

**Minimizing Hospital-Acquired Complications  
by Having the Hospital Gainshare  
the Related Case Cost Savings with Physicians**

**THE FOURTH NATIONAL  
PAY FOR PERFORMANCE SUMMIT**

**The Leapfrog Group  
Reynolds & Company  
Ropes & Gray**

**March 11, 2009**

# PRESENTERS

Leah Binder, CEO  
(202) 292-6711  
[LBinder@leapfroggroup.org](mailto:LBinder@leapfroggroup.org)



James Reynolds, President  
(212) 826-1818  
[JReynolds@jxreynolds.com](mailto:JReynolds@jxreynolds.com)

**REYNOLDS & COMPANY**  
*Customizing Strategic and Financial Solutions*

Daniel Roble, Partner, Health Care Group  
(617) 951-7476  
[Daniel.Roble@ropesgray.com](mailto:Daniel.Roble@ropesgray.com)



# DISCUSSION TOPICS

1. **Introductory** Remarks
2. Why are **Hospital Acquired Conditions** (HACs) Becoming Important Right Now?
3. Is There a Significant **Return on the Investment** in a HAC-focused Gainsharing Program?
4. How Can Federal **Legal Requirements** be Met?
5. Can the **Program Design** Be Customized to Be Attractive for Physicians and Nurses?
6. **Discussion**

# Giant Leaps Forward!

## About the Leapfrog Group

- Formed in 2000 following IOM Report showing medical errors killing up to 100,000 Americans a year
- Commitment to using the purchasing power of employers to leverage giants leaps forward

# Leaps Needed to Address Waste

- Variation in patterns of care—between high and low regions approaching 30% of total health care spending, or \$690 billion
- 40% of all emergency visits are for non-emergent conditions

# Leaps Need to Address Avoidable Adverse Events

- Studies from Harvard Medical School: Adverse events account for 5% of total health care spending (\$100 billion) and half were avoidable
- 5-10% of all inpatients acquire one or more infections, resulting in estimated 90,000 deaths and \$4.5-\$5.7 billion per year.

# Pillars for Improving Quality

**Transparency**

**Standard  
Measurements  
& Practices**

**Reimbursement:  
Incentives  
& Rewards**

# Leapfrog Survey: Unique

- Represent employers/purchasers/consumers interests
- Seeks public accountability
- Rewards high performance
- Full range of measures: "The patient safety hit parade"
- Regional and national in scope
- Free from external political and provider pressure



## From the 2008 Survey...

- 65% of hospitals do NOT take the steps known to prevent hospital acquired conditions
- 30% have appropriate staffing for the ICU
- 6% have computerized medication ordering systems
- Only a handful meet efficiency standards

# The Time Has Come in Washington

- Obama: Reduce family costs by \$2500 per year, Quick action
- Economy hastens action/State pressure
- CMS No-pays/Never Events
- Value-based purchasing (Baucus bill)
- Gainsharing and other innovations

# How Gainsharing Emerged on Leapfrog's agenda

- Aligns financial incentives of clinicians and purchasers
- Addresses long intractable problems of hospital acquired conditions
- Right time in the nation's history to try bold, innovative approaches that reduce costs and improve quality.

*Why are Hospital Acquired Conditions  
(HACs) Becoming Important Right  
Now?*

# CMS' Progress Toward Implementing Value-Based Purchasing

Thomas B. Valuck, MD, JD  
*Medical Officer & Senior Adviser  
Center for Medicare Management*



# What Does VBP Mean to CMS?

- Transforming Medicare from a passive payer to an active purchaser of higher quality, more efficient health care
- Tools and initiatives for promoting better quality, while avoiding unnecessary costs
  - Tools: measurement, payment incentives, public reporting, conditions of participation, coverage policy, QIO program
  - Initiatives: pay for reporting, pay for performance, gainsharing, competitive bidding, coverage decisions, direct provider support



# Statutory Authority: DRA Section 5001(c)

- Beginning October 1, 2007, IPPS hospitals were required to submit data on their claims for payment indicating whether diagnoses were present on admission (POA)
- Beginning October 1, 2008, CMS cannot assign a case to a higher DRG based on the occurrence of one of the selected conditions, if that condition was acquired during the hospitalization



# N.Y. Medicaid ups the ante

*By refusing to pay for 14 'never events,' the nation's biggest Medicaid program could propel other states into action*

In a relatively short period for the healthcare industry, several insurers and hospital associations have adopted positions of not paying for certain medical errors; now, with the New York state Medicaid program establishing its own policy, the stage is set for an even faster growth in the trend, industry experts say.

New York, with the nation's largest Medicaid budget at \$47 billion, stands to garner attention as to how it structures its policy, which was announced earlier this month. New York's approach is noteworthy and has been met with approval by hospitals because they prefer a list of "never events" instead of the more complex hospital-acquired conditions that constitute Medicare's nonreimbursement policy. The state is not the first to jump on the nonpayment bandwagon and its list of events is not as lengthy as lists of other groups with similar policies.

Specifically, New York state officials announced Medicaid would no longer reimburse providers for care related to never events and released a list of 14 events covered under the

new policy (See chart, p. 7). Medicaid will no longer pay for events that clearly should not occur in patient care, said New York State Health Commissioner Richard Daines, a physician. "We wanted to stick to a list of things that, frankly, should never happen," he said. New York's policy begins Oct. 1, the same start date Medicare has given for its own nonreimbursement plan.

