Session 79X
Outpatient to Inpatient: Aligning Independent Physicians for Acute-Care Improvements

Presented by:
Dennis Weaver, MD
James M. Daniel Jr., JD
Outpatient to Inpatient: Aligning Independent Physicians for Acute-Care Improvements

Disclosure of Relevant Financial Relationships

The following faculty of this continuing education activity has no relevant financial relationships with commercial interests to disclose:

• Jim Daniel, JD, MBA
• Dennis Weaver, MD, MBA
Faculty

- Jim Daniel, JD, MBA
- Dennis Weaver, MD, MBA

Learning Objectives

- Recognize how the Hospital Efficiency Improvement Program (HEIP) makes the laws under the Medicare Access and CHIP Reauthorization Act softer and friendlier toward gainsharing initiatives with proven quality and cost improvements.
- Explain the mechanics of a HEIP and how to calculate the ultimate reduction in unnecessary cost and variation to maximize hospital reimbursement under value-based purchasing.
- Understand the legal issues that deserve consideration in establishing and operating a HEIP
Agenda

• Why Our Care Variation Reduction Efforts are Falling Short

• The Hospital Efficiency Improvement Program

• Legal Theory and Implications

• Success Stories

- Your C-Suite’s Top Priority
  Executives Banking on the Promise of Clinical Standardization

<table>
<thead>
<tr>
<th>Top Five Priorities for Hospitals and Health Systems, 2015</th>
<th>Top Five Priorities for Hospitals and Health Systems, 2016</th>
</tr>
</thead>
<tbody>
<tr>
<td>Engaging physicians in cost and quality improvements</td>
<td>Engaging physicians in reducing clinical variation</td>
</tr>
<tr>
<td>Redesigning service portfolios for population health</td>
<td>Redesigning health system services for population health</td>
</tr>
<tr>
<td>Establishing sustainable acute care cost structures</td>
<td>Meeting increasing consumer expectations for service</td>
</tr>
<tr>
<td>Patient engagement strategies</td>
<td>Implementing patient engagement strategies</td>
</tr>
<tr>
<td>Controlling avoidable utilization</td>
<td>Controlling avoidable utilization</td>
</tr>
</tbody>
</table>

n=150 C-Suite Hospital Executives
n=209 C-Suite Hospital Executives
Reducing Clinical Variation Key to Executing on System Imperatives

Market Pressures Creating New Urgency

Major Market Forces
- Mounting margin pressure
- Continuing transition to risk
- Emergence of consumerism
- Industry consolidation

Health System Strategic Imperatives
- Reliability: Standardize the production model to ensure service, clinical quality meet and exceed customer expectations
- Affordability: Streamline the fixed cost structure to reduce cost per case and total care costs
- Accessibility: Diversify access options to meet patients when, where, and how they want

Necessary Lever for Success

Care Variation Reduction is the primary lever for health systems to provide reliable, affordable care.

Clinical Standardization Required to Grow Margins Today

Traditional Margin Levers No Longer Sufficient

"The tactical cost levers that hospitals usually pull — supply chain savings initiatives, capital spending freezes and benchmark-driven headcount reductions — are neither sustainable nor significant enough to achieve the savings they need to survive and thrive."

CFOs’ Estimated Breakdown of Cost Savings Opportunities

Of hospitals projected to have negative profit margin in 2025 if they do not improve productivity or reduce costs
Defining Our Terms

Goals of Care Variation Reduction

- Eliminate overtreatment, under treatment, and mistreatment through adherence to an accepted clinical standard that optimizes quality and reduces unnecessary costs
- Encourage deviation from an accepted clinical standard when clinically necessary

What is an “accepted clinical standard?”

- Has been approved as expected practice by the organization and may be evidence- or consensus-based:
  - Evidence-based practice standards are based on evidence from the literature
  - Practice-based evidence standards are built on internal consensus of experts and closely monitored to determine efficacy and identify needed changes

Critical Success Factors

The goal of reducing care variability is not complete standardization, it is reducing unwarranted variation

Organizations should standardize clinical practice even in the absence of definitive evidence

Clinical standards should improve quality and tackle excess resource use

A Few Key Challenges Standing In Our Way

Physicians are not fully aligned with care variation efforts

The promise of infrastructure investments have yet to be realized

Contributing efforts are complex and siloed

Top executives have not fully committed to a system-led strategy
Investing Heavily in Physician Partners

Growing Hospital Ownership of Physician Practices

86%
Percent increase in hospital ownership of physician practices between 2012 and 2015

31,000
Number of physician practices acquired by hospitals between 2012 and 2015

Employment Not a Silver Bullet for Quality Improvement

Up to two years after conversion, no association was found between switching to an employment model and improvement in any of the four primary composite quality metrics.”

