Community HealthCare Association of the Dakotas:

Legal and Operational Requirements of Clinically Integrated Networks

March 5, 2019

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… Who We Are

Starling Advisors works nationally with Health Centers, Networks, and PCAs to answer the question:

"What changes, if any, do we need to make to insure a role in providing high-quality, comprehensive primary care under value-based arrangements."

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Exploring a Clinically Integrated Network

Project Goals

Prioritize needs to achieve Clinica
requirements, operational comp

- Member survey results
- Key informant interviews
- Ongoing planning with CHAD leadership

Engage health plans in discussion around value-based reimbursement – validate business case

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Today's Discussion

- Today, we will discuss
  - The business of building a network
  - Establishing a shared infrastructure
  - The various legal issues to consider as networks are developed (We are NOT lawyers!)

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THE BUSINESS OF BUILDING A NETWORK

REMINDER! Core Guiding Principle

To remain competitive with non-Health Center based primary care, we believe most Health Centers will participate in Clinically Integrated Networks.

- Some of these networks will be hospital-centric.
- In other cases, these networks will be formed and managed by Health Centers.
- In many states, Health Centers have already begun forming and operating Clinically Integrated Networks.

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What is a Clinically Integrated Network

A ***Clinically Integrated Network*** is a group of independently owned and operated healthcare provider organizations that work together to improve patient outcomes, reduce total cost of care, and improve patient experience…

By integrating, the Network:

- May participate in joint contracting for value-based incentives or base-payments
- Receives protection from anti-trust claims at the Federal and State level

As a result, many groups of Health Centers see Clinically Integrated Networks as an ideal way to participate in Value-Based Payment models.

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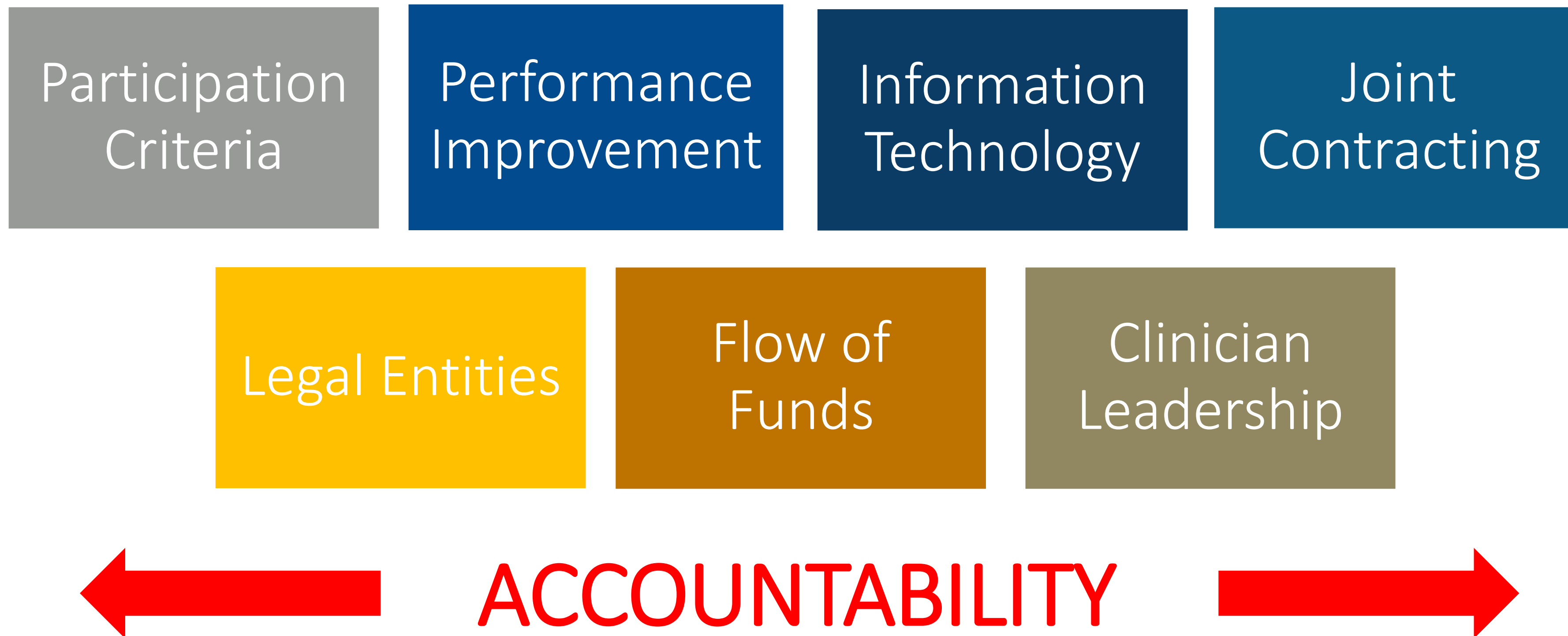
What does integration look like?



