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Gainsharing Arrangements and Bundled Payments: OIG Advisory Opinion and Other Developments

Complying With Legal and Regulatory Requirements, Overcoming Implementation and Operational Challenges

THURSDAY, MAY 17, 2018

1pm Eastern | 12pm Central | 11am Mountain | 10am Pacific

Today's faculty features:

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Gainsharing Arrangements and Bundled Payments: Latest Developments

Agenda for Today's Webinar

- Discuss problems that gainsharing and bundled payment are trying to address
- Identify legal considerations in gainsharing and bundled payment arrangements
  - Discuss recent OIG Advisory Opinion
- Explore existing gainsharing and bundled payment models and demonstrations
- Review FMV considerations and structural guidance

Changing Reimbursement Paradigm

- **Volume➔ Value**
  - Important theme in health care delivery and reimbursement
  - Transitioning toward value based reimbursement models

The Triple Aim

Improving the Experience of Care	Better care for patients through enhanced care coordination and improved patient outcomes
Reducing Per Capita Costs	Smarter spending by holding hospitals accountable for total episode spending, not just inpatient costs
Improving the Health of Populations	Healthier people and communities by improving coordination in health and by connecting care across hospitals, physicians, and other health care providers

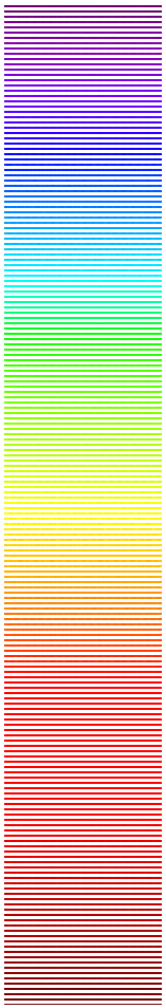
Underlying Motivation

- Money drives performance
- Aligning Financial Incentives
  - Hospitals & Physicians
  - Acute & Post-acute Providers

Big Picture Goals of Gainsharing & Bundled Payments

- Help bridge the gap between fee-for-service and value-based payment methodologies
- Strategic alignment, collaboration, and integration
- Improve quality
- Reduce costs

Spectrum of Alternative Payment Approaches



- Traditional Gainsharing
- Bundled Payments
- Clinical Co-management Arrangements
- ACOs
- Clinically Integrated Network
- Population Health

Legal Considerations

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Applicable Fraud & Abuse Laws

- Anti-kickback statute
- Civil money penalty (CMP) against hospital payments to reduce or limit services
- Stark physician self-referral law

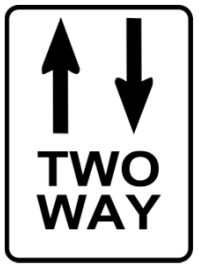
Fundamental F&A Criteria

- Additional Cost
- Over, Under, and Mis-Utilization
- Quality of Care
- Access to Care
- Patients' Freedom of Choice
- Competition
- Exercise of Professional Judgment

Anti-Kickback Statute

- Federal anti-kickback law generally prohibits the provision of any economic benefit in exchange for the referral of patients or business that will be reimbursed under any Federal health care program – 42 U.S.C. § 1320a-7b(b)

- Two-way street – payment or receipt
- Intent-based statute



CMP – Reduce or Limit Services

- Prohibited Conduct
  - Hospital (or critical access hospital)
  - knowingly
  - making payments, ***directly or indirectly***
  - to physician
  - as an inducement to reduce or limit **MEDICALLY NECESSARY** services
  - to Medicare (Parts A or B) or Medicaid patients
  - under the physician's direct care
- 42 USC 1320a-7a(b)

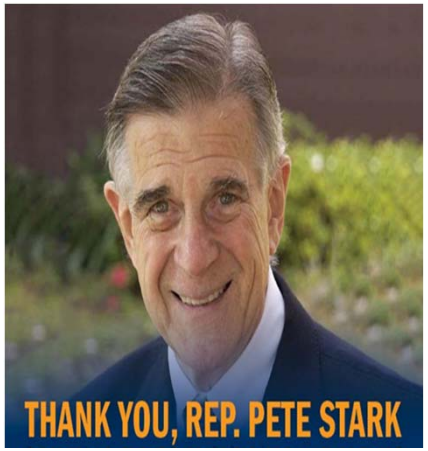
CMP – Reduce or Limit Services

- Much less of an impediment
  - MACRA Limits CMP to MEDICALLY NECESSARY services
  - OIG previously interpreted CMP to apply to any services (including medically unnecessary services)
- Don't ignore
  - Need ***credible medical evidence*** to support efforts

Stark Physician Self-Referral Law

- The federal Stark physician self-referral law generally prohibits a physician from making referrals to an entity for designated health services if the physician (or an immediate family member) has a "financial relationship" with the entity – 42 U.S.C. § 1395nn