A Transformational Time for Physician Practice

A New Physician Mindset

The Traditional Clinical Model

Autonomous decision-makers
Practice according to own training and knowledge
Individually responsible for staying up to date on clinical evidence

A New Physician Mindset

Commit to providing reliable, consistent care
Thoughtfully steward health system resources
Collaborate with a team to define, follow care standards
More Asks Leading to Physician Burnout

Increasing Demands on Physicians’ Time Contributing to Growing Levels of Burnout

Burned Out Physicians Choosing to Work Less

“In the next 1-3 years, do you plan to (check all that apply):”

- Cut back on hours: 21%
- Retire: 14%
- Seek a non-clinical job within healthcare: 14%
- Work part-time: 10%

Percent physicians who sometimes, often, or always experience feelings of burnout: 74%

“Because of rising regulatory burdens and the growing demand for their services, the great majority of physicians responding to the survey indicate they are at capacity or are overextended.”

Burned out physicians may have less capacity to take on responsibilities critical to reducing care variation, like participating on a clinical consensus group.

Resilience Required to Reduce Care Variation

Culture: Does the Organization Have What it Takes?

- Aspirational leaders to drive revolutionary change
- Change management competency
- Values based in reliability, quality, and safety
- Focus on long-term strategy, not expedient gains
- Political capital with physicians and other relevant stakeholders

A Journey Without a Finish Line

“This is a journey that is not complete. You don’t conquer care variation reduction in six months.”

Dr. John Hensing, EVP and CMO, Banner Health
Integrated Capabilities Required to Scale Clinical Transformation

**The Care Variation Reduction Model**

**BUILD**
Governance and Leadership Model
Create a system-level clinical excellence entity with authority to drive system-wide clinical transformation; define leadership roles

**ALIGN**
Physicians and Clinical Stakeholders
Engage employed and private practice physicians in care reliability ambition; align incentives with care variation reduction

**DESIGN**
New Standards of Care
Define new clinical and operational standards; design how standards will be met using a process engineering approach

**EMBED**
Standards in Clinical Workflow
Hardwire standards into point-of-care workflows through EHR-enabled improvements, including clinical decision support

**MEASURE**
Quality and Cost Outcomes
Provide an analytics framework to prioritize opportunities, identify root causes, track adherence to standards and monitor results

**SUSTAIN**
A Culture of High Reliability
Promote core values and norms that encourage knowledge-sharing and organizational learning; develop robust communication and change management capabilities; cultivate a shared sense of ownership over clinical excellence at all organizational levels

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**Common Physician Alignment Models**

A Range of Viable Alignment Options for Accountable Care

<table>
<thead>
<tr>
<th>Alignment Model Category</th>
<th>Down but Not Out</th>
<th>Staging a Comeback</th>
<th>Surging in Popularity</th>
</tr>
</thead>
<tbody>
<tr>
<td>Degree of Effectiveness</td>
<td>Questionable long-term viability; minimal ability to create performance-based incentives</td>
<td>Able to create limited performance-based physician incentives</td>
<td>Substantial opportunity to design performance-based physician incentives</td>
</tr>
<tr>
<td>Types of Alignment Models</td>
<td>Management Services Organization (MSO)</td>
<td>Traditional Physician-Hospital Organization (PHO)</td>
<td>Select Employment</td>
</tr>
<tr>
<td></td>
<td>Joint Ventures</td>
<td>Gainsharing (include with co-management)</td>
<td>Clinically Integrated PHOs</td>
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<td></td>
<td>Medical Directorships</td>
<td></td>
<td>Co-Management</td>
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<td></td>
<td>Recruitment Incentives (individual physicians)</td>
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<td>Bundled Payments</td>
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<td>Physician Services Agreement (PSA)</td>
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Degree of Hospital-Physician Integration

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**A Range of Viable Alignment Options for Accountable Care**

- Management Services Organization (MSO)
- Joint Ventures
- Medical Directorships
- Recruitment Incentives (individual physicians)
- Traditional Physician-Hospital Organization (PHO)
- Gainsharing (include with co-management)
- Select Employment
- Clinically Integrated PHOs
- Co-Management
- Bundled Payments
- Physician Services Agreement (PSA)

These alternatives enabling joint contracting
Common Physician Alignment Models (cont.)

