KING & SPALDING

The Use of Gainsharing in Bundled Payment Arrangements

June 18, 2019

PREPARED FOR:
The National Bundled Payment Summit IX

PRESENTED BY:
Kyle A. Gotchy
Sr. Associate, King & Spalding LLP

Regulatory Overview

- Stark Law: Federal Physician Self-Referral Prohibition - *42 U.S.C. §1395nn*
- Anti-Kickback Statute - *42 U.S.C. §1320a-7b(b)*
- Civil Money Penalty Gainsharing Prohibition – *relaxed by MACRA*
- Others:
  - Internal Revenue Code prohibition on Private Benefit/ Private Inurement
  - State F&A laws

CAUTION: F&A laws were designed for a FFS world and may hinder collaboration in a value-based environment.

The Stark Law

- Basic Prohibition: Prohibits a *physician* from referring Medicare patients for *designated health services* (DHS) to an *entity* with which the physician has a *financial relationship*, unless an *exception* applies.
- Key Terms
  - Entity
  - Remuneration
  - Referral
  - DHS
- Gainsharing and other value based payments almost always trigger a need for Stark analysis

Value-Based Payment Models: F&A Waivers

- F&A Waivers have been issued for the purposes of several VBP Models
  - CJR
  - BPCI Advanced
  - BPCI (Models 1-4)
  - Others: MSSP, Next Gen ACO, etc.
- Waivers Address: Stark, AKS, Gainsharing CMP, BI CMP
- Waivers Do Not Address: laws governing tax-exempt orgs, antitrust, state laws
- Complex:
  - Issued on an ad hoc basis
  - Each model has different waivers with different requirements

F&A Waivers

CJR

- 4 Waivers in Revised Notice (effective Jan 1, 2018)
  - Payments Waiver: Gainsharing Payments & Alignment Payments
  - Distribution Payments Waiver: Collaborator → Collaboration Agent
  - Downstream Distribution Payments Waiver: Collab Agent → Downstream Collab Agent
  - Patient Engagement Incentives Waiver: Hospital → Medicare Patient
- Revised waivers are streamlined, more user friendly

BPCI Advanced

- 4 Waivers
  - Internal Cost Savings Waiver
  - NPRA Shared Payment and Shared Repayment Amount Waiver
  - Partner Distribution Payment and Shared Repayment Amount Waiver
  - Beneficiary Engagement Incentives Waiver

BPCI – Final PY concluded Sept. 2018

- 4 Models → Each model had its own F&A Waivers → Not user friendly

Effect of Waiver Protection

- If a hospital makes a waiver-protected payment to a physician, then the payment does not need to comply with a Stark exception and is immune from AKS prosecution, even if it does not qualify for safe harbor protection.
- What About FMV & Commercial Reasonableness?
  - Payments that qualify for waiver protection do not need to meet the FMV & CR standards because there is no need to meet an exception / safe harbor.
- Do the waivers protect all payments a hospital may make to a physician?
  - **NO**. If payments do not qualify for waiver protection, then they must fit within a Stark exception and will not be immune from AKS prosecution.

FMV & Commercial Reasonableness

Issues

- Are waiver-protected payments included when analyzing a physician's overall compensation under hospital employment or services arrangement?
- Are waiver-protected payments included into a "stacking" analysis?

Different Views

- Waiver-protected payments should not be considered when assessing FMV/CR for Stark/AKS purposes
  - Logic: CMS did not include FMV/CR requirements in the waivers
- Waiver-protected payments should be considered, but the services provided by the physicians increase the FMV range

Relevant Stark Law Exceptions

- Risk-Sharing Arrangements
- Indirect Compensation Arrangements – Definition & Exception
- Personal Services Arrangements
- FMV Compensation
- Bona Fide Employment Relationships

Risk-Sharing Arrangements

What it protects:

- Compensation pursuant to a risk-sharing arrangement
  - Examples: withholds, bonuses, risk pools
- Between (i) an MCO or an IPA; and (ii) a physician
  - Payment Flow: Payments may be made directly or indirectly through a subcontractor
- For services provided to *enrollees* of a *health plan*
  - Concept: MCO shares risk with physicians for cost of care furnished to plan enrollees

Benefits: No FMV, CR, V/V Requirements

- Limits: Must be downstream from MCO → Doesn't work with Medicare FFS

How broad is the exception?

