

HEALTH CAPITAL

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Topics

Anne P. Sharamitaro, Esq. - Vice President of Research | Kathryn Young - Editor

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Growing Support of Gainsharing Arrangements

In the CY 2009 Proposed Physician Fee Schedule, promulgated on July 7, 2008,¹ the Centers for Medicare and Medicaid Services (CMS) proposed a new exception to the Stark law for certain incentive payment (i.e. Pay for Performance) and shared savings programs, including gainsharing arrangements. *Gainsharing* is defined by CMS to be an arrangement "under which a hospital gives physicians a share of the reduction in the hospital's costs (that is, the hospital's cost savings) attributable in part to the physician's efforts."² Historically, gainsharing arrangements were found to violate the Civil Monetary Penalty Statute and the Anti-Kickback Statute, despite potential cost-saving benefits of well-structured arrangements.³ In 2005, however, the Office of Inspector General (OIG) began to approve gainsharing arrangements in light of their cost-saving and quality improving potential, despite the fact that the basic arrangements themselves were still technical violations of the statutes, reasoning that the potential for fraud was reduced when certain safeguards were present. In those that arrangements that it approved, the OIG looked for three types of safeguards: (1) measures that promote accountability and transparency, (2) adequate quality controls, and (3) controls on payments related to referrals.⁴

Following the lead of the OIG, CMS has now recognized that "successful programs often result in improved quality outcomes or cost savings (or both) for the hospital sponsoring the program."⁵ Since the arrangements involve making payments to physicians whose efforts contribute to these successes, however, the self-referral statute (Stark Law) can often be implicated. The concern is that "improperly designed or implemented programs pose [a high risk of program or patient abuse]," and that "additional risk is posed by [gainsharing arrangements] that reward physicians based on overall cost savings without accountability for specific cost reduction measures."⁶ Potential problems include physicians engaging in stinting, cherry picking, steering, and quicker-sicker discharge behaviors.⁷

Recognizing the potential for abuse, but also the potential to improve quality and cost effectiveness, the proposed exception to the Stark Law for properly structured gainsharing arrangements focuses on three crucial aspects: transparency, quality controls, and safeguards against payments for referrals.⁸ The proposed rule would:



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- (1) Apply to a wide variety of gainsharing program structures, but only those which are implemented by a hospital (though CMS is also soliciting comments on how such arrangements could work when implemented by other DHS entities);
- (2) Protect remuneration only in the form of cash (or cash equivalent) payments made by a hospital, and only payments made to physicians who actually participate in the achievement of the patient care quality measures or cost savings measures that are the subject of the particular program; and,
- (3) Allow payments to be made to participating physicians individually or to physician organizations composed entirely of participating physicians, where participating physicians would receive shared savings payments on a *per capitabasis* (CMS is further considering whether to include under the exception physicians in the "qualified physician organization" who choose not to participate in the gainsharing program); also, the rule would not protect physicians who merely refer patients to the hospital but do not otherwise participate in the program.

Nothing in the proposal would limit or prohibit non-physician practitioners from participating in shared savings programs, as they are not covered by Stark Law.

To be protected under the exception, a shared savings program *"must be a documented [in writing] program that seeks to achieve the improvement of quality of hospital patient care services through changes in physician clinical or administrative practices or actual cost savings for the hospital resulting from the reduction of waste or change in physician clinical or administrative practices, without an adverse affect on or diminution in the quality of hospital patient care services."*⁹ Additionally, the program must:

- (1) Include patient care quality or cost savings measures (or both) supported by objective, independent medical evidence indicating that the measures would not adversely affect patient care, and the measures must be listed in CMS' Specifications Manual for National Hospital Quality Measures;
- (2) Employ cost savings measures which use an objective methodology, are verifiable, supported by credible medical evidence indicating that the measures would not adversely affect patient care, be individually traced and reasonably relate to the services provided;
- (3) Be reviewed prior to implementation and at least annually thereafter to ascertain the program's impact on patient quality of care, and that such reviews must be independent medical reviews conducted by a person or organization with relevant clinical expertise;
- (4) Provide for immediate and corrective action (up to and including termination of the program) in the event a review reveals an adverse impact on quality;
- (5) Limit participation in the program to those physicians who are members of the hospitals' medical staff at the commencement of the program, and that participating physicians participate in "pools" of five or more (formed at the commencement of the program) among whom the aggregate cost savings that result from the efforts of the physicians in the "pool" be shared on a *per capitabasis*;
- (6) Support the distribution of shared savings program payments with written documentation;
- (7) Not determine eligibility for physician participation in the program based on the volume or value of referrals or other business generated between the physician the hospital; and,
- (8) Not limit the discretion of physicians to make medically appropriate decisions for their patients, nor limit the availability of, or access of physicians to, any specific item, supply or device that is linked through objective evidence to improved outcomes and which is clinically appropriate and which was available at the commencement of the program.