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Structure: Clinical Integration

- Clinical integration provides the workflows, relationships, and performance management necessary for accountable care and successful models of value based reimbursement
- Establishes the ***legal*** right to organize ***as a network*** with payers for reimbursement
- Results in shared clinical programs (i.e. UM, patient engagement, care planning, etc.)

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Challenges of Network Development

- Establishing and maintaining standards that are more encompassing than membership association standards.

Not everyone will make the journey

- Governance of these network entities must be representative and nimble.
- Creating participation agreements and financial arrangements can be difficult.
- Timelines at the federal and state levels are applying pressure and requiring responses that are faster that many of us are used to.

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Success Predictors

- Early role clarification
  - Establish the role of the first movers and other existing external organizations Provider practices have meaningful participation in strategy and development
- Aligning priorities and expectations
- Shared understanding of the network model construct and opportunities
- Identifying an effective governance model
- Availability of data
- All partners financially invest in the process
- On-going and committed member participation

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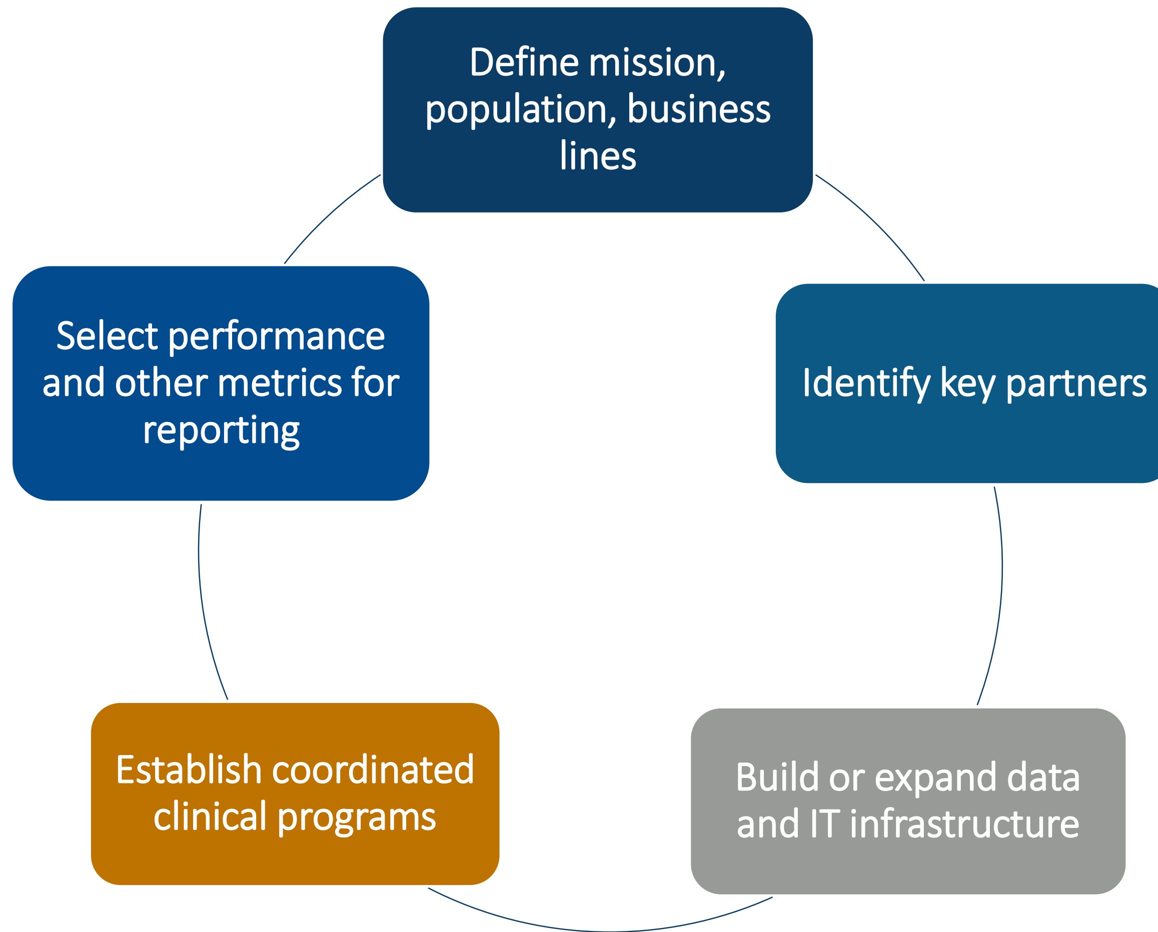
Aligning Your Commitment to Working Together



