by the OIG in the numerous favorable Advisory Opinions it has issued for gainsharing programs
 - Addresses more than traditional gainsharing programs
 - Covers only programs in hospitals
 - Consistent with, but goes beyond OIG opinions to date
 - Extremely narrow application, but indicates willingness to consider expansion
- More detailed information available in handout (contains proposed regulations and preamble discussions)

Proposed Stark Law Exception (cont'd)

- Incentive Payment Programs
 - P4P
 - Quality improvement payments
 - Do not involve cost sharing
- Shared Savings Programs
 - Includes traditional gainsharing
 - “Hybrid models” combining cost sharing measures and quality improvement

Proposed Stark Law Exception (cont'd)

- Solicitation of comments
 - Expansion of proposed exception
 - Beyond hospitals
 - Pass-through payments (similar to recruitment payments)
 - Separate exceptions for incentive payments and shared savings programs
 - Location of exception in § 411.355
 - Arguably, the “stand in the shoes” provision would not apply

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State Laws

- Be aware of state analogues to the CMP, AKS and Stark Law
- Illinois' Health Care Worker Self-Referral Act is more limited in its applicability than the Stark Law to gainsharing arrangements.

Tax Exemption Laws

- Must beware of private inurement, private benefit and excess benefit transactions
- Cannot pay any part of a tax exempt hospital's net earnings to a private individual
 - Query whether a typical gainsharing arrangement does that
 - However, apparently the IRS has indicated in an unpublished ruling that if properly structured, then reasonable compensation to physicians will not jeopardize the hospital's tax exemption

Federal Health Care/Insurance Reform

- Extension of gainsharing demo
- New demo for “accountable care organizations” (“ACOs”)
- Independent Payment Advisory Board (the “IPAB”)

Conclusion

- So, gainsharing is still feasible
- Hew closely to the “guidance” provided by the favorable OIG Advisory Opinions
- Analyze the Stark Law, determine whether the arrangement must fit within an exception and, if so, structure to fit within one of the other exceptions
 - And at all times attempt to fit within as many of the elements of the proposed gainsharing exception as reasonably possible.
- Recognize that the tangible incentives created by the gainsharing arrangement will be short-lived, and will inherently decrease over time
- Keep an eye on what happens with ACOs and what comes out of the IPAB (once it is constituted and begins issuing edicts)



Thank you!

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