

A Practical Guide to Co- Management/Gainsharing/ Shared Savings Arrangements and CMS Payment Models

Presented by:

David Glaser & Marguerite Ahmann

March 11, 2020

Fredrikson
& BYRON, P.A.

Agenda

- Gainsharing/Co-Management Basics
- Episode-Based Payment Initiatives
 - CJR
 - BPCI Advanced
- Implications of AKS/Stark Updates





Gainsharing/Shared Savings/Co- Management/Alignment/ [Your Label Here!]

- What is it?
- Labels don't really matter. What is "Shared Savings"??

Shared Savings

- Goal is reducing waste.
- Savings may be from conservation.
 - Avoiding drug wastage.
 - Avoid using costly service.
- Savings may come from standardization.
- Payment for efficiency is kosher, and popular.
- Savings from lower costs implants.



regular 384⁹

silver 394⁹

ultimate 404⁹

diesel 409⁹

BP
gasoline *Hydrotreated*

CMS Worries About

- Limiting use of quality-improving but more costly devices, tests or treatments: “stinting.”
- Treating only healthier patients: “cherry picking.”
- Avoiding sicker patients: “steering.”
- Discharging patients earlier: “quicker-sicker.”

CMS Seeks to Encourage

- Transparency.
- Quality controls.
- Safeguards against payments for referrals.

Gainsharing/Shared Savings/Co-Management/[Your Label Here!]

- Labels do not matter, but.....
- Law DOES matter.
- Federal law prohibits payments intended to reduce services to Medicare beneficiaries.
- The government used to say gainsharing was illegal. That is totally last century.
- It is 100% clear that gainsharing/shared savings can be done legally.

Gainsharing/Shared Savings/Co-Management/[Your Label Here!]

- Guidance from OIG:
 - At least 16 favorable Advisory Opinions (starting in 2001).
 - “Pending further notice from the OIG, gainsharing arrangements are not an enforcement priority for OIG unless the arrangement lacks sufficient patient in-program safeguards.” 79 F.R. 59715, 59729 (Oct. 3, 2014).
- The advisory opinions offer guideposts:
 - Payment caps.
 - Disclosure.
 - Utilization targets.
 - Hourly payments are low risk.

How Do You Split the Savings?

- The Advisory Opinions are 50-50.
- Advisory Opinions are not law, but they are useful guidance.
- CMS worries when payments exceed the Medicare fee schedule payments.
- Know the 4 big laws.

The 4 Big Laws

- Stark – civil but you MUST meet an exception.
- Antikickback – Criminal, but you don't need to meet a safe harbor. Intent controls.
- Tax Exemption.
- Antitrust.

Can You Have Long Term Payments?

- Conventional wisdom limits payments to one year.
- But see Advisory Opinion 12-22. “The management agreement is written with a three-year term, and thus is limited in duration.”
- Some people claim it only addresses co-management. They’re wrong.
- The payment must be reasonable.

Co-Management Details

- Do you need a new entity?
- Make sure the terms are clear.
- Can physicians really control the key payment factors?
 - Press-Gainey scores?
 - Turn-around times?
 - Scheduling?
 - Staff turnover?
 - Implant use?

The Hidden Trap



Gainsharing: Good Idea Goes Bad

“According to her lawsuit, Kathleen Davis suffered a significant complication after having a Medtronic pacemaker implanted at Methodist in 2004. She said that her cardiologist made a startling confession when she asked what happened to cause a twitching in her abdomen. He told her that she probably would have fared better with another brand of pacemaker, . . .

A Good Idea Goes Bad

. . . but that Methodist administrators had leaned on him to install the Medtronic model to help the hospital collect on what he called a kickback deal, the lawsuit said.”

– Des Moines Register, Feb. 9, 2006.

Think before you type

"Frank [the physician] has made no attempt to comply with the contract. . . . I am prepared to reschedule his devices to be in compliance with the contract," wrote Tim Nelson, a hospital manager who has since left the company, in one e-mail obtained from the court file.

- Des Moines Register, Feb. 9, 2006.

Think before you type

In another e-mail in the court records, Butz [another administrator] wrote: “Frank did say . . . that he would abide by a contract that paid him money for compliance.” In the e-mail, which Butz wrote to Methodist's chief operating officer, David Stark, he said, “Isn't there a joke along these lines — now that we have established what he is, we are simply negotiating over price.”

- Des Moines Register, Feb. 9, 2006.

The Bottom Line

- Hospitals will care about the Bottom Line!
- How you say things really matters.
- Bundled payments are likely here to stay. Cost pressure isn't likely to abate.
- Device companies should be wary of direct involvement. Discounted devices seem quite defensible.

The Bottom Line

- Savings are good.
- Hospitals offering or physicians receiving financial incentives for savings is legal, and wise. Just be smart.
- Shared savings is no riskier than many other practices.