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Operationalize the Business Planning for a New Network

Analyze the potential impact of your new network

Build consensus and identify the best governance model

Prioritize business lines, geography, etc. for business planning

Establish a fund development strategy and secure financial resources that sustain the goals of the CIN

Engage legal and others for key filings and business operations

Formally operational workplan (governance structure, staffing, admin support, contracting, etc.)

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Identifying Key Partners

- What role will existing networks (i.e. the PCA, existing ACOs, or others) play in this new network?
- What capabilities will be housed within the new network?
- Do we need to contract for other services?
- Do we need additional capital?

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Selecting Key Performance Indicators

- Once we agree to go into the contracting market together:
  - Selecting areas of focus (based on the value equation) that we intend to work collectively to improve.
  - Determining how to measure our baseline and then improvement.
  - Agreeing to share this data.

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Build or Expand IT Infrastructure

- Do we have the data reporting capabilities that we need to:
  - Meet our integration requirements?
  - Effectively manage performance?
  - Evaluate performance of the participants?
  - Address the outcomes that are tied to our desired contracts?
  - Engage patients effectively?

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Establishing Clinical Programs

- Can we reach agreement on key areas of clinical focus:
  - Common approaches to care management.
  - Commitments to implement shared evidence-based standards.
  - Staffing of key functions, such as care coordinators or navigators.

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Contracting and Contract Management

- Lastly, do we have the capabilities we need to:
  - Enter into negotiations on behalf of all of the participants.
  - Evaluate contract offers and determine the financial impact.
  - Advise the participants on any gaps in performance that will need to be closed.
  - Create ongoing processes to support achievement of contract financial triggers.

