Convene.
Strategize.
Activate.

TRANSFORMATION
TODAY & TOMORROW

Legal Updates 2019

Forging a Path Forward in a Time of Change

CENTER *for* INTEGRATIVE HEALTH
insight to innovation

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Legal Updates 2019

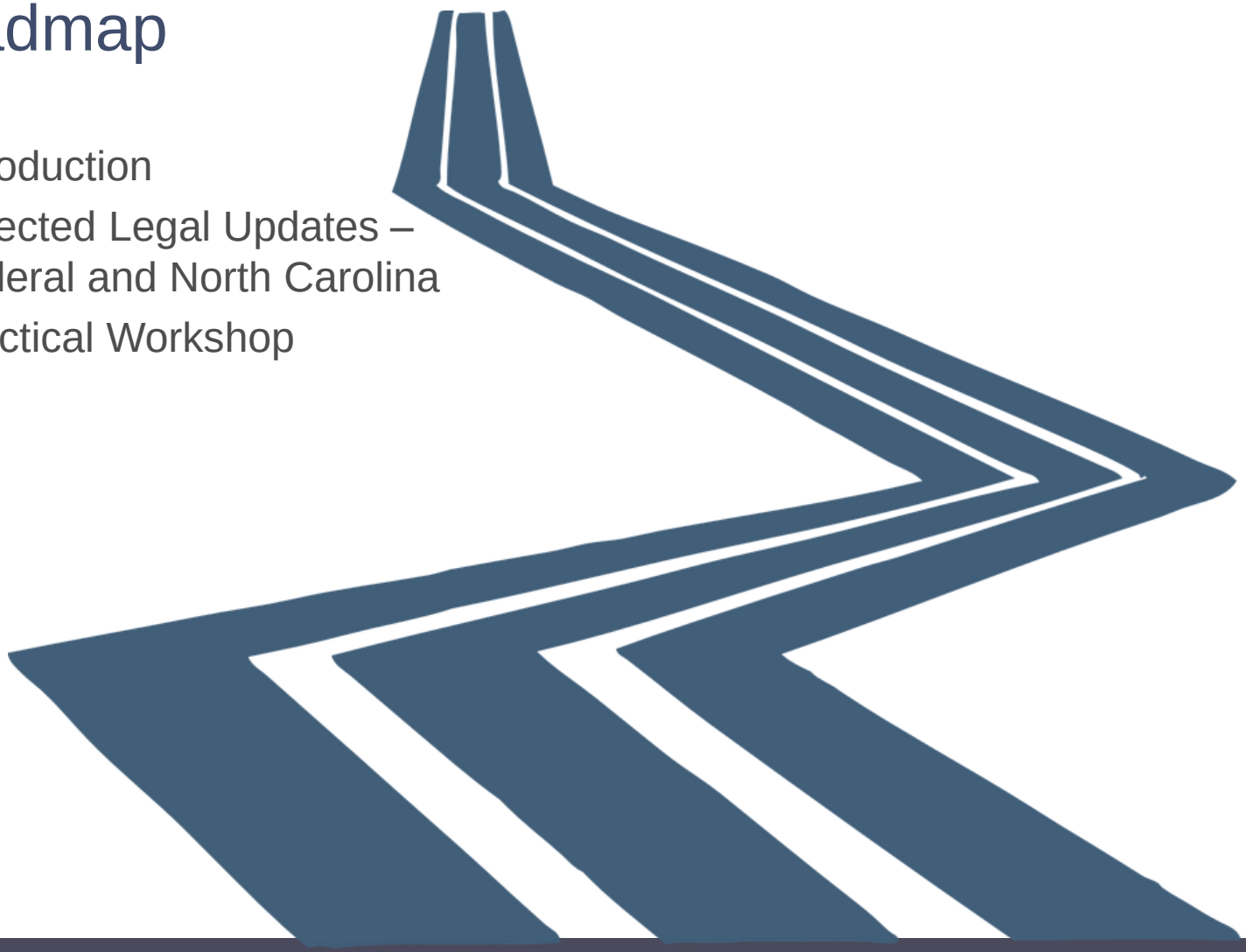
Forging a Path Forward in a Time of Change

December 4, 2019

Robinson Bradshaw

Roadmap

- Introduction
- Selected Legal Updates – Federal and North Carolina
- Practical Workshop



Healthcare Transformation

Navigating Change

NC Medicaid Transformation

They made North Carolina arguably the most innovative state in the country when it comes to improving how health care is delivered and addressing the underlying social and economic drivers, like homelessness, of poor health and high costs.

Cohen and Conway described themselves as rowing in the same direction, in a national health care environment that often seems to have far more oars in the water than it does boats. And given all the failures in spreading and scaling small local health care innovations, both of them were both thinking hard about what can be tested, adapted and exported outside of North Carolina to harness costs and improve quality in the $3.8 trillion U.S. health care system. Other states were watching. POLITICO