- Ownership or compensation
- Strict liability



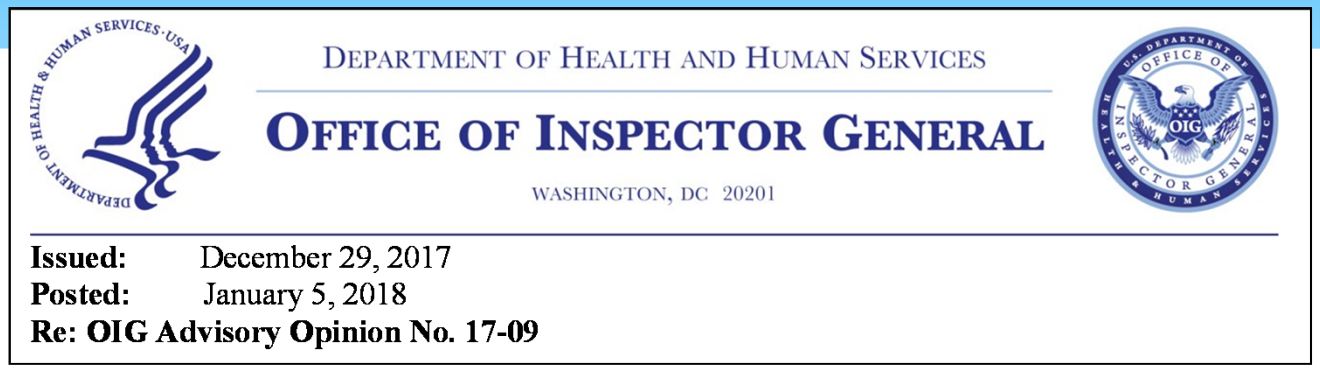
Avenues for Addressing Stark

- Payment not made by hospital or other DHS entity
- Payment not made to physician
  - Create entity

Potentially Relevant Stark Exceptions

- Indirect compensation arrangement
- Employment
- Personal services arrangement
- Fair market value
- Risk sharing arrangement

OIG Advisory Opinion 17-09



DEPARTMENT OF HEALTH AND HUMAN SERVICES

OFFICE OF INSPECTOR GENERAL

WASHINGTON, DC 20201

Issued: December 29, 2017
Posted: January 5, 2018
Re: OIG Advisory Opinion No. 17-09

- Gainsharing Advisory Opinion
- Non-profit acute care hospital shares cost savings for certain spinal surgeries with neurosurgeons in a multi-specialty physician group
- Elements of gainsharing arrangement
  - Use bone protein on as-needed basis
  - Product standardization – 31 recommendations for devices and supplies

OIG Advisory Opinion 17-09 (cont.)

- First gainsharing advisory opinion since MACRA added medically necessary language to CMP

- Despite the change, OIG still found product standardization potentially implicated the CMP
  - Process for developing standardization needs to be done right
  - Need clinical support that standardization is not limiting medically necessary care

OIG Advisory Opinion 17-09 (cont.)

- OIG found sufficient safeguards under Anti-Kickback Statute (AKS)
  - Incentive to increase referrals to hospital is mitigated
  - Neurosurgeons are part of multi-specialty group which retains a portion of savings, but savings used for administrative expenses, not to reward referrals by non-participating physicians
  - Multi-year agreement, but with annual re-basing
  - Standardization requires new clinical process by neurosurgeons
  - Tie incentives to cost savings, so no phantom savings
  - Physician have access to same selection of device and make patient-by-patient determination
  - Not intended to attract other physicians to hospital

OIG Recognizes Reality

- "[A]ppropriately structured gainsharing arrangements may offer significant benefits."
  - OIG Special Advisory Bulletin on Gainsharing
    64 Fed. Reg. 37,985 (July 14, 1999)

- "Properly structured, cost sharing arrangements can serve legitimate business and medical purposes."
  - OIG Advisory Opinion 01-01

What Does OIG Consider to be Properly Structured?

- Commercially reasonable/FMV compensation based on independent appraisal
- Cost savings tied to specific protocol/cost savings activity. Measured based on 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)

What Does OIG Consider to be Properly Structured?

- Not limit physician's ability to make medically appropriate patient decisions
- May condition payment on certain physician choice, but must allow access to same supplies and devices as available previously
- Not induce physicians from other hospitals to join medical staff – must be a member of medical staff at outset of program

Helpful Regulatory Guidance

- Co-Management Advisory Opinion
  - OIG Adv. Op. 12-22 (Jan. 7, 2013)
- Special Advisory Bulletin on Gainsharing
  - 64 Fed. Reg. 37,985 (July 14, 1999)
- Gainsharing Advisory Opinions
  - OIG Adv. Op. 01-01 (Jan. 11, 2001); OIG Adv. Op 05-01 (Feb. 3, 2005); OIG Adv. Op 05-02 (Feb. 17. 2005); OIG Adv. Op. 05-03 (Feb. 17, 2005); OIG Adv. Op. 05-04 (Feb. 17, 2005); OIG Adv. Op. 05-05 (Feb. 25, 2005); OIG Adv. Op. 05-06 (Feb. 25, 2005); OIG Adv. Op. 06-22 (Nov. 16, 2006); OIG Adv. Op. 07-21 (Jan. 14, 2008); OIG Adv. Op. 07-22 (Jan. 14, 2008); OIG Adv. Op. 08-09 (Aug. 7, 2008); OIG Adv. Op. 08-15 (Oct. 14, 2008); OIG Adv. Op. 08-21 (Dec. 8, 2008); OIG Adv. Op. 09-06 (June 30, 2009); OIG Adv. Op. 15-13 (Oct. 14, 2015); OIG Adv. Op. 17-09 (Dec. 29, 2017)