New York's approach was praised by industry officials in the state. New York's Medicaid program takes a more reasonable approach than Medicare, said William Van Slyke, spokesman for the Healthcare Association of New York State, or HANYS. It doesn't go too far in penalizing hospitals for issues that might be out of their control, although there's still room for improvement in the new policy, he said. For example, the state's never event of contaminated medications might not always be the fault of the hospital, he added.

New York's policy is a work in progress, but

it is more sensible than Medicare's approach, said Kenneth Raske, president of the Greater New York Hospital Association. "CMS is going whole hog on matters that are controversial in relation to the science," he said. Neither the GNYHA or HANYS has estimated the financial impact of the state's new policy on hospitals.

With New York making a move on the issue, even more states may also. States typically play "follow the leader" on healthcare policy, but when it comes to implementing those policies, they come out stronger than the federal government, said Bruce Greenstein, a former associate regional administrator for Medicaid in Boston. As more stakeholders get involved with non-payment policies, states have an opportunity to shape what happens nationwide. "It's going to take a few states that take bold leadership positions," Greenstein said.

Two other states recently adopted similar policies. Pennsylvania's Department of Public Welfare announced a policy in January, and Maine recently passed a law effective in July saying hospitals will not bill patients if an error occurs. California and Connecticut also are considering legislation. While many organizations seem to agree that such never events in patient care need to end, they are all approaching their lists and policies in slightly different ways. And none match what Medicare—widely considered to be the catalyst that sparked other payers and hospital associations to adopt their policies—decreed last year (Dec. 10, 2007, p. 6).

Medicare's list includes three never events, but it contains more hospital-acquired condi-



**Bussard: Pa.'s approach is slightly different from N.Y.'s.**



**New York's new Medicaid policy puts pressure on hospitals in the state to be more careful and pushes other states toward implementing their own Medicaid programs.**



*Is There a Significant Return on the  
Investment in a HAC-focused  
Gainsharing Program?*

*Excerpts From*  
**STATUS REPORT**

*Preliminary Estimates of Potential Financial Benefits for Hospitals  
of Reducing the Frequency of  
Four Kinds of Hospital Acquired Complications (HACs)*

**May, 2008**

**REYNOLDS & COMPANY**

*Customizing Strategic and Financial Solutions*

333 East 51st Street

New York, NY 10022

(212) 826-1818

[jreynolds@jxreynolds.com](mailto:jreynolds@jxreynolds.com)

## METHODS OF STUDY

- We started from the premise that the **key characteristics of a successful Gainsharing Program** of this kind would include:
  1. The ability to remap a participating hospital's CMS DRG-based claims information to identify **specific kinds of discharge DRGs within specific Subspecialty Services** which also report on all secondary diagnoses that are non-POA (Present on Admission) complications.
  2. The identification of **specific kinds of HACs** which can be viewed as complications of treatment and which have sufficiently large case volumes and high unit costs that they are considered attractive for the purpose of reducing their frequency.
  3. Determination that the program could be **cost-beneficial** to a wide enough range of hospitals that offer specific kinds of Subspecialty Services to make participation by most hospitals worthwhile.
  4. Assessment that there could be sufficient financial benefits to an **identifiable and workable group of physicians** in each kind of subspecialty service at a given hospital to motivate them to participate.
- Fortunately, we were able to identify a **statewide database**, which contains about 1.7 million hospital discharges for 2006 among about 194 hospitals which also reported on Present on Admission (POA) HACs in that year, for use in this analysis.

- The kinds of high potential **HACs which form the focus** for this report include:
  - **Sepsis**
  - **Ventilator-Acquired Pneumonia**
  - **Pulmonary Embolism/Deep Vein Thrombosis**
  - **Pressure Ulcers.**
  
- In order to estimate the **potential financial benefit** of reducing variable cost per case and producing incremental net income associated with freed up bed days, we calculated **the differences** for:
  - Average values of the key variables for each subspecialty of **cases with no complications of any kind**
  - Average values of key variables for each subspecialty of **cases with only that kind of HAC** and no additional co-morbidities of any kind.

- The **differentials** for each of the four HACs' **variable case costs** were then multiplied by the frequencies of each kind of HAC in each subspecialty and summed across all subspecialties.
- Since we did not have estimates of net revenue per discharge at any level for these patient cases, we **assumed** that:
  - Fixed cost and **variable cost per discharge** each accounted for 50% of total cost per case.
  - **Net revenue per case** was equal to total cost per case so that the operating margin equaled zero.
- The **differentials for each of the four HACs' LOS** were also multiplied by the frequencies of each kind of HAC to estimate the potential for freed up bed days and then:
  - **Incremental bed days** at each hospital were divided by the **average LOS** of each hospital to estimate the potential for incremental discharges
  - **Incremental discharges** were multiplied by the average **variable cost per discharge** at each hospital to estimate the associated potential for incremental improvements in bottom line financial performance.

