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Alternative Payment Models and Related Regulatory Issues: Stark Law, Anti-Kickback Statute, Gainsharing, PIP, MLR

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Alternative Payment Models and Related Regulatory Issues:
Stark Law, Anti-Kickback Statute, Gainsharing, PIP, MLR

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Agenda

Part I: Alternative Payment Models

Part II: Business Risks & Challenges

Part III: Legal Risks & Challenges

Part IV: Valuation Issues

Part V: Discussion Questions

Part I
Alternative Payment Models

General Categories

Payor Arrangements

- Pay for Quality
- Episode-Based Arrangements
- Population-Based Arrangements

Provider Arrangements

- Co-management and gainsharing
- Upside/downside sharing

Payor Arrangements Example: Pay for Quality

CMS Quality Payment Program

- Instituted by MACRA
- Consists of two alternate tracks:
  - Merit-Based Incentive Payment System (MIPS)
  - Advanced Alternative Payment Models (APMs)

MIPS participants are Medicare Part B clinicians

- Such clinicians include Physicians, Physician Assistants, Nurse Practitioners, Clinical Nurse Specialists, and Certified Registered Nurse Anesthetists (and others)

Payor Arrangements
Example: Pay for Quality (cont'd)

Quality Payment Program -- MIPs

- Excluded from MIPs are:
  - Newly enrolled Medicare clinicians
  - Clinicians below the low-volume threshold (Part B allowed charges less than or equal to $90,000 or providing care for 200 or fewer Part B patients per year)
  - Clinicians significantly participating in Advanced APMs ("Qualifying APM Participants") are automatically excluded, and "Partial Qualifying APM Participants" can elect to be excluded

Payor Arrangements Example: Pay for Quality (cont'd)

Quality Payment Program -- MIPs

- Four categories for which Eligible Clinicians report, and on which they are measured:
  - Quality Performance (45% of total score)
  - Promoting interoperability (25%)
  - Cost (15%)
  - Improvement Activities (15%)
- Depending on performance, an Eligible Clinician could receive a positive or negative adjustment of
  - for MIPS payment year 2019, 4%; for MIPS payment year 2020, 5%; for MIPS payment year 2021, 7%; for MIPS payment year 2022 and beyond, 9%
  - Also a bonus pool of up to $500 million per year, which is paid to top performers
  - Payment year is 2 years after performance year (e.g., payments made in 2019 are for performance in 2017)

Payor Arrangements
Example: Pay for Quality (cont'd)

Quality Payment Program – Advanced APMs

- Participants receive a 5% increase in their PFS payments
- Advanced APMs include:
  - Comprehensive Care Joint Replacement (CJR) Payment Model (Track 1 – CEHRT)
  - Comprehensive ESRD Care (CEC) - Two-Sided Risk
  - Comprehensive Primary Care Plus (CPC+)
  - Next Generation Accountable Care Organization (ACO) Model
  - ACO Medicare Shared Savings Program (MSSP), Tracks 1+, 2 and 3

Payor Arrangements Example: Episode-Based CJR

- Comprehensive Care for Joint Replacement (CJR) Model started as a mandatory program, but former Sec'y Price was opposed to the mandatory nature, and regulations in 2017 made it voluntary
- CJR is a bundled payment program whereby CMS pays the standard DRG payment to a participating hospital plus the usual FFS payment to post acute care providers
  - Participant hospital takes two-sided risk for services furnished during an episode
  - The episode begins with admission of a Medicare beneficiary at a participant hospital for an "anchor hospitalization" and ends on the 90th day after the date of discharge
- The FFS payments are compared to the target price, which is based on the historical average costs, minus 3 percent
- Participating hospitals are paid the difference between the costs incurred and the target price if the costs are less than the target price, but are responsible for the difference if the costs incurred exceed the target price
  - Hospital must have a minimum composite quality score for reconciliation payment eligibility
- The DRGs involved are those for lower-extremity joint replacement (LEJR), namely MS-DRG 469 and 470
- Low-volume hospitals and certain beneficiaries (e.g., those entitled to Medicare based on ESRD, or MA Plan enrollees, or assigned to an ACO) are excluded

Payor Arrangements
Example: Episode-Based CJR (cont'd)