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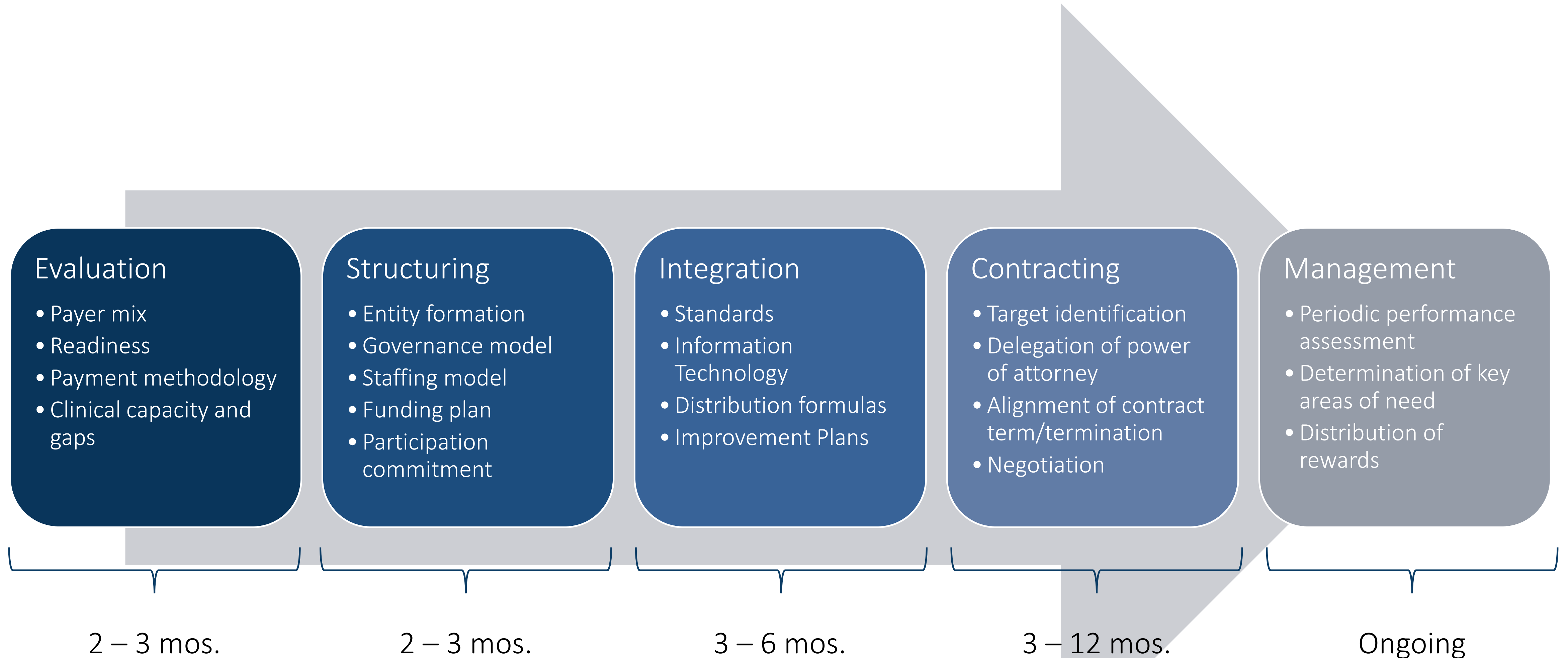
Contracting Network Formation: The Process



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Evaluation

We have found that successful CINs require meaningful input from their potential participants:

- Deeper understanding of high level payer mix data.
- Participation in a survey/data gathering on readiness.
- Identification of practice-level clinical and contracting capacity, needs, and willingness.
- Discussion of appropriate “risk and reward” to seek in payer contracting.

The findings during the evaluation phase inform the type of service lines, infrastructure, priorities, and capacity the network will require.

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Structuring

The process of initiating a new network includes the following:

1. Forming a new entity, if necessary.
2. Developing a Board and Committee model, or expanding capacity of an existing network
3. Developing a clear pathway for clinician engagement, feedback, and oversight
4. Creating an Operating Agreement.
5. Determining staffing plan, outsourced needs, and operating plan and budget.
6. Develop funding plan (self/grant/foundation/private)
7. Request formal commitment of participation, and potentially a capital investment

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What to Expect After Formation

- A CIN requires time and input from its members.
- Expect periodic data requests to strengthen negotiations and clinical planning.
- Anticipate that contracting priorities will:
  - Influence your own strategic planning.
  - Prioritize internal QI resources.
- There may be a need to capitalize a network beyond the initial participation request.
- Opportunities to join the network after the initial participation opportunity are typically controlled by the participation standards and the Board.

