

Gainsharing Arrangements: Legal and Business Considerations

Complying With Legal and Regulatory Requirements When Structuring Arrangements

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Today's faculty features:

Paul W. Pitts, Partner, **Reed Smith**, San Francisco

Curtis H. Bernstein, CPA/ABV, ASA, CVA, MBA, Director, **Sinaiko Healthcare Consulting**, Denver

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Curtis H. Bernstein, CPA/ABV, ASA, CVA, MBA, Sinaiko

Paul W. Pitts, Esq., Reed Smith, LLP



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Agenda

- Definition and description of gainsharing arrangements
- Gainsharing models and demonstrations
- Legal considerations when structuring arrangements
- Review of FMV considerations and structural guidance
- Impact of health care reform and alternative compensation models

Definition and Description of Gainsharing Arrangements

Background

- Gainsharing is a contractual arrangement that sets up a formal reward system in which participants share in cost savings resulting directly from either productivity gains or increased efficiency. Thus physicians participating in a gainsharing arrangement will have a financial stake in controlling hospital costs.
- Under the Medicare Fee-for-Service program, hospitals and physicians are paid separately for care provided in hospitals under Part A and Part B, respectively, which adds to the misalignment between the incentives facing hospitals and those facing physicians.
- There are no direct financial gains to physicians, who often control the use of supplies and selection of devices which are paid for by the hospital, for providing more efficient care and decreasing hospital costs.

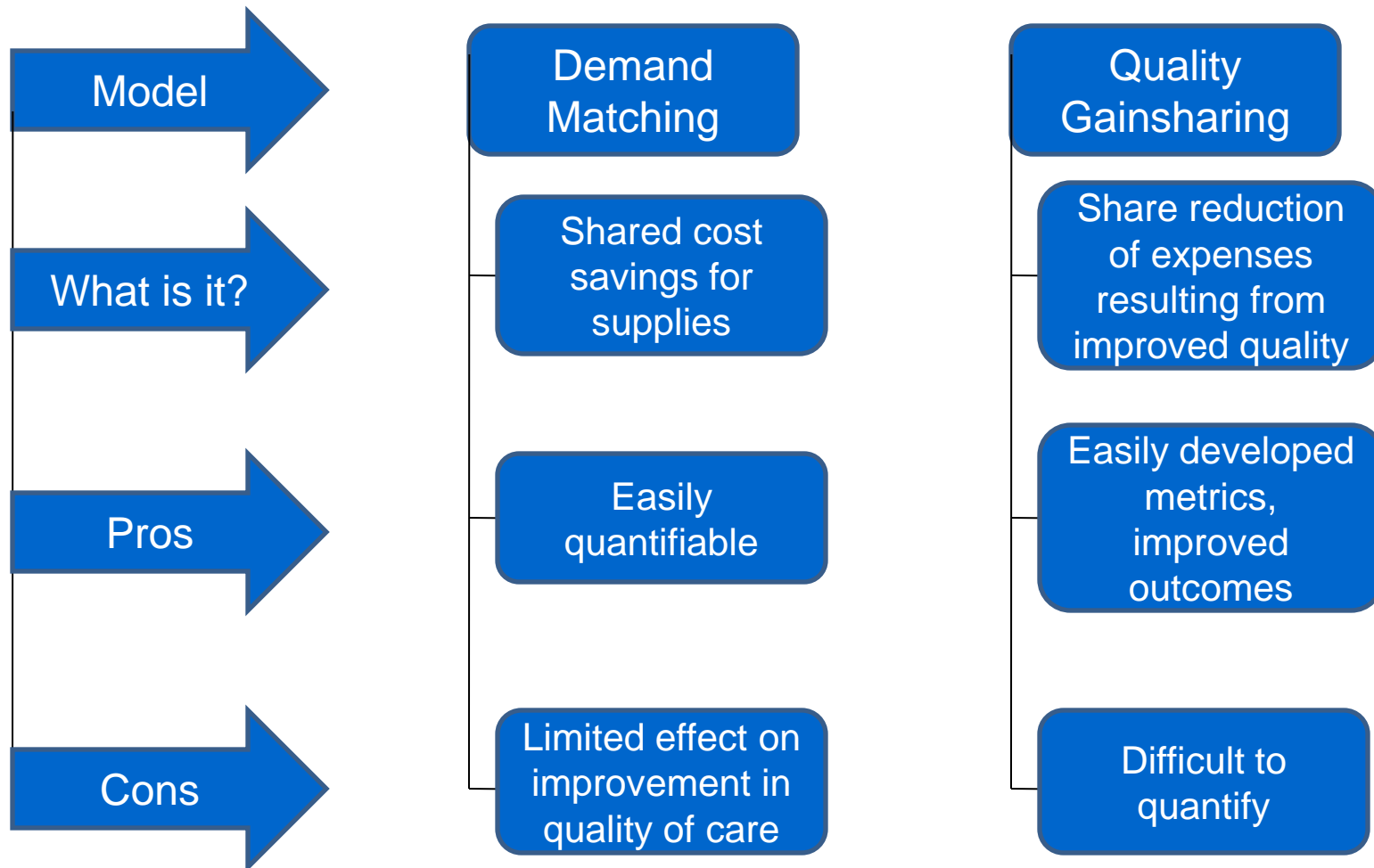
Goals

- Main Goal: To create collaboration and integration among payors, health systems, and physicians
- Sub Goal 1: Improve communication and dialog between the parties
- Sub Goal 2: Increase willingness of all parties to participate in improved healthcare at a lower cost

“Better Health, Better Care, Lower Cost”

- *Dr. Don Berwick, Administrator, CMS*

Gainsharing Models



Business Considerations

- How is healthcare provided at a lower cost while maintaining a high standard of care?
 - Reduction in direct costs
 - ◆ Supplies and staffing costs
 - Better quality care resulting in lower utilization of current system (e.g., LOS) and reduced readmissions
 - ◆ More on-time starts and faster room turnover
 - ◆ Lower infection rates
 - ◆ Better documentation (EMR, coding)
 - ◆ Meeting national quality benchmark standards (e.g., AMI core measures)
 - ◆ Reduce drug adverse events
 - ◆ Reduce duplicate/marginal tests