*Preliminary Findings and  
Conclusions*

## Preliminary Findings and Conclusions

### TOTAL DISCHARGES BY SUBSPECIALTY AND FOUR TARGETED HACs - ALL HOSPITALS AND ALL PAYORS IN 2006

Subspecialty	Total Discharges	Sepsis		Ventilator Associated Pneumonia		Pulmonary Embolism/Deep Vein Thrombosis		Pressure Ulcers		Total Volume of these HACs
		Total	HAC	Total	HAC	Total	HAC	Total	HAC	
Cardiology	337,344	1,972	568	1,272	484	3,183	352	3,015	180	1,584
Endocrinology	52,132	365	161	152	92	352	73	1,325	62	388
Gastroenterology	152,976	1,424	655	547	327	1,066	282	2,355	122	1,386
Hematology	23,631	135	55	40	19	247	24	337	10	108
Immun/Allergy	20,770	187	42	693	77	134	32	145	12	163
Infectious Dis	52,600	5,004	431	1,367	331	871	193	4,425	198	1,153
Nephrology/Renal	55,035	842	230	156	105	524	107	2,618	66	508
Neurology	84,798	566	289	764	211	591	137	1,172	100	737
Oncology/Med&Rad	49,273	798	364	228	145	1,288	184	911	102	795
<b>Pulmonary Med</b>	<b>157,371</b>	<b>5,668</b>	<b>2,370</b>	<b>3,110</b>	<b>876</b>	<b>3,873</b>	<b>737</b>	<b>5,968</b>	<b>798</b>	<b>4,781</b>
Rheumatology	8,762	45	17	10	7	68	11	137	5	40
Other Medicine	12,118	76	29	21	15	159	14	439	19	77
Cardiac Surgery	27,348	237	156	251	143	338	186	179	66	551
<b>Colon-Rectal Surg</b>	<b>29,257</b>	<b>996</b>	<b>654</b>	<b>324</b>	<b>246</b>	<b>559</b>	<b>342</b>	<b>313</b>	<b>88</b>	<b>1,330</b>
<b>General Surgery</b>	<b>125,742</b>	<b>2,125</b>	<b>839</b>	<b>530</b>	<b>343</b>	<b>2,446</b>	<b>809</b>	<b>2,910</b>	<b>222</b>	<b>2,213</b>
Neurosurgery	23,613	252	150	300	128	647	319	295	64	661
Ophthalmology	3,430	3	1	3	2	12	3	10	0	6
Oral Surgery	2,133	8	5	7	3	12	5	13	1	14
<b>Orthopedics</b>	<b>143,650</b>	<b>637</b>	<b>297</b>	<b>237</b>	<b>177</b>	<b>1,526</b>	<b>847</b>	<b>1,903</b>	<b>309</b>	<b>1,630</b>
Otolaryngology	20,855	62	21	60	38	140	37	113	11	107
Plastic Surgery	13,519	46	32	23	10	37	17	20	8	67
Thoracic Surgery	14,300	247	145	173	94	1,118	210	356	33	482
Urology	38,956	313	161	67	43	361	138	356	24	366
Vascular Surg	27,433	544	305	282	171	1,044	218	761	93	787
Gynecology	44,035	79	48	26	19	257	131	82	15	213
Psychiatry	89,982	27	13	9	6	194	21	189	8	48
Substance Abuse	72,496	41	24	72	23	89	21	45	3	71
Rehabilitation Med	27,693	179	61	8	4	994	285	1,254	83	433
Ungrouped	8,468	312	160	133	77	211	72	304	48	357
<b>Total</b>	<b>1,719,720</b>	<b>23,190</b>	<b>8,283</b>	<b>10,865</b>	<b>4,216</b>	<b>22,341</b>	<b>5,807</b>	<b>31,950</b>	<b>2,750</b>	<b>21,056</b>
<b>Percent of Totals</b>	<b>N.A.</b>		<b>36%</b>		<b>39%</b>		<b>26%</b>		<b>9%</b>	<b>24%</b>
<b>Average number of these HACs per hospital</b>	<b>N.A.</b>		<b>42</b>		<b>21</b>		<b>29</b>		<b>14</b>	<b>106</b>

### HAC-Related Variable Case Costs

- The **differential in total and variable cost per case** between HAC-only cases and cases without any co-morbidities, across all subspecialties, are shown below for each kind of HAC included in this analysis:

<u>HAC</u>	<u>Differential Total Cost/Case</u>	<u>Differential Variable Cost/Case</u>
➤ Sepsis	\$10,782	\$5,395
➤ VAP	10,969	5,485
➤ PE/DVT	12,691	6,346
➤ PU	11,251	5,626.