Hospital Cost Savings

- A hospital wants to lower implant costs. Can it offer to share 50% of the savings with its orthopedic surgeons? Can it share 75%?
- Must the surgeons set up a new entity for this?
- Can the hospital include employed physicians in the program?

Quality Improvement

- A hospital has poor door to cath time. It proposes to pay physicians a bonus if the hospital moves from the 75th to the 50th percentile nationally.
- What if the bonus is for shaving 10 minutes off the time?

Service Line

- Patients have complained about the OB department. The hospital proposes to turn over management of the service line to the largest OB group in town, with pay linked to patient satisfaction scores and increase in deliveries.
- Is it better or worse if the hospital makes the offer to EVERY OB group?

CMMI: Innovation Models

Categories

- ◆ **Accountable Care**
Accountable Care Organizations and similar care models are designed to incentivize health care providers to become accountable for a patient population and to invest in infrastructure and redesigned care processes that provide for coordinated care, high quality and efficient service delivery.
- ◆ **Episode-based Payment Initiatives**
Under these models, health care providers are held accountable for the cost and quality of care beneficiaries receive during an episode of care, which usually begins with a triggering health care event (such as a hospitalization or chemotherapy administration) and extends for a limited period of time thereafter.
- ◆ **Primary Care Transformation**
Primary care providers are a key point of contact for patients' health care needs. Strengthening and increasing access to primary care is critical to promoting health and reducing overall health care costs. Advanced primary care practices – also called “medical homes” – utilize a team-based approach, while emphasizing prevention, health information technology, care coordination, and shared decision making among patients and their providers.
- ◆ **Initiatives Focused on the Medicaid and CHIP Population**
Medicaid and the Children's Health Insurance Program (CHIP) are administered by the states but are jointly funded by the federal government and states. Initiatives in this category are administered by the participating states.
- ◆ **Initiatives Focused on the Medicare-Medicaid Enrollees**
The Medicare and Medicaid programs were designed with distinct purposes. Individuals enrolled in both Medicare and Medicaid (the “dual eligibles”) account for a disproportionate share of the programs' expenditures. A fully integrated, person-centered system of care that ensures that all their needs are met could better serve this population in a high quality, cost effective manner.
- ◆ **Initiatives to Accelerate the Development and Testing of New Payment and Service Delivery Models**
Many innovations necessary to improve the health care system will come from local communities and health care leaders from across the entire country. By partnering with these local and regional stakeholders, CMS can help accelerate the testing of models today that may be the next breakthrough tomorrow.
- ◆ **Initiatives to Speed the Adoption of Best Practices**
Recent studies indicate that it takes nearly 17 years on average before best practices - backed by research - are incorporated into widespread clinical practice—and even then the application of the knowledge is very uneven. The Innovation Center is partnering with a broad range of health care providers, federal agencies professional societies and other experts and stakeholders to test new models for disseminating evidence-based best practices and significantly increasing the speed of adoption.

Episode-Based Payment Initiatives

Episode-based Payment Initiatives	Episode-based Payment Initiatives	Episode-based Payment Initiatives
BPCI Advanced	Comprehensive Care for Joint Replacement Model	Oncology Care Model
<p>BPCI Advanced is a voluntary episode payment model that will qualify as an Advanced Alternative Payment Model (APM) under the Quality Payment Program to test a new iteration of bundled payments.</p>	<p>The Center for Medicare & Medicaid Services is seeking input on this proposed model that aims to improve care and reduce costs for hip and knee replacements through episode-based payments.</p>	<p>This innovative new payment model for physician practices administering chemotherapy aims to provide higher quality, more coordinated oncology care at lower cost to Medicare.</p>
Stage: Applications Under Review, Ongoing	Stage: Ongoing	Stage: Ongoing

Comprehensive Care for Joint Replacement (CJR)

- Makes hospital responsible for cost of a bundle from admission to 90 days post discharge for nearly all Part A/B payments for Total Hip/Knee replacements (DRGs 469/470).
- Hospital gets bonus/penalty based on target price, patient satisfaction and outcomes measures.

CJR Details

- Hospitals may, but are not required to incent other care providers/suppliers (“collaborators”).
- Other care providers are not at direct risk, so the hospital will feel real pressure.
- Participation Agreements (similar to gainsharing) are a legitimate alignment tool for hospitals and surgeons.
- The big point: hospitals have responsibility, but not power. Can’t limit patients.

“Episode of Care”

- Hospital is responsible for all costs in the episode.
- Costs that may seem unrelated to joint replacement are included (MH/CD, hospice).
- Target prices are based on historical data.
- Is this really rationing?? What are other explanations?