Developing a Gainsharing Arrangement – Business Considerations

- **Service area covered**
 - Cardiology, orthopedic surgery, anesthesiology
 - Full surgical care
- **Physician participation**
 - Full participation may not occur at outset
 - Services provided on a group or individual basis
- **Setting metrics**
 - Developed independently or in conjunction with participating physicians
 - Goals are definable and measurable
 - ♦ Identifying comparable systems and accessing data
- **Measuring success**
 - Tools in-place to successfully track on a perpetual basis
- **Compensation once measures are achieved**
 - Compensation based on predefined goals (e.g., current cost per encounter) and allocation method (e.g., 50% of cost savings)
 - Incentive is weighted toward improvement at beginning and then moves toward performance relative to peer group
 - ♦ Weighting can be maintained to emphasize improvement

Gainsharing Models and Demonstrations

Demonstration Projects

- Initially performed by Medicare in the early 1990s under a Coronary Artery Bypass Graft Demonstration project.
 - Five year project
 - Saved Medicare \$42 million on patients treated in demonstration hospitals
 - ◆ 10% from expected spending

New Jersey Demonstration Project #1

- Application submitted in 2001
- Eight hospitals covering all of the All Patient Refined (APR) DRGs
 - Maximum pools of Part A hospital savings for each APR-DRG treated in the hospital to be shared with the medical staff
 - Limited to 25% of total Part B payments received by the physician
 - Pools converted to a per-discharge cost for each APR-DRG, based on average cost of the lowest 90% of cases.
 - Responsible physicians identified for each hospitalization and they became eligible for bonuses if the average cost of their cases did not exceed the mean cost of the 90 percent baseline group of cases
- Terminated in its early implementation period

New Jersey Demonstration #2

- CMS approved 12 New Jersey hospitals and their participating physicians to test gainsharing
 - Three year program
 - Offers physicians financial incentive to work with hospitals to lower costs
 - ◆ Includes stringent quality controls to protect patient
 - Designed around three cost areas: efficiency strategies, quality standards, and financial incentives
- In second year of program

Medicare Demonstration Project

- Began October 1, 2008
- Two sites: Beth Israel Medical Center in New York City and Charleston Area Medical Center in Charleston, West Virginia
 - BIMC continued participation through September 30, 2011 and CAMC elected to end participation as of December 31, 2009
- CAMC demonstration was limited to cardiac DRGs

March 28, 2011 Report to Congress

- Demonstration project is Secretary's response to requirements under Section 5007(e)(3) of the Deficit Reduction Act of 2005 as amended by Section 3027 of the Affordable Care Act
 - Began October 1, 2008
 - Test and evaluate methods 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 performance with sharing of remuneration

Beth Israel Medical Center

- BIMC included most medical and surgical DRGs in their demonstration.
- Enrollment was voluntary for physicians.
- A pool of bonus funds was prospectively estimated from hospital savings on the basis of the following factors:
 - Total available incentive is a percentage of the best practice variance for each APRDRG.
 - Best practice variance = (actual spending - best practice cost)
 - Best practice cost = spending of the lowest-cost 25th percentile
- If no hospital savings were realized, no bonus are allocated to participating physicians. The total available incentive was defined as:
 - *total available incentive = X% x (actual spending - 25th percentile spending)*
 - where X% = the percentage of spending (X%) to allot to the incentive pool
- An incentive pool calculation was made for every APR-DRG and then summed across all APR-DRGs.

BIMC Demonstration Project

- Each patient is assigned to one practitioner who takes financial responsibility for the care of the patient
 - For medical patients, the responsible physician is the attending physician
 - For surgical patients, the responsible physician is the surgeon
- Bonus is calculated as a percentage of the maximum performance incentive, based on performance
- Gainsharing payment is capped at 25% of the physician's affiliated Part B reimbursement
- Standards to be eligible for bonus:
 - Overall admission rates within seven days must not increase
 - Adverse events and malpractice experience must not increase
 - Physicians must attain standards set for selected quality measures and administrative requirements
 - Increased post-acute care use by participating physicians will be reviewed for appropriateness

BIMC Results Through Report

- Staff estimates savings as a result of reduction in length of stay resulting from:
 - Use of electronic health records
 - More efficient use of consults
 - Improved communication and management of imaging choices
 - Streamlining evidence based care through implementation of protocols
 - Implementation of interdisciplinary rounds
 - More efficient operating room management
 - More appropriate use of intensive care unit beds

Quality Assurances

- *BIMC* proposed a range of physician quality standards, which, if not met by individual physicians, would make them ineligible for the gainsharing bonus. These overall standards are as follows:
 - Overall readmission rate within 7 days must not increase
 - Adverse events and malpractice experience must not increase.
 - Physicians must comply with available quality measures.
- Complete evaluation results will be available through a report to Congress that is due in March 2013 and a final report to CMS that is due in December 2014

Charleston Area Medical Center

- Focused on cardiac DRGs.
- CAMC anticipated that internal savings would be generated by the following initiatives:
 - examination of practice differences,
 - utilization of laboratory resources as needed,
 - evaluation of product usage,
 - increase in patient flow, and
 - negotiation of lower prices for medical devices and supplies
- The CAMC proposal did not propose Medicare savings and expects costs savings to be internal to the hospital.
- CAMC proposed to measure physician care provided on several factors to ensure that quality of patient care remained the same. Worse performance on any of the following standards for an individual physician would make him or her ineligible to receive the gainsharing bonus:
 - Readmission rates
 - Repeat procedures
 - Patient outcomes
 - Major events during procedures
 - Antithrombotic usage

CAMC Results Through Report

- Estimated savings are:
 - Surgical costs reductions made via negotiated rates on devices and implants
 - Reduced physician variation in practice patterns
 - Reduction in infections, complications, and readmissions for cardiac and orthopedic procedures

IHA Bundled Episode Payment and Gainsharing Demonstration

- Test the feasibility of bundling payments to hospitals, surgeons, consulting physicians and ancillary providers for selected inpatient surgical procedures
 - Limited to California
 - Funded by the Agency for Healthcare Research and Quality
 - Expands the current pilot that has focused on commercial PPO patients receiving total hip and total knee replacement in Los Angeles and Orange counties.
- In 2011, IHA added additional procedures including diagnostic cardiac catheterization, cardiac angioplasty with stents, and knee arthroscopy with meniscectomy

Legal Considerations when Structuring Arrangements

Gainsharing in Medicare

Gainsharing has had a slow start in federally funded health care due in part to certain fraud and abuse laws, including the Civil Monetary Penalty Law (CMPL), the federal anti-kickback statute and, to a lesser extent, the federal physician self-referral law (“Stark law”).