### HAC-Related Length of Stay

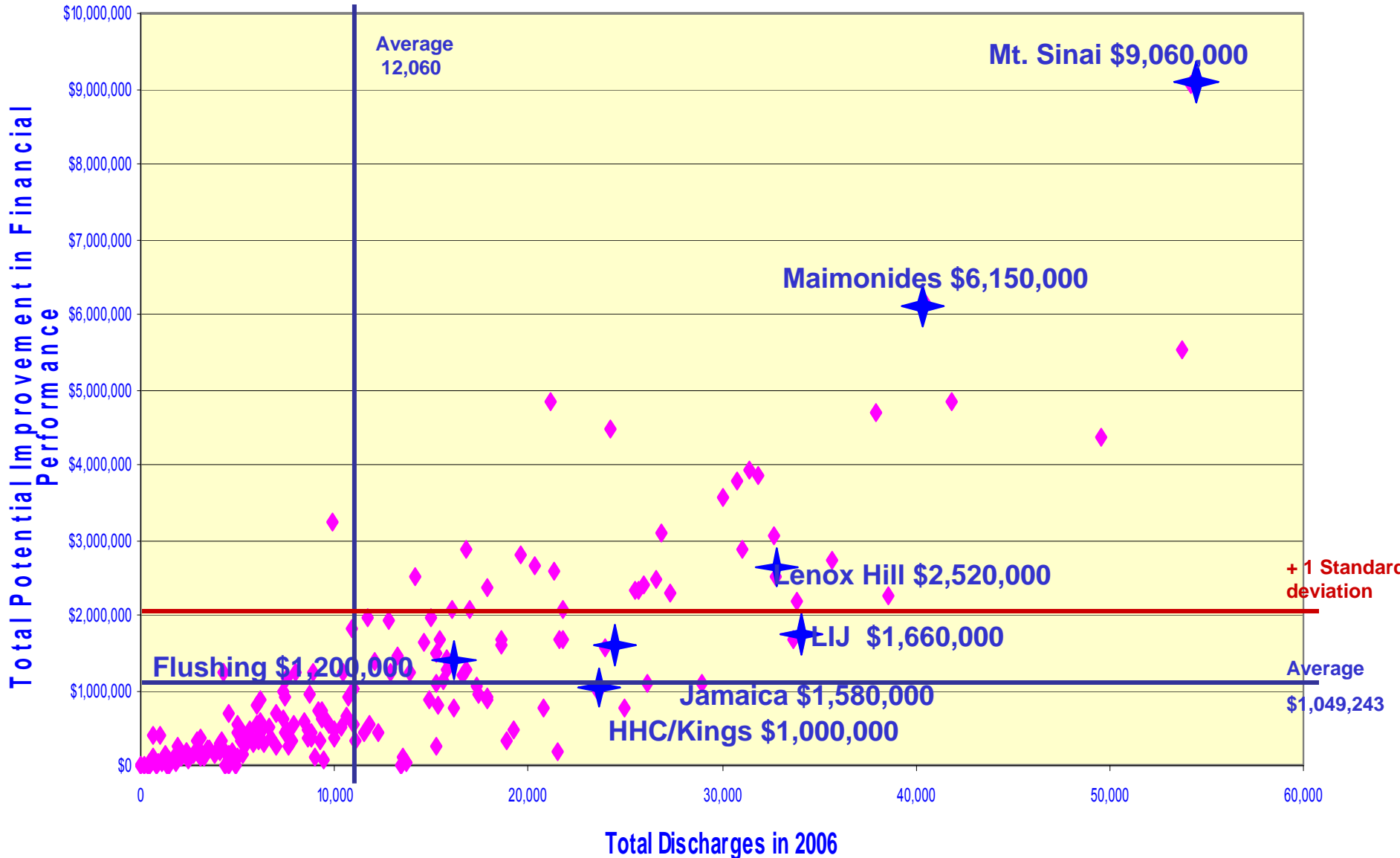
- The **differentials in Length of Stay** between HAC-only cases and cases without any co-morbidities, across all subspecialties, are shown below for each kind of HAC included in this analysis:

<u>HAC</u>	<u>Differential LOS in Days</u>
➤ Sepsis	6.9
➤ VAP	3.5
➤ PE/DVT	4.9
➤ PU	6.0.



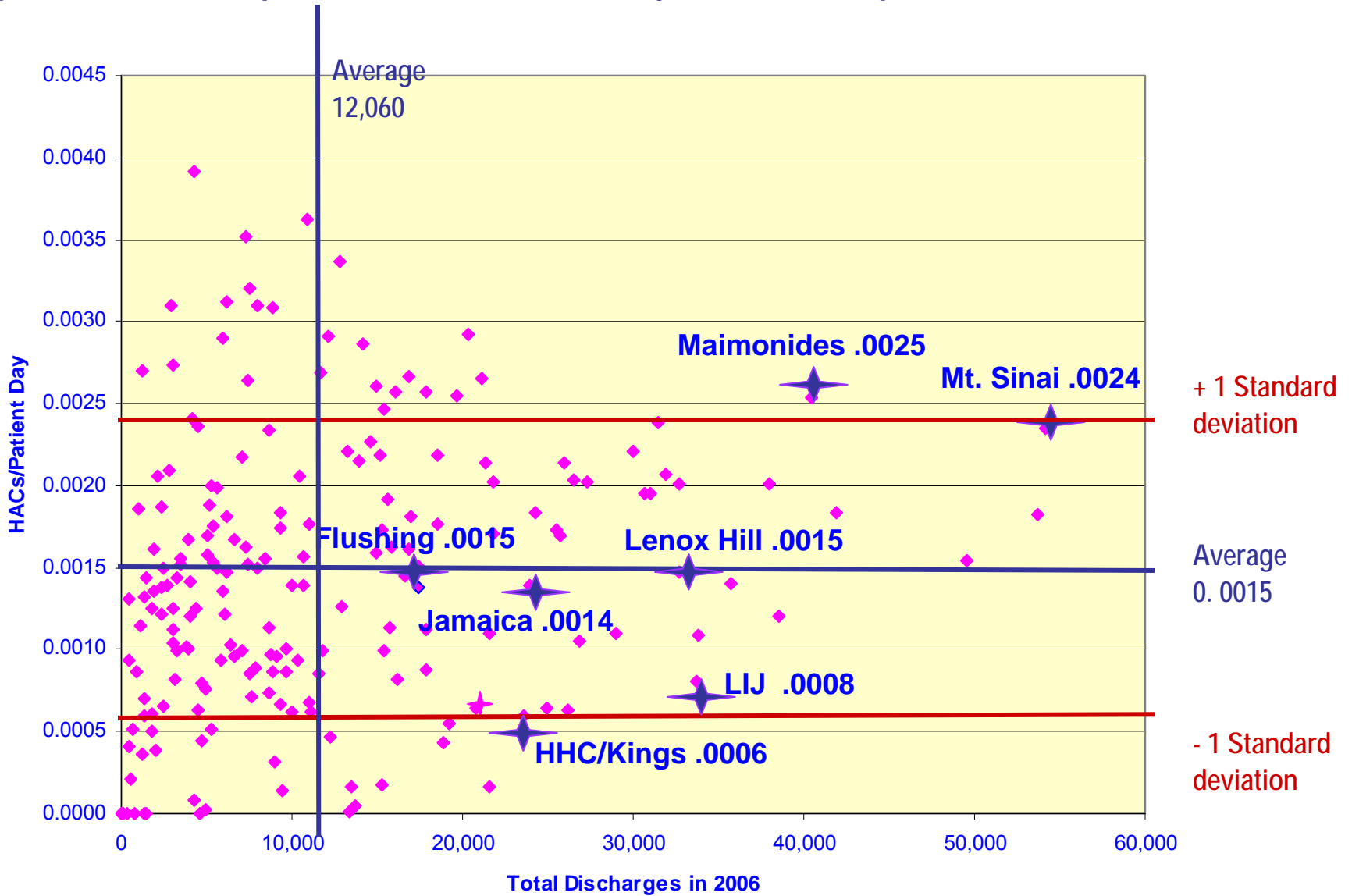
# POTENTIAL IMPROVEMENTS IN FINANCIAL PERFORMANCE BY REDUCING FREQUENCY OF SELECTED HACS & BACKFILLING BEDS AMONG 194 NYS HOSPITALS IN 2006