Models and Demonstrations

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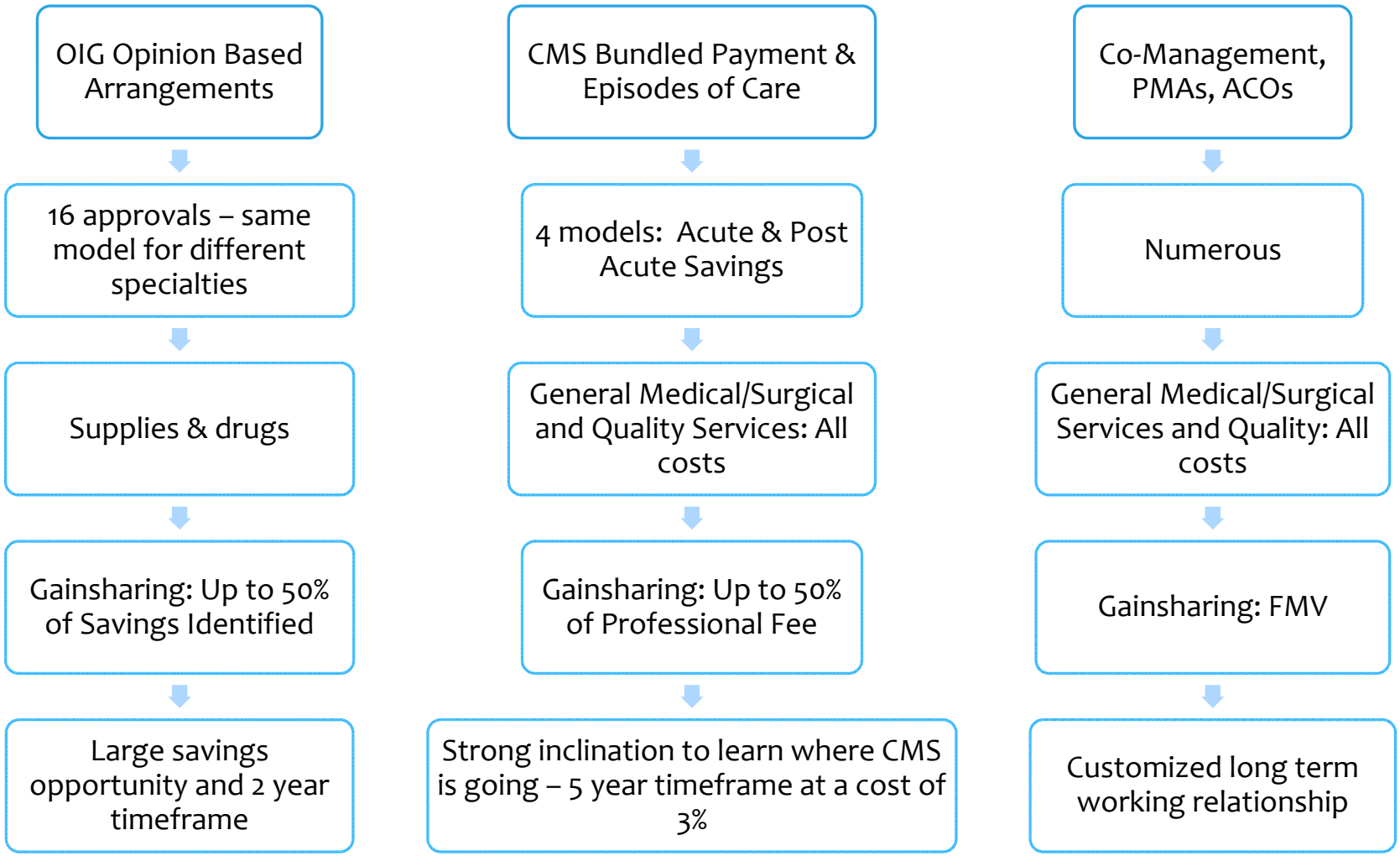
Various Models

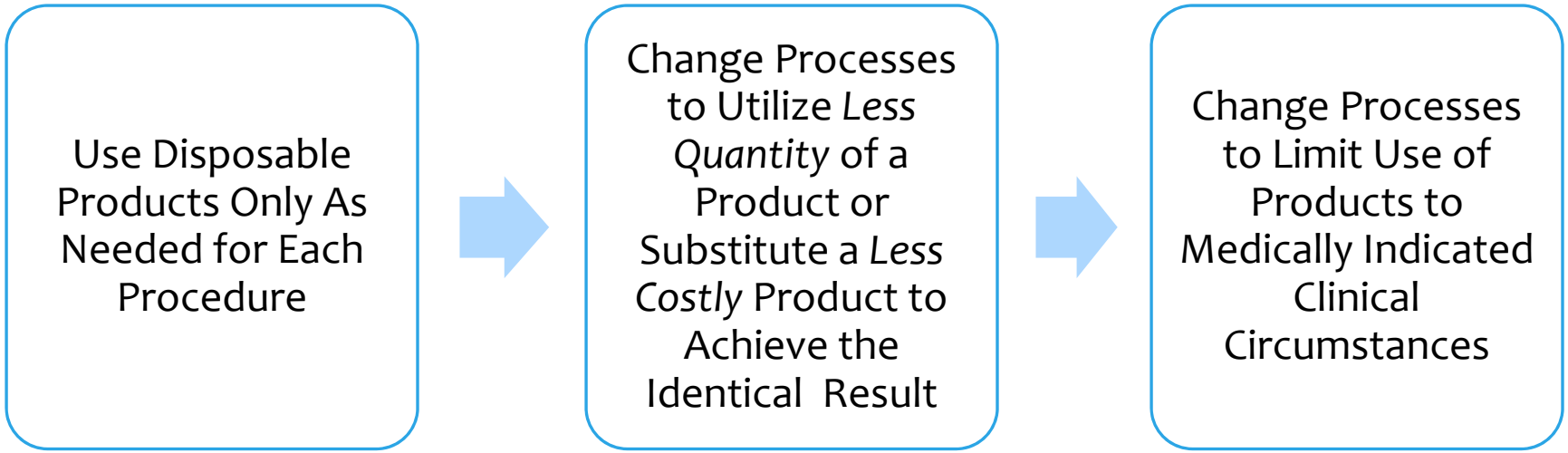
- Traditional Gainsharing – OIG Opinion Based Arrangements
- Bundled Payments – Medicare prescribed protocols
  - Bundled Payments for Care Improvement (BPCI) program
  - Comprehensive Care for Joint Replacement (CJR) program
  - Bundled Payments for Care Improvement (BPCI) program – Advanced 29 IP + 3 OP
  - Episode Payment Models (EPMs)
- Clinical Co-management Arrangements
- ACOs
- Clinically Integrated Networks
- Population Health