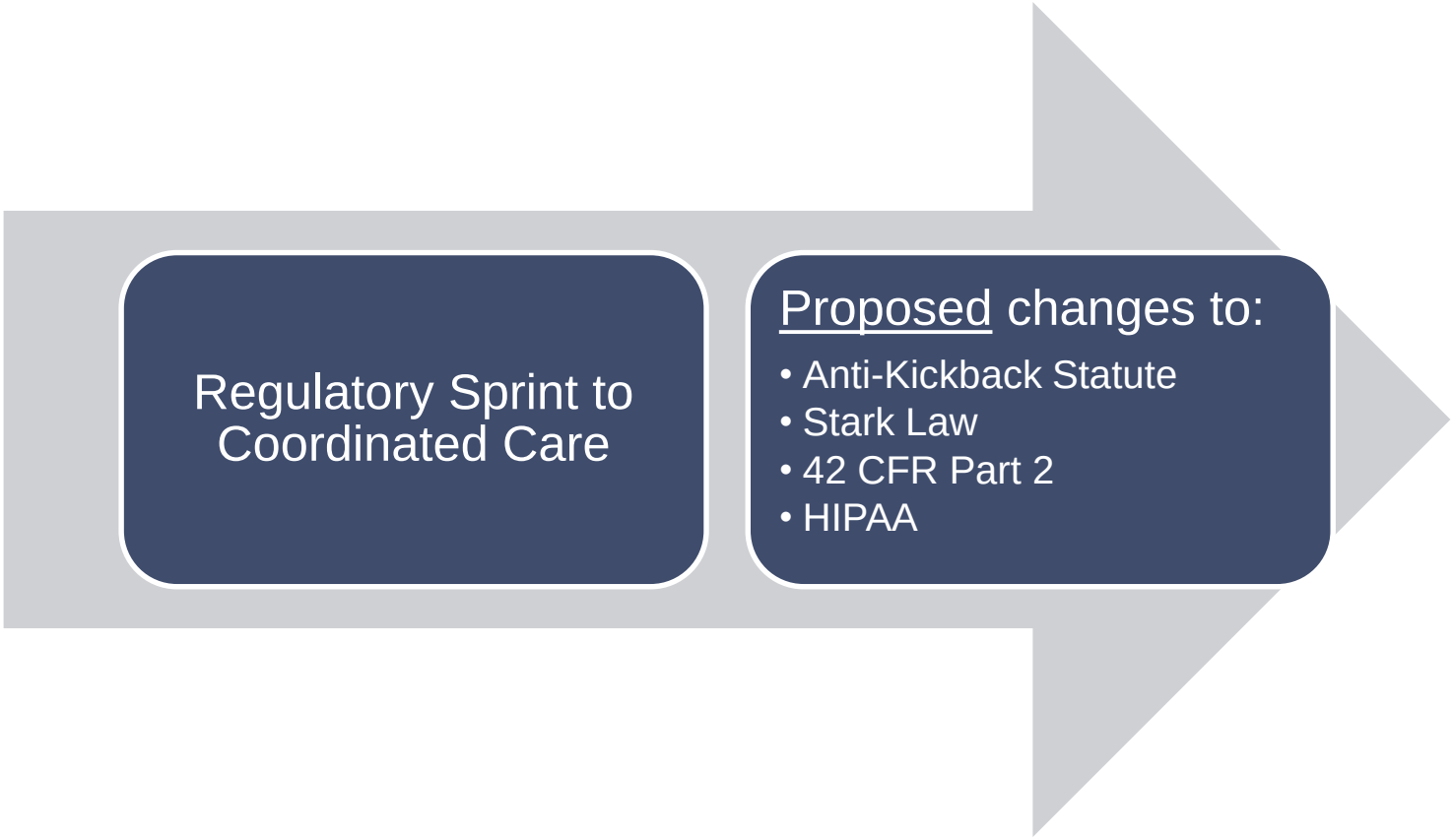
This year, Blue Cross announced that it had signed five of the largest health systems in the state to contracts linking payments to total costs of care for their patient populations and quality measurements, not to hospital stays or surgical procedures.

Duke University Health System is one of those big groups. "It's so clear that change is necessary," said Dr. Thomas Owens, president of Duke University Hospital in Durham. The New York Times

"The suspension of work and the wind-down process will begin tomorrow," the department said. "Once suspended, managed care cannot easily or quickly be restarted. The department will not decide on a new go-live date until it has program authority within a budget that protects the health and safety of North Carolinians and supports the department's ability to provide critical oversight and accountability of managed care." WRAL.com

Selected State and Federal Legal Updates

Federal Law Updates



AKS Prohibition

"Whoever knowingly and willfully ***offers*** or ***pays*** (or ***solicits*** or ***receives***) any ***remuneration*** (including any kickback, bribe or rebate) directly or indirectly, overtly or covertly, in cash or in kind to any person ***to induce*** such person … to ***purchase, lease, order or arrange for or recommend purchasing, leasing, or ordering*** any good, facility, service or item ***for which payment may be made, in whole or in part, under a Federal healthcare program***, shall be guilty of a felony…, shall be fined not more than $25,000 or imprisoned for not more than five years, or both." 42 U.S.C. § 1320a-7b(b) (emphasis added).

Key Concepts

Anyone	• Any person, not limited to providers or hospitals
Knowingly and Willfully	• Intent to induce is required but • AKS is violated if just one purpose of remuneration is to induce illegal referral
Solicited/Received Offered/Paid	• Applies to both sides of a transaction
Remuneration	• Payment in cash or in kind, direct or indirect, overt or covert
Induce Business	• Includes referrals for any service or item

Stark Law – The Basic Rule

- Prohibits **physicians** from **referring** patients to an **entity** for the furnishing of certain **designated health services** (DHS) that are otherwise reimbursable by Medicare, if the physician or an immediate family member has a **financial relationship** with that entity, unless an **exception** applies

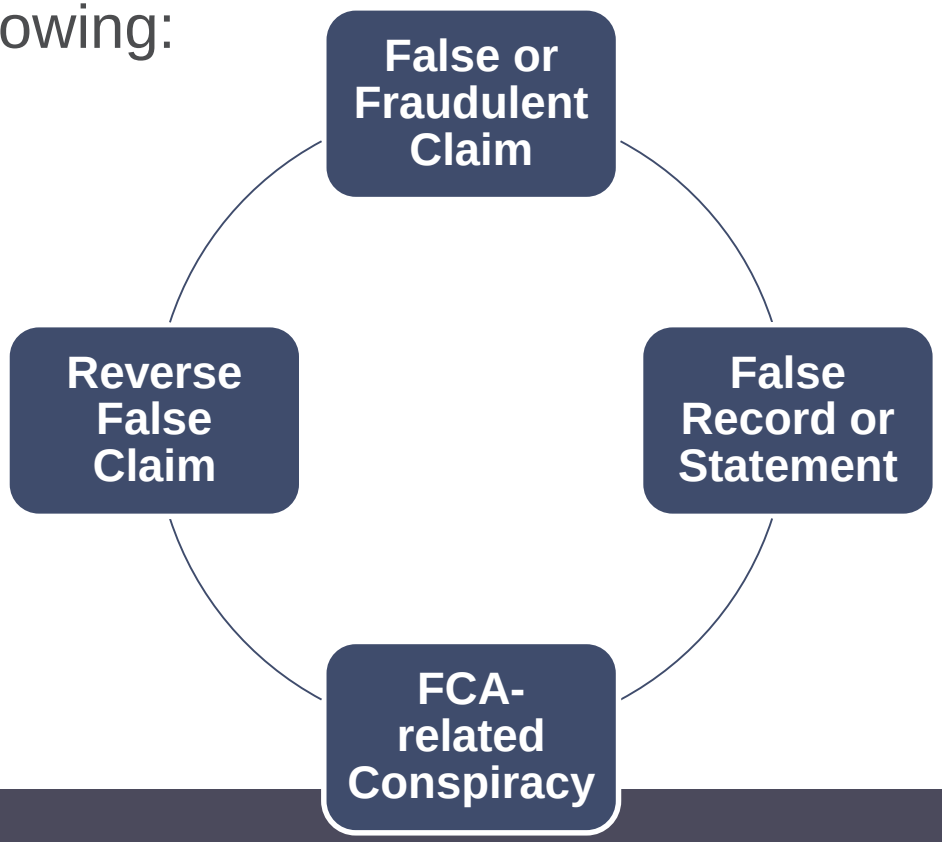
- Prohibits entities that provide DHS reimbursable by Medicare from billing the Medicare program for any items or services that result from a prohibited referral