- "Enrollee" & "Health Plan" - 42 CFR § 1001.952(l)
- What about "MCO"?

Breadth of RSA Exception

Comment: A commenter welcomed the new exception for risk-sharing arrangements, *but requested a definition of the term "managed care organization"* as used in the exception or clarification in preamble language that the new exception is meant to cover all risk-sharing compensation paid to physicians by an entity downstream of any type of health plan, insurance company, or health maintenance organization (HMO). *A commenter sought clarification that the downstream entity could itself be an entity that furnishes DHS, such as a hospital.*

Response: *The new exception is meant to cover all risk-sharing compensation paid to physicians by an entity downstream of any type of health plan, insurance company, HMO, or Independent Practice Association (IPA), provided the arrangement relates to enrollees and meets the conditions set forth in the exception. All downstream entities are included.* We purposefully declined to define the term "managed care organization" so as to create a broad exception with maximum flexibility.

Phase II: 69 Fed Reg, 16053, 16114 (March 26, 2004)

Breadth of RSA Exception – Fully Utilized?

4. Please share your thoughts on the utility of the current exception at 42 CFR 411.357(n) for risk-sharing arrangements.

CMS Stark RFI, 83 Fed. Reg. 29524, 29526 (June 25, 2018)

Illustrative Response:

"***The current exception for risk sharing arrangements is specifically written for MCOs and IPAs.*** With the increased focus on value-based care, [Commenter] believes the exception for risk sharing, or a similar exception, should be expanded to account for sharing the risk of patient care costs outside of the limited scope of an MCO or IPA. In order to achieve the savings necessary under commercial payor contracts, and to achieve other quality standards, these types of arrangements should be permissible between a hospital and physician. Some of the risk sharing could be related to the cost per case or equipment and supplies costs."

Remaining Exceptions – Common Requirements

FMV

- Comp must be within the range of FMV

Commercial Reasonableness:

- "An arrangement will be considered 'commercially reasonable' in the absence of referrals if the arrangement would make commercial sense if entered into by a reasonable entity of similar type and size and a reasonable physician . . . of similar scope and specialty, even if there were no potential DHS referrals."

  Phase II: 69 Fed. Reg. 16053, 16093 (March 26, 2004).

Volume/Value

- Comp may not be determined in a manner that takes into account the v/v of any referrals or other business generated between the parties.
  - Unresolved: Is percentage-based comp based on v/v?

Indirect Compensation Arrangements

Definition – *42 CFR § 411.354(c)(2)*

- Unbroken chain of persons/entities with financial relationships linking referring physician and DHS entity
- Referring physician receives *aggregate* comp that varies with, or takes into account, the v/v of referrals or other business generated for the DHS entity
- DHS entity knows or should know about how the comp varies

Exception *- 42 CFR § 411.357(p)*

- Comp received by referring physician is FMV for services/items
- Comp doesn't vary w/ v/v of referrals or other business generated for the DHS entity
  - May apply Special Rules on Comp – *42 C.F.R. 411.354(d)*

Payments Linked to Quality Improvements – V/V, FMV, CR

Phase III Commentary:

> ". . . compensation related to patient satisfactions goals or other quality measures unrelated to the volume or value of business generated by the referring physician and unrelated to reducing or limiting services would be permitted under the personal services arrangement exception . . . (for example, compensation to reward physicians for providing appropriate preventative care services….)."
>
> *72 Fed. Reg. 51011, 51046 (Sept. 5, 2007)*

Are quality payments FMV & commercially reasonable?