<table>
<thead>
<tr>
<th>Attributes</th>
<th>Joint Venture</th>
<th>PSA¹</th>
<th>Bundled Payment</th>
<th>Gainsharing</th>
<th>Co-Management</th>
<th>Clinical Integration</th>
<th>Extensive Employment</th>
</tr>
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<tr>
<td>Selective Membership</td>
<td></td>
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<tr>
<td>Care Standards</td>
<td></td>
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<tr>
<td>Coordination Infrastructure</td>
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<tr>
<td>Performance Management</td>
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<tr>
<td>Meaningful Incentives</td>
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<tr>
<td>Joint Contracting²</td>
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</tr>
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Degree of Hospital-Physician Integration

- No Ability
- Minimal Ability
- Moderate Ability
- Significant Ability
- Complete Ability

¹) Physician Services Agreement – new generation
²) Assumes FTC-compliant clinical integration entity

Hospital Efficiency Improvement Program
Definition and Objectives of HEIP

**What is HEIP?** A hospital contracts with a CIN to engage a select subset of its participating physicians to undertake a series of processes, performance, and/or clinical initiatives on the basis of enhanced quality, outcomes and/or efficiency initiatives within the hospital. For enhancements achieved, the hospital provides the CIN a fair market value (“FMV”) compensation which the CIN would use, in part, to both reimburse and provide performance-based incentives to physicians for their efforts in the HEIP program.

**Common HEIP Objectives**

- **Collaborate**
  - Key medical and surgical specialties
  - Best practice evidence-based guidelines

- **Improve Process and Outcomes**
  - Process and performance
  - Patient care
  - Cost and efficiencies

- **Accountability**
  - High degree of interdependence
  - Physician to physician

- **Financial Improvements**
  - Align physicians to adherence and improvements
  - Reduce unwarranted variability and inefficiencies
Co-Management vs HEIP?
Individual, Siloed Approach vs Collaborative, Aligned Initiatives

Co-Management
(single specialty)

- Significant time and effort to negotiate multiple agreements
- Specialties work in a siloed fashion towards specific goals
- Other specialties seek co-management agreements but do not drive targeted cost savings

Hospital Efficiency Improvement Plan
(inclusive of multiple specialties)

- Collaborative: all inpatient-focused specialties incented to reach same outcomes, yielding better collaboration
- Inclusive: all specialties inflecting inpatient outcomes are eligible for rewards
- High-impact: incentives focus specialists on improvement areas with greatest ROI

HEIP Initiative Examples

<table>
<thead>
<tr>
<th>Setting of Care</th>
<th>Transitions of Care</th>
<th>Clinical Efficiency</th>
<th>Procedure Management</th>
<th>Condition Management</th>
</tr>
</thead>
<tbody>
<tr>
<td>Operating room</td>
<td>Length of stay opportunities</td>
<td>Appropriate level of care</td>
<td>Cardiology services</td>
<td>Heart failure</td>
</tr>
<tr>
<td>Emergency department</td>
<td>Readmission opportunities</td>
<td>Evidence-based standardization</td>
<td>Hospitalists/ intensivists</td>
<td>Sepsis</td>
</tr>
<tr>
<td>Critical care</td>
<td>Admission/ discharge protocols</td>
<td>Blood utilization</td>
<td>Musculoskeletal</td>
<td>Osteoarthritis</td>
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</tbody>
</table>
Evolving to a Multi-Specialty Contract Model

Case in Brief: Opal Health System¹

• Large hospital system in the Midwest with a Clinically Integrated Network (CIN)

• Worked with Advisory Board Consulting to implement the Hospital Efficiency Improvement Program across its five regions

• Regions select initiatives and incentive goals based on an analysis of cost improvement opportunities (e.g., LOS, readmissions, blood utilization)