- Only Participants in CJR are hospitals – a physician group cannot be a Participant, but may be a "CJR collaborator," and can be paid a gainsharing payment from a Participant Hospital under a Distribution Agreement
- Gainsharing payment from a Participant Hospital to a Physician Group Practice cannot exceed 50 percent of the Medicare-approved amounts under the PFS for items and services billed by that PGP and furnished to the CJR beneficiaries/patients of the Hospital
- PGP can pay a gainsharing payment to a physician, but payment cannot exceed 50% of the total Medicare-approved amounts under the PFS for items and services furnished by the physician to the Participant Hospital's CJR beneficiaries during CJR episodes that occurred during the same performance year for which the Hospital accrued the internal cost savings or earned in the reconciliation payment that comprises the gainsharing payment being distributed
- Hospital can require PGPs to take risk, but Hospital must take at least 50% risk regarding the total repayment amount to CMS

Payor Arrangements Example: Episode-Based BPCI

BPCI (Bundled Payment for Care Initiative) and, now, BPCI Advanced is a Medicare bundled payment program

- Target Price = historical average cost established by CMS – 3%
- CMS contracts with a Participant (usually a Convener Participant) with respect to certain episodes of care (a/k/a bundles), and pays its usual FFS payment to participating physician group practices (PGPs) and hospitals, and to any post-acute providers during the 90 day post acute period
- If CMS's total payment for the bundle is below the Target Price, CMS pays the difference to the Participant, which then distributes a certain amount to the PGPs and hospitals. If CMS's total payment is above the TP, it collects the difference from the Participant, which then collects a portion of that from the physicians and hospitals
  - Stop loss protection
  - Quality metrics must be achieved, and no cherry picking or steering
  - 50% cap on savings – Convener Participant can distribute to the PGP no more than 50% of the aggregate savings generated by the PGP, and the PGP can distribute to any physician no more than 50% of the savings generated by that physician

Payor Arrangements
Example: Population-Based ACOs

- Accountable Care Organizations (ACOs) are groups of physicians, hospitals, and other providers and suppliers, who associate with each other to provide coordinated care to patients, for the purpose of lowering costs (e.g., through eliminating duplicate services) and raising quality (e.g., through preventing medical errors)
- MSSP – Medical Shared Savings Plan
- Pioneer ACO
- Next Generation ACOs

Provider Arrangements Example: Gainsharing

Internal Cost Savings Programs

- Essentially gainsharing programs. A provider or supplier (usually a hospital) enters into arrangements with others (usually physicians) to reduce *its* costs in performing certain services and to share the savings produced by the reduction of costs.
- This is in contrast to programs in which the *payor* pays a portion of its savings to providers/suppliers.
- CMS defines ICS, for purposes of the CJR program, as "the measurable, actual, and verifiable cost savings realized by the participant hospital resulting from care redesign undertaken by the participant hospital in connection with providing items and services to beneficiaries within specific CJR episodes of care. Internal cost savings does not include savings realized by any individual or entity that is not the participant hospital."

Provider Arrangements Example: Co-Management

Co-Management Agreements

- Hospital will pay physicians to manage a particular service line, such as orthopedic surgery
- Physician group will be paid a flat fee for managing the service line, plus an incentive payment (which may come from a specific amount that is set aside)
  - Incentive metrics are geared toward quality and patient satisfaction and are not related to the volume or value of services
- Physician or physicians from Physician Group may be contracted as medical directors
  - Co-management agreements are sometimes referred to a medical directorships on steroids

Part II
Business Risks and Challenges

Risk-Sharing Considerations

- Importance of “risk”
  - For payors, opportunity to cede premium risk and to reduce risk-based capital requirements
  - For providers, opportunity to benefit directly from effective care management and good outcomes
- Distribution of accountability and risk across continuum of care is key
  - Requires thoughtful selection of, and coordination with, partners
- Role of innovation in mitigating risks
  - Coordinating care, providing new services, improving data analytics

General Challenges

- Target population
  - Episode- or population-based? How are patients assigned to providers? Risk adjustment methods?
- Performance measures
  - Process- or outcome-based? Relevant benchmarks? Realistic? Aligned with other payor programs?
- Adequate capital
  - Investments in data collections, support services, reserve funds, etc.
- Platform for performance
  - Coordinating care, case management, sharing data