Interest in gainsharing arrangements grew after the OIG issued more favorable Advisory Opinions beginning in 2005. Cost pressure and interest in integrated models has spurred more recent interest.

Civil Monetary Penalty Law (CMP)

- The CMP prohibits hospitals and physicians from knowingly making or receiving a payment, either directly or indirectly, to a physician as an incentive to reduce or limit services to Medicare or Medicaid fee-for-service beneficiaries.
- A gainsharing model that aimed to save money by having physicians negotiate lower prices for supplies with one manufacturer in exchange for reducing or eliminating the options from other manufacturers could violate CMP if a reduction in choices of supplies could lower the quality of care to beneficiaries
- Each violation is subject to a \$2,000 fine, up to \$100,000

OIG's Implementation of the CMP Statute

- No regulations implementing statute. A proposed rule issued but never adopted.
- July 1999 Special Advisory Bulletin is the primary source of guidance.
- OIG refused to issue advisory opinions on proposed gainsharing arrangements until 2001 and has issued 15 favorable opinions to date, including 4 in 2008 and 1 in 2009.
- OIG first granted approval to gainsharing programs lasting more than one year in 2008. The limited duration of gainsharing programs was seen as a safeguard against potential patient harm.
- The OIG stated that gainsharing arrangements “may offer significant benefits where there is no adverse impact on the quality of care received by patients” and that the CMP is violated even if the hospital's payment to the physician “need not be tied to an actual diminution in care, so long as the hospital knows that the payment may influence the physician to reduce or limit services.”

Anti-Kickback Statute (AKS)

- The AKS prohibits hospitals from knowingly and willfully paying, soliciting, or receiving any remuneration to induce referrals of items or services provided under any federally funded program.
- A gainsharing model in which hospitals pay physicians for cost savings from changes in physician behavior (such as ordering of tests or treatments) for Medicare beneficiaries could violate AKS.
- AKS is a criminal statute, whereas CMP is a civil statute.
- A violation of AKS could result in up to 5 years in prison, a \$25,000 fine, and mandatory exclusion from participation in Medicare or Medicaid.

Why Is the OIG Concerned with Programs Focused on Reducing Costs?

The OIG's concerns include, but are not limited to, the following:

1. stinting on patient care;
2. “cherry picking” healthy patients and steering sicker (and more costly) patients to hospitals that do not offer such arrangements;
3. payments in exchange for patient referrals; and
4. unfair competition (a “race to the bottom”) among hospitals offering cost-savings programs to foster physician loyalty and to attract more referrals.

Threshold Inquiry under CMP Statute

“A threshold inquiry is whether the Arrangement induces physicians to reduce or limit items or services.”

If so, does the arrangement have sufficient safeguards so that the OIG would not seek sanctions under sections 1128A(b)(1)-(2) of the Act?

See OIG Advisory Opinion No. 09-06.

CMP Statute Gainsharing Advisory Opinions

- **OIG typically concludes that some or all aspects of the arrangement would constitute an improper payment under the CMP statute but that it would not seek sanctions.**
- **OIG has provided favorable opinions to incentive plans for verifiable cost-savings from standardizing supplies or reducing administrative expenses as long as quality is not adversely affected and volume/case mix changes are not rewarded.**
- **Product substitutions are found to implicate the CMP Statute.**

OIG Opinions

OIG Opinion	Physicians eligible to participate	Source of savings	Distribution of savings
05-01	Cardiac surgeons	<ul style="list-style-type: none"> ▪ opening surgical supplies (trays and similar as needed) ▪ blood cross-matching only as needed ▪ substitution, in whole or in part, of less costly items ▪ product standardization for certain cardiac devices 	50% of savings to the surgical group, who will then distribute to individual physicians
05-02	Multiple cardiology groups	<ul style="list-style-type: none"> ▪ standardization of cardiac catheterization devices ▪ use of certain vascular devices as needed 	50% of savings attributable to each specific group
05-03	Cardiac surgeons	<ul style="list-style-type: none"> ▪ opening surgical supplies (trays and similar) as needed ▪ blood cross-matching only as needed 	50% of savings attributable to the group
05-04	Five cardiology groups	<ul style="list-style-type: none"> ▪ standardization of cardiac catheterization devices ▪ use of certain vascular devices as needed 	50% of savings attributable to each specific group

OIG Opinions (Continued)

OIG Opinion	Physicians eligible to participate	Source of savings	Distribution of savings
05-05	Cardiology Group	<ul style="list-style-type: none"> ▪ standardization of cardiac catheterization devices ▪ use of certain vascular devices as needed 	50% of savings from curbing use or waste in current cardiac catheter lab practice
05-06	Cardiac Surgery Group	<ul style="list-style-type: none"> ▪ opening surgical supplies (trays and similar as needed) ▪ use of certain vascular devices as needed ▪ substitution, in whole or in part, of less costly items ▪ product standardization for certain cardiac devices 	50% of savings
06-22	Cardiac Surgery Group	<ul style="list-style-type: none"> ▪ opening surgical supplies (trays and similar) as needed ▪ substitution, in whole or in part, of less costly items ▪ product standardization for certain cardiac devices 	50% of cost savings

OIG Opinions (Continued)

OIG Opinion	Physicians eligible to participate	Source of savings	Distribution of savings
07-21	Cardiac Surgery Group	<ul style="list-style-type: none"> ▪ opening disposable cell saver components only when excessive bleeding ▪ opening surgical supplies (trays and similar) as needed ▪ substitution, in whole or in part, of less costly items ▪ product standardization for certain cardiac devices 	50% of cost savings
07-22	Anesthesiology	<ul style="list-style-type: none"> ▪ limit the use of a specific drug and a device used to monitor patients' brain function to only as needed ▪ substitution, in whole or in part, of less costly items ▪ product standardization for certain fluid warming hot lines used in cardiac surgical procedures 	50% of cost savings
08-09	Orthopedic surgery groups Neurosurgery group	<ul style="list-style-type: none"> ▪ limiting use of bone morphogenetic protein to as needed ▪ standardize the use of certain spine fusion devices and supplies where medically appropriate 	No more than 50% of savings