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ESTABLISHING SHARED INFRASTRUCTURE

Shared Infrastructure

- An integrated network must show evidence that the members of the network are able to perform differently with the network than without.
- Creates cost and operational efficiencies across the network.
- May be accomplished by establishing infrastructure directly within the network or through an arrangement between the CIN and a vendor, third party administrator, or managed services organization (MSO)

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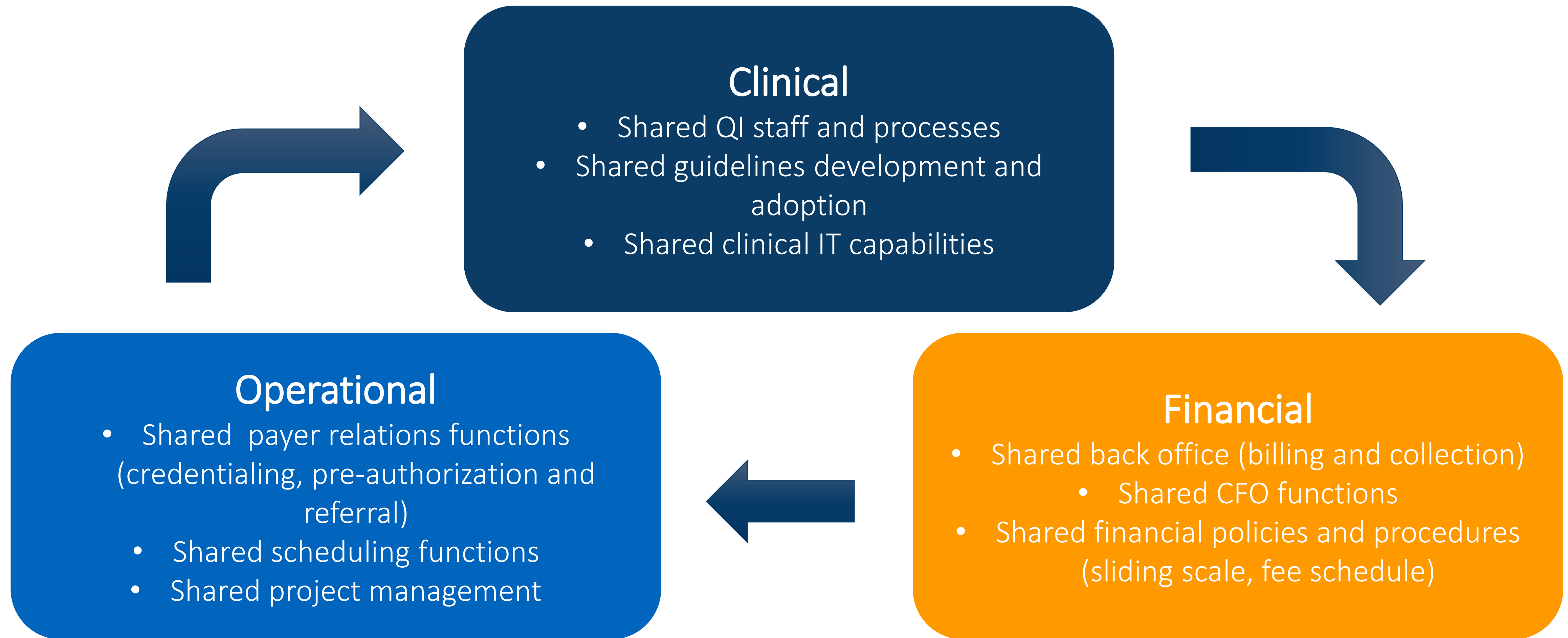
Shared Infrastructure
Examples



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Shared Infrastructure

Taking a cue from the Medicare Shared Savings Program (MSSP), integrated networks should include the following shared operations:

1. Ability to promote evidence based practice
2. Ability to support patient engagement
3. An infrastructure that supports performance management and reporting
4. A consistent plan for care coordination

Will also likely include:

1. Shared training and TA infrastructure

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Shared Infrastructure:
Budget Development

- Initial budgets should account for both start up and ongoing support
  - Legal counsel
  - Contract negotiation
  - Administrative support
  - Infrastructure investment (i.e. data, care coordination, etc.)
  - Shared clinical functions
- Funding the budget will likely include capital investments collected a intervals from members at various milestones of development
- Typically, payer revenue does not flow into a network during its first 12 months, therefore networks should leverage the following:
  - Grant funding leveraged through key partnerships
  - “Advanced payment” opportunities such as the Medicare ACO Investment Funding
  - Capital investments from participating partners

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Shared Infrastructure:
Budget Development (cont.)