Payments made under shared savings programs:

- (1) Must be distributed on a *per capitabasis*;
- (2) May not include any amount that takes into account the provision a greater volume of Federal health care patient procedures or services than the volume provided by the participating physician or qualified physician organization during the period of the same length immediately preceding the commencement of the program as that covered by the payment; and,
- (3) Must be limited in duration (no shorter than 1 year and no longer than 3 years) and amount.

There are two potential ways to limit amount of payments, one or both of which may be adopted:

- (1) Limits based on set percentages of cost savings available to hospital through program; and,
- (2) Limits to address the risk that physicians will continue to receive financial rewards for already implemented changes.

Also, arrangements in which physicians receive payments for actions taken that result in a reduction below a predetermined target based on objective historical and clinical measures will not be protected.

Additionally, CMS is considering whether to extend the exception for "*qualified physician organizations*" to multi-specialty physician practices composed of both participating and non-participating physicians. To promote transparency, hospitals and participating physicians will be required to disclose the nature of the program to patients affected by it. Requirements related to transparency include:

- (1) Tracking of the ages and payors of patient population treated by participating physicians (to prevent cherry picking, etc);
- (2) Limiting physician payment to only that which is related to the physician's own efforts, combined with the efforts of the other physicians in their pool, on a per capita basis;
- (3) Applying all measures uniformly to all patients, including Medicare beneficiaries (and not applying them disproportionately to Federal health care program beneficiaries), with the possibility of having the program audited; and,
- (4) Prohibiting the counseling or promotion of a business arrangement or other activity that violates any Federal or State law.¹⁰

During the open comment period which ended on August 29, 2008, CMS received an overwhelming amount of support for the exception from physician groups. Additional support came from the American Medical Association, which recognized the potential from gainsharing arrangements to improve health care delivery systems, but also advised CMS to be cautious due to the potential of shared savings programs to implicate fraud and abuse laws.¹¹ Congressman Pete Stark (D-CA) disagreed with a broad exception to the self-referral laws he authored, arguing that gainsharing programs run counter to the goals of self-referral laws because they "*create financial incentives for physicians to refer patients to particular hospitals, not necessarily because it is in the best interest of the patients, but because physicians stand to gain financially from doing so.*"¹² Rep. Stark suggests that CMS should wait to make changes to the self-referral law until after the completion of three gainsharing demonstration projects which have been authorized by Congress. Whether or not CMS listens to his suggestions, however, will be revealed on November 1, 2008, when the Final Rule is set to be issued.

¹73 Fed. Reg. 38502 (July 7, 2008).

²73 Fed. Reg. 23692 (April 30, 2008).

³73 Fed. Reg. 23692 (April 30, 2008).

⁴73 Fed. Reg. 23693 (April 30, 2008).

⁵73 Fed. Reg. 38548 (July 7, 2008).

⁶73 Fed. Reg. 38550 (July 7, 2008).

⁷73 Fed. Reg. 38550 (July 7, 2008).

⁸73 Fed. Reg. 38552 (July 7, 2008).

⁹73 Fed. Reg. 38552 (July 7, 2008).

¹⁰Everything from 73 Fed. Reg. 38552-58 (July 7, 2008).

¹¹ "Physicians Support Gainsharing Exemption; Stark Says Proposal Risks Fraud, Abuse," BNA Health Law Reporter, Sept. 11, 2008, pg 1198.

¹² "Physicians Support Gainsharing Exemption; Stark Says Proposal Risks Fraud, Abuse," BNA Health Law Reporter, Sept. 11, 2008, pg 1198.