Gainsharing – which one to choose?



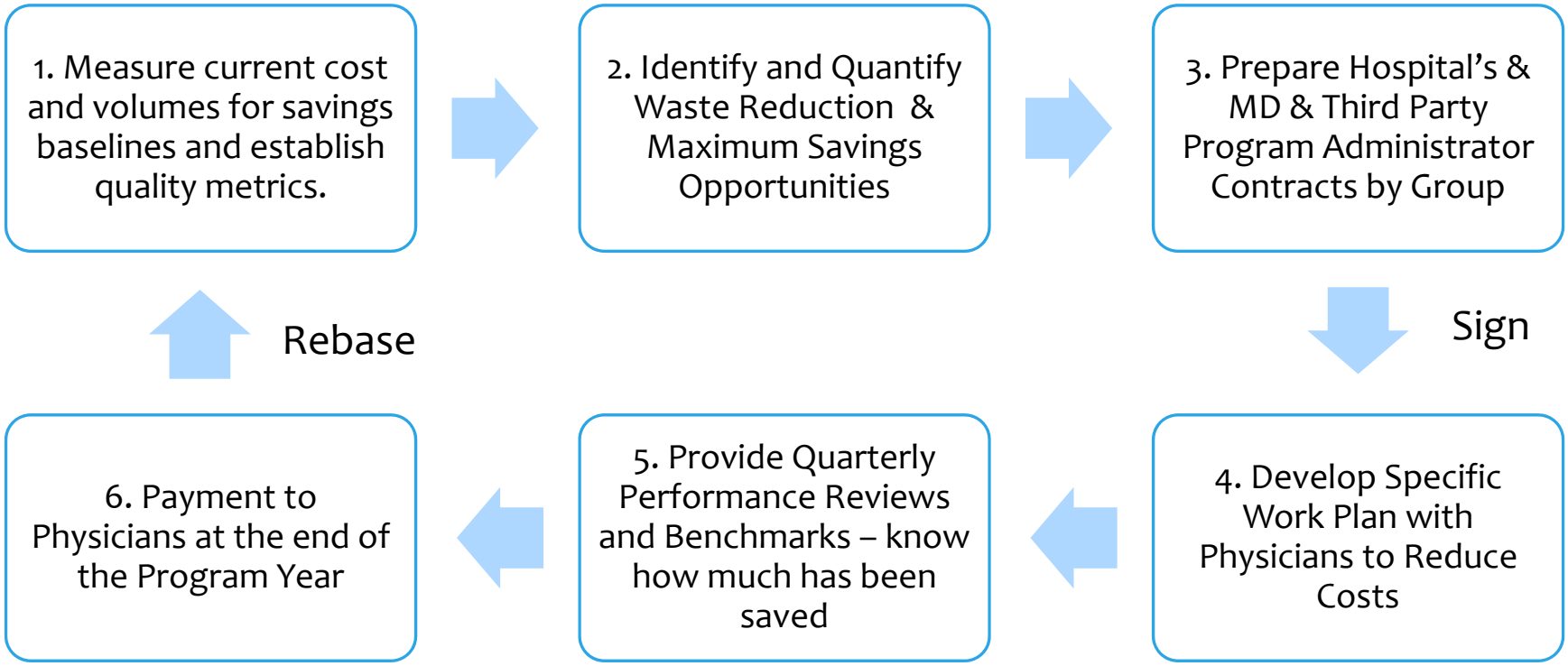
OIG Opinion Gainsharing Opportunities

Three Categories of Cost and Utilization Savings with the Monitoring of Quality

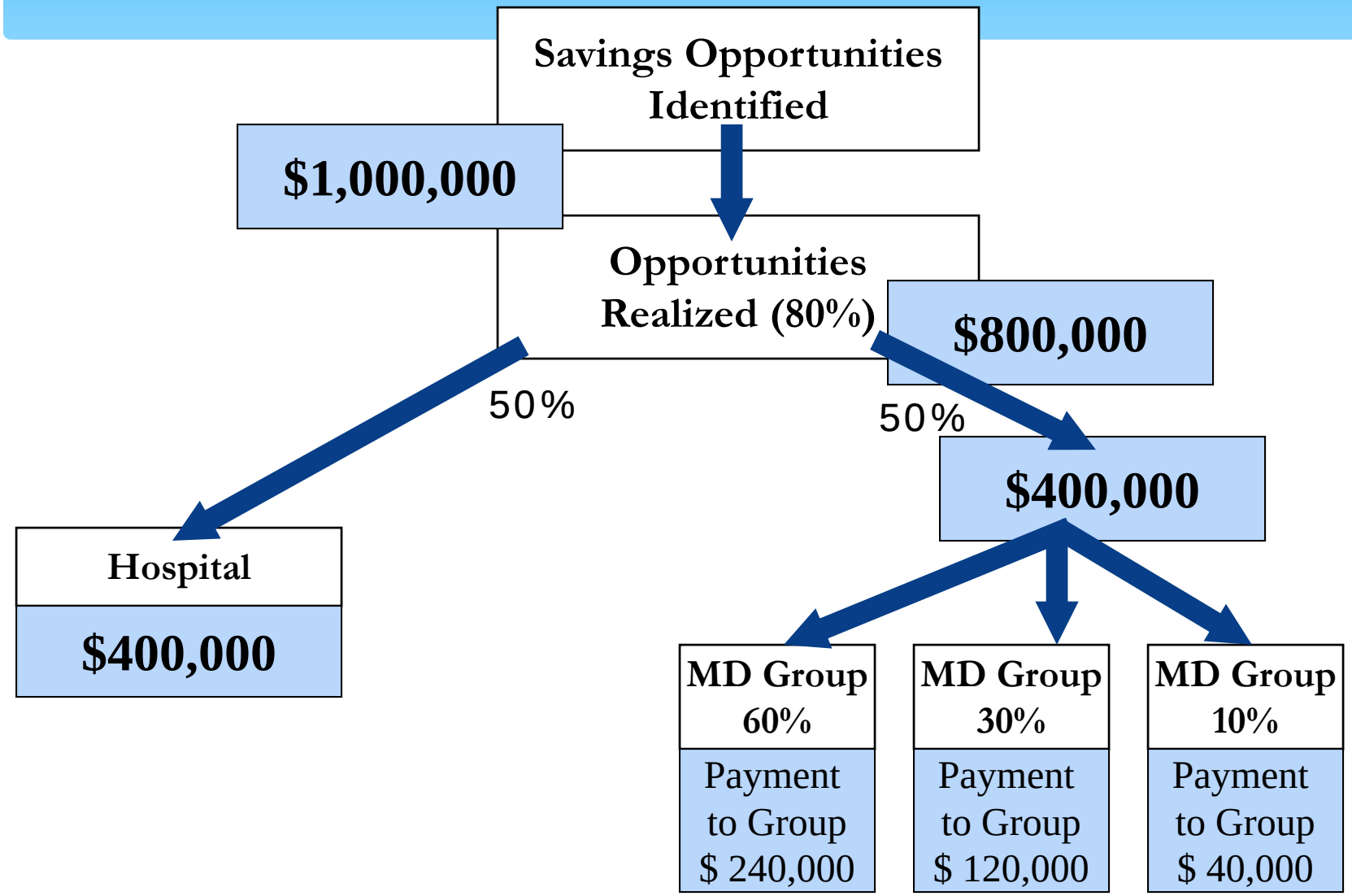


Shared savings is not derived from quality metrics

Steps in Gainsharing



Flow of Funds



OIG Gainsharing Program
CAN NOT:

- Pay for Future Volume / Value of Referrals
- Pay a Physician for Individual Performance
- Pay for Historical Performance
- Pay a Physician if Quality or Severity Decreases
- Exclude "Qualified" Physicians
- Pay Physicians an Unlimited Amount of Money