- Are payments being made to right party?
  - Is the physician who is receiving the payment really responsible for the quality outcomes on which the payment are based?
- How is FMV determined?

Cost Reduction Metrics – V/V

Examples

- Lowering device/drug costs, average cost per case, readmissions, etc.

Stark doesn't care about incentives to reduce referrals, right?

- Phase II Commentary - 69 Fed. Reg. 16053, 16088 (March 26, 2004)
  - Question: May a hospital pay employed physicians for meeting hospital drug utilization targets?
  - CMS Answer: There "is no exception that would permit payments to physicians based on their utilization of DHS, except as specifically permitted by the risk sharing arrangements, prepaid plans and personal services arrangements exceptions. None of those exceptions permit those payment other than in the context of services provided to enrollees of certain health plans."
  - Explanation: "We believe that the Congress intended to limit these kinds of incentives consistent with the civil monetary penalty provision at section 1128A(b)(1) of the Act that prohibits a hospital from paying physicians to reduce or limit care to hospital patients. Given that prohibition, we cannot say that payments based on lowering utilization present no risk of fraud or abuse. Our specific authority in section 1877(e)(2)(D) of the Act to add additional requirements to the employment exception is limited to requirements needed to protect against program or patient abuse. Since section 1128A(b)(1) of the Act represents a legislative determination of potential abuse, we cannot create an exception for those activities."
  - Similar commentary in Phase III
- Despite MACRA opening door, CMS has not created such an exception.

Regulatory Sprint to Coordinated Care

"It's a sprint. Sprint from the governmental point of view, okay, so let's not get overly excited here."

Eric Hargan
Deputy Secretary, HHS
USC-Brookings Schaeffer Initiative for Health Policy
Jan. 30, 2019

CMS RFI – Stark Law (June 25, 2018)

- 392 Comments (3,500 pgs)
- "We recommend that you identify concerns regarding the applicability of existing [Stark] exceptions . . . and/or the ability of the arrangements to satisfy the requirements of an existing exception, as well as the extent to which [Stark] . . . may be impacting commercial [APMs] and novel financial arrangements."
- What additional exceptions are required to protect financial arrangements between hospitals and physicians participating in same APM? (ACOs; bundled payments; two-sided risk models in FFS environment)
- Requested thoughts re utility of:
  - RSA Exception; and
  - PSA Exception's special rule for comp under a physician incentive plan

#RS2CC

OIG RFI – AKS & Beneficiary Inducements CMP (Aug 27, 2018)

- 359 comments

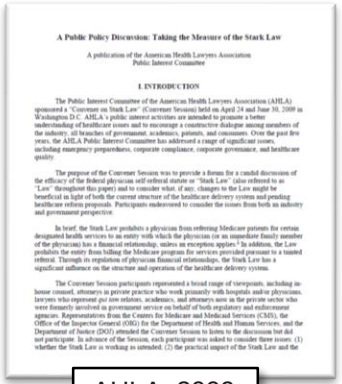
Ch-Ch-Ch-Changes?

We are actively working on an update to our Stark regulations to be issued later this year. Some of the changes include clarifying the regulatory definitions of volume or value, commercial reasonableness and fair market value; addressing issues such as lack of signature, incorrect dates or other areas of technical noncompliance; and updating the regulation to address a world in which there are cybersecurity and electronic health records requirements,

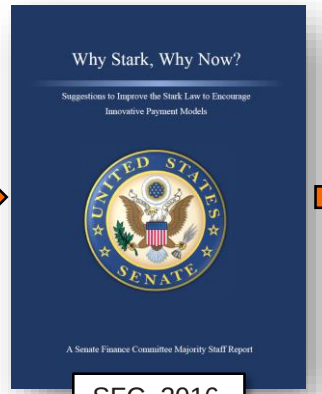
This will represent the most significant changes to the Stark law since its inception. It is our hope that these changes will help spur better care coordination and help support our work to remove barriers to innovation while continuing to provide appropriate safeguards for our programs.