“Episode of Care”

- Physicians’ services
- Inpatient hospital services (including hospital readmissions)
- Inpatient psychiatric Facility services
- Long Term Care Hospital services
- Inpatient Rehabilitation Facility services
- SNF services
- Home Health Agency services
- Hospital outpatient services
- Outpatient therapy services
- Clinical laboratory services
- DME
- Part B drugs and biologicals
- Hospice services
- Per Beneficiary Per Month payments under models tested under section 1115A of the Act

Limits on Risksharing

- Must set terms before care is furnished to any patients.
- Must agree upon quality criteria that the collaborator must satisfy in order to receive the payment.
- The total distribution payments paid to a physician practice in a year may not exceed 50% of the total Medicare physician fee schedule payments for services to CJR beneficiaries.
- Only physicians who actually perform services to CJR beneficiaries during at least one episode of care may receive any portion of the gainsharing payment.
- Must use EFT.

Issues for Participation Agreements

- Physicians must realize there is more of a cap on their gain than loss.
- Do you have control over the factors determining payment?
- What is the worst that can happen?
- Can you have a multi-party agreement?

How Can Clinics Distribute Payments?

- Only physicians involved in an episode of care may receive any payment.
- Payment needn't be equal. (In most cases it CAN'T be.)
- CMS seems to want payment based on involvement. Does this support larger payment to more “active” physicians?

What are the quality metrics?

- THA/TKA Complication measure:
 - acute myocardial infarction;
 - pneumonia, or sepsis/septicemia within 7 days of admission;
 - surgical site bleeding, pulmonary embolism or death within 30 days of admission; or
 - mechanical complications, periprosthetic joint infection, or wound infection within 90 days of admission. (50%)
- Hospital Consumer Assessment of Health Providers and Systems Survey Measure (HCAHPS) survey. (Patient satisfaction tool covering bathrooms cleanliness to pain management. (40%))
- Voluntary submission of outcomes & risk variable data. (10%)

Quality Metrics Notes

- Collaborators have limited impact on many measures.
- Metrics are converted to points.
- Generally speaking, must avoid being in the bottom 30% of either measure to receive any reconciliation payment.
- Quality Improvement Points awarded for a 3 decile improvement.

CJR: Proposed Rule

- Key Changes:
 - Extends CJR through December 31, 2023 for certain participant hospitals (currently scheduled to end on December 31, 2020).
 - “Episode of care” revised to include outpatient hip and knee replacements.
 - Revises gainsharing caps.
 - Single reconciliation period.
- Comments due April 24, 2020.

Bundled Payments for Care Improvement Advanced

- BCPI-A: Builds on the “Classic” Program.
- Voluntary, retrospective payment model.
- Holds clinicians and provider organizations accountable for quality and costs of care across a defined episode comprising either a hospitalization or procedure and 90 subsequent days.
- Qualifies as an Advanced APM.

How it works

- Claims for an inpatient stay (Anchor Stay) or an outpatient procedure (Anchor Procedure) at an acute care hospital trigger clinical episodes.
- Participants bear financial risk for total cost of care for all Medicare FFS services and items provided during a clinical episode.
- Payment tied to target prices and performance on quality measures.

Stakeholders

- Participants
- Episode Initiators
- NPRA Sharing Partners
- Medicare FFS Beneficiaries

Stakeholders, cont.

- Participants:
 - “Convener Participant” brings together multiple EIs, facilitates coordination among its EIs and bears and apportions financial risk under the Model.
 - “Non-Convener Participant” an EI bearing financial risk only for itself.
- “Episode Initiator” or “EI”
 - Medicare-enrolled provider or supplier that can trigger a Clinical Episode under the Model, i.e., PGPs or ACHs, including ACHs where outpatient procedures are performed in hospital outpatient departments (HOPDs).

Stakeholders, cont.

- “NPRA Sharing Partner” means a Participating Practitioner, a PGP, an ACH, an ACO, or a PAC Provider that is not the Participant and is:
 - participating in BPCI Advanced Activities; and
 - identified as an NPRA Sharing Partner on the Financial Arrangement List; and
 - has entered into a written NPRA Sharing Arrangement.