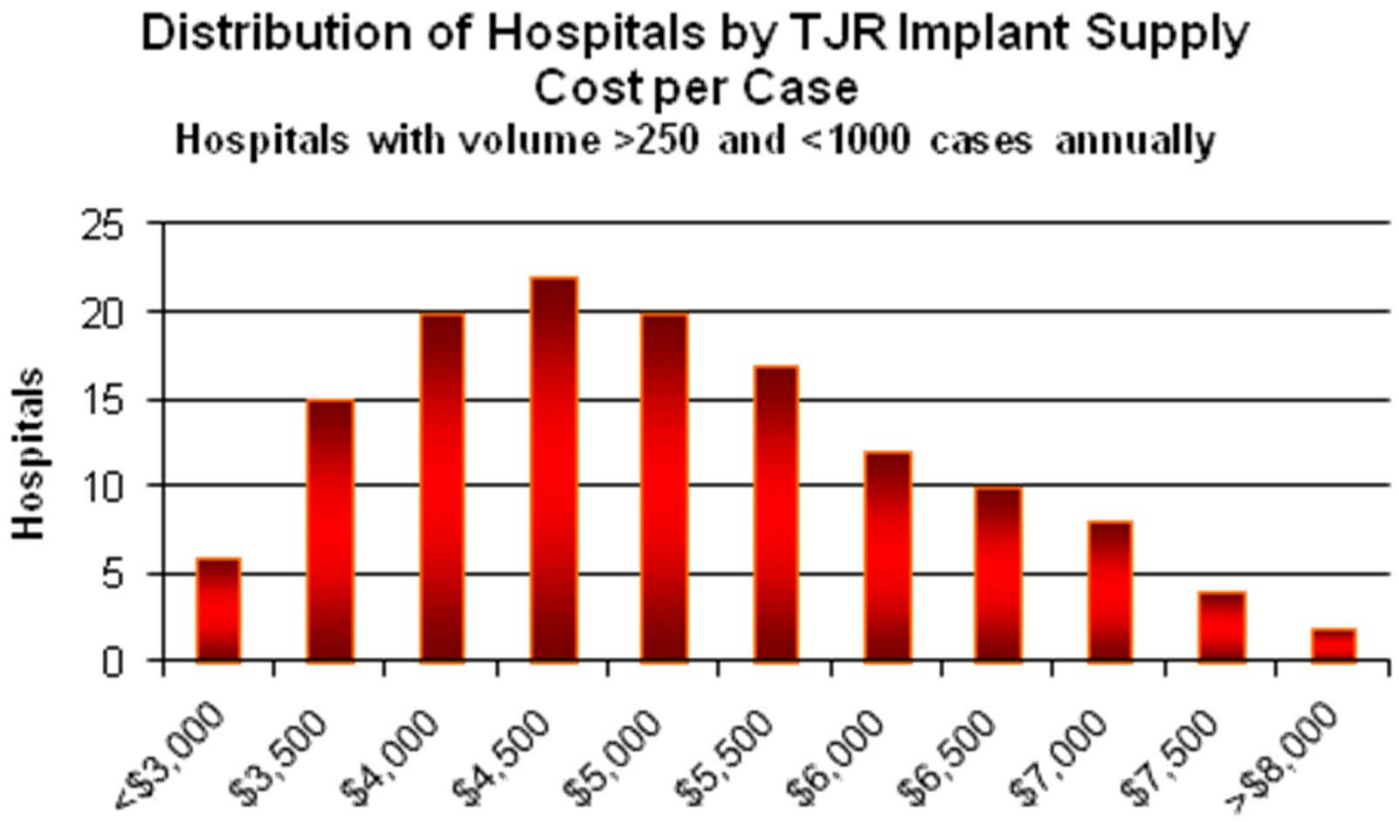
Opportunity by Physician Group

- Each group's opportunity is dependent on the cost they control.
- Case types have different levels of cost.
- Opportunities for cost reduction are based on the types of cases the group performs and how many cases

Example of OIG Submitted List: Knee Replacement

ITEM	SAVINGS
Knee Implants	$1989
Suture Routine	$11.68
1000 Drape	$2.59
Disposable Tourniquet	$17.59
Instrument Pouch	$4.03
Gown and Hood	$73.28
Bone Cement	$70.44
Reinfusion Unit	$135.53
Foley Catheter	$9.16
Proximate	$5.77
Plastic Boots	$3.47
Freight	$19.27
Osteonics Burr	$3.73
Saw Blades	$20.92
Dressings	$22.67
Whitney Curette	$20.03

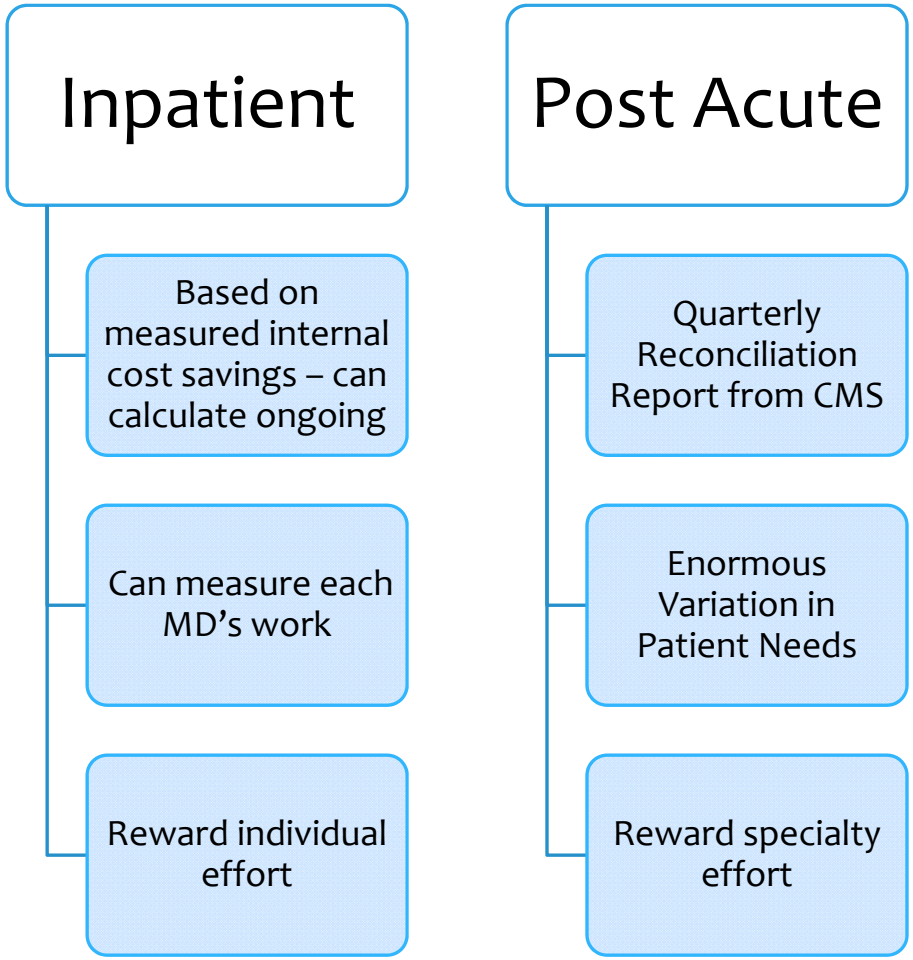
Total Joint Implant Expense / Case



OIG Opinion Gainsharing Program Tips from a Program Administrator

- Quality Metrics
- Define the patient population and initiatives carefully
- Maximum savings dollar amount is defined per initiative
- Patient Disclosure
- Surgeon Invitation to Participate (all that are credentialed and privileged to perform the procedure)
- Transparency (FAQs & Group Meeting & Reports)
- Minimum 2 year agreement (100-50=75)
- Participation is voluntary (conscientious objector)
- Evidence Folder
- It only takes one disgruntled person to call the OIG
- OIG Opinion 17-09 – MD overhead allowance or conservative hospital