*(Sepsis, Ventilator Acquired Pneumonia, Pulmonary Embolism/Deep Vein Thrombosis & Pressure Ulcers)*



# FREQUENCY OF SELECTED HACs/PATIENT DAY & NUMBER OF HOSPITAL DISCHARGES AMONG 194 NYS HOSPITALS IN 2006

(Sepsis, Ventilator Acquired Pneumonia, Pulmonary Embolism/Deep Vein Thrombosis & Pressure Ulcers)



*How Can Federal Legal Requirements  
Be Met?*

# *Legal Compliance Addresses Four Topics:*

- **The Stark Law**

- An indirect arrangement may not implicate the Stark Law
- The fair market value compensation services exception
- The personal services exception
- The indirect compensation exception
- The employment exception
- The possible exception (see attachment)

- **The Anti-Kickback Statute**

- The employment safe harbor
- Satisfy a facts and circumstances test

- **The Civil Monetary Penalty Law**

- An independent, expert physician would certify that the care provided to the hospital's patients is not reduced or limited by the quality sharing program, and therefore the CMP Statute is not implicated or violated
- Apply for an Advisory Opinion from the OIG but simultaneously start the program and place cost savings into an escrow account to be paid out once a favorable Advisory Opinion is received
- Create a program where payments are not made to the physicians
- Create a program where hospital does not remunerate the physicians but provides, for example, new hospital-owned equipment
- The issue of creating a program that does not include federal beneficiaries

- **The Tax Laws**

- If a tax-exempt hospital is involved, use an independent valuator to certify that payments are FMV

# *Obeying the Law*

Compliance is required to ensure that the payments made to the physicians as part of a quality gainsharing initiative meet relevant regulatory requirements. Here are some issues to consider:

## **1. Clinical and financial transparency of quality indicators:**

- Use of specific, objective, generally accepted clinical indicators
- Separate calculation for each quality indicator

## **2. Safeguards against adverse impact on patient care:**

- Based on credible, objectively measured medical support
- Ongoing monitoring and measurement by independent third parties to determine the program's success and to confirm that the program is not having an adverse impact on clinical outcomes

## **3. Safeguards against disproportionate federal health care program costs:**

- Absence of procedures that are disproportionately performed on federal health care program beneficiaries
- Payments to the physicians based on all procedures with respect to each performance indicator regardless of the patients' insurance coverage
- Capping potential savings
- Calculations based on the hospital's actual out-of-pocket acquisition costs and not on accounting conventions
- Absence of steerage

## **4. Safeguards against inappropriate reductions in service:**

- Use of objective historical and clinical measures
- Use of baseline thresholds

## *Obeying the Law (cont.)*

### **5. Patient and physician safeguards:**

- Use of a program mission statement
- Voluntary physician participation
- Termination of physician participation if noncompliant
- Disclosure of program in writing to patients

### **6. Limitations on financial incentives to participating physicians:**

- Payments may only be made to physicians participating in the quality gainsharing program if the quality of care at the hospital is improved as evidenced by satisfying the preestablished quality goals and the cost savings are generated as a result of the program
- Financial incentives to physicians are reasonably limited in duration
- Fair market value compensation is defined in advance with the physicians
- Payments are based on quality results, not cost savings
- Program is not used to attract new referring physicians or to increase referrals from existing physicians
- Total savings are limited by meeting appropriate utilization standards

# *Obeying the Law (cont.)*

## Gainsharing Programs

Comparison of Requirements in Proposed Stark Exception, Factors Related to the Anti-Kickback Statute (“AKS”) and Civil Monetary Penalties Law (“CMP”) in OIG Advisory Opinions, and Factors Outlined by the IRS Related to 501(c)(3) Requirements Against Private Inurement and Private Benefit

	<b>Stark Requirements in Proposed Exception<sup>1</sup></b>	<b>AKS and CMP Factors in OIG Advisory Opinions<sup>2</sup></b>	<b>IRS Factors that weigh in favor of preserving 501(c)(3) status<sup>3</sup></b>
<b>Type</b>	Exception would apply both to savings-based programs and to quality-based programs.	Advisory Opinions have addressed only savings-based programs, not quality-based programs.	The 2002 IRS information letter addresses a program aimed at reducing costs, increasing efficiency, and maintaining quality.
<b>Term</b>	One to three years.	One to three years. One three year program involved a private insurer’s payments to a hospital so the physicians’ percentage participation was in essence fixed by a third party, the private insurer. Second three year program involved annual re-basing.	Not addressed.
<b>Documentation</b>	Requires signed agreement, specifying remuneration in detail sufficient to be verified independently, with baselines and performance measures clearly identified.	Not addressed (although programs that have sought an Advisory Opinion have, through that process, necessarily have involved similar documentation).	Substantial documentation of the program and participation by hospital and physicians in data collection efforts established by the program evaluator.