False Claims Act (FCA)

The FCA imposes liability on a person who *knowingly* submits or engages in any of the following:

"Knowingly"

= actual knowledge or acting in deliberate or reckless disregard of truth or falsity of information



Proposed Updates – Anti-Kickback Statute and Stark Law

- Value-Based Care Exceptions/Safe Harbors
- Donations of EHR and Cybersecurity Technologies
- Exceptions for certain patient engagement and support tools

42 CFR Part 2 – Overview

Proposed rules would ease restrictions in some circumstances:

- Between Part 2 Provider and Non-Part 2 Providers
- No individual named for disclosures for benefit purposes
- Central Registries
- Prescription Drug Monitoring Programs
- Employee Devices

42 CFR Part 2 – Central Registries and PDMP

Central Registries

- Current – Only disclose SUD records to another Part 2 program
- Proposed – Expand to allow non-Part 2 providers with existing treatment relationship to query registry
- Purpose – Prevent over-prescription of opioids and avoid fatal drug interactions

Prescription Drug Monitoring Programs

- Current – Part 2 programs not permitted to disclose unless exception applies
- Proposed – Permit disclosure with patient consent
- Purpose – Avoid adverse events like overdue or fatal drug interaction

HIPAA

- Stay Tuned….

Questions

Enrollee & Provider Appeals

Following the Medicaid Transformation

Overview

- Appeals Following the Medicaid Transformation
- Appeals at Crossover
- Overview of Appeals Process
- Enrollee Appeals
- Provider Appeals
- Examples

Material Differences Following Medicaid Transformation

New Types of Appeals

- Adverse Benefit Determinations
- Adverse Disenrollment Determinations

Expedited Appeals

- When an Expedited Appeal is Presumed
- Time to Resolve Expedited Appeals

Deadlines

- Filing Appeals
- Resolving Appeals

Appeals at Crossover to Managed Care

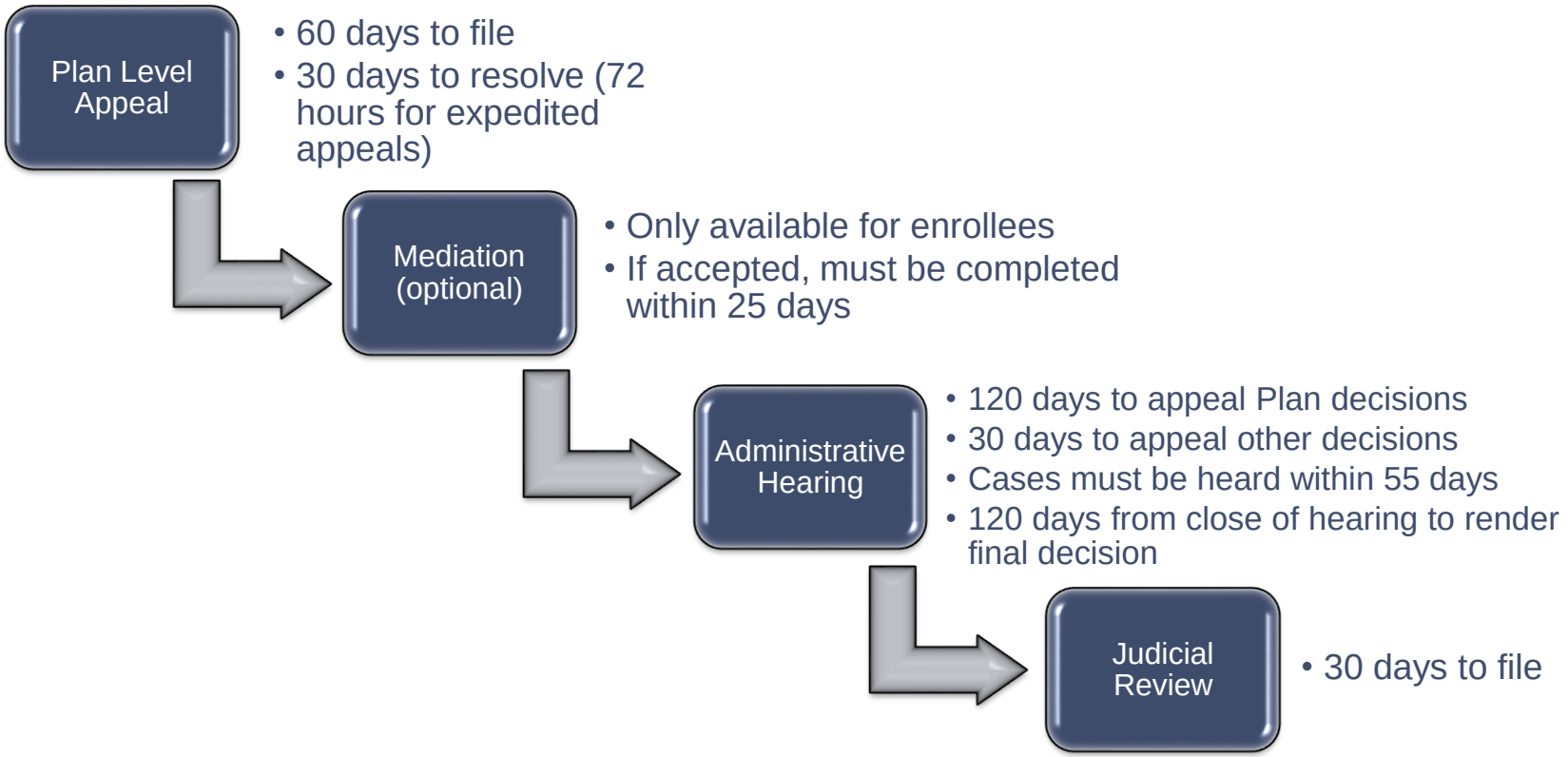
Prior to Enrollment in Plan:

- Service Denials prior to enrollment must submit new request to new Plan.
- For services provided prior to enrollment, follow old appeals process.

After Enrollment in Plan:

- Plans must honor continuation of enrollee's FFS authorizations for first 90 days.
- If the authorization extends beyond 90 days, and the Plan terminates or reduces the service, enrollees are entitled to an appeal.
- Claims for dates of service following launch should be submitted in accordance with the new appeals procedure.

Overview of Appeals Process



Plan-Level Grievances and Appeals

- Each Plan is required to develop a grievances and appeals process to be approved by DHHS
- The process must comply with federal law and Due Process requirements
- All grievances and appeals must be resolved at lowest level of escalation
- DHHS will (eventually) provide Ombudsman services to assist enrollees and providers

Grievances


Non-Appealable Complaints
Available for Enrollees and Providers
Must be Resolved in Timely Manner
Monitored by DHHS

Enrollee Appeals – Appealable Decisions

Adverse Benefit Determinations

Plan-Level Appeal

- Denial of service or reduction of previously authorized service
- Denial of payment
- Failure to provide services in a timely manner
- Failure to resolve grievances and appeals
- Denial of rural enrollee's rights
- Denial of request to dispute financial liability

Adverse Disenrollment Determinations

Administrative Hearing

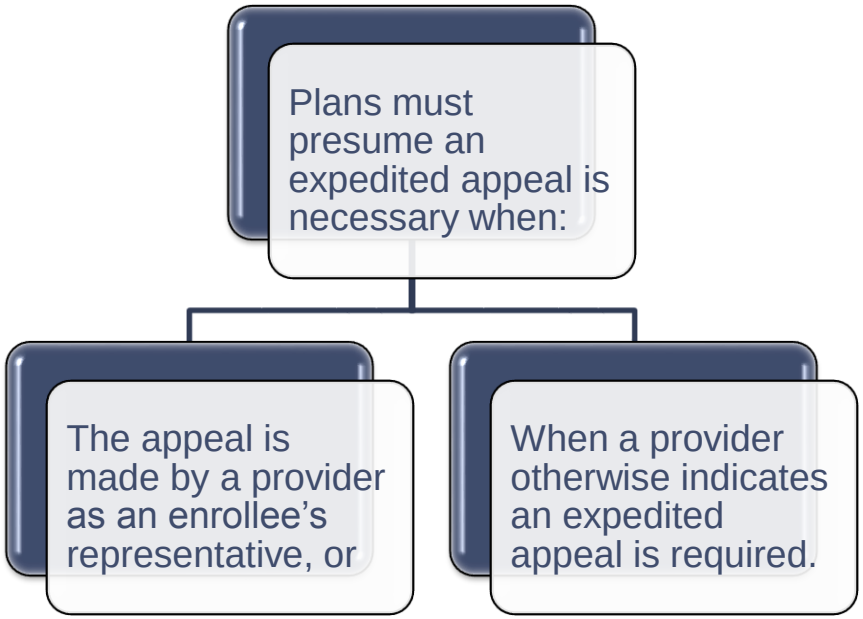
- Denial of enrollee requests to disenroll from a Standard or Tailored Plan
- Approval of a request by a Standard or Tailored Plan to disenroll an enrollee

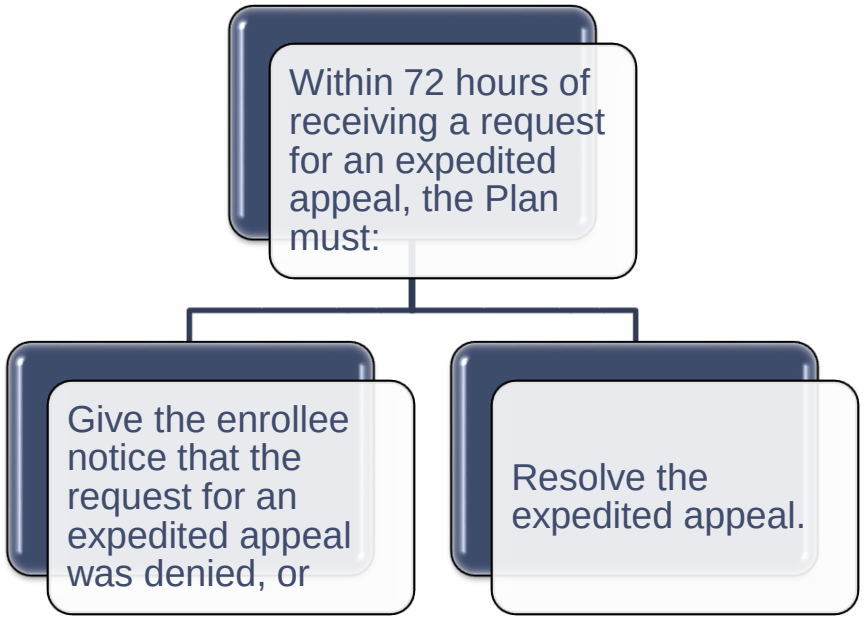
Other Adverse Determinations

Administrative Hearing

- Any decision by DHHS to deny, terminate, suspend or reduce a Medicaid service or authorization through the FFS program

Expedited Appeals





Continuation of Enrollee Benefits Pending Appeals

Adverse Benefit Determinations by Plan:

- The Plan must continue to provide the service at issue pending appeal if all of the following are met:
  - Request filed by enrollee before the later of 10 days of receiving notice or the effective date of the adverse decision;
  - The service at issue was previously authorized;
  - The services were ordered by an authorized provider;
  - The period covered by the original authorization has not expired; and
  - The enrollee timely files for continuation of benefits.