Bundled Payments: Two different opportunities for gainsharing with individual physicians



BPCI Advanced

Episodes

29 Inpatient Clinical Episodes

- Disorders of the liver excluding malignancy, cirrhosis, alcoholic hepatitis *(New episode added to BPCI Advanced)
- Acute myocardial infarction
- Back & neck except spinal fusion
- Cardiac arrhythmia
- Cardiac defibrillator
- Cardiac valve
- Cellulitis
- Cervical spinal fusion
- COPD, bronchitis, asthma
- Combined anterior posterior spinal fusion
- Congestive heart failure
- Coronary artery bypass graft
- Double joint replacement of the lower extremity
- Fractures of the femur and hip or pelvis
- Gastrointestinal hemorrhage
- Gastrointestinal obstruction
- Hip & femur procedures except major joint
- Lower extremity/humerus procedure except hip, foot, femur
- Major bowel procedure
- Major joint replacement of the lower extremity
- Major joint replacement of the upper extremity
- Pacemaker
- Percutaneous coronary intervention
- Renal failure
- Sepsis
- Simple pneumonia and respiratory infections
- Spinal fusion (non-cervical)
- Stroke
- Urinary tract infection

3 Outpatient Clinical Episodes

- Percutaneous Coronary Intervention (PCI)
- Cardiac Defibrillator
- Back & Neck Except Spinal Fusion

3

https://innovation.cms.gov/Files/fact-sheet/bpci-advanced-generalfs.pdf

Coexisting Gainsharing Arrangements

Annual Perspective

Combination Model 470/469 ONLY

	Volume	Hospital Savings	Surgeon Share	Annual Gain Share	Total	Average Per Case		
CJR	500	$1,735,760	$750	$375,000		$	5,887	ASP
Non_Med	460	$1,596,899	$1,736	$798,450		$	3,472	Savings
		$3,332,659			**$1,173,450**	$	2,415	Target
$ 3,472	Savings Per Patient							

All BPCI Model 470/469 ONLY

	Volume	Hospital Savings	Surgeon Share	Annual Gain Share	Total	Average Per Case		
CJR	500	$750,000	$750	$375,000		$	5,887	ASP
Non_Med	460	$690,000	$750	$345,000		$	1,500	Savings
		$1,440,000			**$720,000**	$	4,387	Target
$ 1,500	Savings Per Patient							

Review of FMV Considerations

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FMV Definition

1. *Fair market value* means the value in arm's-length transactions, consistent with the general market value.
2. "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