<sup>1</sup> See 73 Fed. Reg. 38502, 38604–06 (July 7, 2008). Medicare has not promulgated final regulations as it continues to take comments on the proposed regulations.

<sup>2</sup> See, e.g., OIG Advisory Opinion 07-22 (Dec. 28, 2007).

<sup>3</sup> See Information Letter 2002-0021 that outlines factors for determining whether a gainsharing arrangement might have an adverse effect on the tax-exempt status of a not-for-profit hospital.

## *Obeying the Law (cont.)*

	<b>Stark Requirements in Proposed Exception<sup>1</sup></b>	<b>AKS and CMP Factors in OIG Advisory Opinions<sup>2</sup></b>	<b>IRS Factors for conserving 501(c)(3) status</b>
<b>Sponsor</b>	Exception would be available only for hospital-based programs; programs sponsored by other entities would not be eligible.	Not addressed.	The 2002 Information Letter involves an NFP hospitals; however, the IRS states that the factors would apply to any physician incentive compensation arrangement.
<b>Physician Participation</b>	All participants must have been on the hospital's medical staff at the commencement of the program.  At least five physicians must participate with respect to each measure. All physicians in the same department or specialty must be invited to participate.	All participants must have been on the hospital's medical staff at the commencement of the program.  No size requirement, but programs have been on a departmental basis, and a recent Advisory Opinion cited ten participating physicians..	Provider should only be rewarded based on services he/she personally performs.  Only physicians and other licensed health care providers who are fully credentialed at the hospital to perform the services for which payment is sought are included within the incentive payment plan.
<b>Medical Justification</b>	Measures must be supported by independent medical evidence confirming that their implementation will not adversely affect patient care.	Same.	An independent organization conducts an evaluation of the program that includes review of the quality of care provided under the program.



## *Obeying the Law (cont.)*

	<b>Stark Requirements in Proposed Exception<sup>1</sup></b>	<b>AKS and CMP Factors in OIG Advisory Opinions<sup>2</sup></b>	<b>IRS Factors for conserving 501(c)(3) status</b>
<b>Measures</b>	<p>Measures must use an objective methodology, be verifiable, and be tracked individually.</p> <p>Quality-based measures must be listed in the CMS/JCAHO Specification Manual for National Hospital Quality Measures (the “CMS/JCAHO Specifications”).</p>	<p>Measures must be clearly and separately identified and must be transparent.</p> <p>With respect to quality-based measures, cites with approval the CMS/JCAHO Specifications. If quality measures are not based on the CMS/JCAHO Specifications, CMS will undertake an independent medical review.</p>	<p>Quality of care and patient satisfaction are considered as measures.</p>
<b>Thresholds</b>	<p>Payments are not permitted with respect to performance above or below thresholds established by reference to baseline hospital performance and national or regional data.</p>	<p>Same (although reference must be to hospital and industry, not “national or regional,” data).</p>	<p>Not addressed.</p>
<b>Continued Availability</b>	<p>Physicians must have access to the same selection of items, supplies, and devices as available prior to the program’s commencement, and must have access to new technology.</p>	<p>Same (although, when limited to one-year programs, there are no specific requirements with respect to new technology).</p>	<p>Not addressed.</p>

## *Obeying the Law (cont.)*

	<b>Stark Requirements in Proposed Exception<sup>1</sup></b>	<b>AKS and CMP Factors in OIG Advisory Opinions<sup>2</sup></b>	<b>IRS Factors for conserving 501(c)(3) status</b>
<b>Calculation of Payments</b>	<p>Payments must be limited in duration and amount.</p> <p>Cost-savings payments must be measured by comparison of actual acquisition costs.</p>	Same.	<p>The incentive payments to an individual physician or to a group of physicians may be neither 25% more than, nor 25% less than, the amount the physician or group of physicians would have been paid under the traditional Medicare program for the services provided to beneficiaries covered under the program, as determined on an annual basis.</p> <p>Incentive payments are based on aggregate costs of all similarly covered beneficiaries, such as Medicare patients discharged under a given DRG and/or group of related DRGs and do not reflect the experience of individual beneficiaries.</p> <p>Where compensation is based on net revenue, the arrangement should continue to accomplish the organization's charitable purpose, such as keeping expenses within budgeted amounts where expenses determine the amounts charged for charitable services.</p> <p>The compensation arrangement should not have the potential for reducing the charitable services or benefits that the organization would otherwise provide.</p>

## *Obeying the Law (cont.)*

	<b>Stark Requirements in Proposed Exception<sup>1</sup></b>	<b>AKS and CMP Factors in OIG Advisory Opinions<sup>2</sup></b>	<b>IRS Factors for conserving 501(c)(3) status</b>
<b>Payments</b>	<p>Participating physicians must be paid on a per capita basis.</p> <p>Payments may not include amounts attributable to increased volume of procedures performed on federal health care program beneficiaries.</p> <p>Payments in successive years may not take into account achievements realized in a prior year.</p> <p>Payments may not be based, in whole or in part, on a reduction in length of stay.</p> <p>CMS may limit physicians' share of cost savings to 50%.</p>	<p>Same.</p> <p>Same.</p> <p>Same.</p> <p>Programs have not involved payments based on reduction in length of stay.</p> <p>Programs have not involved payments to physicians in excess of 50% of cost savings.</p>	<p>The IRS will look at whether total compensation is reasonable (taking into consideration factors such as employment contracts, physician specialty, and location) and whether the compensation arrangement includes a reasonable maximum earnings amount to protect against windfall.</p>