Seema Verma
Federation of American Hospitals
2019 Public Policy Conference
March 4, 2019

Will past recommendations be realized?



AHLA, 2009



SFC, 2016


CMS RFI, 2018

- Will this opportunity for reform slip by?
- How much can CMS do within its rulemaking authority?
  - CMS may create regulatory exceptions for financial relationships that it determines do "not pose a risk of fraud and abuse." 42 U.S.C. 1395nn(b)(4).

Gainsharing in Bundled Payment Programs

2019 Bundled Payment Summit

Kristin Oberfeld
Associate Principal, Sg2

June 18, 2019

Agenda

Importance of Physician Alignment

Potential Savings Pools

Mechanics of Gainsharing Programs

Key Considerations & Decision Points

All-Payer Gainsharing Models

Physician Alignment is a Cornerstone of Bundled Payment Strategy

Bundled Payment Critical Success Factors

Physician alignment and leadership	Create engagement and financial incentives that align interests with physicians to support care redesign across episodes of care and support margin improvement.
Care plan redesign and care navigation	Design and implement care protocols that promote excellent patient outcomes and reduce non–value-added provider services from prehospitalization to 90 days.
Preferred post-acute care network	Create a network of high-quality, post-acute care providers who will work with you to implement optimal care plans for your patients.
Informed data analytics	Add actionable and relevant data tools to measure current and predicted Medicare reconciliation payments and internal cost savings.

Physician Alignment

- Engage with physicians and care teams around care redesign.
- MACRA—establish an aAPM path for physicians.
- Utilize gainsharing opportunities under CMS waivers.

Where do the Savings Come From?

Net Payment Reconciliation Amount

Reduction of Medicare Spend in Key Performance Areas:

- Readmissions
- PAC provider utilization
- SNF length of stay
- Home health visits
- Consulting physician utilization

Medicare's Costs

Internal Cost Savings (ICS)

Reduction of Hospital Internal Costs:

- Implants and devices
- Pharmacy
- Blood utilization
- Other medical/surgical supplies
- Overall direct costs

Hospital's Costs

In regard to internal cost savings:

Per the CMS FAQs released on August 6, 2019, an ACH that is a non-convener participant ***cannot contribute its own internal cost savings*** to the BPCI Advanced savings pool.

Hospitals are responding by creating all-payer gainsharing models to share in ICS outside of the CMS programs.

ACH = acute care hospital; PAC = post-acute care.

How Does it Work?

In connection with the BPCI Advanced program, the OIG has provided waivers of certain Fraud and Abuse Laws. Savings can legally be shared with physicians as long as all program rules are followed:

How much can you make?

The total amount of NPRA shared payments made by the participant to a given NPRA sharing partner must not exceed 50% of the total Medicare FFS payment during the performance period.

Orthopedic Surgeon Maximum Cap

$1,393 (Avg Part B spend per MJRLE case) X 50% Cap = $697 (Avg max sharing $ per MJRLE case)

Capped on $, not on volume

As of May 1, 2019, CMS released an addendum to the BPCI Advanced Participation Agreement that eliminates this language.

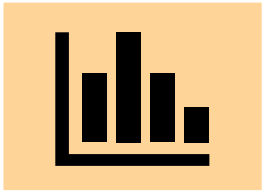
What does this mean? ***Flexibility.***

MJRLE = major joint replacement of the lower extremity; NPRA = net payment reconciliation amount; OIG = Office of Inspector General.
Source: CMS. BPCI Advanced request for applications. January 9, 2018; Sg2 Analysis 2018.

Physician Alignment With Gainsharing in BPCI Advanced

What is required of a NPRA Sharing Partner?

Enter into a NPRA sharing arrangement with the participant.



Achieve the quality performance targets necessary to receive NPRA shared payments (will be detailed in sharing arrangement).

Be engaged in BPCI Advanced activities.