Other Adverse Determinations by DHHS:

- DHHS must reinstate services to the level or manner prior in place to the action giving rise to the appeal.

Note:

- If the enrollee loses the appeal, DHHS or the Plan (as applicable) may recoup the cost of any services furnished during the appeal process.

Provider Appeals

Types of Appeals

- Plan Decisions:
  - A Plan's decision not to include a provider in its network
  - Program integrity-related findings or activities
  - Findings of fraud, waste or abuse
  - Findings or recovery of overpayments
- DHHS Decisions:
  - Denial or reduction of payments under FFS
  - Denial or suspension of participation in Medicaid FFS

Process

- Plan decisions must be appealed at the Plan level first
- DHHS decisions are subject to appeal through administrative hearings
- The procedure for provider appeals is the same as for enrollee appeals, with some minor differences

Example 1

- John Doe received a prior authorization for services under Medicaid FFS prior to being enrolled in a Standard Plan. After 90 days, the Plan terminated his prior authorization.
  - Where should he file for an appeal?
  - How can he get an expedited appeal?
  - Will he be entitled to continuation of the service pending the appeal?

Example 2

- DHHS decided to disenroll Jane Doe from a Tailored Plan and enrolled her into a Standard Plan.
  - Where should she file an appeal?
  - What are her rights pending the appeal?

Example 3

- Plan recently informed Provider that Provider has been regularly overpaid for services, and Provider must return a significant overpayment amount to Plan. Provider disagrees and has decided to appeal the decision.
  - Where should Provider file for an appeal?
  - What can Provider do if its initial appeal is denied?

Questions

Practical Workshop Overview

- Subpoena troubleshooting
- Contracts 101
- Value-based contracting
- Health care transactions

STATE OF NORTH CAROLINA

Union County

File No. 19-CVD-1000

In The General Court Of Justice
☒ District ☐ Superior Court Division

JANE JONES

Additional File Numbers

VERSUS

JOHN JONES

SUBPOENA

G.S. 1A-1, Rule 45; 8-59, -61, -63; 15A-801, -802

Party Requesting Subpoena: ☒ State/Plaintiff ☐ Defendant

NOTE TO PARTIES NOT REPRESENTED BY COUNSEL: *Subpoenas may be produced at your request, but must be signed and issued by the office of the Clerk of Superior Court, or by a magistrate or judge.*

TO

Name And Address Of Person Subpoenaed:
REBECCA SMITH
GOOD BEHAVIORAL HEALTH
123 Main St.
Monroe, NC 28200

Alternate Address

Telephone No.: 704-300-3000

Telephone No.

YOU ARE COMMANDED TO: *(check all that apply)*

☒ appear and testify, in the above entitled action, before the court at the place, date and time indicated below.
☐ appear and testify, in the above entitled action, at a deposition at the place, date and time indicated below.
☒ produce and permit inspection and copying of the following items, at the place, date and time indicated below.
☐ See attached list. *(List here if space sufficient)*

All medical records and school records for Sally Jones (DOB 1/1/04) and Joe Jones (DOB 1/1/01).
Will it benefit the patient(s) for Rebecca to testify?
Are you authorized by the parent/guardian or the court to produce the records requested?
What is the minimum information needed for the court case?
Does the attorney really want Rebecca to testify? Can the attorney say when the witness will be called?
Would a summary suffice?
Does the subpoena give enough time to the witness/agency?
Was the subpoena properly served? [Beware of out-of-state subpoenas.]

Name And Location Of Court/Place Of Deposition/Place To Produce:
Union County Courthouse
100 Main St.
Monroe, NC 28200

Date To Appear/Produce, Until Released: December 9, 2019

Time To Appear/Produce, Until Released: 9:30 ☒ AM ☐ PM

Name And Address Of Applicant Or Applicant's Attorney:
D. Blaine Sanders
ROBINSON, BRADSHAW & HINSON, P.A.
101 North Tryon Street, Suite 1900
Charlotte, North Carolina 28246

Telephone No. Of Applicant Or Applicant's Attorney: **704-377-2536**

Date: December 4, 2019

Signature: /s/ D. Blaine Sanders

☐ Deputy CSC ☐ Assistant CSC ☐ Clerk Of Superior Court
☐ Magistrate ☒ Attorney/DA ☐ District Court Judge
☐ Superior Court Judge