- Budgets should include conservative estimates of revenue from gains from performance relative to payer contracts
- A portion of these gains should be retained to support ongoing operating expenses of the network
- Budgets should account for the distribution of gains back to members who meet the required performance measures
- Budgets will also likely include the repayment of investor contributions

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Shared Infrastructure:
Performance Improvement

- Common elements of a shared Performance Improvement shared infrastructure include:
  - Data Aggregation/Warehouses – Provides Network with ability to monitor performance and evaluate QI strategies
  - Shared QI staff and processes – Common resources to help all Participants improve
  - Care Coordination – Centralized or de-centralized capacity to outreach to non-compliant patients

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Shared Infrastructure:
Performance Improvement

- A network-level clinical program is often required
- Based up on the goals and existing clinical infrastructure of the network members, the range of clinical services may vary
  - Clinical outcome and care coordination measurement
  - Evidence-based guidelines
  - Shift towards population management
  - Targeted clinical interventions
  - Patient experience

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LEGAL CONSIDERATIONS FOR CLINICALLY INTEGRATED NETWORKS

Typical Legal Structure for CINs

- Because of the financial risk involved with payer contracting activities, it is usually advised to establish a separate legal entity
- Most health centers and PCAs who establish a CIN set it up as an LLC, either with single owner (i.e. PCA only) or as a joint venture with multiple owners (i.e. PCA and health centers)
- Separate for profit entities help protect nonprofit status of health centers and PCAs related to issues of "earned income" and create a firewall between the CIN and its owners for liability purposes.
- Most groups decide to keep the actual staffing and business operations of the CIN very lean, opting to contract out for staffing, admin, etc. These contracts can be structure as managed service agreements and may include "buying" services back from the PCAs or service contracts with health centers, third party administrators, vendors, or consultants. The decision to do this is not a legal one, rather a practical one.
- These new entities will require a separate governance (i.e. Board) structure with organizing documents including operating agreements (similar to a XX at nonprofits) and participation agreements that bind health centers to the various programs and contracts of the CIN. The Board plays an integral role in oversight and accountability (more on this later!).

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Legal Considerations for CINs: Antitrust

- Market Concentration and Integration
  - CINs must be able to demonstrate the appropriate level integration that demonstrates their collective clinical and financial integration benefits patients without creating a negative impact on the market or unlawful activities (i.e. group boycotting, anti-competitive impact, etc.)
  - Will require legal review and opinion

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Legal Considerations for CINs: Federal Fraud and Abuse

- Stark, Antikickback and Civil Monetary Penalties
  - The same rules will apply to the CIN that apply to health centers
  - The CIN cannot use any flow of funds to reward referrals or other preferential treatment

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Legal Considerations for CINs: Patient Privacy

- HIPAA, Privacy and Confidentiality
  - As the CIN will likely, at some point, gather and utilize patient level data, safeguards will need to be put in place to assure HIPAA and privacy compliance
  - Will be addressed both through technology and data safeguards as well as policies, procedures, and a formal compliance program

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Legal Considerations for CINs: State Requirements

- Any Applicable State Laws
  - Will require legal review and opinion

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Final Thoughts

- Establishing a CIN requires thoughtful planning and a clear vision of what you want to accomplish
- Setting up the functions of a new network takes time and resources
- Leveraging the infrastructure and expertise that you already have will go a long way in keeping the network lean, flexible, and cost-efficient
- Legal input along the way will be critical

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Questions?