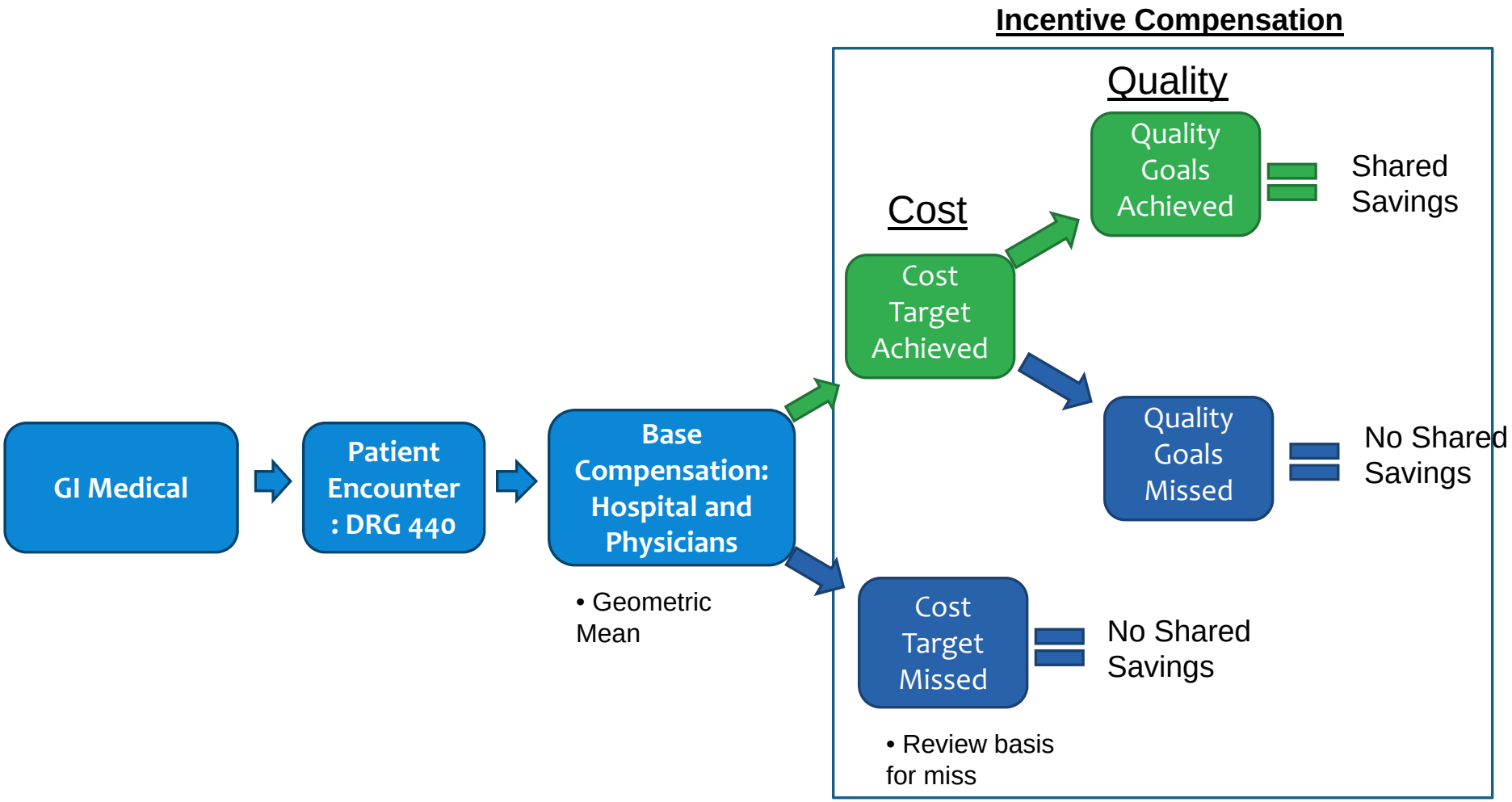
Cost Approach

- 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

Shared Savings Criteria



Savings Calculation

Report for Dr. John Doe – Attending Physician

GI Medical Bundle

DRG	Encounter	Actual Cost	Target Cost	Savings	LOS < GMLOS	Order Set Used	30 Day Readmission (same MDC)
379	**1**	**$3,755**	**$5,066**	**$1,311**	**Y**	**Y**	**N**
379	**2**	**$3,900**	**$5,066**	**$1,166**	**Y**	**Y**	**N**
379	**3**	**$3,650**	**$5,066**	**$1,416**	**Y**	**Y**	**N**
388	**4**	**$12,993**	**$14,773**	**$1,780**	**Y**	**Y**	**N**
388	**5**	**$13,565**	**$14,773**	**$1,208**	**Y**	**Y**	**N**
391	6	$7,920	$8,940	$1,020	Y	N	N
391	**7**	**$7,225**	$8,940	**$1,715**	**Y**	**Y**	**N**
391	8	$9,579	$8,940	($639)	Y	Y	N
440	**9**	**$4,000**	**$5,893**	**$1,893**	**Y**	**Y**	**N**
440	**10**	**$4,445**	**$5,893**	**$1,448**	**Y**	**Y**	**N**
440	**11**	**$4,770**	**$5,893**	**$1,123**	**Y**	**Y**	**N**
440	12	$5,050	$5,893	$843	N	Y	N
TOTALS		**$80,852**	**$95,136**	**$14,284**			
ELIGIBLE SAVINGS				**$11,644**			

Indicates a mortality. Even though savings were generated, and this case they will be excluded from distribution.

Cost and quality measures must be met for savings to be distributed. These cases are excluded from eligible savings, and any savings generated will go back to Hospital.

Gray indicates savings eligibility

Attending Physician (30%)	**$3,493.20**
Hospital (50%)	**$5,822.00**
Consultant (20%)	**$2,328.80**

TOTAL PAYOUT:	**$11,644**

Benchmarking Compensation

ORTHOPEDIC SURGERY

Year	N	25th	Median	75th	90th
2015	841	$445,693	$576,677	$802,244	$1,127,851
