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FORWARD

Navigating New and Establishing Approaches to Provider Collaboration

Session #803

Friday, May 21, 2021
8- 9 a.m.

Presenters

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Learning Objectives

- Explore established and new approaches to provider collaboration arrangements that might include telehealth, preferred provider arrangements and clinically or financially integrated networks.
- Understand key federal and state laws that apply to provider collaboration arrangements as you consider the legal and operational benefits and challenges of collaboration.
- Develop strategies for successful and compliant business arrangements.

Agenda

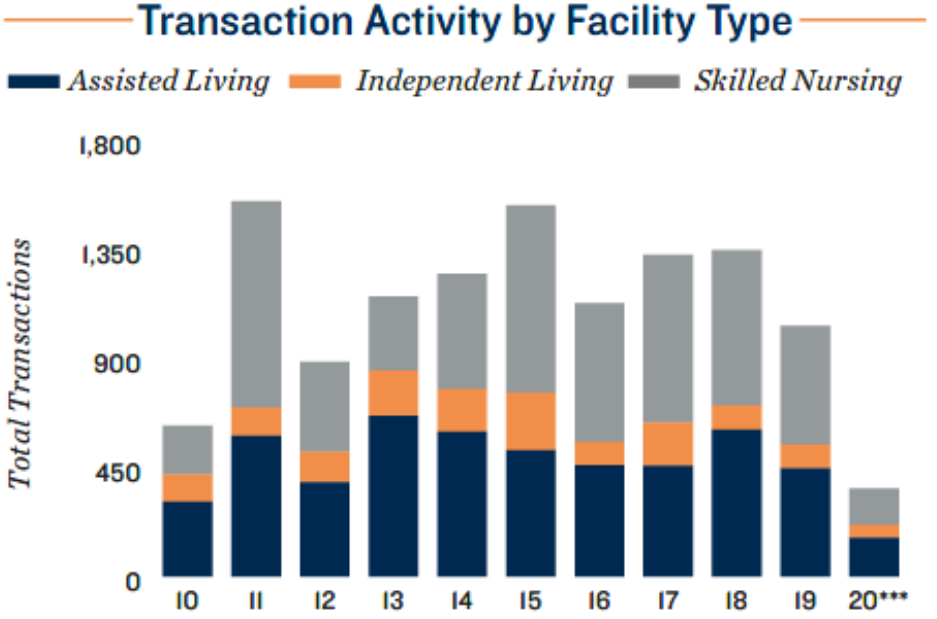
1. Provider Collaboration Overview
2. Case Study 1: Lease / timeshare
3. Case Study 2: Telehealth collaboration
4. Case Study 3: LTC participant in bundled payment model
5. Case Study 4: Preferred provider arrangement
6. Case Study 5: Risk sharing (value-based and/or Clinically Integrated Network)

Provider Collaboration

Factors Driving Collaboration

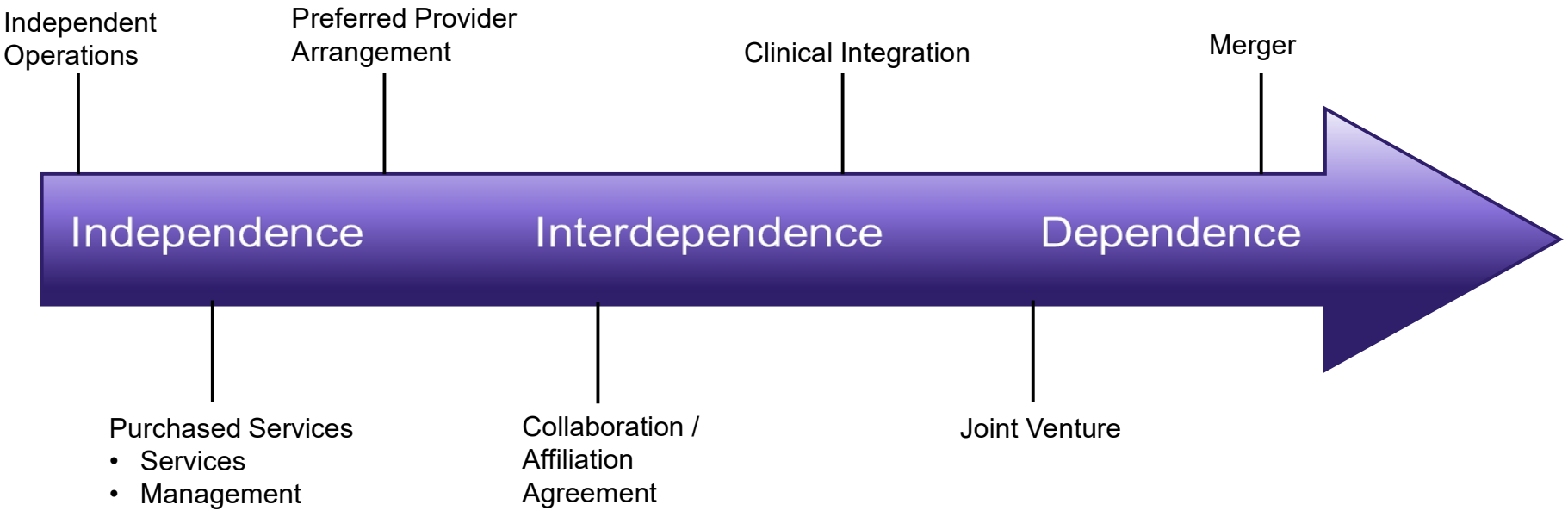
- General financial distress
- Need to contain cost and achieve efficiencies
- Improving quality of care
- Capital/technology investments
- Payor/Medicare drive to outcome-based reimbursement
- Patient needs
  - Growth in aging population
  - Service expansion
  - Geographic expansion
- Staffing shortages
- Increased competition with private-equity backed consolidation and national players