Perspective of Physician Groups

- Challenges of APMs
  - More complex than pure fee-for-service
  - Physicians are less able (and willing) to bear downside risks than other partners
  - Significant upfront capital investments needed to succeed
    - Data infrastructure, reporting requirements, care coordination, etc.
  - Cultural shift and changed practice patterns
  - Concern that pay is tied to metrics they cannot control
- But there are opportunities for physician groups to succeed
  - Physician groups are key partners for developing cost-efficient provider networks and coordinating care
  - Cost-saving opportunities generally are hospital-based, not physician-based

Perspective of Physician Groups (cont'd)

Factors that influence success and limit risk:

- Alignment through consolidation and integration
  - Difficult for small practices to compete and to make necessary investments
- Clinical integration and development of protocols
  - Enhancing the role of clinical staff
  - Clinical care guidelines and protocols focused on quality and desired outcomes

Perspective of Physician Groups (cont'd)

Factors that influence success and limit risk (cont'd):

- Investing in care management tools
  - EHR/IT connections and data reporting
  - Case managers
- Financial integration and managing financial risk
  - Align physician incentives with practice incentives
  - Risk-bearing should be incremental

Perspective of Hospitals

- Challenges of APMs:
  - Cost savings can translate to lost revenue
  - Requires significant upfront capital investments
    - Often hospitals/health systems must bear upfront costs for partner physician groups
  - Often bear most, if not all, of the downside risk prospectively
  - Need for new support functions (e.g., care management, post-discharge management)
  - Post-acute network development

Perspective of Hospitals (cont'd)

- APMs can be net gains for many hospitals/systems
- Keys to success:
  - Scale is important
    - Community or rural hospitals will have harder time
  - Well-structured participation/distribution agreements
  - Focus on reducing costs: aligning services, clinician accountability, and care management
  - Focus on quality: clinical care guidelines, coordinated care teams, precise documentation
  - Infrastructure to measure performance

Perspective of ASCs

- ASCs (like other ambulatory providers) may be well-positioned to succeed in APMs
  - Lower cost, higher volume outpatient setting
- Critical partners in APMs for lowering costs, achieving network adequacy
- Similar challenges: investments in data reporting, training physicians, employing clinical protocols

Perspective of Post-Acute Care Providers

- Role in APMs will vary by sub-sector
- Skilled Nursing Facilities
  - APMs tend to favor home health care to SNF due to lower costs
  - Limited Medicare referral options because of 3-day inpatient admission rule (although sometimes waived in APMs)
- Home Health Agencies
  - Opportunity to play big role in APMs
  - Can provide important case management and real-time monitoring services that save costs

Perspective of Post-Acute Care Providers (cont'd)

- Challenges of APMs
  - Investing in data/technology infrastructure to provide cost-saving interventions
  - Demonstrating value to ACOs/hospitals/etc.
  - Economies of scale – value of horizontal integration among post-acute care providers as well as vertical integration with health systems

Part III
Legal Risks and Challenges

Summary

- Anti-Kickback Statute/Civil Monetary Penalty (CMP) Statute (and State anti-kickback statutes)
- Physician Self-Referral Statute (Stark) (and State practitioner self-referral statutes)
- False Claims Act
- Gainsharing Prohibition in CMP Statute
- Beneficiary Inducement Provision of CMP Statute
- HIPAA Regulations (and State health care privacy laws)
- Antitrust Laws and FTC Guidance
- State Fee Splitting Statutes

AKS and CMP

- The AKS prohibits one from knowingly and willfully soliciting or receiving (or paying or offering to pay) remuneration
  - in return for referring an individual to a person for the furnishing or arranging for the furnishing of any item or service for which payment may be made in whole or in part under a Federal health care program, or
  - in return for purchasing, leasing, ordering, or arranging for or recommending purchasing, leasing, or ordering any good, facility, service, or item for which payment may be made in whole or in part under a Federal health care program
- AKS is a criminal statute, and decision whether to prosecute resides solely with DOJ
  - Gov't must prove guilt beyond a reasonable doubt
- Violation of the AKS is a felony, punishable by a fine of up to $100K and imprisonment of not more than 10 years

AKS and CMP (cont'd)

- The AKS contains a few statutory exceptions, for certain types of arrangements that are deemed not to involve "remuneration," and the OIG has issued many more exceptions (safe harbors) through regulations
  - No statutory exception or regulatory safe harbor geared specifically toward alternative payment arrangements, although the OIG is considering whether to issue one
  - Most APMs will not meet the existing safe harbor for personal service arrangements and management contracts because the OIG does not consider formulaic compensation (e.g., a percentage of savings) to be "set in advance" in the "aggregate"