• Achieved $11 million in the first year of HEIP, with a three-year target of $58 million

HEIP Requires a 3-Step Program Rollout

- Identify High-ROI Impact Areas
  • With consulting support, Opal Health System reviews all-payer claims data, drilling down to DRG-level
  • Analysis reveals greatest opportunities to minimize unnecessary inpatient variability

- Match High-Impact Initiatives to Specialties
  • All identified opportunities become an initiative (initiatives vary based on region)
  • Every specialist in the CIN³ who can inflect outcomes on an initiative(s) invited to participate in HEIP
  • Select specialists take on leadership roles within initiative committees and are responsible for care pathway development

- Structure an Outcomes-Based Rewards Program
  • Maximum compensation calculated by third party valuation group
  • 10% allocated to select specialists in leadership roles, 90% allocated for incentive pool
  • Management and incentive fees are paid by the hospital to the CIN, which distributes rewards to specialists
Opal Health Incents Specialists for Improvement on Outcomes

Initiative Goals

- Initiative committees set annual goals based on desired practice change

Three-Tiered Target

- Committees set three performance targets, factoring in current performance

Corresponding Payout Levels

- Specialists earn payouts for the initiatives to which they are assigned based on performance

<table>
<thead>
<tr>
<th>Initiative Goals</th>
<th>Three-Tiered Target</th>
<th>Corresponding Payout Levels</th>
</tr>
</thead>
<tbody>
<tr>
<td>Goal for Joint Replacement Initiative: Use of demand match protocol for appropriate implant selection</td>
<td>Stretch Goal: +10%</td>
<td>Percentage of Incentive Pool Earned:</td>
</tr>
<tr>
<td>Goal for Blood Utilization Initiative: Adherence to utilization guidelines regarding ordering of blood products and hemoglobin indications</td>
<td>Performance Target: Improvement Baseline: -10%</td>
<td>Stretch Goal: 100%</td>
</tr>
<tr>
<td></td>
<td></td>
<td>Performance Target: 75%</td>
</tr>
<tr>
<td></td>
<td></td>
<td>Improvement Target: 50%</td>
</tr>
</tbody>
</table>

1. Hospital provides payouts to the Clinically Integrated Network, which then distributes for payouts to specialists

Bound to Hit Some Implementation Hurdles

Implementation Challenges at Opal Health System

- 30 Co-Management Agreements
- 1 HEIP Contract

- Which metrics overlap between the existing co-management agreements and the HEIP contract? How do we eliminate redundancies?
- Should we sunset our co-management agreements?
- How do we structure HEIP across a multi-regional health system, with varying levels of performance?
- How does the infrastructure for HEIP interface with that of our CIN?

Advisory Board Consulting

- Offers comprehensive physician alignment support to help organizations empower their physicians as leaders and partners, and deliver targeted improvement in the areas that impact integration
- Implementing HEIP at multiple partner sites
- To learn more, please visit: https://www.advisory.com/consulting
A Positive Trajectory at Opal Health
HEIP Produces Significant First-Year Cost Savings

$11M
Annualized savings achieved in first year

$58M
Target cost savings over a three-year period

Savings estimated to grow incrementally larger as the program matures and system implements new initiatives

Creating a Co-Management Relationship

Case in Brief: Coastal Community Hospital

About
- 400-bed acute care, not-for-profit hospital on the East Coast
- More than 800 physicians on the medical staff

Challenges
- Implement a new vision for the hospital’s heart and vascular center
- Create stronger affiliations with the top cardiologists in a highly competitive market

Solution
- In-depth service line assessment of key financial, quality and operational components
- Comprehensive ROI analysis
- Interim Development Manager for the heart and vascular center
Collaboration Yields Positive Results

<table>
<thead>
<tr>
<th>Area of Improvement</th>
<th>Positive Results¹</th>
</tr>
</thead>
</table>
| Vibrant cardiovascular community | • Achieved new levels of physician engagement and loyalty  
• Co-developed Innovative strategies and programming  
• Physicians participated in over 15 provider development and community outreach programs |
| Ability to act as a body while maintaining private practices | • Cohesive voice for cardiovascular physicians  
• Increased influence over cardiovascular planning & physician compliance  
• Comprehensive cardiac review and weekly heart failure meetings |
| Quality Improvements | • AMI, Vascular SCIP, HF, Cardiac Surgery SCIP, score results achieved at top 10th percentile based on national standards |
| Cost savings efforts | • Achieved $1.2m in global (EP, Cardiac surgery, vascular, interventional) cost efficiency savings, above $800k target threshold  
• Achieved new program development/implementation: Same Day PCI, Valvular Heart Disease Clinic and Syncope Management Program |