Q3/Q4 2020 Transactions



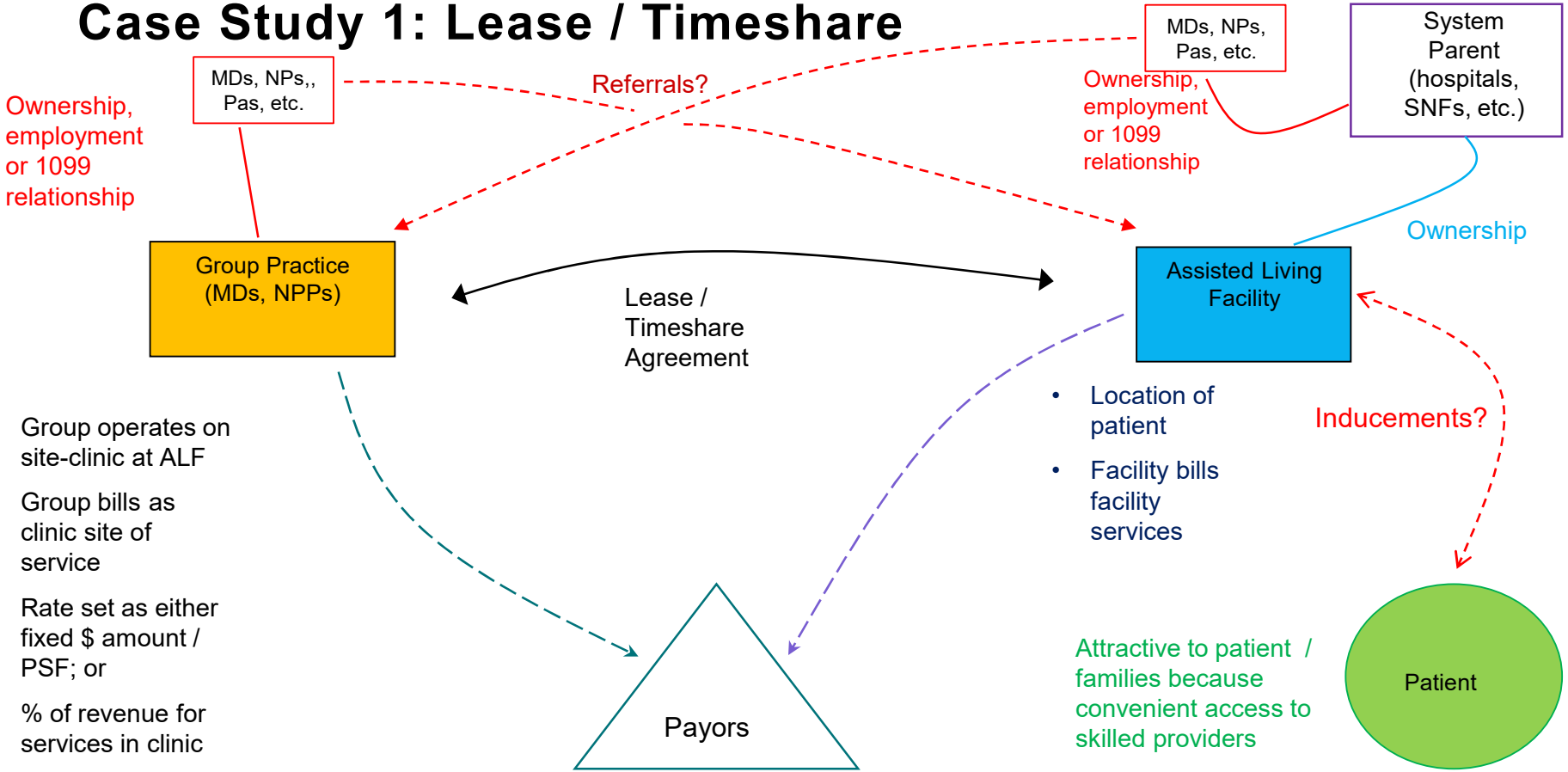
* Through second quarter
** Trailing 12 months through second quarter
*** Through October 11, 2020
Sources: Marcus & Millichap Research Services;
NIC Map® Data and Analysis Service (www.nicmap.org)

A Range of Available Relationships



Case Studies

Case Study 1: Lease / Timeshare

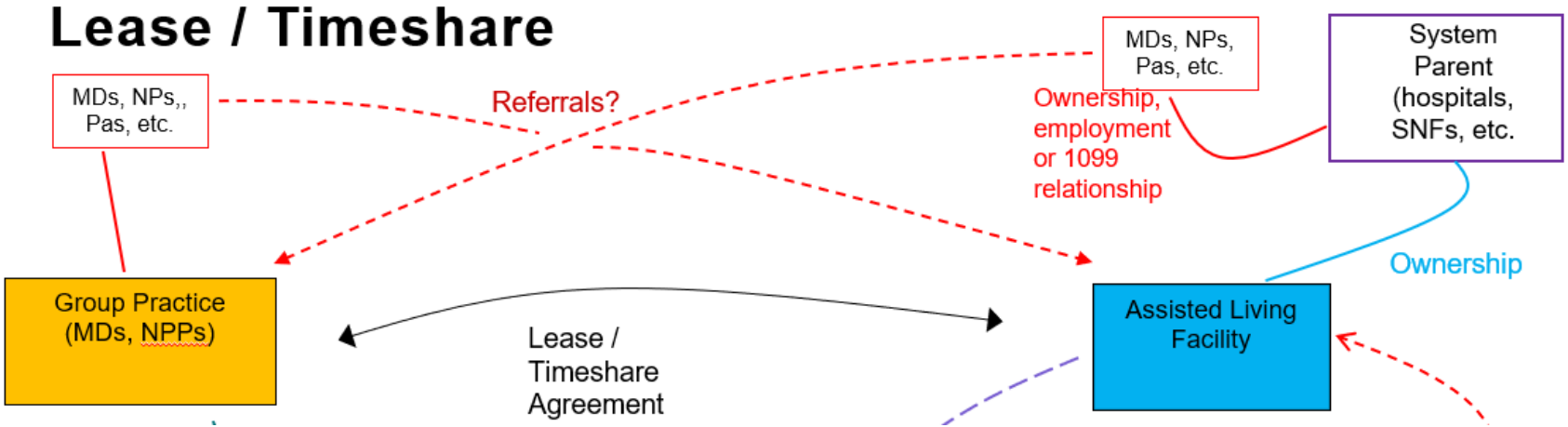


How is Lease / Timeshare Developed?

- Agreement between facility and physician / non-physician practitioner group for purposes of running on-site clinic
- Access to space, equipment and potentially supplies, administrative or professional support services and related items needed for lessee to operate clinical site of service
- Lessee bills for services with leased location functioning as a practice location
- Payor agreements updated to reflect new site of service
- Distinguished from arrangements where provider renders services in long term care facility
- Attractive to group because of access to patient population
- Attractive to facility because of on-site expertise

Key Legal Issues: Anti-Kickback Statute

- Prohibits knowing and willful offer, payment, solicitation or receipt of "remuneration" to induce or reward referral of items or services reimbursable by federal health care programs
- Penalties include felony conviction, fines up to $100,000 for each violation, or imprisonment for not more than 10 years, or both
- "Remuneration" includes anything of value



- "Safe harbors" exist to protect many arrangements, but most are difficult to satisfy