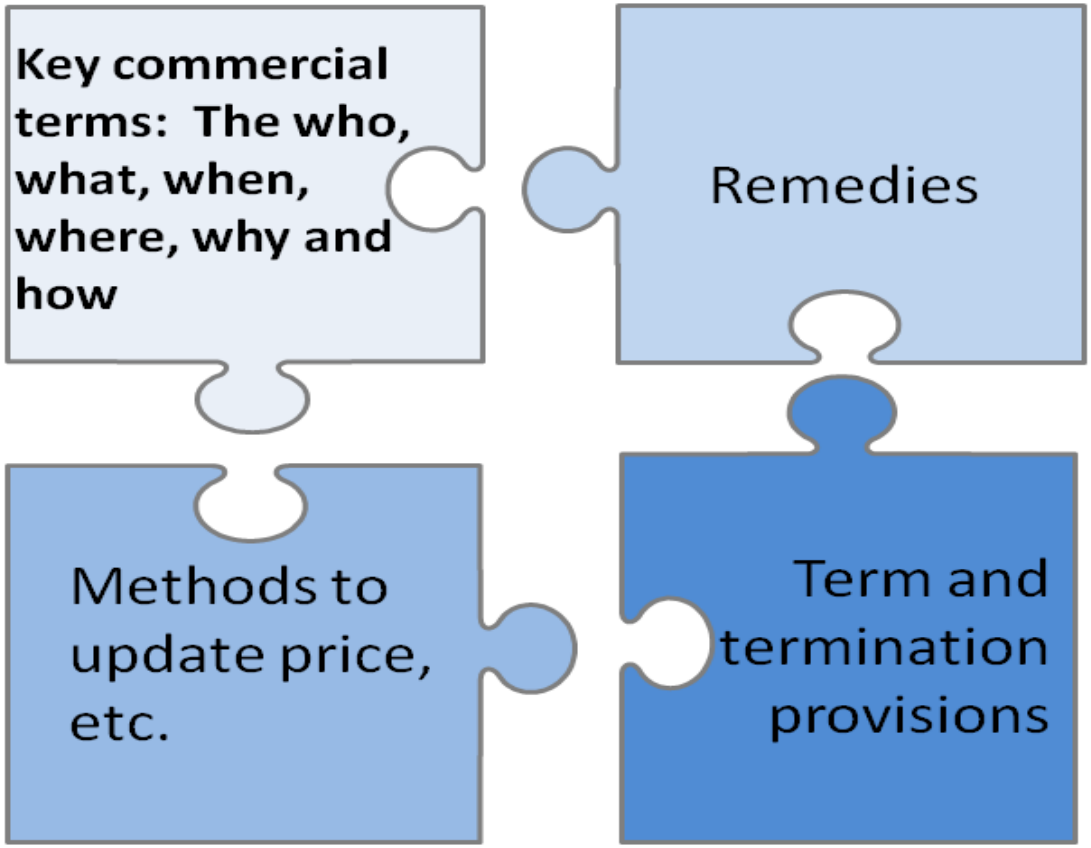
RETURN OF SERVICE

I certify this subpoena was received and served on the person subpoenaed as follows:

By ☐ personal delivery. ☒ registered or certified mail, receipt requested and attached.
☐ telephone communication by Sheriff *(use only for a witness subpoenaed to appear and testify).*
☐ telephone communication by local law enforcement agency *(use only for a witness subpoenaed to appear and testify in a criminal case).* **NOTE TO COURT:** *If the witness was served by telephone communication from a local law enforcement agency in a criminal case, the court may* ***not*** *issue a show cause order or order for arrest against the witness until the witness has been served personally with the written subpoena.*
☐ I was unable to serve this subpoena. Reason unable to serve: _____.

Service Fee $	☐ Paid ☐ Due	Date Served	Name Of Authorized Server (type or print)	Signature Of Authorized Server	Title/Agency

BRIEF CONTRACTUAL PRIMER: Is it all there?



Selected Tips and Tricks

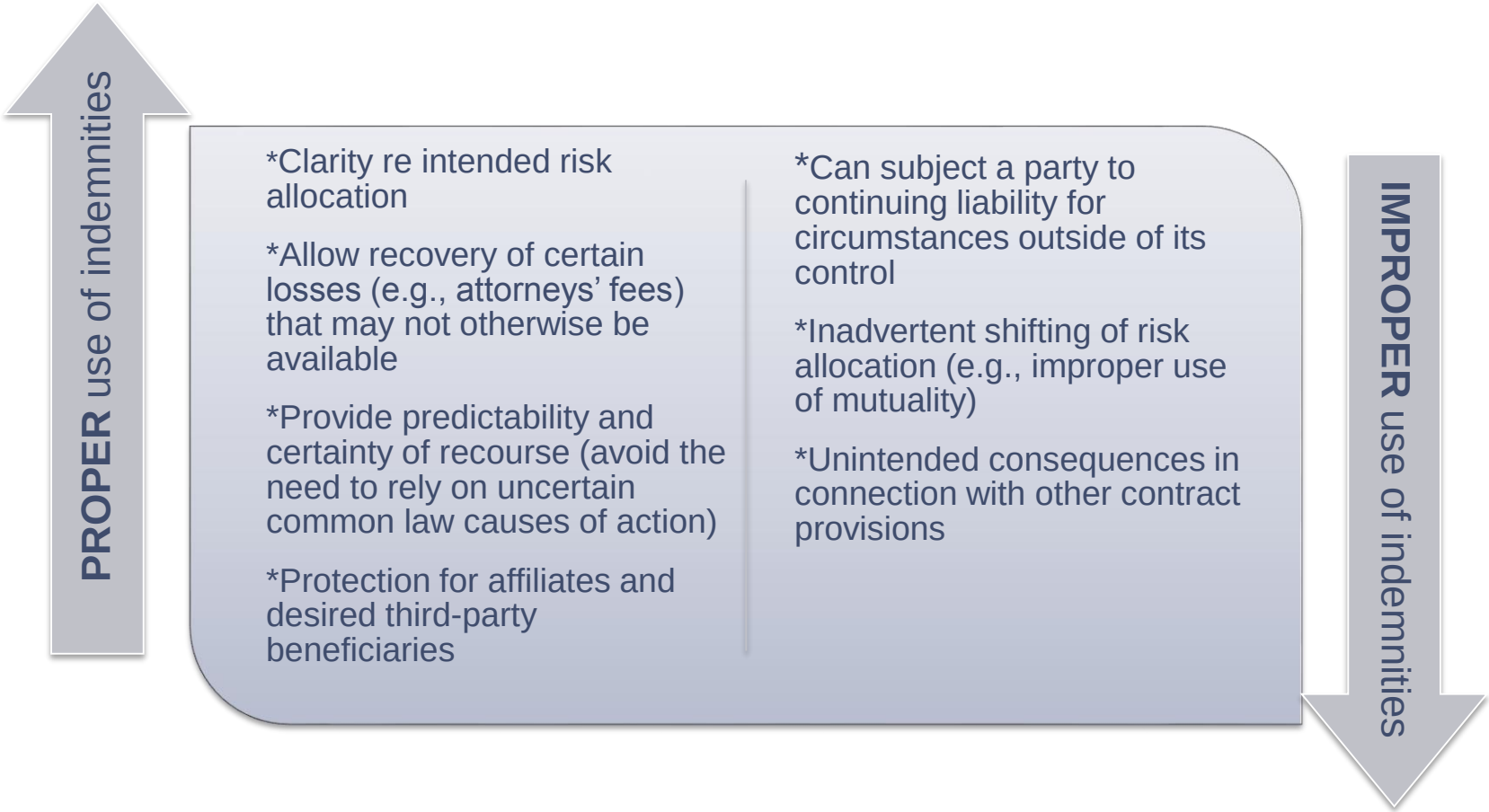
Plan for change

- “This Agreement shall have a term of 10 years.”
- “Insurer shall pay Provider $20 per CPT Code X.”