- Furnishing direct patient care to BPCI Advanced beneficiaries in a manner that reduces cost or improves quality
- Engaging in care redesign
- Reporting on program quality measures
- Using CEHRT
- Performing a minimum of 4 MIPS improvement activities

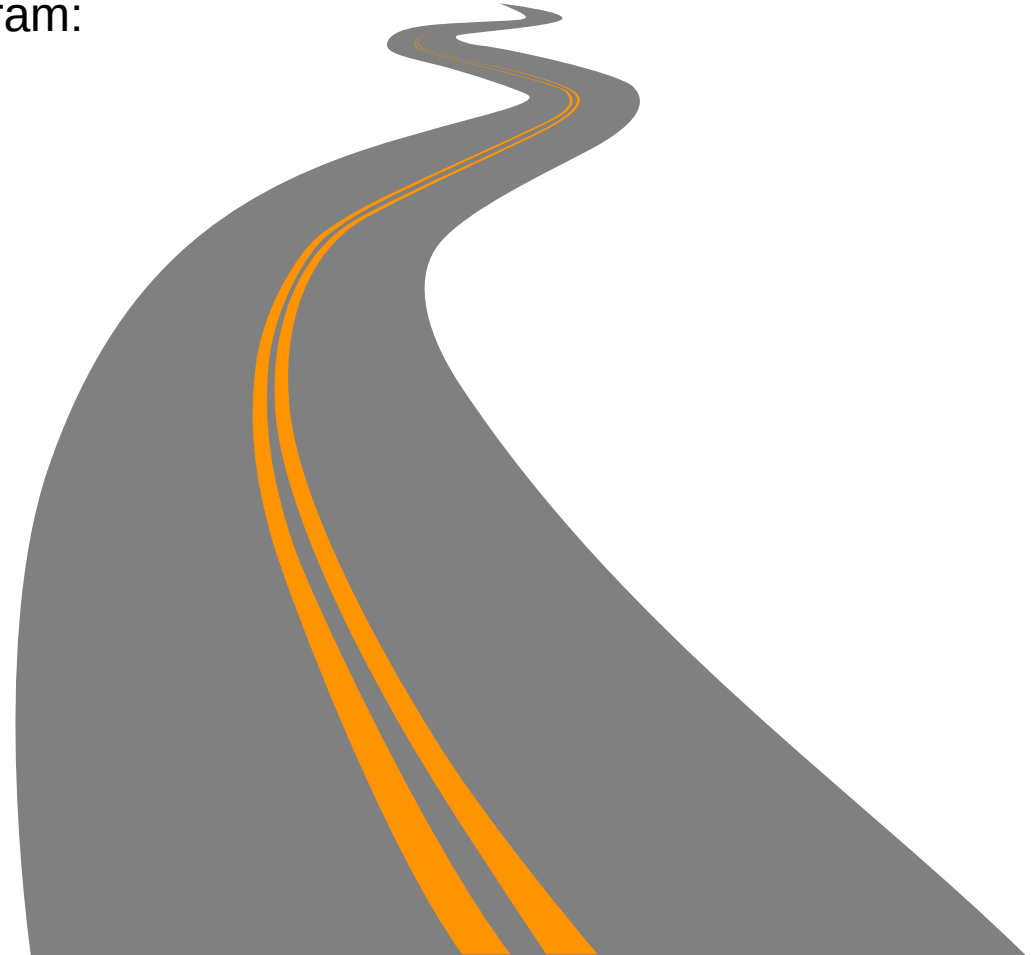
CEHRT = certified electronic health record technology. **Source:** CMS. BPCI Advanced request for applications. January 9, 2018.

What Must be Considered When Setting Up a Gainsharing Program?