Bundles/Episodes

Inpatient Clinical Episodes (31):

- Spine, Bone, and Joint
 - Back and neck except spinal fusion
 - Double joint replacement of the lower extremity
 - Fractures of the femur and hip or pelvis
 - Hip and femur procedures except major joint
 - Lower extremity/humerus procedure except hip, foot, femur
 - Major joint replacement of the lower extremity (MJRLE)**
 - Major joint replacement of the upper extremity
 - Spinal fusion*
- Kidney
 - Renal failure
- Infectious Disease
 - Cellulitis
 - Sepsis
 - Urinary tract infection
- Neurological
 - Seizures*
 - Stroke

- Cardiac
 - Acute myocardial infarction
 - Cardiac arrhythmia
 - Cardiac defibrillator
 - Cardiac valve
 - Congestive heart failure
 - Coronary artery bypass graft
 - Pacemaker
 - Percutaneous coronary intervention
 - Transcatheter Aortic Valve Replacement*
- Pulmonary
 - COPD, bronchitis, asthma
 - Simple pneumonia and respiratory infections
- Gastrointestinal
 - Bariatric Surgery*
 - Disorders of the liver excluding malignancy, cirrhosis, alcoholic hepatitis
 - Gastrointestinal hemorrhage
 - Gastrointestinal obstruction
 - Inflammatory Bowel Disease*
 - Major bowel procedure

Outpatient Clinical Episodes (4):

- Back and neck, except spinal fusion
- Cardiac defibrillator
- Major joint replacement of the lower extremity (MJRLE)**
- Percutaneous Coronary Intervention

*Indicates new Clinical Episode for Model Year 3

**This is a multi-setting Clinical Episode category. Total Knee Arthroplasty (TKA) procedures can trigger episodes in both inpatient and outpatient settings.

NPRA Sharing

- Written arrangements, called “NPRA Sharing Arrangements” govern contributions/distributions of internal cost savings, NPRA, and shared repayments.
- Must be executed contemporaneously with the establishment of the arrangement, before care is furnished, and have a term of at least one year.

Internal Cost Savings

- Measurable, actual, and verifiable cost savings, resulting from Care Redesign undertaken by the NPRA Sharing Partner.
- Must be determined in accordance with a methodology is substantially based on criteria related to quality of care and the provision of BPCI Activities.
- All NPRA Sharing Partners must be treated the same – i.e., NPRA Sharing Arrangements must include “a uniform methodology for calculating contributions of Internal Cost Savings across all of the Participant’s NPRA Sharing Partners, which may differ by healthcare provider type.”

Issues for Participation/NPRA Agreements

- Mandatory terms from the CMS Participation Agreement and Waivers.
- “Downstream” compliance.
- Making the math work – and aligning the legal language.

MY1/2 Takeaways

- Retroactive withdrawal option was popular, but 80% are sticking it out for MY3.
- Certain episodes faring better than others.
- Frustration over confusing/ever-changing Model requirements.

What changed for MY3?

Q49: What changes to the Model are being implemented prior to the start of MY3?

A49: On May 1, 2019, CMS distributed to current Participants an Amendment to the 2018 BPCI Advanced Participation Agreement that will address the following changes:

- Removal of the 50 Percent Cap on NPRA Sharing Payments to PGPs and individuals;
- Revising the termination policy to allow a Participant, including a Convener Participant, to submit a new application for MY3 even if a Participant terminated their agreement under the Retroactive Withdrawal Policy;
- Updating Secondary Repayment Source (SRS) requirements and calculations to allow for recoupment of outstanding Medicare debt from Downstream EIs
- Allowing submission of a single list to identify Eligible Clinicians participating in BPCI Advanced for the Quality Payment Program (QPP); and
- Waving originating site for the Telehealth Payment Policy Waiver

The Amended and Restated Participation Agreement for MY3 that will be distributed in September 2019 will incorporate the changes included in the amendment, and other new policies for participation.

<https://innovation.cms.gov/Files/x/bpciadvanced-general-faq.pdf>

FAQ

- Selecting clinical episodes.
- MJRLE episode selection.
- Hospital-PGP precedence rules.
- Participation options.
- Outpatient service locations.

CMS/OIG: Changing Approach

- CMS Models
- OIG Fraud and Abuse Waivers
- Implications of AKS/Stark Proposed Rules

AKS Proposed Rule

- Outcomes-based payments safe harbor:
 - “payments from a principal to an agent that: (i) reward the agent for improving (or maintaining improvement in) patient or population health by achieving one or more outcome measures that effectively and efficiently coordinate care across care settings; or (ii) achieve one or more outcome measures that appropriately reduce payor costs while improving, or maintaining the improved, quality of care for patients.”
- OIG is considering scope of eligible participants and defined arrangements.

Stark Proposed Rule

- Three new exceptions for value-based arrangements – one may impact gainsharing:
 - Value-Based Entities (VBE) engaged in value-based activities.
 - Value-based arrangement would mean an arrangement for the provision of at least one value-based activity for a target patient population between or among: (1) the value-based enterprise and one or more of its VBE participants; or (2) VBE participants in the same value-based enterprise.

Proposed Rules: Potential Issues

- Inconsistency between the OIG/CMS approaches.
- Scope of eligible participants and arrangements.
- Complicated and more restrictive than program waivers.

Questions?

The Presenters



David Glaser

612.492.7143

dglaser@fredlaw.com



Marguerite Ahmann

612.492.7495

mahmann@fredlaw.com