2015	1,036	$460,786	$582,056	$733,926	$1,002,336
2015	1,273	$430,000	$525,143	$646,750	$814,257

- Problems with this data:
  - Old
  - National
  - Combination of administrative, clinical, call coverage, surgery center profit
  - Not presented on an hourly basis

Benchmark Compensation

ORTHOPEDIC SURGERY					
Year	N	25th	Median	75th	90th
2015	38	$150	$200	$250	$267
2015	24	$219	$261	$330	$394

- Problems with this data:
  - Old
  - National
  - Very limited sample size
  - For hourly specific duties and not to incentivize behavior

Determining FMV

Revenue At Risk

Metric	Financial Pay for Performance Impact	Public Reporting	Quality / Safety Risk	CMS Focus / Improvement Opportunity
30 DAY READMISSION				
AMI	HRRP	Hospital Compare	Moderate	Moderate
THA/TKA	HRRP / CJR	Hospital Compare	Moderate	High
MORTALITY				
AMI	VBP	Hospital Compare	Moderate	Moderate
CABG	None	Hospital Compare and STS	Moderate	Low
Sepsis	None	None	High	High
Stroke	None	Hospital Compare	Moderate	Moderate

Allocating Pool of Funds

Metric	Volume	Average Cost	Extended	Revenue at Risk
30 DAY READMISSION				
AMI	28	$10,831	$303,261	Portion of 3%
THA/TKA	16	$12,208	$195,325	Portion of 3%
MORTALITY				
AMI	11	$32,126	$353,391	25% of 2%
CABG	2	$50,940	$101,879	
Sepsis	87	$26,712	$2,323,959	
Stroke	5	$19,568	$97,838	

Allocating Pool of Funds

Metric	Baseline	Target	Exceptional	Percent of Pool
30 DAY READMISSION				
AMI	10.62%	9.82%	9.29%	3.7%
THA/TKA	3.27%	3.02%	2.86%	5.2%
MORTALITY				
AMI	0.69	0.65	0.52	2.9%
CABG	0.85	0.54	0.48	2.2%
Sepsis	0.96	0.81	0.76	5.9%
Stroke	0.81	0.50	0.39	2.2%

Questions & Comments

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