Available Safe Harbors: Equipment & Space

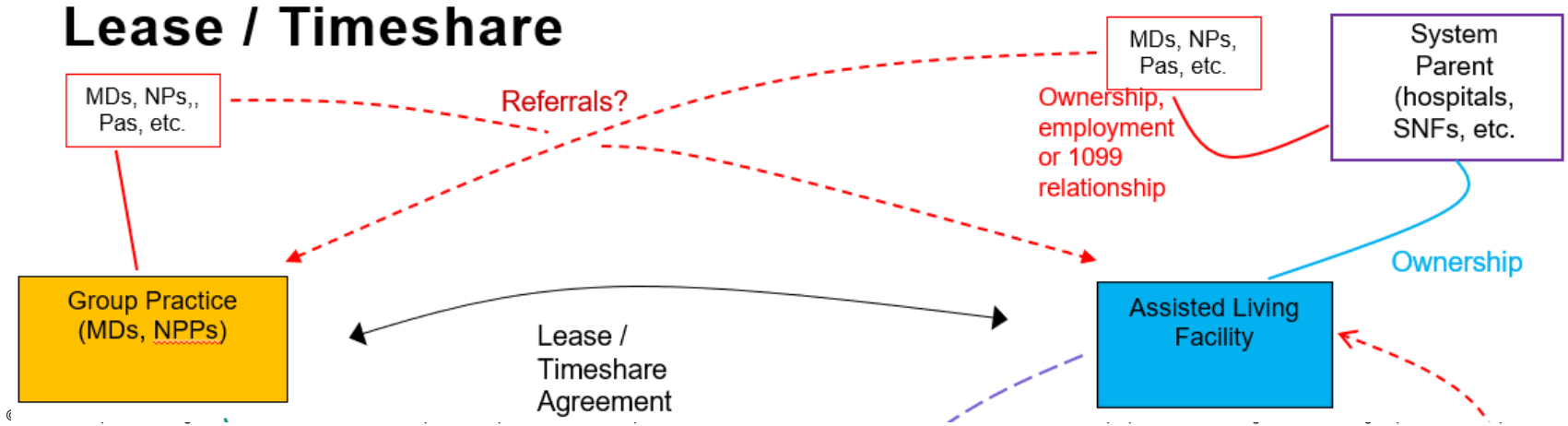
- Arrangement in writing, signed, specifies all equipment / premises at issue
- If no full time access, must specify schedule of intervals of use, precise length and exact rent for intervals
- Term of at least one year
- Aggregate rent set in advance, consistent with fair market value and not taking into account volume / value of referrals or other business
- Aggregate inputs rented does not exceed what is reasonably necessary to accomplish commercially reasonable purpose of arrangement

Available Safe Harbors: Personal Services

- Similar elements to space / equipment rental safe harbors
- 2020 “Sprint” rulemaking modified safe harbor to make much more flexible:
- Eliminates requirement that aggregate payment be set out in advance (i.e., the full amount)
- Instead, requires payment methodology be set out in advance
- Similar to Stark Law exception for fair market value arrangements and personal services arrangements
- Also eliminates requirement that part-time services needed to have complete schedule, precise length of intervals and exact charge for intervals set out in written agreement in advance

Key Legal Issues: Stark Law

- Unless an exception applies, Stark Law prohibits a physician from referring patients for designated health services ("DHS") to an entity, or the entity from billing for the DHS, if the physician has a "financial relationship" with the entity
- Penalties include: denial or repayment, per claim fines of $15,000, and permissive or mandatory exclusion. Violations also typically form basis for False Claims Act prosecutions
- Financial relationships can be based on ownership or compensation and can be direct or indirect.



Lease Exceptions

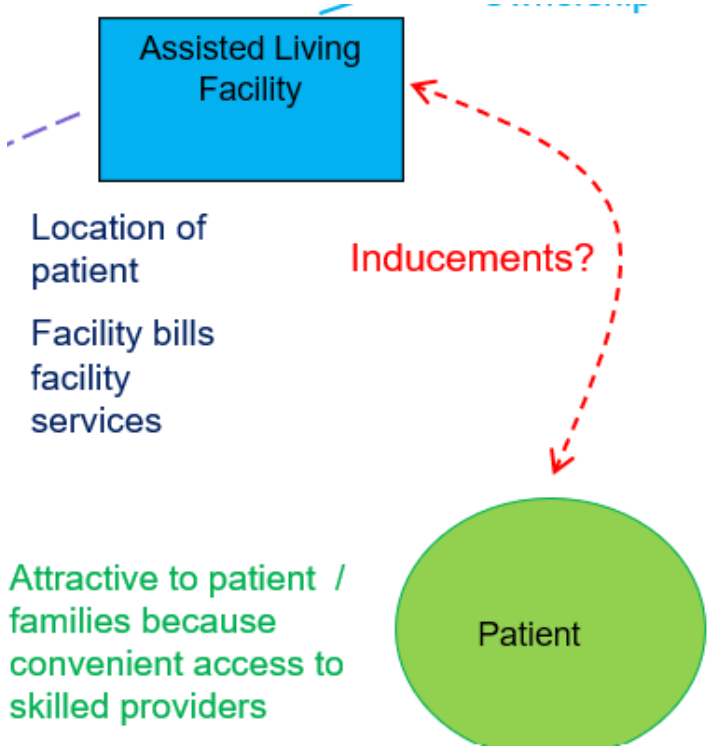
- Set out in writing, signed, specifies premises / equipment covered
- Term of at least 1 year
- Leased inputs not more than reasonable and necessary for legitimate business purpose
- Sharing / exclusive use
- Rental charges set in advance, consistent with fair market value
- Rental charges do not take into account volume / value of referrals or other business
- Restrictions on percentage-based / per-use payment methodologies
- Arrangement must be commercially reasonable
- Limitations on holdovers

Timeshare Exception

- Available for timeshare arrangements that include use of premises, equipment, personnel, items, supplies or services. Must involve physician and hospital / physician organization.
- Must be used predominantly for provision of E&M services
- Use of premises, equipment, services, etc. for E&M on same schedule as used for DHS
- Protects “use” of premises (not possessory interest)
- Certain equipment excluded from protection (advanced imaging, radiation therapy, lab / pathology (unless CLIA-waived)).
- Equipment located in same building as E&M location; may be used to furnish only DHS incidental to E&M at time of patient’s visit
- Compensation set in advance, consistent with fair market value, not determined in manner that takes volume / value of referrals / other business generated into account
- Restrictions on percentage-based / per-use fees

Key Legal Issues: Beneficiary Inducement

- Beneficiary Inducement “CMP” prohibits any person or entity from offering remuneration to a Medicare or Medicaid beneficiary if that remuneration is likely to influence the beneficiary's selection of a provider
- Penalties include fines of up to $15,270 per item/service provided
- Definition of remuneration amended to include exceptions which went into effect in 2017. New exceptions include:
  - Copayment reductions for certain hospital outpatient department services;
  - Certain remuneration that poses a low risk of harm and promotes access to care;
  - Coupons, rebates, or other retailer reward programs that meet specified requirements;
  - Certain remuneration to financially needy individuals; and
  - Copayment waivers for the first fill of generic drugs.



Key Legal Issues: Beneficiary Inducement

- Exception: Promoting access to care
  - Items / services that improve beneficiary's ability to obtain items and services payable by Medicare or Medicaid
  - Pose a low risk of harm to Medicare / Medicaid beneficiaries (and the programs themselves)
    - Unlikely to interfere with, or skew, clinical decision-making
    - Unlikely to increase costs to federal health care programs or beneficiaries through overutilization or inappropriate utilization; and
    - Not raising patient safety or quality of care concerns
  - Not cash, cash equivalents or copay / deductible waivers

- Exception: Financial need
  - Offer, transfer of Items / services for free or less than FMV
  - Not part of any advertisement / solicitation
  - Not tied to provision of items / services reimbursable by Medicare / Medicaid
  - Reasonable connection between items / services and medical care of individual
  - Good faith determination of financial need
  - Not cash or cash equivalents

Case Study 2: Telehealth Collaboration

- Assisted Living Facility is located in a rural area, making access to in-person primary care services difficult.
- Primary Care Clinic agreed to purchase telehealth equipment—including a laptop, webcam, microphone and video conferencing software—and gift it to the Assisted Living Facility.
- With the help of this new equipment, AL residents experiencing cold and flu symptoms can access medical care without having to visit a healthcare facility, where they risk spreading the virus to others.