The Roadmap

The following items are key considerations required to successfully establish a NPRA Sharing Arrangement within the BPCI Advanced program:

- Physician Participation Criteria
- Maximum Cap Calculation
- Savings Pool Considerations
- Quality Measurement
- Administrative Costs
- Contract Development and Execution

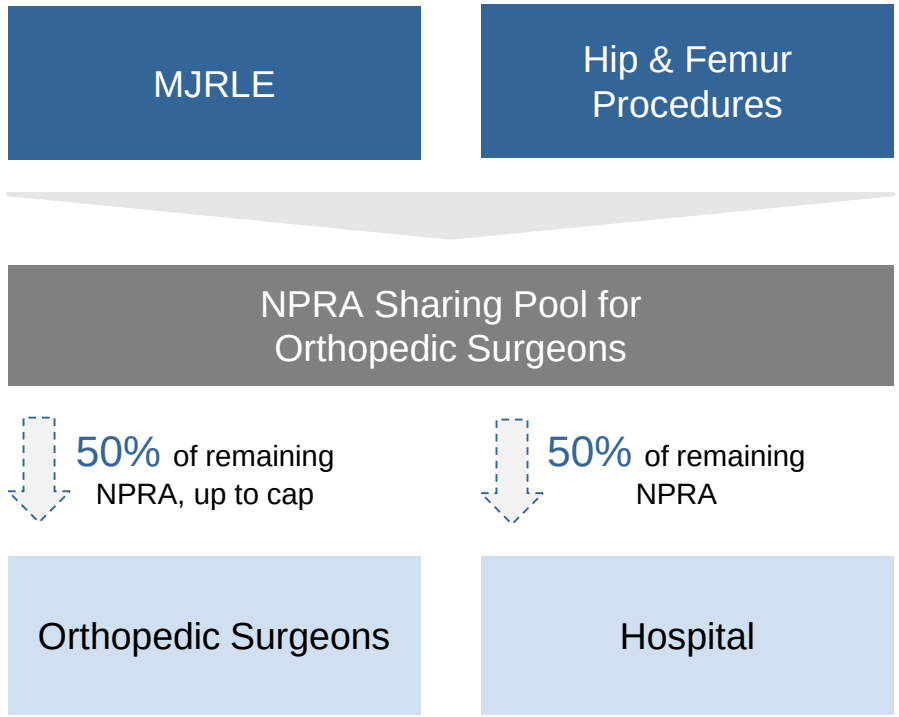


NPRA Sharing Arrangement Example: Funds Flow

How does the NPRA sharing model work?

- Savings Pool: The combined NPRA for the 2 orthopedic episodes, MJRLE and hip & femur, will be available for distribution to the orthopedic surgeons.*
- Funds Flow: Orthopedic NPRA will be split 50% to the physicians and 50% to the hospital. No administrative costs will be recovered prior to the split.
- Programmatic Requirements: The physician distributions will be quality adjusted.

CMS rule: Participant can only share the amount of NPRA that is received in aggregate across all clinical episodes.



*Distributions will only be made to eligible physicians who have completed the requirements for being a NPRA sharing partner within the BPCI Advanced program.
Source: Sample distribution per Sg2 client experience.

All-Payer Gainsharing Arrangement Summary

Major Difference From BPCI Advanced Gainsharing: No Waivers Provided

The standard for commercial gainsharing relies on previous OIG opinions. The most recent opinion was released in late 2017. Petitioning for an OIG opinion is a burdensome and time-consuming process—the OIG recommends following the criteria that have already been set out.

The Key Components

- Volume gets capped—only save on the number of cases in the baseline.
- Quality must meet or exceed baseline performance.
- Steering committee is key and must meet quarterly to monitor program.
- Third-party administrator that doesn't receive savings is recommended.
- Savings can be up to a 50%/50% split—not capped at MD level like BPCI-A
- Baseline must be reset every year.

QUESTIONS

Sg2, a Vizient company, is the health care industry's premier authority on health care trends, insights and market analytics. Our analytics and expertise help hospitals and health systems achieve sustainable growth and ensure ongoing market relevance through the development of an effective System of CARE.

Sg2.com
847.779.5300