¹ Results as of December 2012

Key Design and Legal Considerations

• HEIP Design
• Federal Anti-Kickback Statute
• Stark Law
• Civil Monetary Penalty Statute
• Tax Exempt Issues
• Provider-based Status Rules
HEIP Agreement Between System and CIN
Core Components Sit Adjacent to CIN Framework

**Participation Agreement**
- Central Agreement with Market-Based Activities
- Specify duties and obligations
- Selected physician participants
- Payment methodology
- Term of the agreement (Minimum 1 Year)

**Program Development/FMV**
- Define Program Initiatives
- Ascertain Physician Activities
- Document Baseline and Benchmark
- Third Party FMV

**Physician Compensation**
- Maximum/Minimum amount to be paid must be set in advance
- Payment cannot vary by volume, referrals, or other business relationships
- Distributions may be made quarterly or annually (with annual true-up)

Anatomy and Process of HEIP
Locally Implemented, Market Funded, and Benefit to Accrue to Market

1. Define the program’s initiatives (system and market-based initiatives)
2. Map initiatives to performance measurement technology; validate metrics
3. Third party valuation
4. Payment maximum/minimum set (aggregate network vs. market approach)
5. Develop distribution methodology/payment term
6. Monitor, track, and report CIN’s performance pursuant to HEIP
7. Based on CIN’s performance, hospital(s) fund payment to HEIP (market/system)
8. Benefits achieved (e.g., quality and efficiency) accrue to the individual facilities

**Tracking Adherence to HEIP Performance**
- CIN or System Office
- Local Market

**Funds Flow**
- CIN to System Office to Local Market
HEIP Relationship to CIN and Flow of Funds

How it works: Payment under HEIP is made directly from the health system to the CIN, based on the market’s performance on program initiatives. The CIN then reimburses participating physicians who provided services under HEIP. Downstream payments to physicians may include: per capita payment; incentive benchmark payment; and time spent in activities.

CIN distributes funds at the local market level based on physician’s TIN.

HEIP Benefits

<table>
<thead>
<tr>
<th>System/Hospitals</th>
<th>CIN/Physicians</th>
</tr>
</thead>
<tbody>
<tr>
<td>Aligns providers with Health System quality and efficiency initiatives</td>
<td>Strengthens relationship with Health System</td>
</tr>
<tr>
<td>Improves public quality metrics</td>
<td>Generates funds to support CIN infrastructure</td>
</tr>
<tr>
<td>Standardizes care</td>
<td>Provides monetary rewards for improving efficiency and quality</td>
</tr>
<tr>
<td>Creates provider incentives to minimize waste</td>
<td>Prepares physicians and network for quality-based reimbursement</td>
</tr>
</tbody>
</table>
HEIP Examples

<table>
<thead>
<tr>
<th>Initiative</th>
<th>Description</th>
</tr>
</thead>
<tbody>
<tr>
<td>Readmissions</td>
<td>Reduce readmission rate for key conditions &amp; frequent utilisers with patient education &amp; transitions of care focus</td>
</tr>
<tr>
<td>Mortality &amp; Sepsis</td>
<td>Improve mortality scores &amp; overall sepsis</td>
</tr>
<tr>
<td>Public Reporting Scores</td>
<td>Improve scores in publicly reported programs (VBP, HAC, SIM)</td>
</tr>
<tr>
<td>Resource Utilization</td>
<td>Reduce IM &amp; FM CM adjusted Cost/Case to Hospitalist levels</td>
</tr>
<tr>
<td>Radiology Utilization</td>
<td>Eliminate MRI, CT, Nuclear ordered on last 2 days of IP stay</td>
</tr>
<tr>
<td>Laboratory Utilization</td>
<td>Eliminate ordering of CPK test in conjunction with Troponin</td>
</tr>
<tr>
<td>Pharmaceutical Utilization</td>
<td>Switch to generic drugs &amp; optimize therapeutic substitutions</td>
</tr>
<tr>
<td>Implant Utilization</td>
<td>Reduce implant &amp; surgical supply spend by standardization</td>
</tr>
<tr>
<td>Documentation</td>
<td>Improve CHF &amp; COPD documentation v. national benchmarks</td>
</tr>
<tr>
<td>Employee Health Benefit Costs</td>
<td>Reduce total cost per individual in high-risk &amp; rising-risk populations covered by self-insured health plan</td>
</tr>
</tbody>
</table>