Key Legal Issues: Anti-Kickback Statute

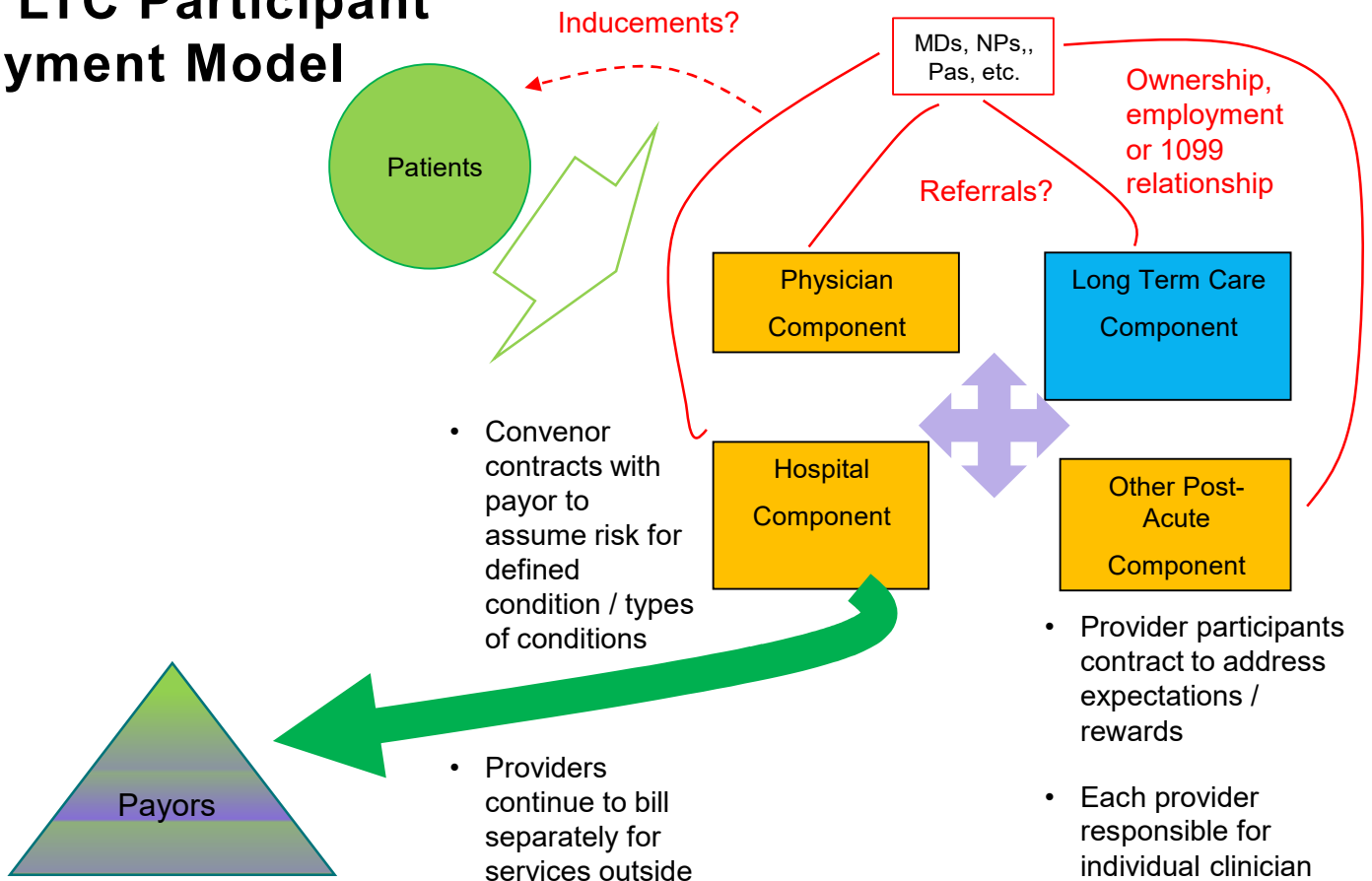
- Issue: Was the free equipment gifted to the AL facility in exchange for patient referrals?
- The gift of free equipment implicates the federal Anti-Kickback Statute
  - Likely that the AL Facility will refer at least some residents to the Primary Care Clinic
  - OIG has long held that the provision of free or below-market items or services to actual or potential referral sources is highly suspect
    - Risk that the gift is viewed as remuneration for past or future patient referrals.
  - AKS is implicated when the free items have independent value to recipients, or relieve recipients of financial responsibility that they would otherwise have
- OIG FAQs create flexibility during the Covid-19 public health emergency, but not more broadly

Safeguards / Risk Mitigation

1. Referrals cannot be required
   - There should not be repayment or other compensation tied to referrals
     - E.g., AL Facility should not be expected to pay for the equipment unless it meets certain criteria
2. Document the purpose behind the gift
   - Residents must be the ones benefiting
   - Should educate staff on the basis for the arrangement and the fact that referrals are not required
3. Include safeguards to prevent patient steering and protect freedom of choice
4. Ensure the technology is not restricted/limited in a way that makes it compatible only with the donor
5. AL Facility should not be required to market or advertise on behalf of the donor

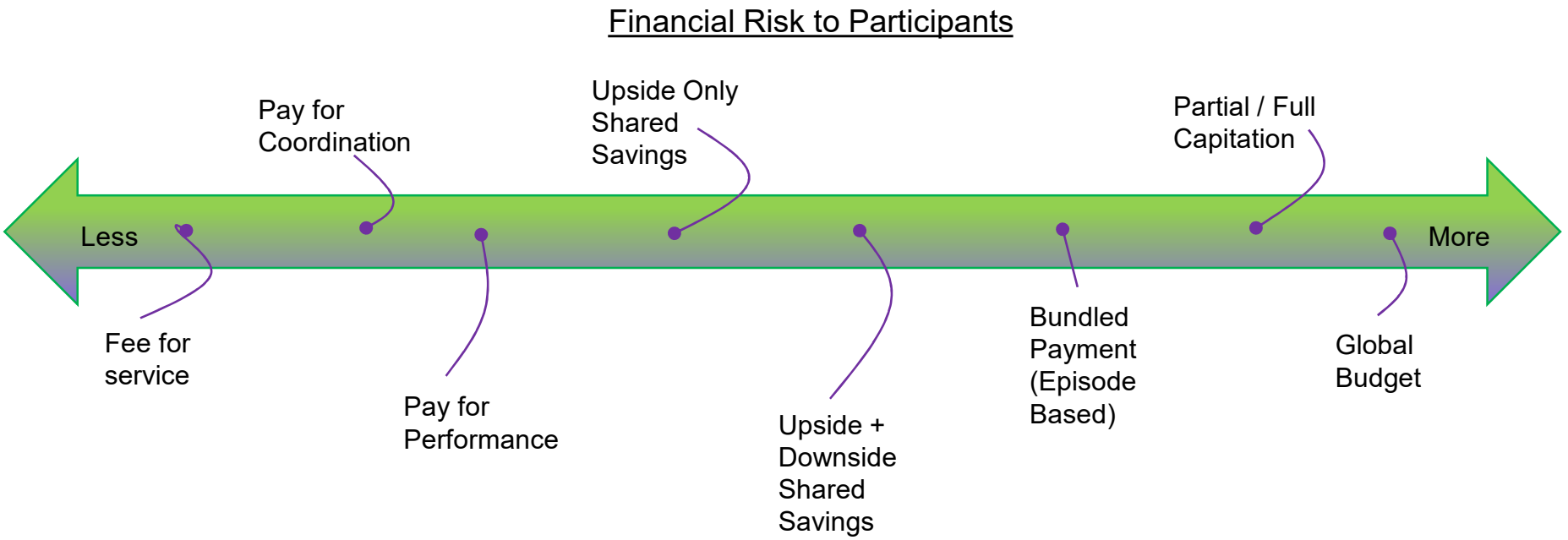
Case Study 3: LTC Participant in Bundled Payment Model