AKS and CMP (cont'd)

- The CMP Statute punishes AKS violations through CMPs, "assessments," and exclusion from Federal health care programs
- Authority for enforcement is delegated to the HHS OIG
- Gov't has to prove violation only by a preponderance of the evidence
- OIG issues advisory opinions on whether it would seek sanctions under the CMP statute for actual or proposed arrangements addressed by the requestor of the opinion
  - Although a favorable advisory opinion technically pertains only to the specific arrangement that is the subject of the AO, and insulates that arrangement only from penalties under the CMP statute, as a practical matter, any arrangement that is on all fours with the subject arrangement has no risk of being sanctioned under the CMP Statute or prosecuted under the AKS
- OIG has Self Disclosure Protocol through which the disclosing party may receive a lesser penalty than if the OIG successfully brought an action for penalties or entered into a settlement

Stark

- Stark prohibits a physician who has (or whose immediate family member has) a “financial relationship” from referring a Medicare patient to an “entity” for the furnishing of “designated health services” (“DHS”), and prohibits the entity from billing Medicare or other payor for such DHS, unless an exception applies.
  - Inpatient and outpatient hospital services, among others, are DHS
  - “Financial relationship” is a direct or indirect ownership/investment interest or compensation arrangement (e.g., a gainsharing arrangement between a physician group and a hospital would create a “direct compensation arrangement” between the physician owners of the group and the hospital, and possibly an “indirect compensation arrangement” between the employee or independent contractor physicians of the group and the hospital)

Stark (cont'd)

- There are several statutory and many regulatory exceptions
- There is no gainsharing exception – one proposed in 2008 but never finalized
- There are several compensation arrangement exceptions that may be applicable to alternative payment arrangements, including the exceptions for
  - Personal service arrangements (42 CFR 411.357(d))
  - Fair market value arrangements (42 CFR 411.357(l))
  - Indirect compensation arrangements (42 CFR 411.357(p))
  - Risk-sharing arrangements (42 CFR 411.357(n))

False Claims Act

FCA will be implicated if

- Knowing Stark violation occurs
- There is an AKS violation
- Provider or supplier receives an overpayment and fails to report/return it timely (60-day Rule)
  - New Issue: physician group receives bonus payment under MIPS and then discovers its reporting of quality metrics was incorrect
- Remember: under *Escobar*, false statement or certification must be material to Gov't's decision to pay for there to be FCA liability

Gainsharing Prohibition: CMP

- Located in § 1128A(b) of the SS Act, 42 U.S.C. 1395a-7a(b)
- Amended by MACRA (2015) to clearly apply only to incentive payments by a hospital to a physician to limit or reduce medically *necessary* care
- Prior to MACRA, OIG construed the prohibition to apply to the limiting/reducing of medically unnecessary care and medically necessary care
    - Because of the MACRA amendment, the provision is not as significant as it once was
    - OIG has stopped issuing waivers of the prohibition
- Prohibition only applies to payments to physicians who are involved in the direct patient care of the patient

Gainsharing Prohibition: Medicare Advantage

- § 1852(j)(4) of the SSA Act (42 USC 1395w-22(j)(4)) places limitations on "physician incentive plans"
- No MA plan may operate a physician incentive plan unless it provides satisfactory assurances to the Secretary that:
  - No payment is made directly or indirectly to a physician or physician group as an inducement to reduce or limit medically necessary services
  - If the plan places a physician/physician group at "substantial financial risk" for services not provided by the physician or physician group, the plan must provide stop-loss protection
    - SL protection must be "adequate and appropriate" based on CMS standards that take into account the number of physicians placed at such substantial financial risk in the group or under the plan and the number of individuals enrolled with plan who receive services from the physician/group

Beneficiary Inducement Prohibition

- § 1128A(a)(5) of SSA Act (42 USC 1395a-7a(a)(5)) prohibits a person from offering or giving remuneration to any Medicare beneficiary or Medicaid recipient such person knows or should know is likely to influence such individual to order or receive from a particular provider/supplier any item or service for which payment may be made by Medicare or Medicaid
  - Where this provision is implicated, so too is the AKS
  - *De minimis* threshold of $15 in value per occurrence/$75 per year
  - Statutory exceptions to the definition of "remuneration" in section 1128A(i), including incentives (i) given to individuals to promote the delivery of preventive care, and (ii) that promote access to care and pose a low risk of program and patient abuse (for both (i) and (ii), as determined in regulations)