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Robert James Cimasi, MHA, ASA, FRICS, MCBA, AVA, CM&AA, serves as President of **HEALTH CAPITAL CONSULTANTS (HCC)**, a nationally recognized healthcare financial and economic consulting firm headquartered in St. Louis, MO, serving clients in 49 states since 1993. Mr. Cimasi has over thirty years of experience in serving clients, with a professional focus on the financial and economic aspects of healthcare service sector entities including: valuation consulting and capital formation services; healthcare industry transactions including joint ventures, mergers, acquisitions, and divestitures; litigation support & expert testimony; and, certificate-of-need and other regulatory and policy planning consulting.

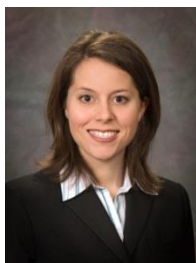
Mr. Cimasi holds a Masters in Health Administration from the University of Maryland, as well as several professional designations: Accredited Senior Appraiser (ASA – American Society of Appraisers); Fellow Royal Intuition of Chartered Surveyors (FRICS – Royal Institute of Chartered Surveyors); Master Certified Business Appraiser (MCBA – Institute of Business Appraisers); Accredited Valuation Analyst (AVA – National Association of Certified Valuators and Analysts); and, Certified Merger & Acquisition Advisor (CM&AA – Alliance of Merger & Acquisition Advisors). He has served as an expert witness on cases in numerous courts, and has provided testimony before federal and state legislative committees. He is a nationally known speaker on healthcare industry topics, the author of several books, the latest of which include: *“The U.S. Healthcare Certificate of Need Sourcebook”* [2005 - Beard Books], *“An Exciting Insight into the Healthcare Industry and Medical Practice Valuation”* [2002 – AICPA], and *“A Guide to Consulting Services for Emerging Healthcare Organizations”* [1999 John Wiley and Sons].

Mr. Cimasi is the author of numerous additional chapters in anthologies; books, and legal treatises; published articles in peer reviewed and industry trade journals; research papers and case studies; and, is often quoted by healthcare industry press. In 2006, Mr. Cimasi was honored with the prestigious *“Shannon Pratt Award in Business Valuation”* conferred by the Institute of Business Appraisers. Mr. Cimasi serves on the Editorial Board of the Business Appraisals Practice of the Institute of Business Appraisers, of which he is a member of the College of Fellows.



Todd A. Zigrang, MBA, MHA, ASA, FACHE, is the Senior Vice President of **HEALTH CAPITAL CONSULTANTS (HCC)**, where he focuses on the areas valuation and financial analysis for hospitals and other healthcare enterprises. Mr. Zigrang has significant physician integration and financial analysis experience, and has participated in the development of a physician-owned multi-specialty MSO and networks involving a wide range of specialties; physician-owned hospitals, as well as several limited liability companies for the purpose of acquiring acute care and specialty hospitals, ASCs and other ancillary facilities; participated in the evaluation and negotiation of managed care contracts, performed and assisted in the valuation of various healthcare entities and related litigation support engagements; created pro-forma financials; written business plans; conducted a range of industry research; completed due diligence practice analysis; overseen the selection process for vendors, contractors, and architects; and, worked on the arrangement of financing.

Mr. Zigrang holds a Master of Science in Health Administration and a Masters in Business Administration from the University of Missouri at Columbia, and is a Fellow of the American College of Healthcare Executives. He has co-authored *“Research and Financial Benchmarking in the Healthcare Industry”* (STP Financial Management) and *“Healthcare Industry Research and its Application in Financial Consulting”* (Aspen Publishers). He has additionally taught before the Institute of Business Appraisers and CPA Leadership Institute, and has presented healthcare industry valuation related research papers before the Healthcare Financial Management Association; the National CPA Health Care Adviser's Association; Association for Corporate Growth; Infocast Executive Education Series; the St. Louis Business Valuation Roundtable; and, Physician Hospitals of America.



Anne P. Sharamitaro, Esq., is the Vice President of **HEALTH CAPITAL CONSULTANTS (HCC)**, where she focuses on the areas of Certificate of Need (CON); regulatory compliance, managed care, and antitrust consulting. Ms. Sharamitaro is a member of the Missouri Bar and holds a J.D. and Health Law Certificate from Saint Louis University School of Law, where she served as an editor for the Journal of Health Law, published by the American Health Lawyers Association. She has presented healthcare industry related research papers before Physician Hospitals of America and the National Association of Certified Valuation Analysts and co-authored chapters in *“Healthcare Organizations: Financial Management Strategies,”* published in 2008.