Sample Flow of Funds
Based on Shared Savings

*Percentages used to indicate relative proportions of fixed funds made available to participants. Payments from savings pools are typically based on tiered payment.
Distribution Methodology

Funds allocated to each Tier will be equally distributed to physicians who meet those tier expectations

Funds Saved Via Outcome Goals

Funds Distribution Pool

All Network Physicians
Cardiologists
Orthopods

0% - Tier 0: UNSATISFACTORY
10% - Tier 0: MEETS EXPECTATIONS
90% - Tier 0: EXCEEDS EXPECTATIONS

Quality Metrics
Outcome Goals

OIG Advisory Opinions

<table>
<thead>
<tr>
<th>OIG Opinion</th>
<th>Eligible Parties</th>
<th>Source of Savings</th>
<th>Safeguards</th>
<th>Distribution</th>
<th>OIG Analysis</th>
</tr>
</thead>
<tbody>
<tr>
<td>06-02 Non-physician employees</td>
<td>Cost-saving suggestions that the Hospital adopts in its operations</td>
<td>No payment made to physicians, no rewards for suggestions that would reduce health care services, no rewards for suggestions that identify specific vendors, no rewards for suggestions that shift costs to Federal health care programs, employee receiving payment would not have the decision-making authority to implement the suggestion</td>
<td>Percentage of the cost savings derived during year one of implementation</td>
<td>Some payments might implicate AKS if the necessary criteria were present</td>
<td></td>
</tr>
<tr>
<td>01-01 Cardiology group</td>
<td>Curb inappropriate use or waste of medical supplies, e.g. surgical supplies</td>
<td>Historical and clinical measures to create a floor below which no savings/payments could occur</td>
<td>Credible medical support that there will be no adverse effects on patient care</td>
<td>50% of year one savings directly attributable to changes in practices</td>
<td>Implicates Gainsharing CMP, but declined to impose sanctions</td>
</tr>
<tr>
<td>05-01 Cardiology group</td>
<td>Curb inappropriate use or waste of medical supplies</td>
<td>Historical and clinical measures to establish a &quot;floor&quot;</td>
<td>Evidence of no adverse effect on care</td>
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<td>06-02 Cardiology (groups 5)</td>
<td>Cardiopulmonary use of waste of medical supplies • Standardization of surgical devices • As an indirect use of vascular devices</td>
<td>• Transparency • Evidence of no adverse effect or use • Payments based on procedures regardless of insurance • Historical and clinical measures to establish a floor • Physician access to full selection of devices and use is based on patient's clinical determinations • Written disclosures • Limited to duration and amount • Per capita distribution</td>
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<tr>
<td>06-03 Cardiology group</td>
<td>Cardiopulmonary use of waste of medical supplies • Use of supplies • Billing overreporting</td>
<td>• Transparency • Evidence of no adverse effect or use • Payments based on procedures regardless of insurance • Historical and clinical measures to establish a floor • Physician access to full selection of devices and use is based on patient's clinical determinations • Written disclosures • Limited to duration and amount • Per capita distribution</td>
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<td>06-04 Cardiology group (groups 5)</td>
<td>Cardiopulmonary use of waste of medical supplies • Standardization of surgical devices • As an indirect use of vascular devices</td>
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### Additional Information

- **50% of year one savings directly attributable to changes in practice.**
- **Implies Gainsharing CMP, but OIG declined to impose sanctions.**
- **Arrangement could implicate AKS, but OIG would decline to impose sanctions.**
- **Per capita distribution.**
## OIG Advisory Opinions