OIG Opinions (Continued)

OIG Opinion	Physicians eligible to participate	Source of savings	Distribution of savings
08-15	Two cardiology groups	<ul style="list-style-type: none"> ▪ standardization of cardiac catheterization devices ▪ use of certain vascular devices as needed ▪ substitution for less costly antithrombotic medications 	Share of savings for three years
08-21.2	Four cardiology groups One radiology group	<ul style="list-style-type: none"> ▪ standardization of cardiac catheterization devices ▪ Use of certain vascular devices as needed ▪ Substitution for less costly contrast agents and antithrombotic medications 	Share of savings for two years
09-06	Cardiology group Vascular surgical group Interventional radiology group	<ul style="list-style-type: none"> ▪ Standardize the types of cardiac catheterization devices and supplies (stent, balloons, interventional guidewires and catheters, vascular closure devices, diagnostic devices, pacemakers, and defibrillators) 	50% of savings, separately for each group

Factors Important to the OIG

- Commercially reasonable/FMV compensation based on independent appraisal
- Cost savings tied to specific protocol/cost shavings activity. Must be measured on basis of existing volume (no incentive to change volume)
- Ensure quality is measured and maintained
- Transparency and disclosure to patients
- Monitor change in case mix (protect against steering away more costly patients)

Gainsharing Distribution to Physicians

- Each patient is assigned to one practitioner who takes financial responsibility for the care of the patient.
- Gainsharing payments are capped according to CMS policy at 25% of the physician's affiliated Part B reimbursements.

Selection of Performance Measures

- Shared savings measures vs. quality measures
 - Shared savings measures may provide more flexibility in program design (quality measures may need to be listed in CMS Specifications Manual for National Hospital Quality Measures)
 - Shared savings may create more uncertainty under CMP Statute
 - May also have limits with shared savings measures (e.g., CMS proposal to limit payment to 50% of savings over base year, and/or restrictions on amount of savings paid per year in multi-year contracts)
 - Physicians may gravitate to shared savings over using quality measures

Selection of Performance Measures

- Performance measures must be supported by "credible medical evidence"
- Payment may not be based on reduction in hospital stays
- Role of third-party payor important (e.g., payor may establish quality incentive under hospital payor agreement that cannot be achieved without assistance of medical staff)
- Measures must not be a sham or reflect payments for referrals

Physician Choice of Treatment

- Program may not limit physicians' ability to make medically appropriate patient decisions.
- Program may condition payment on a certain physician choice, but hospital must allow access to same supplies and devices as available before.
- Physicians must be able to use new technology that meets same FDA and Medicare coverage decisions as items/supplies included in program.
- Physicians should not receive payments involving a product with respect to which the physician has an investment interest or consulting contract.
- Disclose any conflicts-of-interest.

Selection of Physicians

- May not select physicians based on the volume/value of referrals
- Potential physician concerns over selection process:
 - May limit participation to a specialty or department (but if all will participate, some physicians may benefit from efforts of others)
- Hospitals should not use program to induce physicians from other hospitals to join staff - must be a member of medical staff at onset of program

Physician Self-Referral Law (Stark):

- The Stark Law prohibits physicians from referring Medicare and Medicaid patients to entities with which the physician has a financial relationship unless the activity falls within a regulatory exception.
- Most gainsharing programs include a financial relationship between the hospital and physicians to which physicians are referring patients for inpatient or outpatient hospital services.
- As a result, the gainsharing program must meet a Stark exception.
- Stark is a strict liability statute and does not require intent for a violation.
- A violation can result in up to a \$15,000 fine, damages up to three times the fine, and exclusion from participating in Medicare and Medicaid.

Proposed Stark Exception for Incentive Payments and Shared Savings Plans

- CMS proposed new exception for incentive payments and shared savings plans.
- The proposed exception would permit remuneration by a hospital to physicians on its medical staff
- See 73 Fed. Reg. 38548 (July 7, 2008); see also 73 Fed. Reg. 69793 (Nov. 19, 2008)

Proposed Stark Exception

- 16 standards
- Similarities to factors found in favorable OIG advisory opinions.
- Quality measures must be listed on CMS' Specification Manual for National Hospital Quality Measures
- Applies to “cost savings resulting from reduction in waste or changes in physician or clinical practices”
- Performance measures to be judged against baseline historic and clinical data

Proposed Stark Exception

- At least 5 physicians must participate in each performance measure – service line may have less than 5 physicians.
- Independent medical review prior to commencement and annually thereafter
- Physicians must have access to same selection of items as before commencement of program – implications of standardization initiatives – ties between doctors and pharma or device companies could impact clinical decisions
- Targets developed by comparing to national/regional performance norms – may not be available benchmarks

Proposed Stark Exception

- Term of no less than 1 nor more than 3 years
- Re-basing – cannot periodically rebase standards or pay for “maintenance” of quality/efficiency gains
- Remuneration set in advance and cannot change during term – no opportunity to set new performance standards and reappraise during multi-year agreement

Proposed Stark Exception

- Proposed exception not finalized
- The public was critical of the proposed exception as not guarding against program or patient abuse. The industry criticized the proposal as unhelpful.
- The 2009 MPFS Final Rule reopened the comment period and solicited comments on specific areas.