- Providers collaborate in payor model to reward cost / quality targets within episode of care (e.g., hip replacement)
- Opportunity for outcomes / quality based incentives
- Not all services included (.e.g., unrelated, certain high-cost, etc.)



- Convenor contracts with payor to assume risk for defined condition / types of conditions
- Providers continue to bill separately for services outside of bundle
- Provider participants contract to address expectations / rewards
- Each provider responsible for individual clinician work

Shift to Value-Based Payment



Bundled Payment Model

- Specifics vary by program, payor, scope of services covered under the bundle
- One provider (convenor) initiates the bundle. Convenor bears financial risk for model.
- Participating providers bill / reimbursed under appropriate payment system
- Program participants agree to seek savings by changing practice patterns and controlling claims. Other commitments such as quality reporting, meeting performance metrics (e.g., reducing hospital readmissions, shorter lengths of stay) included.
- Skilled nursing facility, other post acute share in payment risk with convenor (e.g., hospital) and take active role in managing patients within specific care episode
- Convenor receives payment from payor / regulator for savings
  - Savings (or costs, if losses occur) allocated among participants under agreed upon model

Bundled Payment Model

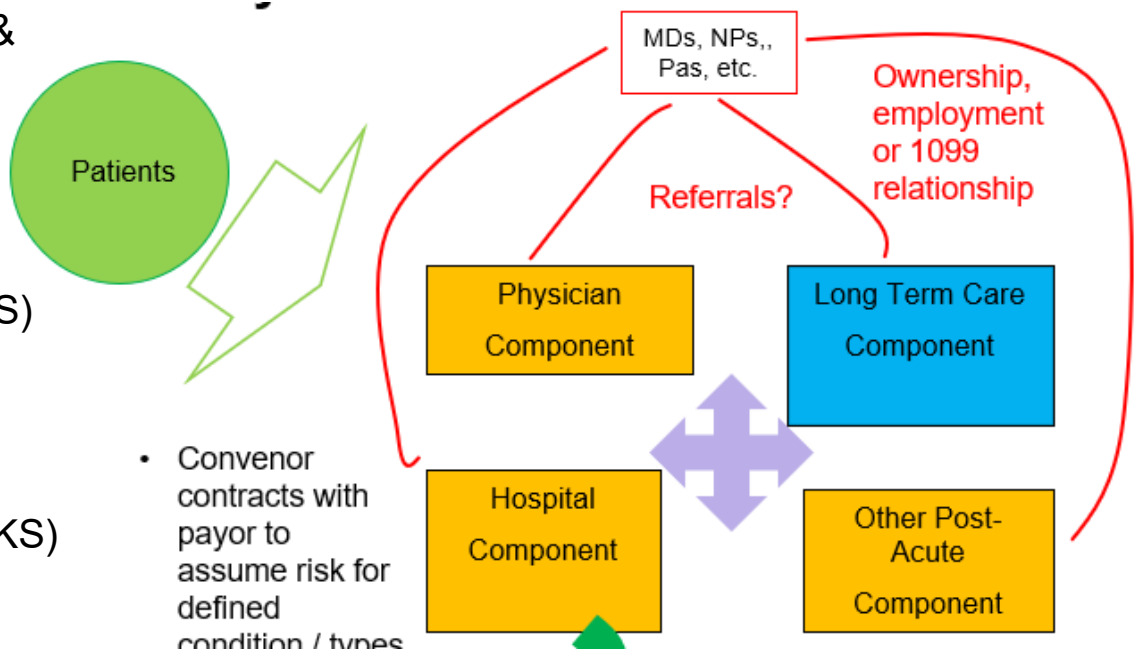
- Participants seek to achieve savings by modifying post-acute care patterns and controlling claims billed to payors for covered episode (reduce costs):
  - Shortening SNF stays and balancing against risks of hospital readmission
  - Bypass SNF and send patients directly from hospital to home or send patients to SNFs that meet targets for shorter length of stay
  - Adopt care transition / care management protocols
  - Access to providers at SNF / ALF and / or support for home health care to avoid hospitalizations
- Waiver of 3-day inpatient stay for access to SNF care
- Bonus availability depends on hitting quality targets
- Performance on hospital readmissions, other measures determines how much of share
- All occurs against backdrop of general quality reporting / value-based purchasing that applies in underlying payment model

Stark Law & Anti-Kickback Statute

- What exceptions have historically been available?
  - Employment
  - Personal services arrangements
  - Fair market value arrangements
  - Indirect compensation arrangements
  - Electronic health records / cybersecurity
- Limited number of “waivers” for certain CMS / CMMI bundled arrangements
  - E.g., ACOs under MSSP; BPCI waivers
- Critical issues in meeting Stark Law exceptions:
  - Fair market value payments
  - Compensation that takes the volume / value of referrals into account
  - Commercial reasonableness

Stark Law & Anti-Kickback Statute

- Three new value-based Exceptions & Safe Harbors:
  - Full Financial Risk
    - Greatest financial risk, greatest flexibility
  - Meaningful (Stark) / Substantial (AKS) Financial Risk
    - Compromise + complexity
  - Value-based arrangements (Stark) / Care Coordination arrangements (AKS)
    - Reduced financial risk, added complexity



Framework for Value-Based Exceptions / Safe Harbors

Value-Based Activity	• Provision of item or service; taking of action; refraining from action • Must be reasonably designed to achieve at least one VB Purpose • Proposed Stark rule provided this does not include making a referral. Final Stark rule walks this back, providing that care planning activities that meet definition of "referral" quality as "taking an action" • For AKS, making a referral, on its own, is not a VB Activity
Value-Based Enterprise	• Two or more VBE participants • Collaborating to achieve at least one VB Purpose • Each of which is a party to a VB Arrangement with the other or at least one other VBE Participant in the VB Enterprise • Accountable body or person responsible for financial and operational oversight • Governing document indicating the VB Enterprise and how the VBE Participants intend to achieve its VB Purposes

Framework for Value-Based Exceptions / Safe Harbors

VBE Participant	• A person or entity that engages in at least one value-based activity as part of a value-based enterprise
Value-Based Purpose	• Coordinating and managing care of TPP • Improving quality of care for TPP • Reducing costs / expenditures without reducing quality of care for TPP • Transitioning from delivery / payment system based on volume to mechanisms based on value (quality, cost control) for TPP
Target Patient Population	• Identified patient population selected by VBE using legitimate and verifiable criteria set out in advance in writing and that further the VB Enterprise's VB Purposes
Value-Based Arrangement	• Arrangement for provision of at least one value-based activity for the TPP to which the only parties are (1) a VB Enterprise and one or more of its VB Participations; or (2) VBE participants in the same VB Enterprise.