Fraud & Abuse in FFS vs. APM Worlds

FFS World	APM World
Concern that reimbursement incentives may yield overutilization	Use reimbursement incentives to reduce utilization
Concern that reimbursement incentives may yield stinting	Use reimbursement incentives to encourage efficiencies
Reduce the opportunity for financial incentives to influence care	Use financial incentives to drive cost-cutting and quality-enhancing behavior
Generally isolate referral partners from intertwining financial relationships	Generally encourage referral partners to develop intertwining financial relationships

Fraud and Abuse Waivers

- CMS and OIG have issued fraud and abuse waivers for several programs, including
  - ACO Models (MSSP, Pioneer, and Next Generation)
  - Bundled Payment for Care Improvement (BPCI) 1st Generation Models, and BPCI Advanced
  - Comprehensive Care for Joint Replacement (CJR) Model
  - Oncology Care Model (OCM)
  - Comprehensive ESRD Care (CEC) Model
  - Maryland All-Payer Model Care Redesign Program
  - Medicare Diabetes Prevention Program (MDPP) Expanded Model

See https://www.cms.gov/Medicare/Fraud-and-Abuse/PhysicianSelfReferral/Fraud-and-Abuse-Waivers.html

CMS Issues RFI for Stark

- On June 25, 2018 CMS published a Request for Information on Stark
- Primary motivation appears to be CMS's awareness that Stark may have an adverse effect on providers' willingness to participate in integrated delivery models, APMs, and value-based arrangements
- CMS requested comments on whether such arrangements can be protected under existing Stark exceptions, the need for new exceptions for APMs, how to define "commercial reasonableness," and modifications to the definition of fair market value
- The President's FY 2019 Budget includes a legislative proposal for a new Stark exception for arrangements involving APMs

OIG Issues RFI for AKS

- On August 27, 2018, OIG published an RFI, seeking input from the public on how to address "any" regulatory provisions that may act as barriers to coordinated care or value-based care.
- Specifically, OIG says it wants to identify ways in which it might modify or add new AKS safe harbors exceptions to the beneficiary inducement provision of the CMP Statute's definition of "remuneration" in order to foster arrangements that would promote care coordination and advance the delivery of value-based care, while also protecting against harms caused by fraud and abuse.

OIG Issues RFI for AKS

- OIG is particularly interested in thoughts on topics that include, but are not limited to:
    - (i) The structure of arrangements between parties that participate in APMs or other novel financial arrangements designed to promote care coordination and value;
    - (ii) need for new/revised safe harbors, and exceptions to the definition of "remuneration" under the beneficiary inducements provision of the CMP Statute to promote beneficial care coordination, patient engagement, and value-based arrangements;
    - (iii) terminology related to APMs, value-based arrangements, and care coordination;
    - (iv) special considerations for rural providers and others serving underserved populations

Other Considerations

1. Antitrust

- If third party is negotiating terms of APM between commercial payor and physicians (joint contracting), antitrust laws will be implicated
- If arrangement involves sufficient financial or clinical integration, Gov't will apply the rule of reason. See Statements of Antitrust Enforcement in Health Care (in particular Statement 8), available at https://www.justice.gov/atr/statements-antitrust-enforcement-policy-health-care#CONTNUM_61
- Using the messenger model (if practicable) can avoid antitrust concerns because there will be no "joint contracting"

Other considerations

2. HIPAA/State medical privacy laws

- One must be cognizant of whether disclosure of PHI will be compliant with HIPAA and State law (and State law is not preempted by HIPAA if it is more restrictive than HIPAA)
  - Business associate agreement may be needed

3. State insurance laws

- If physicians or other providers/suppliers are taking risk, depending on the nature of the risk and the State(s) involved, they could be considered to be engaging in the business of insurance

4. State Fee Splitting Laws

- Issue is whether shared savings implicate fee splitting statutes

Deep Dive:
Lessons from Advisory Opinions

Gov't's concerns include:

- Cherry-picking and steering
- Overutilization and inappropriate medical decision-making
- Diminution of quality/limiting medically necessary care
- Capture of referral sources
- False reporting of metrics
- Gifts to beneficiaries to induce choice of provider/supplier

Deep Dive into Advisory Opinions: Gainsharing Arrangements

- OIG has issued many favorable (and no unfavorable) advisory opinions on gainsharing
- Latest opinion is from 2017 (17-09)
- Opinions analyze proposed or actual arrangement under both the CMP Statute Gainsharing Prohibition and the AKS
- CMP Statute Gainsharing Prohibition analysis is much less important due to MACRA amendment
  - AO 17-09 contains an abbreviated analysis

Deep Dive into Advisory Opinions: Gainsharing Arrangements (cont'd)

The OIG has expressed what it considers to be the potential benefits and risks of gainsharing arrangements:

> Properly structured, arrangements that share cost savings can serve legitimate business and medical purposes. Specifically, properly structured arrangements may increase efficiency and reduce waste, thereby potentially increasing a hospital's profitability. However, such arrangements can potentially influence physician judgment to the detriment of patient care. Our concerns include, but are not limited to, the following: (i) stinting on patient care; (ii) "cherry picking" healthy patients and steering sicker (and more costly) patients to hospitals that do not offer such arrangements; (iii) payments in exchange for patient referrals; and (iv) unfair competition (a "race to the bottom") among hospitals offering cost-savings programs to foster physician loyalty and to attract more referrals.
>
> -- OIG Advisory Opinion, 09-06

Deep Dive into Advisory Opinions: Gainsharing Arrangements (cont'd)

- Legal risks in gainsharing arrangements primarily involve the AKS
  - Arrangements can be structured to comply with Stark exception, or fall outside of Stark altogether
  - CMP Statute's Gainsharing Prohibition should not be a problem
  - But there is some irreducible risk under the AKS
- AKS analysis in the AOs contain many safeguards
  - However, one cannot tell which safeguards OIG considered essential to issuing a favorable opinion, as opinions do not reveal which were volunteered by the requestors, as opposed to being insisted upon the OIG
  - Standard for receiving favorable AO high
  - Nevertheless, helpful to look at the AOs

Deep Dive into Advisory Opinions: Gainsharing Arrangements (cont'd)

AKS Safeguards in Advisory Opinions:

- The incentive payments would be distributed to the surgeons on a per capita basis
- The potential savings are capped based on the number of surgeries performed by the surgeons on Federal health care program beneficiaries in the relevant base year
- Aggregate payment to surgeons does not exceed 50% of projected cost savings
- Annual rebasing
- Evidence-based clinical guidelines and product standardization evaluation
- Surgeons' incentives tied to actual, verifiable cost savings attributable to each recommendation implemented during spinal fusion surgeries.
- Physicians have available the same selection of devices and supplies while the arrangement is in place as they did prior to the arrangement.
- Only physicians who are already on the hospital's medical staff participate in the arrangement

Deep Dive into Advisory Opinions: Co-Management Agreements

- AO 12-22 is the only one on co-management agreements to date. There, Hospital entered into a cardiac catheterization co-management agreement with Physician Group
- Group was the only cardiology group on Hospital's medical staff and the only physician group in the town in which Hospital was located that provided cardiac catheterization services
- Under the Management Agreement, the Group provided management and medical direction services for Hospital in exchange for a co-management fee comprised of (1) a fixed fee per year, and (2) an incentive bonus
- Group certified that, to the extent revenue derived from the Arrangement resulted in dividends payable to the Group's owners, the Group distributed them based on each owner's pro rata share of ownership

Deep Dive into Advisory Opinions: Co-Management Agreements (cont'd)

- The incentive bonus consisted of the following components:
  - Requestor's employee satisfaction (5%)
  - Patient satisfaction with Requestor's Labs (5%)
  - Improved quality of care within the Labs (30%)
  - Cost savings measures attributable to CC Lab procedures (60%)
- An important fact was that there was a fixed amount set aside to fund the incentive bonus
- Depending on how well Group performed on any component, it received 0, 50%, 75% or 100% of the money set aside for that component

Deep Dive into Advisory Opinions: Co-Management Agreements (cont'd)