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<th>OIG Opinion</th>
<th>Eligible Parties</th>
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<th>Safeguards</th>
<th>Distribution</th>
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</thead>
<tbody>
<tr>
<td>08-06 Orthopedic surgery group</td>
<td>Cuts inappropriate use or waste of medical supplies</td>
<td>• Standardization of spine fusion devices and supplies</td>
<td>• Transparency</td>
<td>50% of year one savings directly attributable changes in practice</td>
<td>Implies discontinuing CMP, but OIG would decline to impose sanctions. Arrangement could implicate AKS, but OIG would decline to impose sanctions.</td>
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<tr>
<td>08-15 Cardiology group (2)</td>
<td>Cuts inappropriate use or waste of medical supplies</td>
<td>• Standardization of cannulation supplies (e.g. catheters, balloons, guide wires)</td>
<td>• Transparency</td>
<td>50% of year one savings directly attributable changes in practice</td>
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<tr>
<td>08-21 Cardiology group (5)</td>
<td>Cuts inappropriate use or waste of medical supplies</td>
<td>• Standardization of catheterization supplies (e.g. stents, balloons, guide wires)</td>
<td>• Transparency</td>
<td>50% of year one savings directly attributable changes in practice</td>
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### 2017 Congress on Healthcare Leadership

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<td>08-06 Cardiology group (International radiology group Vascular surgery group)</td>
<td>Cuts inappropriate use or waste of medical supplies</td>
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<td>12-22 Cardiology group (management agreement)</td>
<td>Cuts inappropriate use or waste of medical supplies</td>
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**2017 Congress on Healthcare Leadership**
The Stark Law

Basic prohibition:

Unless an exception applies, a physician may not refer DHS to an entity with which the physician or an immediate family member has a financial relationship, and an entity may not bill for such DHS.
Relevant Exceptions to the Stark Law

Indirect Compensation Relationship:

- Unbroken chain
- Physician receives aggregate compensation from the entity with a direct arrangement that varies with the volume or value of referrals to DHS entity (i.e. hospital)
- CMS: a fixed payment varies with the volume or value if it exceeds FMV
- DHS entity has actual knowledge of, or acts in reckless disregard or deliberate ignorance of, the fact that the referring physician receives aggregate compensation that varies with, or takes into account, the volume or value of referrals or other business generated by the referring physician for the entity furnishing DHS

Indirect Compensation Exception:

- Compensation is fair market value
- Does not vary with v/v of referrals or other business generated
- Set out in writing, signed by parties, specifying the services covered by the arrangement
- Does not violate AKS

Risk-Sharing Arrangements:

- Compensation pursuant to a risk-sharing arrangement (e.g. withhold, bonuses, risk pools) between a MCO or an IPA and a physician (either directly or indirectly) for services provided to enrollees of a health plan
- Arrangement cannot violate AKS or any federal/state law governing billing or claims submission
MACRA—April 2015

• Permanently repealed the Sustainable Growth Rate formula for Medicare physician payment and created a framework for payments based on value over volume
• Starting in 2019, physicians will choose from two payment models:

**MIPS**

*Merit-Based Incentive Payment System*

Annual payment increase or decrease based on performance. Physicians are scored on 4 categories using existing quality measures (PQRS, EHR Incentive Program, Value-Based Payment Modifier):
- Clinical quality
- Meaningful Use
- Resource use
- Clinical practice improvement

**APM**

*Alternative Payment Models*

If 25% of a physician’s Medicare revenue comes via an AMP in 2018, the physician gets a 5% bonus. Reflecting a move toward value-based payment, beginning in 2021, a 50% threshold is needed to receive a bonus.

MACRA and Gainsharing

**Gainsharing CMP Modified:**

• Prohibits a hospital from knowingly making a payment to a physician as an inducement to reduce or limit medically necessary services provided to Medicare or Medicaid beneficiaries who are under the care of a physician.

• The elimination of a CMP for payments made to induce the reduction on non-medically necessary services provides protection for physicians (and hospitals) as they begin to embrace a more efficient and value-based health care environment.
No Gainsharing CMP Waivers

In light of [MACRA], payments by hospitals to induce physicians to reduce or limit medically unnecessary services no longer implicate the Gainsharing CMP… Thus, a waiver of the Gainsharing CMP is no longer necessary to carry out the Shared Savings program, which, by its terms, promotes quality and patient care goals like fostering efficient medically necessary care, but not stinting on medically necessary care.