Existing Stark Exceptions

- Can existing exceptions protect a gainsharing arrangement?
- The PSA and FMV exceptions contain requirement that compensation be FMV and “set in advance” and not vary with volume/value of referrals
- “Set in advance” permits a specific formula that is set in advance, can be objectively verified and does not vary with volume/value of business generated (e.g., fixed payment for objective quality metrics)
- Percentage compensation arrangements can “be set in advance”

Special Considerations for Risk-Based Contracts

- Physician incentive arrangements related to Medicare risk-based managed care contracts, similar Medicaid contracts, and Medicare Advantage plans are subject to CMS regulation under sections 1876(i)(8), 1903(m)(2)(A)(x), and 1852(j)(4) of the Act (respectively).
- For further guidance on risk-based contracts see the OIG letter regarding hospital-physician incentive plans for Medicare and Medicaid beneficiaries enrolled in managed care plans (dated August 19, 1999), available on the OIG's website.
- See also 42 C.F.R. § 417.479 (Medicare HMOs or competitive medical plans); 42 C.F.R. § 422.208 (Medicare Advantage plans); 42 C.F.R. § 438.6 (Medicaid risk plans).

Tax-Exempt Considerations

No inurement, private benefit or excess benefits

- Reasonable compensation (base fee, each component of bonus fee, and in aggregate)
 - ◆ Not based on service-line net earnings
 - ◆ Members of medical staff are disqualified persons.
 - ◆ If co-manager overpaid, then excess benefit is awarded.
 - ◆ Tax first imposed on recipient (physicians) of 120% but up to 200% if not paid promptly.

See Rev. Rul. 69-383 (the arrangement entered into between hospital and radiologist does not constitute inurement of net earnings to a private individual within the meaning of section 1.501(c)(3)-1(c)(2) of the regulations).

Tax-Exempt Considerations

May achieve a rebuttable presumption of reasonable compensation under intermediate sanctions regulations

- ◆ Board/committee obtains appropriate comparability data.
- ◆ Members of Board/committee have no personal interest in the arrangement.
- ◆ Board/committee approves the arrangement in advance w/o participation by any person with a conflict of interest.
- ◆ Document basis for decision, approval date, members present, comparability data, and members recused.
- ◆ Board reviews/approves documentation as being reasonable, accurate and complete
- ◆ Shifts burden to IRS to disprove reasonableness.

See IRC § 4958; 26 C.F.R. 53.4958 – IT *et. seq.*

Tax-Exempt Considerations

Rev. Proc. 97-13 durational limits may be applicable if agreement involves private use of tax-exempt bond-financed space

Review of FMV Considerations and Structural Guidance

FMV Definition

- *Fair market value* means the value in arm's-length transactions, consistent with the general market value.
- “General market value” means the price that an asset would bring as the result of *bona fide* bargaining between **well-informed buyers and sellers who are not otherwise in a position to generate business for the other party**, or the compensation that would be included in a service agreement as the result of *bona fide* bargaining between well-informed parties to the agreement who are not otherwise in a position to generate business for the other party, on the date of acquisition of the asset or at the time of the service agreement.

FMV Definition

- Usually, the fair market price is the price at which *bona fide* sales have been consummated for assets of like type, quality, and quantity in a particular market at the time of acquisition, or the compensation that has been included in *bona fide* service agreements with comparable terms at the time of the agreement, where the price or **compensation has not been determined in any manner that takes into account the volume or value of anticipated or actual referrals.**
- With respect to rentals and leases described in § 411.357(a), (b), and (l) (as to equipment leases only), “fair market value” means the value of rental property for general commercial purposes (not taking into account its intended use). In the case of a lease of space, this value may not be adjusted to reflect the additional value the prospective lessee or lessor would attribute to the proximity or convenience to the lessor when the lessor is a potential source of patient referrals to the lessee. For purposes of this definition, a rental payment does not take into account intended use if it takes into account costs incurred by the lessor in developing or upgrading the property or maintaining the property or its improvements.

FMV Considerations

- Comparison to appropriate base of comparable hospitals
- Appropriately calculating cost savings per encounter
- Assigning to a single physicians to avoid double payment

Cost Approach

- Time spent by physicians on various tasks necessary to improve quality of care and reduce cost of care, including but not limited to:
 - Researching medical device and pharmaceutical use, cost, and alternatives
 - Educating patients and staff on medical devices and pharmaceuticals
 - Reviewing with patients procedure and post procedure care (including patient follow up)
 - Developing evidence based protocols / pathways
 - Creating / Reviewing / Approving dashboard quality and strategic benchmarks
 - Reviewing complications and developing strategies to improve