- The OIG did its usual pre-MACRA CMP Statute Gainsharing Prohibition Analysis
- With respect to the AKS, the OIG noted the following as favorable facts:
  - Hospital certified that the fixed fee and the incentive bonus were FMV, and the fact that the Group provided substantial services under the Management Agreement reduced the risk that the compensation was payment for referrals
  - Compensation paid to Group did not vary with the number of patients, so an increase in referrals to Hospital did not result in an increase in compensation paid to the Group
  - Because Hospital operated the only CC Lab within a 50-mile radius, and because Group did not provide CC services anywhere but at Hospital, it was unlikely that Hospital offered compensation to Group under the Arrangement as an incentive for the Group's physicians to refer business to the Labs instead of to a competing cardiac catheterization lab
  - The Arrangement had a quality component in the incentive bonus that was well defined and the cost savings component involves specific changes in CC lab procedures, which Group was responsible for implementing

Deep Dive into Advisory Opinions: Co-Management Agreements (cont'd)

Stark Analysis

- The Management Arrangement was between a hospital (DHS entity) and a physician group ("physician organization" as defined at 411.351)
- Therefore, the Management Arrangement created a "direct compensation arrangement" between each physician owner of Group and the Hospital (due to the "stand in the shoes" principle at 411.354(c))
- Applicable exceptions would be the exception for personal service arrangements, and the similar exception for fair market value compensation
  - Both require FMV compensation and that the compensation not be directly or indirectly related to the volume or value of referrals
  - Both require compensation be "set in advance" but formulaic compensation such as that in the incentive bonus would qualify as set in advance under Stark (but not for purpose of AKS safe harbor)

Deep Dive into Advisory Opinions: Co-Management Agreements (cont'd)

Stark Analysis

- Compensation was not determined in a manner that took into account the value or volume of referrals because the incentive bonus pool was a fixed amount and the metrics were not volume or value based
- The above analysis applies to the physician owners of the group. If there were physician non-owners of the group, there would have been no direct compensation arrangement between those physicians and Hospital, and possibly no indirect compensation arrangement as well
  - If no direct compensation or indirect compensation arrangement between a physician and a DHS entity, Stark will not be implicated (unless an ownership interest is involved)

Deep Dive into Advisory Opinions: Co-Management Agreements (cont'd)

Stark Analysis

- What if Physician Group had formed a management company (ManageCo) and the Management Arrangement was between ManageCo and Hospital?
- In that case, there would have been no direct compensation arrangement between any physician in Group – owner or not – and Hospital, and possibly no indirect compensation arrangement as well
  - ManageCo would not be a "physician organization" and therefore the "stand in the shoes" principle would not apply