Flexible termination cures many ills

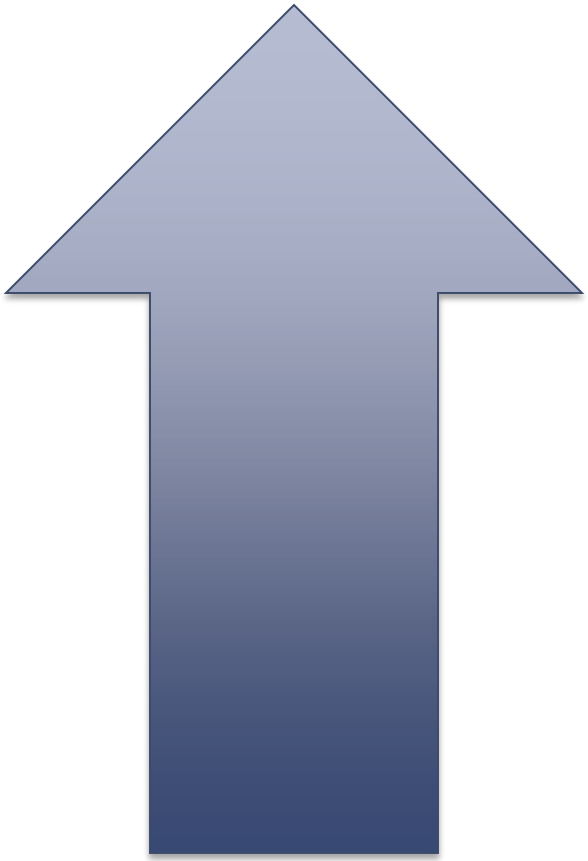
KEY PROVISION

Indemnification



Value-Based Care: On the Rise

- The past 10 years have marked a shift toward value-based care.
- Providers, payors and consumers are on board.



What is Value-Based Care?

Fee-for-service

- Traditional Model
- Reimbursement based on volume of services
- Incentivizes quantity

Value-based care

- New Model
- Reimbursement tied to quality of care
- Incentivizes quality

Types of Reimbursement

Pay-for-Coordination	Pay-for-Performance	Bundled/Episode of Care Payment
Shared Savings	Capitation	Global Budget

Shared Savings/Shared Risk

Compensation based on:

- Actual costs to agreed-upon benchmark
- Quality performance

Shared Savings/Shared Risk

Important factors:

- Compensation formula
- Quality benchmarks
- Member attribution
- Reconciliation timeline
- Dispute mechanism
- Data sharing

Bundled Payments

- Single episode-based payment
- Providers assume risk for any complications during episode of care

Bundled Payment

Important factors:

- Services Included (Excluded)
- Timing
- Amount of Payment
- Catastrophic Episodes

Capitation

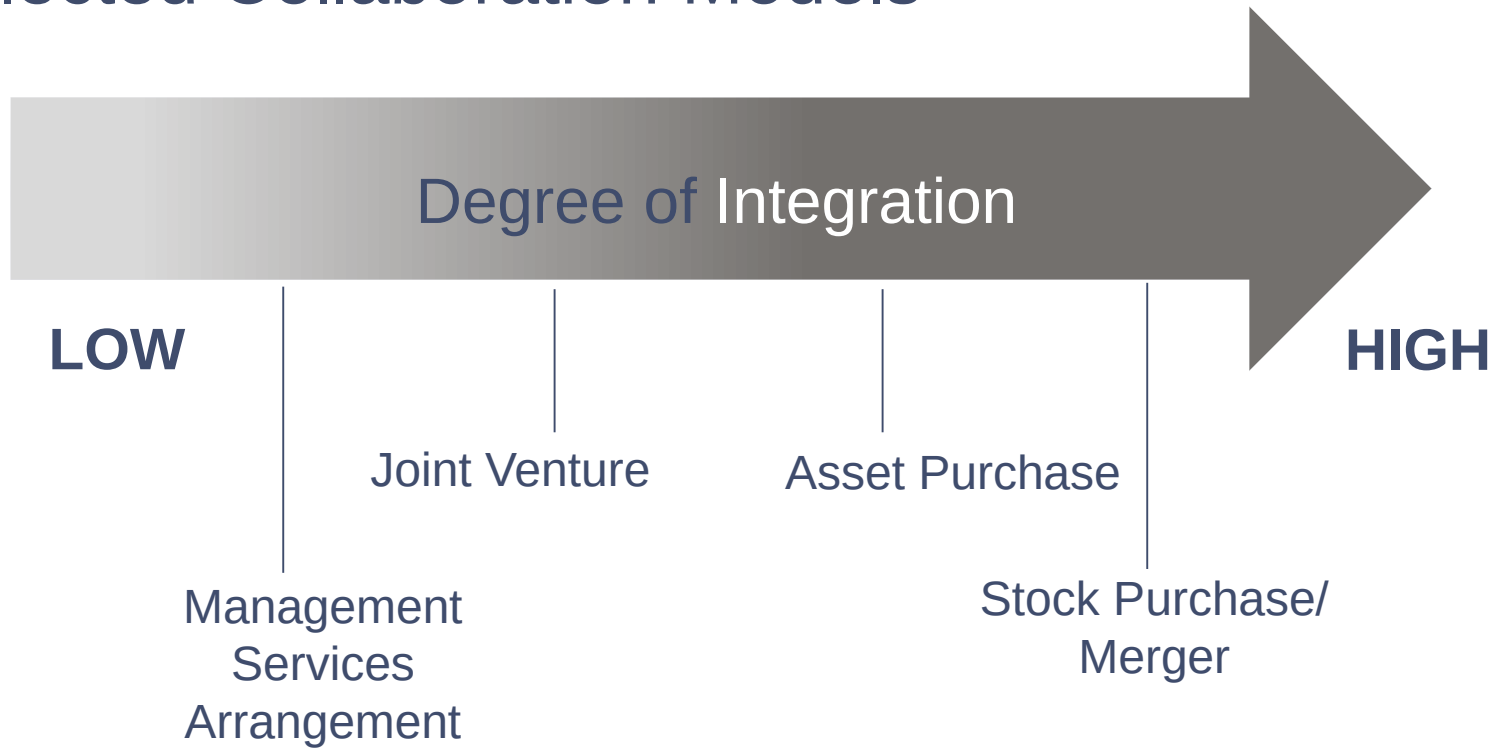
- FULL RISK!
- PMPM payment
- Responsible for all of certain area of care