Value-Based Arrangements (Stark) & Care Coordination Arrangements (AKS)

- General Requirements:
  - Must be set forth in writing and signed by parties and specify key terms (TPP, remuneration, VB Purpose, outcome measures etc.)
  - No inducement to reduce or limit medically necessary services
  - Must protect patient choice, independent medical judgment and physician's ability to make decisions in best interest of patients
  - Cannot condition on referrals of patients who are not part of TPP, or volume / value of any other business generated that is not part of VB Arrangement (AKS)
  - Ongoing monitoring requirement to ensure parties have furnished VB activities, whether VB activities will further VB purpose and progress towards achieving any outcome measures
  - Parties must terminate VB activity if not furthering VB purpose
  - Grace period for terminating ineffective VB activity
  - Must be commercially reasonable
  - Records must be maintained for at least 6 years

Care Coordination Agreements (AKS)

- Only protects non-monetary remuneration
- Used predominantly to engage in VB Activities that are directly connected to coordination and management of care for TPP and does not result in more than incidental benefit to persons outside TPP
- Cannot induce VBE Participants to furnish medically unnecessary services
- Must specify one or more specific outcome measures that are monitored, assessed and prospectively revised as needed
- Must monitor and assess performance no less frequently than annually; and terminate within 60 days if determined value-based arrangement is unlikely to further coordination, results in major quality deficiencies, or unlikely to meet outcome measures
- Recipient must pay at least 15% of offeror's costs or FMV of remuneration (paid one-time or at reasonable, regular intervals)

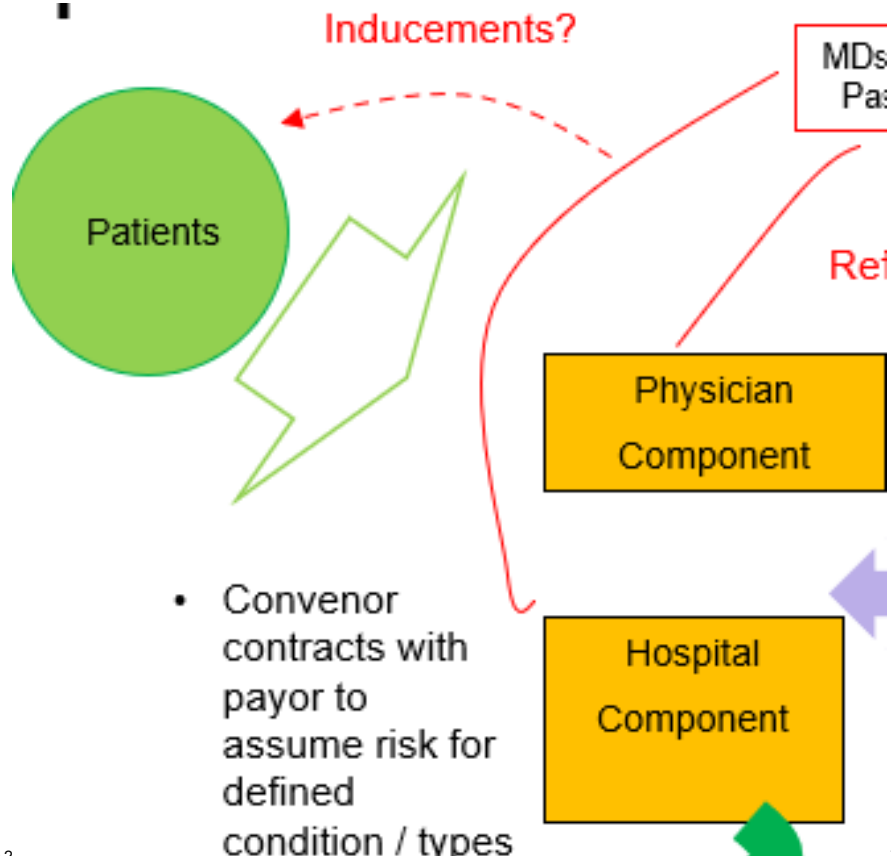
Care Coordination Agreements (AKS)

- Writing must specify offeror's costs of remuneration (and accounting methodology used to determine costs) or the FMV of remuneration
- Remuneration cannot be exchanged or used for marketing services furnished by VBE or VBE Participants to patients or for patient recruitment activities
- Special rules for "limited technology participants" and "digital health technology"
  - Any remuneration by limited technology participant cannot be conditioned on recipient's use of items or services made, distributed or sold by limited technology participant
- Arrangement must be in writing and signed in advance of, or contemporaneous with, commencement of VB Arrangement and any material changes
- Remuneration cannot be diverted, resold or used by recipient for unlawful purpose

Value-Based Arrangements (Stark)

- Protects monetary and non-monetary remuneration
- Remuneration must be for or result from VB Activities undertaken by recipient for patients in TPP
- Outcome measures against which recipient is measured are optional
- If outcome measures are used, they must be objective and measurable and determined prospectively (including if any changes are made)
- Payment methodology is set in advance
- Remuneration not conditioned on referrals of patients not part of TPP or business not otherwise covered under VB Arrangement

Key Legal Issues: CMP (reductions in care & inducements)



- Prohibits hospitals from knowingly providing payment, directly or indirectly, to physician as inducement to reduce or limit medically necessary services, provided to Medicare / Medicaid beneficiaries
  - Civil monetary penalties (“CMPs”) for violations
- Before 2015, law was obstacle to arrangements that wanted to provide financial incentives to reduce unnecessary care / wasteful medical services
- Beneficiary inducement issues?