Part IV
Valuation Issues

Valuation

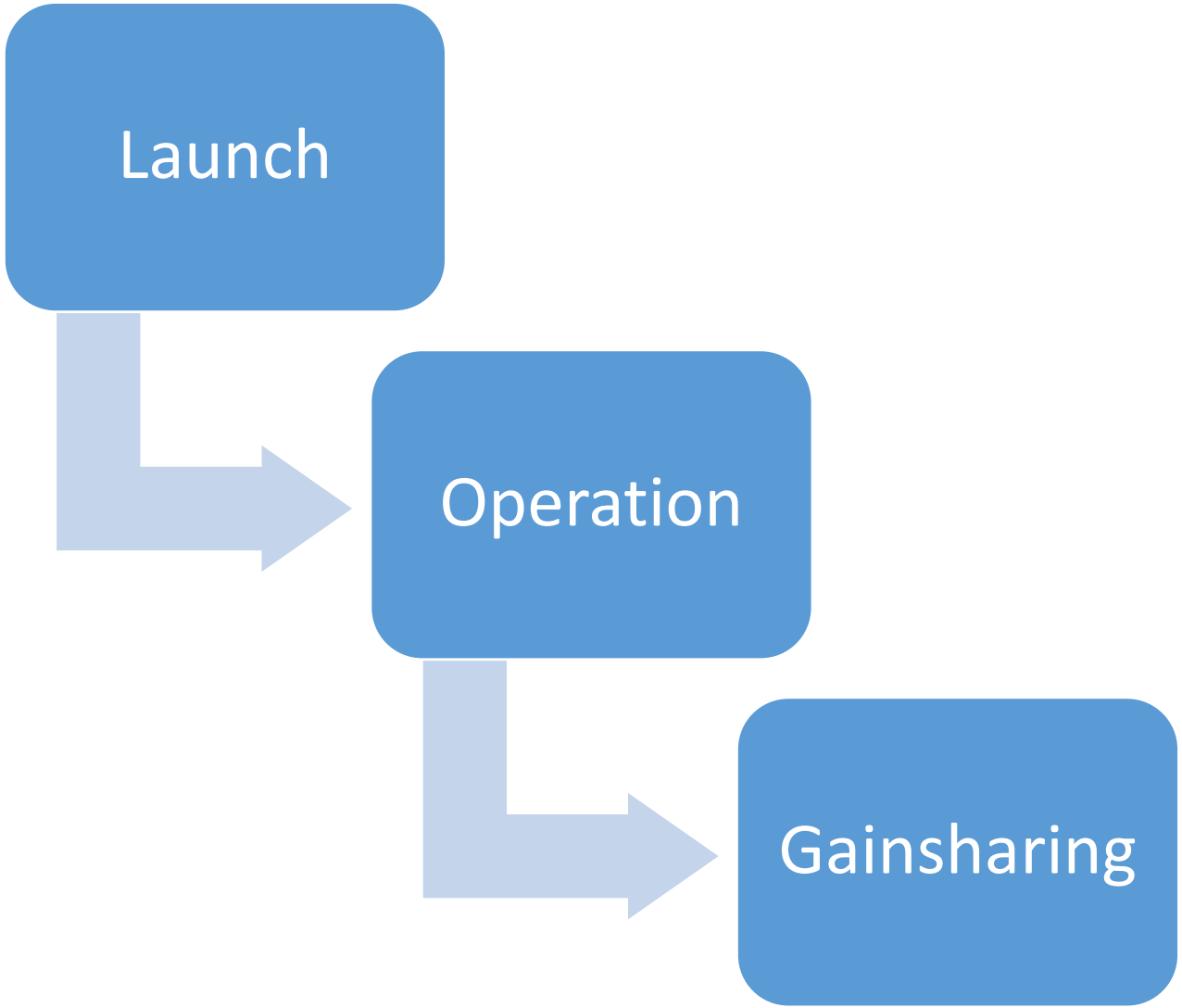
- Accurate modeling of APMs is critical for two reasons:
  - (1) Viability
  - (2) Compliance
- Novel valuation challenges
  - How does one determine “value?”
  - Fair market value?
  - Commercially reasonable?

Commercially Reasonable

"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 [designated health service] referrals" – CMS

69 Fed. Reg. 16053, 16093 (Mar. 26, 2004)

Lifespan of an APM



Launching the APM

- Building a network of providers
  - Participant selection
  - Legal structure of network
  - Determine gainsharing upside/downside
- Upfront investments
  - EHR/IT investments
  - Data systems
  - Management and staffing
  - Care protocols
- Contracting with payors

Operating the APM

- Ongoing management costs
  - Data analytics
  - Monitoring patient panel and costs
  - Centralizing care
- Supporting physicians
  - Case managers
  - Coordinated care teams
- Patient incentive programs

Gainsharing

- What kind of APM?
  - One-sided: participants only reap the upside gains
  - Two-sided: participants on hook for excessive costs
- Gainsharing upside: distribution of gains
  - Allocation between system and physicians
  - Allocation between the physicians
- Gainsharing downside: who is responsible?
  - Alternative: sharing expenses, rather than risks

The Big Picture

- Goal: show the APM is commercially reasonable
- Meaning: the upside of the APM is actuarially worth the downside risks and costs across the APM's lifespan
- Why? Commercial reasonableness helps rebut inferences under fraud and abuse laws that such arrangements are intended to gain referrals
- Takeaway: engage financial analysts who are familiar with APMs and can help build commercially reasonable structures

Part V
Discussion Questions

Discussion Questions

- How important are the waivers?
- How should a health system think about a request to bear all downside risk and leave physicians with an upside-only deal?
- How should one think about attracting physicians to an APM through the financial benefits that are available in it?
- How far can one push the "access to care" exception to remuneration for purposes of the beneficiary inducement CMP?
- How should one think about distributions from a risk-bearing organization to physicians? Are *per capita* distributions important?
- What about distributions of more than 50% of savings to physicians?
- In a provider-based arrangement, should annual rebasing be seen as a requirement based on the Advisory Opinions?
- In a provider-based arrangement, should prior-year procedure counts cap future-year savings?

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