Key Considerations for Any Value-Based Contract

Questions

Healthcare Collaborations

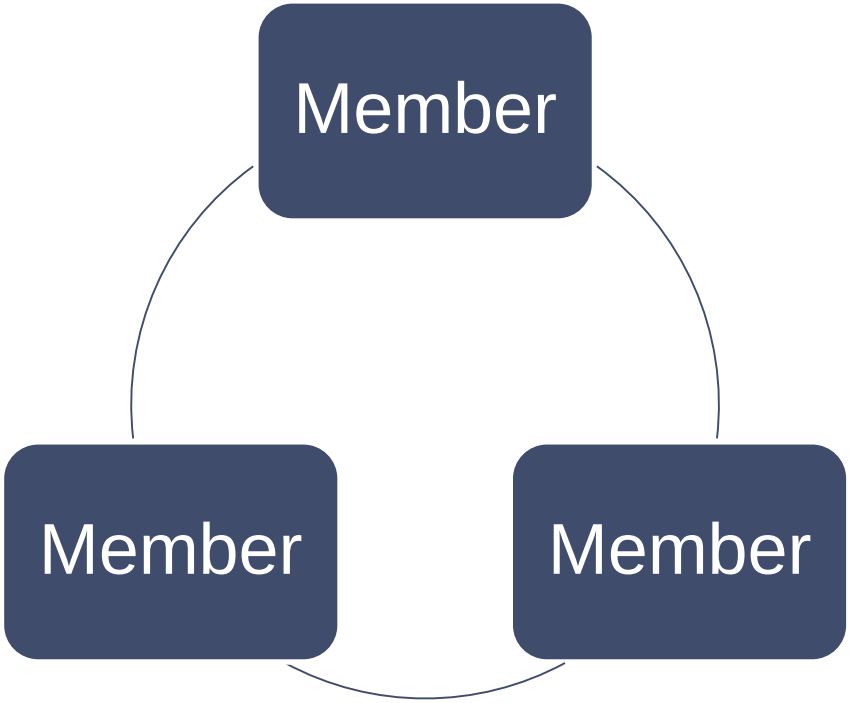
Selected Collaboration Models



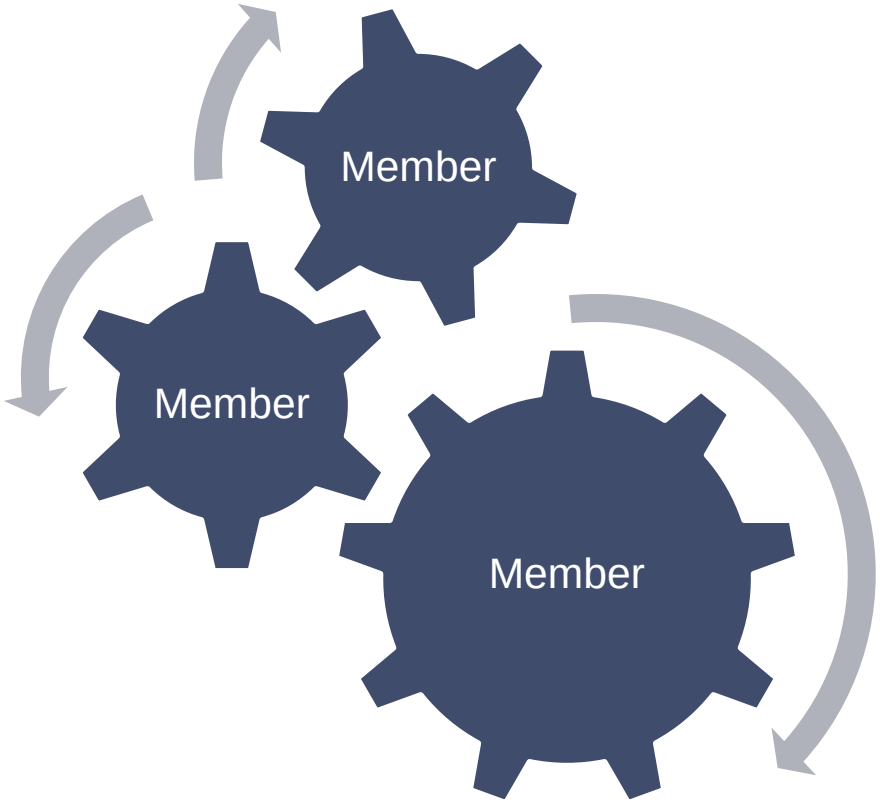
* Speaking in generalities (there are deal-specific nuances)

Accountable Care Organizations (ACOs)

- An ACO is a group of providers that assume responsibility to manage care for a defined group of patients.
- ACOs can have many different structures and participants.
  - There are specific structural requirements for participation in CMS programs.
- The most common types of reimbursement for ACOs are:
  - Shared Savings
  - Bundled Payments
  - Capitation



Clinically Integrated Networks (CINs)



- CINs are groups of individual healthcare providers that join together as a network to improve patient care by:
  - Enhancing communication between providers,
  - Adhering to standard quality procedures and
  - Adopting preventative health measures.
- Members of a network that have achieved clinical integration may collectively contract away from antitrust concerns.
- Clinical integration may be used as a stepping stone to create an ACO.

CAPSTONE

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