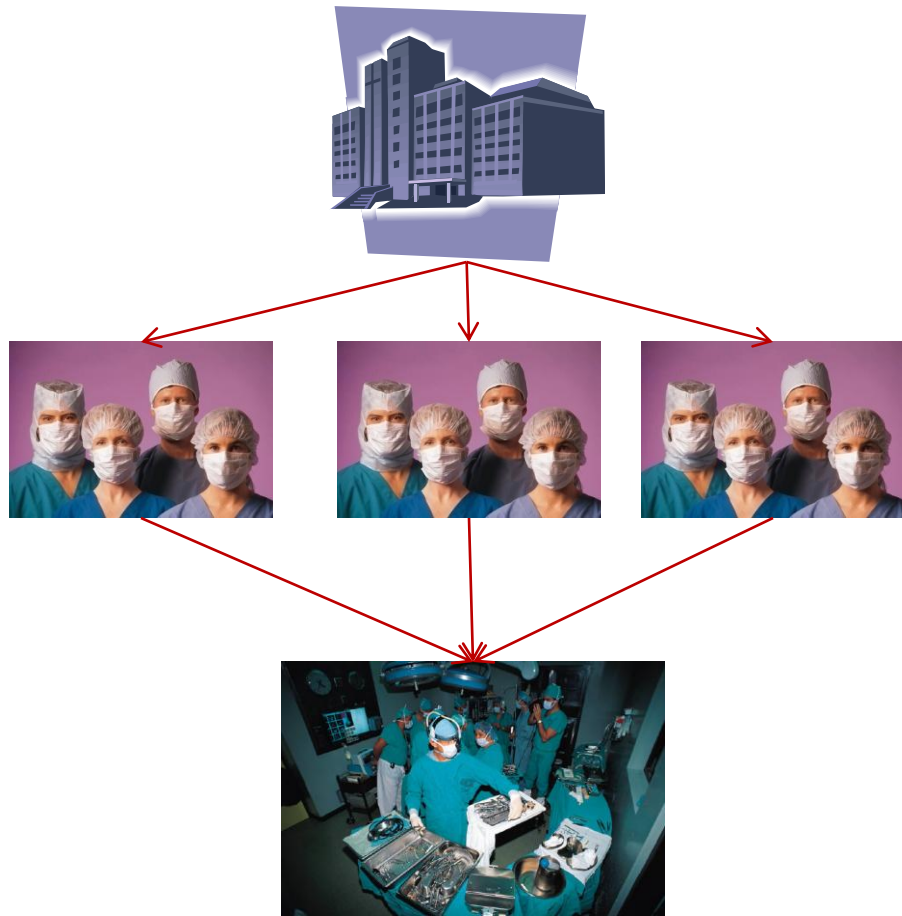
FMV Considerations

- Relationship to all other agreements with a physician:
 - ◆ Clinical staffing agreement
 - ◆ Call coverage agreements
 - ◆ Medical directorship agreements
 - ◆ Department/division chair agreements
 - ◆ Physician lease/lease-back agreements
- Allocation of value among participating physicians within a medical group
- Engagement of valuator by counsel to obtain benefit of attorney-client privilege to facilitate discussion of preliminary issues without waiving privilege

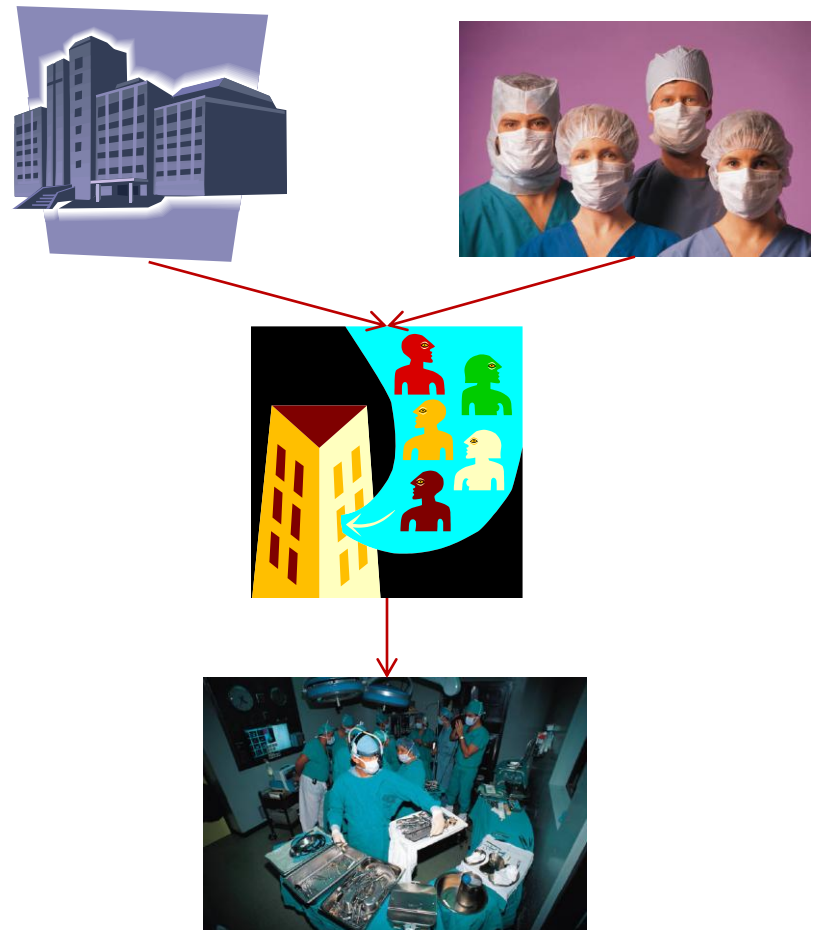
Impact of Health Care Reform and Alternative Compensation Models

Clinical Service Line Co-Management Arrangements

Gainsharing



Co-Management



Gainsharing vs. Co-Management

	Gainsharing	Co-Management
Contracted with individual physicians or group of physicians?	Generally individual	Generally group
Ability to include additional physicians	Easy, separate agreement with each physician	Difficult, agreement with management company; must sell shares in management company reducing current investors interest in bonus pool
Ease of administrative management	Difficult, must track each physicians progress individually	Easy, group's ability to achieve levels, one check to issue
Are the participating physicians required to attend management or other meetings?	No	Yes
Are the participating physicians involved with setting the quality measures?	Possibly	Yes
How is compensation paid?	All incentive based on actual performance	Base compensation for time spent and incentive for actual performance
Are physicians involved in the day-to-day management of the department?	Somewhat	Yes
When are quality metrics reset?	Possibly never	Annually
Compensation	Incentive	Fixed plus incentive
Allocation of Compensation	Individually based on actual performance	Hourly based on time commitments and / or distributed based on company ownership

Medicare Shared Savings Program (Gainsharing waivers)

ACO Regulatory Guidance

Several federal agencies issued guidance related to ACOs, including:

- Internal Revenue Service (IRS) issued a notice requesting comments and a fact sheet regarding the need for guidance on participation by tax-exempt organizations in ACOs
- CMS and the Office of Inspector General (OIG) published an interim final rule establishing waivers of federal fraud and abuse laws
- Federal Trade Commission (FTC) and the Department of Justice (DOJ) jointly issued an Antitrust Policy Statement

Five Fraud and Abuse Waivers

Waivers available to ACOs to limit liability under the health care fraud and abuse laws for certain arrangements under the Medicare Shared Saving Program

- Pre-Participation Waiver
- Participation Waiver
- Waiver for Patient Incentives
- Shared Savings Distribution Waiver
- Compliance with Stark Law Waiver

Financial relationships, of course, still qualify for existing exception or safe harbors

ACO Pre-Participation Waiver

- Protects from AKS, Stark Law, and Gainsharing CMP liabilities
- Requires *bona fide* intent to participate
- Can include outside parties
- But certain entities excluded as parties – e.g., drug and device manufacturers, distributors, DMEPOS suppliers
- Long list of potential start-up costs described – e.g., capital contributions, legal fees, incentives to attract physicians, performance-based compensation
- ACO governing body must make a *bona fide* determination that arrangement is reasonably related to SSP
- Protection is limited in time
- Documentation is required – but not signed agreements
- Public disclosure required – on Internet