## *Obeying the Law (cont.)*

	Stark Requirements in Proposed Exception <sup>1</sup>	AKS and CMP Factors in OIG Advisory Opinions <sup>2</sup>	IRS Factors for conserving 501(c)(3) status
<b>Physician Interests</b>	<p>Payments are not permitted with respect to items, supplies, or devices with respect to which a participating physician has an investment or ownership interest or a compensation arrangement.</p>	<p>Not addressed.</p>	<p>The arrangement should be established by an independent board of directors governed by a substantial conflicts of interest policy that restricts affected physicians from voting on the arrangement.</p> <p>The relationship between the health care organization and the physician must be at arm's-length.</p> <p>The compensation arrangement should not transform the principal activity of the organization into a joint venture with a physician or serve as a device to distribute all or a portion of the health care organization's profits to those in control of the organization.</p>

## *Obeying the Law (cont.)*

	<b>Stark Requirements in Proposed Exception<sup>1</sup></b>	<b>AKS and CMP Factors in OIG Advisory Opinions<sup>2</sup></b>	<b>IRS Factors for conserving 501(c)(3) status</b>
<b>Quality Monitoring</b>	<p>Periodic review is required to protect against inappropriate reductions or limitations in services.</p> <p>An independent monitor must review the program prior to commencement and at least annually thereafter to ensure no diminution in patient care services.</p>	Same.	<p>The arrangement should take into account quality of care and patient satisfaction. An independent organization conducts an evaluation of the program that includes a review of the quality of care provided under the program.</p>
<b>Additional Monitoring</b>	<p>CMS may require monitoring of case severity, age, and payor mix of the patient population affected by the program.</p>	<p>Same monitoring requirement. Physicians whose referral patterns are found inappropriately to change must be subject to termination from the program.</p>	<p>The arrangement should not reduce charitable services or benefits provided by the organization.</p> <p>The arrangement should provide a real discernable benefit or business purpose other than benefit to providers, i.e. efficiency or economy.</p> <p>The arrangement should include controls to prevent against unwarranted benefits or unnecessary utilization.</p>

## *Obeying the Law (cont.)*

	<b>Stark Requirements in Proposed Exception<sup>1</sup></b>	<b>AKS and CMP Factors in OIG Advisory Opinions<sup>2</sup></b>	<b>IRS Factors for conserving 501(c)(3) status</b>
<b>Uniform Application by Payor</b>	CMS may require that procedures not be disproportionately performed on federal health care program beneficiaries, and that all measures be applied uniformly to all patients, including Medicare beneficiaries.	Same.	Incentive payments are based on aggregate costs of all similarly covered beneficiaries, such as Medicare patients discharged under a given DRG and/or group of related DRGs and do not reflect the experience of individual beneficiaries.
<b>Notice to Patients</b>	Hospitals must provide prior written notice that identifies the participating physicians, discloses the performance payments, and describes the measures.	Same, although less granular specification of notice requirements.	The hospital informs eligible beneficiaries, upon admission to the hospital as patients, about the program and, upon request, provides nonproprietary information regarding any nontraditional payment arrangements involving incentives.
<b>Government Access</b>	Certain records must be made available to the government on request.	Not addressed (although programs that have sought an Advisory Opinion have been subject to government review).	IRS has audit rights subject to three- year statute of limitations.

## *Obeying the Law (cont.)*

- If a Managed Care Organization is involved
  - **The Stark Law**
    - Personal services exception which protects risk sharing arrangements that comply with the Physician Incentive Plan regulations
    - The risk sharing exception
    - The prepaid health plan exception
  - **The Anti-Kickback Statute**
    - Eligible Managed Care Organization Safe Harbor
  - **The Civil Monetary Penalty Statute**
    - Physician incentives plans relating to Medicare and Medicaid contracting health plans are subject to regulation by the Secretary of DHHS in lieu of being subject to the CMP Statute
    - No specific payment is made to the physician to reduce or limit medically necessary services with respect to a specific patient
    - The substantial financial risk test

# *Determining Fair Market Value*

## **The possible components of FMV are:**

- Time and effort expended by the physician in participating in the Gainsharing Program, i.e. sweat equity
- The results achieved by the physician, e.g. improvements in quality of care
- The lost revenue experienced by the physician as a result of participating in the Gainsharing Program, e.g. reduced LOS, fewer tests
- New risks being undertaken by the physician