Case Study 4: Preferred Provider Arrangement

- Hospital wants to improve its post-discharge planning operations
- Hospital enters into a “Preferred Provider Agreement” with a Home Health Agency (“HHA”)
  - HHA agrees to follow certain identified protocols related to patient care
    - E.g., Medication review and management, staff qualifications, etc.
  - In exchange, Hospital agrees to refer patients to HHA on a preferred basis
    - Hospital agrees not to market other home care providers or otherwise designate other home care providers as “preferred providers”
- Hospital is not paid for its referrals to the HHA and compensation is not otherwise exchanged as part of this arrangement
- Hospital retains the right to terminate/suspend the Preferred Provider Agreement if Hospital suspects any HHA activities constitute a threat to the health or welfare of any patient, or fails to meet Hospital’s standards

Key Legal Issues: Anti-Kickback Statute and Stark Law

- Preferred Provider Agreements are permitted, if structured correctly
- Basis of the arrangement must be legitimate
  - Improve patient outcomes and reduce costs
  - Purpose cannot be to secure or reward referrals
- Must evaluate compliance with the Anti-Kickback Statute and the Stark Law
  - Cannot guarantee or require referrals
  - AKS is a big risk with these arrangements
    - Regulators are often skeptical of preferred provider arrangements because they believe that they are mechanisms for providers to lock down referrals from a partner
    - Although HHA is not compensating the Hospital, there is still risk
      - A regulator could argue that, in exchange for referrals, the HHA is providing Hospital with something else of value (e.g., free services)
    - Does this fit within AKS safe harbor?
  - Consider whether the arrangement implicates the Stark Law

Key Legal Issues: Protecting Patient Choice

- Must ensure freedom of patient choice
  - Fundamental concept underlying many of the applicable laws
    - E.g., Medicare Conditions of Participation, state laws, underlying policy in AKS and Stark Law
  - Enabling free choice of provider is a critical compliance safeguard
  - Hospital should not be prohibited from marketing other home care providers or designating other providers as “preferred providers”
  - Hospital must present list of available providers and include appropriate disclaimers
  - Hospital, staff and patients cannot be penalized for selecting different provider
- Also important in terms of mitigating liability

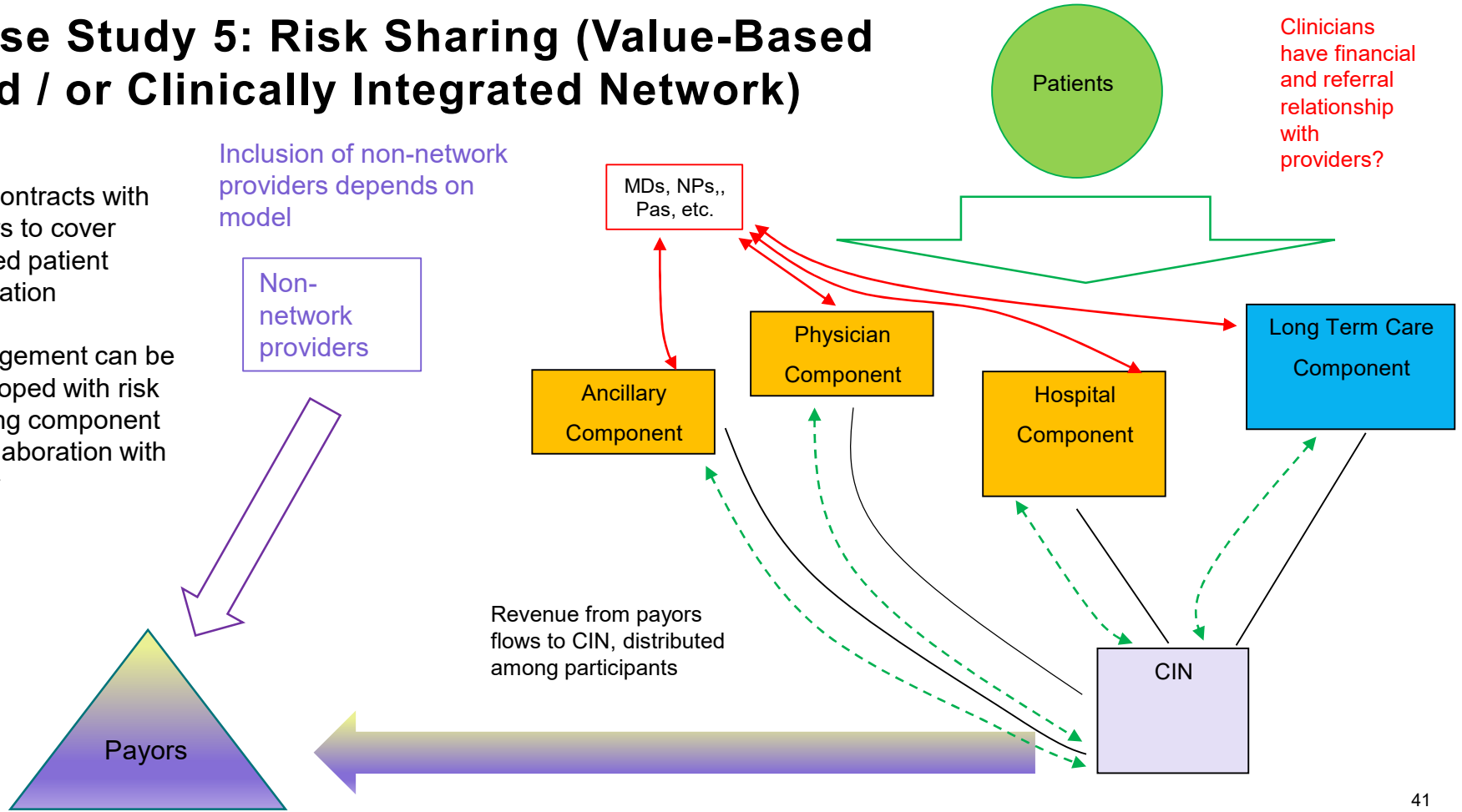
Safeguards / Risk Mitigation

Safeguards:

1. Confirm there is a legitimate basis for the arrangement
2. Structure it to fall within AKS safe harbor, to the extent possible
3. Carefully draft the Preferred Provider Agreement
4. Ensure all policies, contracts and documented arrangements clearly state that referrals are not required
5. Educate staff to ensure that they are aware that referrals are not required
6. Be alert to documentation which suggests noncompliant intent
   - E.g. Avoid financial analysis of resulting referrals
7. Understand that relationships that increase utilization will be viewed with greater skepticism

Case Study 5: Risk Sharing (Value-Based and / or Clinically Integrated Network)

- CIN contracts with payors to cover defined patient population
- Arrangement can be developed with risk sharing component in collaboration with payor



Clinically Integrated Network

- What is a CIN?
  - Network of providers who coordinate and use evidence-based clinical guidelines to reach benchmarks that lead to efficient, high quality care to patients at reduced costs
  - Focus on interdependence and cooperation through variety of mechanisms
- Legal structure
  - Separate legal entity or created via contract?
- Governance
  - Board responsible for oversight / direction
  - Representative leadership (from participants / specialties)
  - Committees to develop quality, cost, related targets / protocols
  - Reserved powers
- Who can participate?
  - Mix of providers needed to drive quality improvement and reach cost targets

Clinically Integrated Network

- How is it formed?
  - Bylaws / operating agreement
  - Network participation agreement (providers make available services to CIN population)
  - Contract with payors
  - Master agreement
  - Others? Management agreement, HIPAA and related agreements
- How does revenue flow work?
  - Financial contributions to form CIN
  - Distribution of shared savings; allocation of responsibility for shared losses
  - Incentive payments related to quality, outcomes, cost targets, etc.
  - Claims from non-network providers depend on model (e.g., counted against CIN budget?)
- Importance of information technology in a CIN

Key Legal Issues: Antitrust Laws

- Competing health care providers jointly “fixing” prices
  - Guarding against “spillover” collusion
- Per se rule
- Rule of reason
- Balancing procompetitive benefits from clinically integrated network against illegal price fixing / other forms of anticompetitive activity
- Federal Trade Commission & U.S. Department of Justice guidance on clinically integrated networks

Antitrust Laws

What is “clinical integration”?