ACO Participation Waiver

- Protects from AKS, Stark Law, and Gainsharing CMP liabilities
- Requires *bona fide* intent to participate
- Can include outside parties
- Broad protection to undefined “arrangements”
- OIG/CMS seeking comment as to whether certain entities should be excluded as parties – e.g., drug and device manufacturers, distributors
- Must be in good standing (waiver expires 6 months after participation ends) and ACO must meet governance standards
- ACO governing body must make a *bona fide* determination that arrangement is reasonably related to SSP – same as pre-part.
- Documentation is required – but not signed agreements – maintained for 10 years
- Public disclosure required – on Internet

Patient Incentives Waiver

- Addresses beneficiary inducements CMP and AKS
- Liability waived for items provided to beneficiaries for free or below FMV
- ACO is in good standing
- Reasonable connection between items/services and medical care
- Items or services are in-kind
- Items or services are preventative or advance certain treatment goals
- No gifts such as tickets, beauty products, etc.
- Currently limited to assigned ACO beneficiaries

Compliance with Physician Self-Referral Law Waiver

- Waives application of CMP Statute's gainsharing provisions and the federal anti-kickback statute to any financial relationship reasonably related to the purposes of the Shared Savings Program between or among the ACO, its participants, and its ACO providers/suppliers that meet a Stark law exception

Shared Savings Distribution Waiver

- Waives application of the Stark law, gainsharing provisions of the CMP Statute and the federal anti-kickback statute with respect to distributions and use of shared savings by an ACO
- ACO must have participation agreement and remain in good standing
- Distributed to ACO participants, ACO providers/suppliers or used for activities that are reasonably related to purpose of Shared Savings Program
- Payments to physicians can not be made knowingly to induce the physician to reduce or limit medically necessary items or services

Observations on the ACO Waivers

- Extraordinary broad – new waivers would allow previously prohibited activities – e.g., could allow payments for physicians for reductions in LOS
- Assuming procedural requirements met – risk is potential exclusion from ACO programs – versus previous risk of liability under the F&A laws
- Audit trail—required contemporaneous documentation and maintain records for 10 years
- Public disclosure of arrangements required under pre-participation and participation waiver, and until CMS and OIG release further information regarding public disclosure requirements, disclosure must be made on Internet
- CMS and OIG are not codifying these waivers
- CMS and OIG plan to limit the waivers in the future

Value-Based Purchasing Incentives

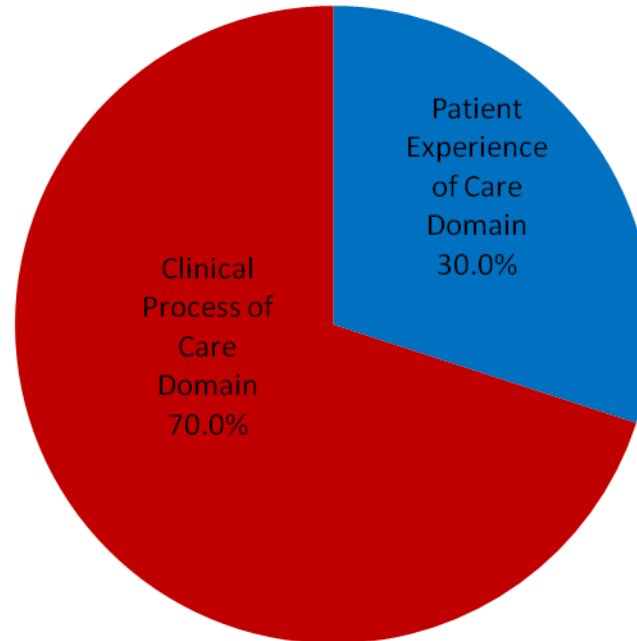
Hospital Value Based Purchasing Program

- Hospitals are given points for Achievement and Improvement for each measure or dimension, with the greater set of points used
- Points are added across all measures to reach the Clinical Process of Care domain score
- 70% of Total Performance Score based on Clinical Process of Care measures
- 30% of Total Performance Score based on Patient Experience of Care dimensions

12 Clinical Process of Care

Measures:

- 1.AMI-7a Fibrinolytic Received Within 30 Minutes of Hospital Arrival
- 2.AMI-8 Primary PCI Received Within 90 Minutes of Hospital Arrival
- 3.HF-1 Discharge Instructions
- 4.PN-3b Blood Cultures Performed in the ED Prior to Initial Antibiotic Received in Hospital
- 5.PN-6 Initial Antibiotic Selection for CAP in Immunocompetent Patient
- 6.SCIP-Inf-1 Prophylactic Antibiotic Received Within One Hour Prior to Surgical Incision
- 7.SCIP-Inf-2 Prophylactic Antibiotic Selection for Surgical Patients
- 8.SCIP-Inf-3 Prophylactic Antibiotics Discontinued within 24 Hours After Surgery
- 9.SCIP-Inf-4 Cardiac Surgery Patients With Controlled 6AM Postoperative Serum Glucose
- 10.SCIP-Card-2 Surgery Patients on a Beta Blocker Prior to Arrival That Received a Beta Blocker During the Perioperative Period
- 11.SCIP-VTE-1 Surgery Patients with Recommended Venous Thromboembolism Prophylaxis Ordered
- 12.SCIP-VTE-2 Surgery Patient Who Received Appropriate Venous Thromboembolism Prophylaxis Within 24 Hours