80 FR 66725, October 29, 2015

Other Legal Issues

Tax Exempt Issues:
- Assets of charitable organization cannot be used for private inurement, private benefit, or excess benefit
- Compensation must be reasonable and not based on “net earnings” of the hospital or service line

Provider-Based Status Rules:
- Provider-based rules apply to a hospital-licensed service either on-campus or “off-campus” hospital department
- If co-management of an “off-campus” location, the clinical staff (except physicians and NPs) must be directly employed by the hospital
Fraud and Abuse Waivers

- Pioneer Accountable Care Organization (ACO) Model
- Bundled Payment of Care Improvement (BCPI) Models
- Health Care Innovation Awards (HCIA) Round Two
- Comprehensive ESRD Care (CEC) Model
- Comprehensive Care for Joint Replacement (CJR) Model
- Next Generation ACO Model
- Oncology Care Model (OCM)
- Part D Enhanced Medication Therapy Management (MTM) Model
- Medicare Shared Savings Program

Practical Guidelines to Consider

- Commercial-only payor vs. all payor
- Avoid double accounting
- Assess the availability of waivers
- Payment metrics must be measurable and demonstrate improved efficiency and reduced cost of patient care
- Metrics should focus on best practices and an evidence-based approach to the provision of services
- Metrics should be reviewed and periodically evaluated and revised by an independent third-party serving as a quality committee
- Balance care reduction metrics with quality metrics
  - LOS metric offset by readmission metric
    - If LOS decreases by readmission increases, physicians receive no payment for either metric
  - Supply/equipment metric offset by infection rate metric
    - Ensure that a physician uses the most clinically appropriate equipment, not simply the item that will provide him or her with a larger gainsharing profit
Safeguards

- Identify specific actions that would produce savings, such as limiting the inappropriate use of supplies
- Present credible medical support that there will be no adverse effects on patient care
- Transparent and disclosed to patients
- Include periodic reviews of quality of care by an independent organization
- Include protections against inappropriate reductions in services by utilizing objective, historical, and clinical measures to establish baseline thresholds
- Limit the physicians eligible to participate to limit the likelihood of the arrangement reducing referrals (e.g. physicians already on staff)
- Limit the amount of shared savings and the time during which physicians can share cost savings to prevent hospitals from using these arrangements as a mechanism to include physician referrals
- Avoid rewarding physicians for increasing referrals to the hospital, such as capping potential savings based on the number of prior year admissions
- Monitor changes in the severity, age, and insurance coverage of patients affected by the arrangement

HEIP Regulatory Considerations

Civil Monetary Penalties:
- No adverse patient care effects
- No referral shifting, care stinting, cherry picking, pay based on number of patients
- Physician flexibility when medically appropriate
- Three-year cap

Stark, Anti-Kickback, and Tax Exemption:
- Compensation must be fair market value
- Compensation may not vary based on patient numbers
- Pay directly attributable to physician action
- Evidence-based support for quality initiatives
- No rewarding referrals
HEIP Overview: Lessons Learned

1. Compensation FMV—not based on referrals—less than 50% projected cost savings
2. Restrict participation to providers who are actively involved—direct impact
3. Select concrete initiatives based on historical data, national standards, and clinical literature
4. Provide clear documentation of the recommended improvement steps for each selected initiative
5. No restriction on physician access to suppliers/devices
6. Regulatory monitor

HEIP Takeaways

HEIP is a means of achieving collaboration and cooperation across service lines to facilitate hospital-wide goals and objectives (as opposed to service line-specific objectives).

Due to bigger scale, FMV within a HEIP is often higher than service line co-management.

HEIP is a possible means of supporting a CIN infrastructure build.
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Jim Daniel, JD, MBA is an attorney at the law firm HDJN, exclusively focused on the diverse legal needs of healthcare clients. Mr. Daniel has dedicated his practice to counseling clients in the development of new delivery models and alignment structures, including bundled payment, patient-centered medical homes, accountable care organizations (ACOs), and clinically integrated networks (CINs). He also routinely advises on issues related to antitrust, corporate governance, fraud and abuse, joint ventures, mergers and acquisitions, reorganizations, and tax.

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