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Next & Final Member Webinar

April 2, 2019 11AM Central:

Governance and Equity – understanding how your Health Center will participate in, and benefit from, Clinically Integrated Network activities.

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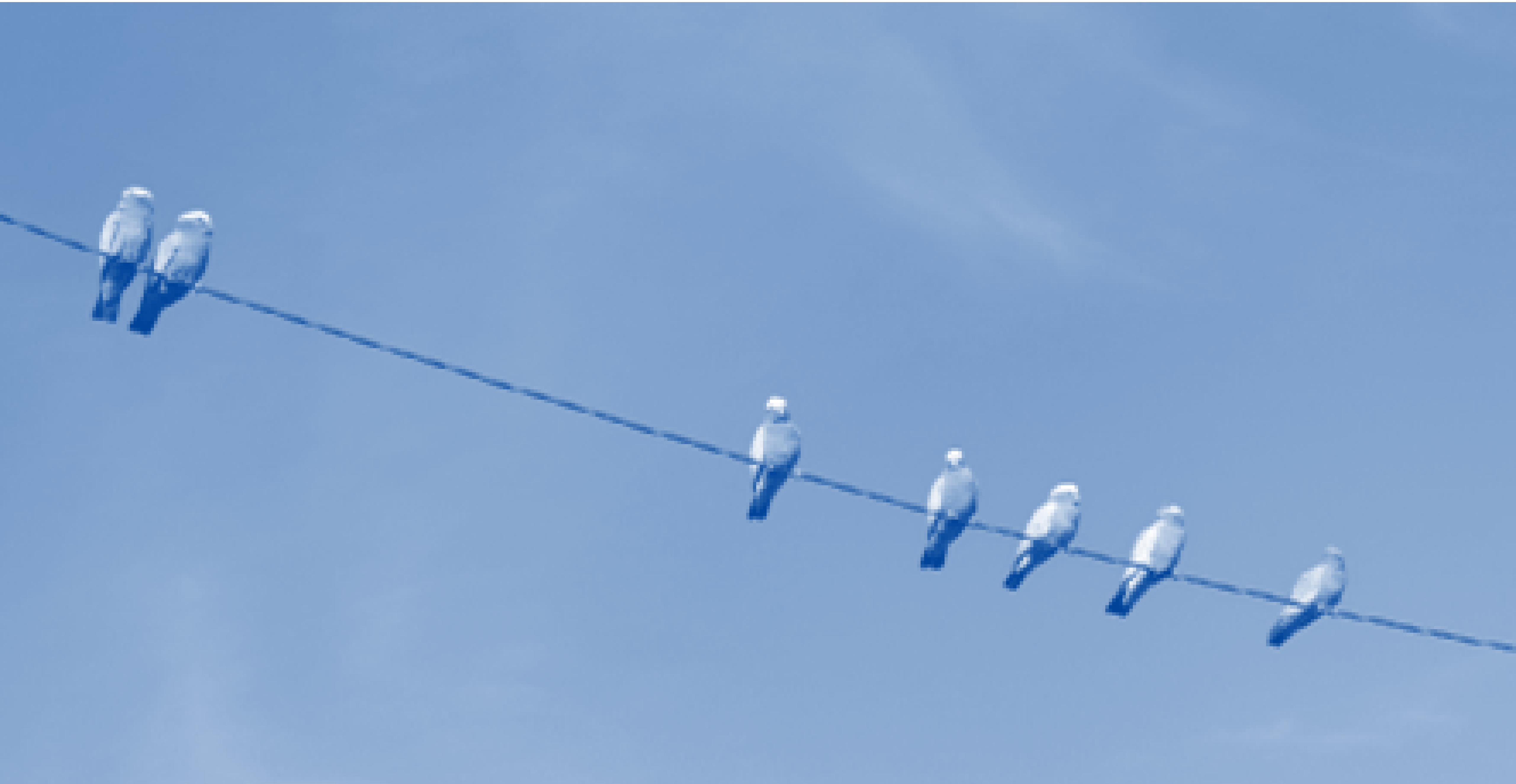

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