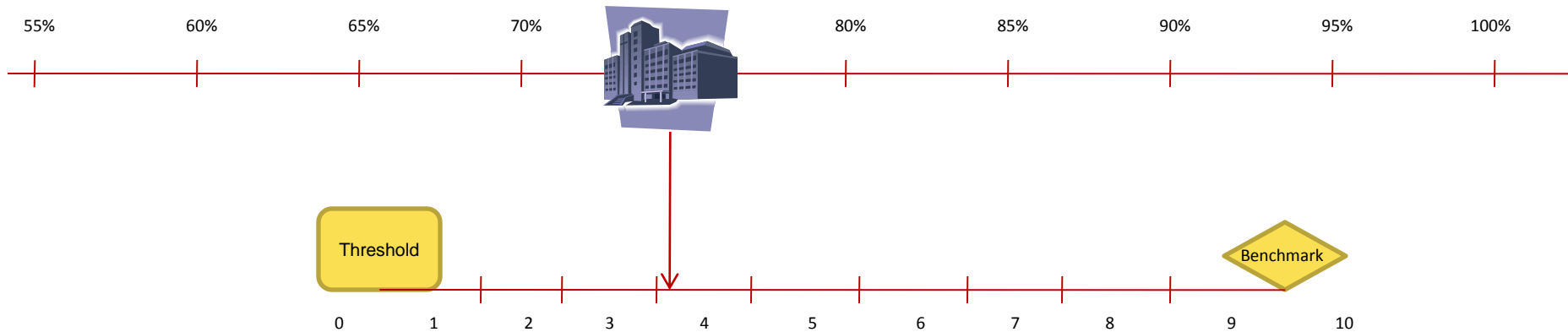
8 Patient Experience of Care Dimensions:

- 1.Nurse Communication
- 2.Doctor Communication
- 3.Hospital Staff Responsiveness
- 4.Pain Management
- 5.Medicine Communication
- 6.Hospital Cleanliness & Quietness
- 7.Discharge Information
- 8.Overall Hospital Rating

Point System

- How are Achievement Points awarded?
 - Hospital rate at or above the Benchmark: 10 Achievable Points
 - Hospital rate less than the Achievement Threshold: 0 Achievement Points
 - If the rate is equal to or greater than the Achievement Threshold and less than the Benchmark: 1-9 Achievement Points
- How are Improvement Points awarded?
 - Hospital rate at or above the Benchmark: 10 Improvement Points
 - Hospital rate less than or equal to Vaseline Period Rate: 0 Improvement Points
 - If the hospital's rate is between the Baseline Period Rate and the Benchmark: 0-9 Improvement Points

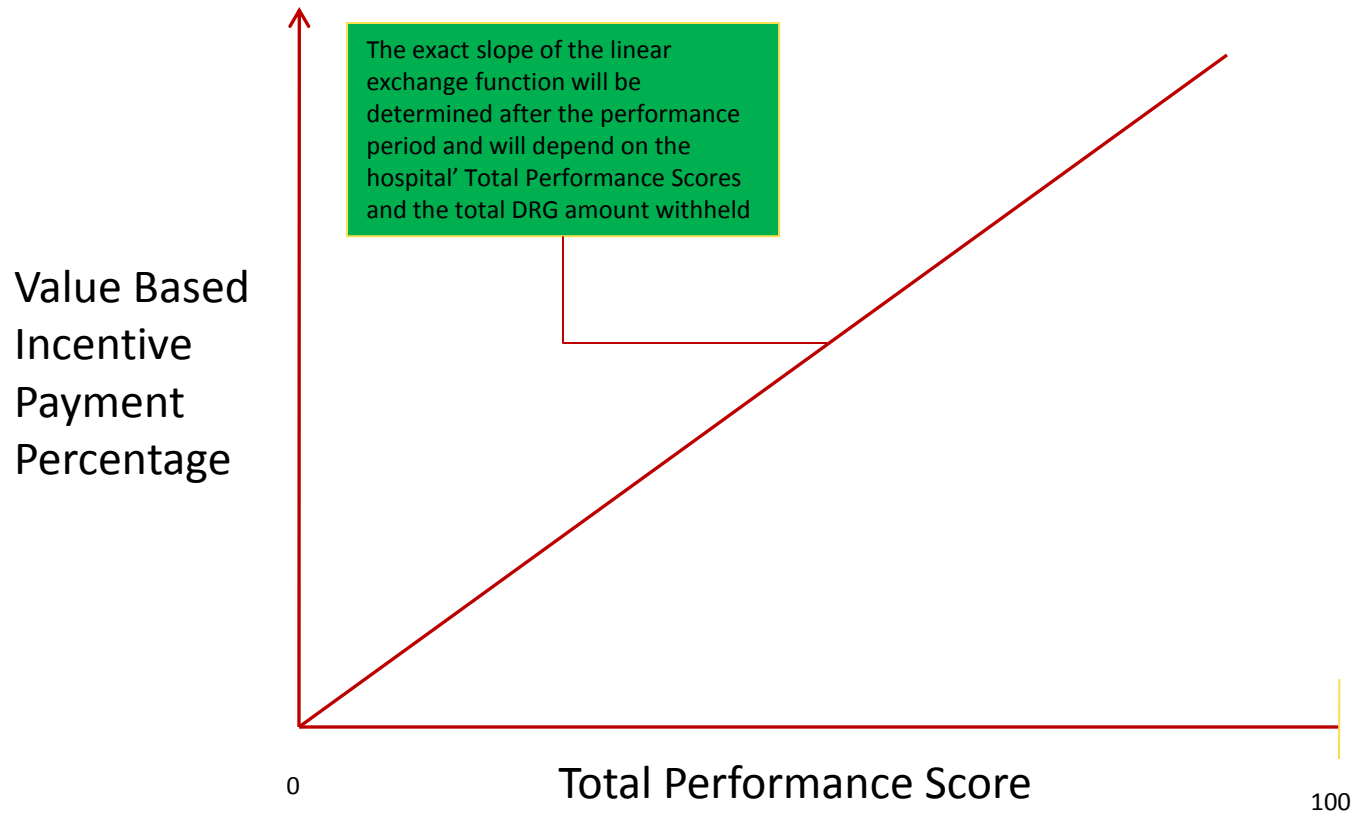
Sample Calculation - Performance



$$9 \times \left(\frac{\text{Hospital's Performance Period Score}^1 - \text{Achievement Threshold}}{\text{Benchmark} - \text{Achievement Threshold}} \right) + 0.5$$

¹ As used in these formula, the "score" refers to the hospital's performance rate.

Relationship of Score to Compensation



Questions & Comments



**Curtis H. Bernstein, CPA/ABV, ASA,
CVA, MBA, Sinaiko, (720) 240-4440,
curtis.bernstein@sinaiko.com**



**Paul W. Pitts, Esq., Reed Smith, LLP,
(415) 659-5971, ppitts@reedsmith.com**