“... an active and ongoing program to evaluate and modify practice patterns by the network's physician participants and create a high degree of interdependence and cooperation among the physicians to control costs and ensure quality”

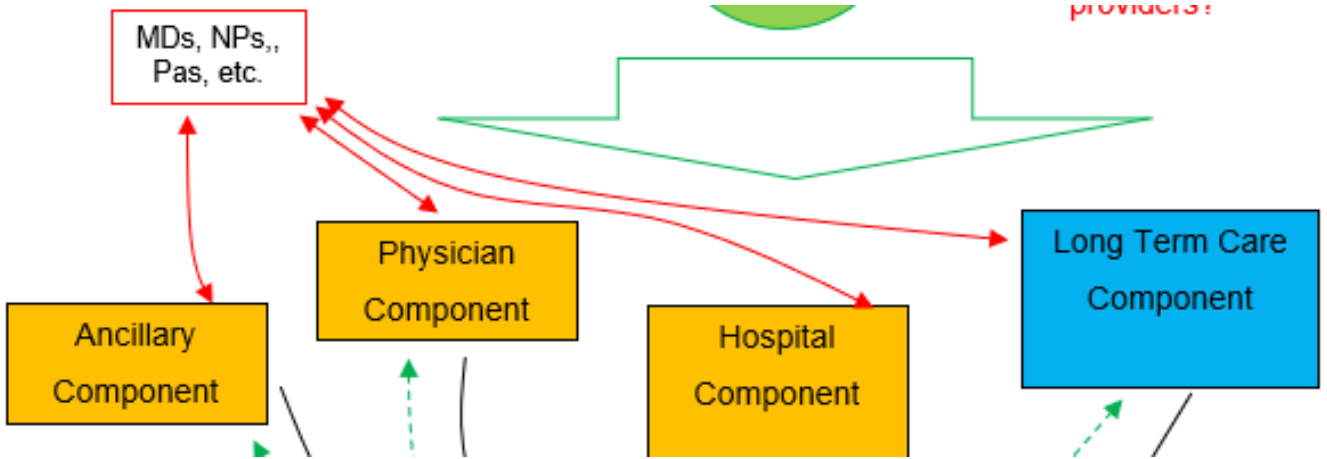
*Source: 1996 Joint Statements of Antitrust Enforcement Policy in Health Care by the Federal Trade Commission and U.S. Department of Justice

Antitrust Laws

- What does clinical integration look like?
  - Reserved powers for participants
  - Physician led and governed
  - Evidence-based care protocols (e.g., clinical pathways, care coordination)
  - Strong provider network with aligned goals and objectives (e.g., utilization review, QA)
  - Shared EMR for use by participants, with support for clinical decision making and related metrics
  - Organized systems of integrated care across care settings
  - Aligned incentives with payers, employers, and network participants
  - Capital to fund CIN infrastructure development and management
  - Quality programs and outcomes that support value-based care
  - Selective recruitment & penalties for poor effort / results
- What does financial integration look like?
  - Contracting with payor on capitated basis (partial / full capitation)
  - Use of percent-of-premium arrangement with payor
  - Global budget / total cost of care
  - Other forms of financial risk sharing

Key Legal Issues: Stark Law & Anti-Kickback Statute

- Prohibits physicians from referring patients for designated health services paid by Medicare to entities with which physicians / family members have a financial relationship, unless exception can be met
- Financial relationships include direct and indirect ownership and compensation arrangements



Meaningful Downside / Substantial Financial Risk Exception & Safe Harbor

- General Requirements:
  - Protects monetary / nonmonetary remuneration
  - Does not protect ownership/investment interests
  - Must be in writing
    - AKS: Need all “material terms”, including how recipients meaningfully share in risk, evidencing substantial downside risk, VBAs, TPP and type of remuneration.
    - Stark: Description of nature and extent of physician's downside risk must be in writing
  - No inducement to reduce or limit medically necessary services
  - Permits conditioning referrals (requirement must be in writing and respect patient / payor preference)
  - Remuneration does not take into account volume/value of referrals or condition remuneration on referrals outside of TPP or business not covered by VBA (AKS)
  - Remuneration not conditioned on referrals of patients not part of TPP or business not covered under VBA (Stark)
  - Must be at meaningful risk for entire duration of VB Arrangement
  - Records must be maintained for at least 6 years

Meaningful / Substantial Financial Risk

Key Distinctions	
AKS	**Stark**
VBE must be at <u>substantial downside financial risk</u> from the payor. 3 ways to do this: • Shared savings w/repayment obligation (at least 30% of shared losses) • Clinical episode of care w/ repayment obligation (at least 20% of total losses) • Partial capitation payment (prospective, per-patient payment designed to produce material savings)	**No requirement for VBE to be at risk**
VBE participant must <u>meaningfully share</u> in downside financial risk. 2 ways to do this: • Assumes 2-sided risk for at least 5% of total VBE risk pursuant to VBE's assumption of substantial downside risk; • Receives prospective, per-patient payment for predefined set of services / items furnished to TPP and does not bill payor for predefined items / services	**Physician is at <u>meaningful downside financial risk</u> if VB purpose not met.** To qualify, physician must be: • Responsible to pay entity <u>no less than 10%</u> of value of remuneration received under VBA. • Means physician must repay or forgo no less than 10% of remuneration under VB Arrangement

Meaningful / Substantial Financial Risk

- AKS
  - VBE has assumed (or is contractually obligation to assume within 6 months) substantial downside risk from payor for at least one year
  - Remuneration is:
    - Used “predominantly” to engage in VB Activities that are directly connected to services / items for which VBE has assumed substantial downside financial risk, unless exchanged in manner that meets all other safe harbor conditions
    - Directly connected to at least 1 of 3 VBE's purpose for TPP (care coordination and management of care, improving quality or reducing costs to, growth in expenditures of payors without harming quality)
  - Remuneration cannot be exchanged or used for marketing services furnished by VBE or VBE Participants to patients or for patient recruitment activities

- Stark
  - Remuneration is for and results from value-based activities by recipient for patients in target population
  - Methodology to determine remuneration must be "set in advance" (Stark definition)
  - Focus is on “physician” having risk (not the entity having risk)
  - No phase-in period permitted

Conclusion

- Shift to value-based programs likely to continue (35.8 % of US health care payments now tied to risk-based payments linked to quality and / or population-based payments linked to quality:
  - 53.6% of Medicare Advantage
  - 40.9% of traditional Medicare
  - 30.1% of commercial payors
  - 23.3% of Medicaid
- Four years ago, approximately 25% of health care reimbursement linked to risk / population and quality
- One goal of ACA was to bend the cost curve, but clearly more work to be done:
  - CMS: health care spend as $ of GDP to increase from 17.7% (2018) to 19.7% (2025)
  - Medicare expected to experience fastest spending growth of all payors (7.6% per year over 2019—2028)
- Increased pressure on providers to find innovative ways to collaborate

Thank you!

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