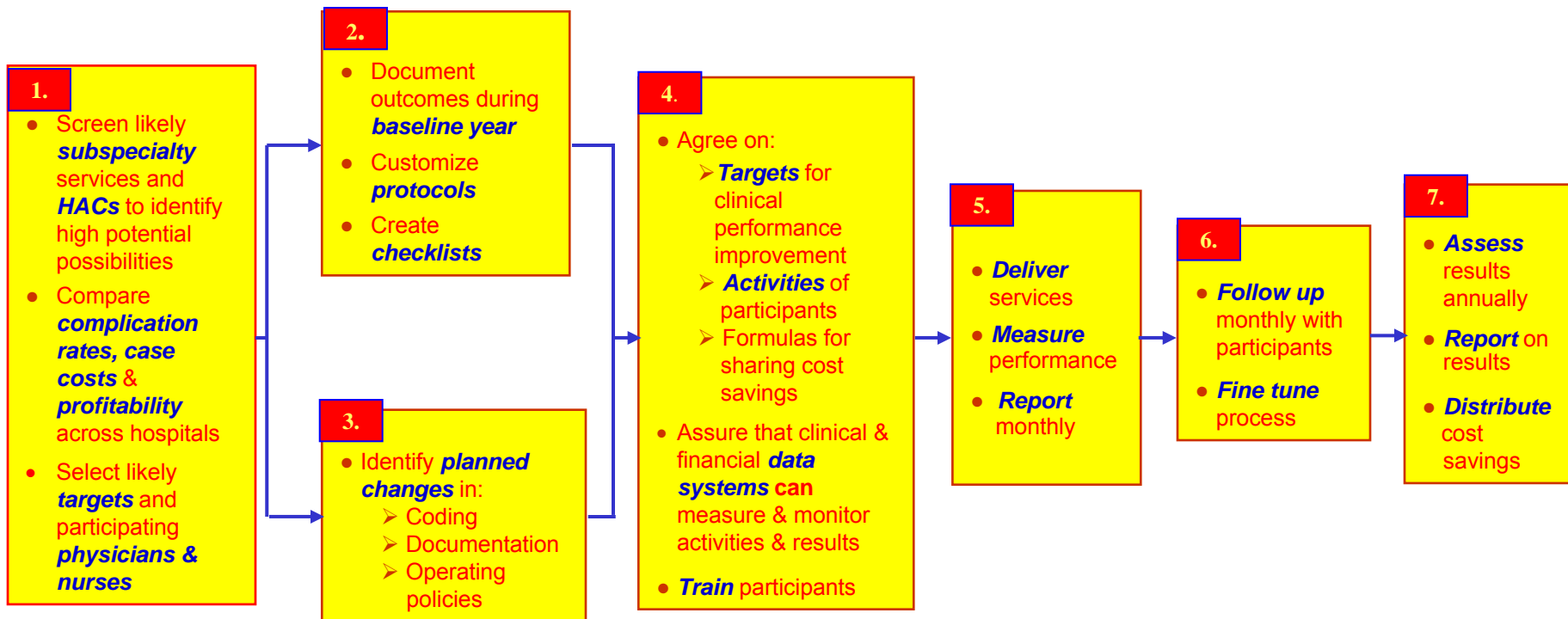
## **Examples of Possible FMV Compensation Methodologies:**

- Hourly rate for each physician multiplied by the hours devoted by the physician to the Gainsharing Program
- Multiply the physician's annual compensation level by the percentage of the physician's patient revenue related to procedures affected by the clinical protocols in the Gainsharing Program, with the physician's compensation capped at an amount no more than 25% above the amount the physician would have been paid traditionally under Medicare on an annual basis.
- Formula involving two or more FMV components



*Can the Program Design Be Customized  
To Be Attractive for Physicians and  
Nurses?*

# The Launch of a HAC-Focused Gainsharing Program Entails Seven Tasks



# *Our Approach to Redesigning and Improving Performance is Evidence-Based and Practical.*

1. Usual **Task Force members:**
  - Chief of Targeted Subspecialty Service and all attending physicians
  - Related nurses and technicians
  - Chief Medical Officer
  - Chief Information Officer.
2. **Performance characteristics** to review for problems and opportunities:
  - Relative and absolute frequency of specific kinds of HAC complications by Subspecialty and DRG
  - LOS and excess cost per case
  - Cases and complications by patient care unit
  - Patient care patterns
  - Potential cost savings and profit improvement by payment type.
3. **Problems and opportunities to be addressed:**
  - Risk levels and clinical protocols
  - Operational practices, including coding, documentation and clinical care process
  - LOS and Case Costs
  - Payment rates – whether per case or per diem.
4. Consensus on **design changes** to improve clinical and operational effectiveness.
5. Methods for **monitoring adherence** to process design, reporting on frequency of complications and measuring financial results.

## *Preliminary Estimates of Longest Elapsed Time for Designing, Implementing and Evaluating the HAC Gainsharing Demonstration*

PROJECT PHASES & TASKS	MONTHS OF ELAPSED TIME																																						
	1	2	3	4	5	6	7	8	9	10	11	12	1	2	3	4	5	6	7	8	9	10	11	12	1	2	3	4	5	6	7	8	9	10	11	12			
<b>PHASE ONE: DESIGN &amp; DEVELOPMENT</b>	<b>YEAR ONE</b>												<b>YEAR TWO</b>												<b>YEAR THREE</b>														
1. Identify One Subspecialty which Includes One to Three Kinds of High Cost Complications to Target for Improvements and Form Task Force	■																																						
2. Document Baseline Year Results, Customize Protocols and Create Checklists		■	■	■	■	■																																	
3. Identify Required Operating and Care Process Changes			■	■	■	■	■																																
4. Support Task Force in Setting Performance Targets and Agreeing on Financial Arrangements and Training Participants							■	■	■	■	■																												
5. Improve Clinical and Financial Data Systems For Timely Monitoring							■	■	■	■	■	■																											
<b>PHASE TWO: PILOT IMPLEMENTATION</b>																																							
1. Deliver Services & Report																																							
2. Monitor and Analyze Performance													●	●	●	●	●	●	●	●	●	●	●	●															
3. Fine Tune Protocols & Methods													●	●	●	●	●	●	●	●	●	●	●	●															
<b>PHASE THREE: REPORTING &amp; EVALUATION</b>																																							
1. Evaluate Results																																			■	■			
2. Distribute Savings																																				■			

# *Discussion*