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ACOs, IPAs, CINs and PHOs: Legal Issues Behind the Acronyms

An Update on Formation and Antitrust Issues

January 9, 2019

Agenda

Some terminology

Entity formation issues

Antitrust issues

Managing antitrust risks

Confusing and Overlapping Terminology

- Independent practice association (IPA)
  - Sometimes called Individual Practice Association
  - Sometimes consist of physicians only; sometimes consist of physicians + hospitals and other providers
- Physician hospital organization (PHO)
  - Consist of both hospitals and physicians, and possibly other provider types
- Clinically integrated network (CIN)
  - Similar to the above
- Accountable care organization (ACO)
  - Popular in the context of the Medicare Part A/B program
  - But used elsewhere and otherwise similar to the above
- Healthcare collaborative (HCC)
- Sometimes the name is not indicative at all

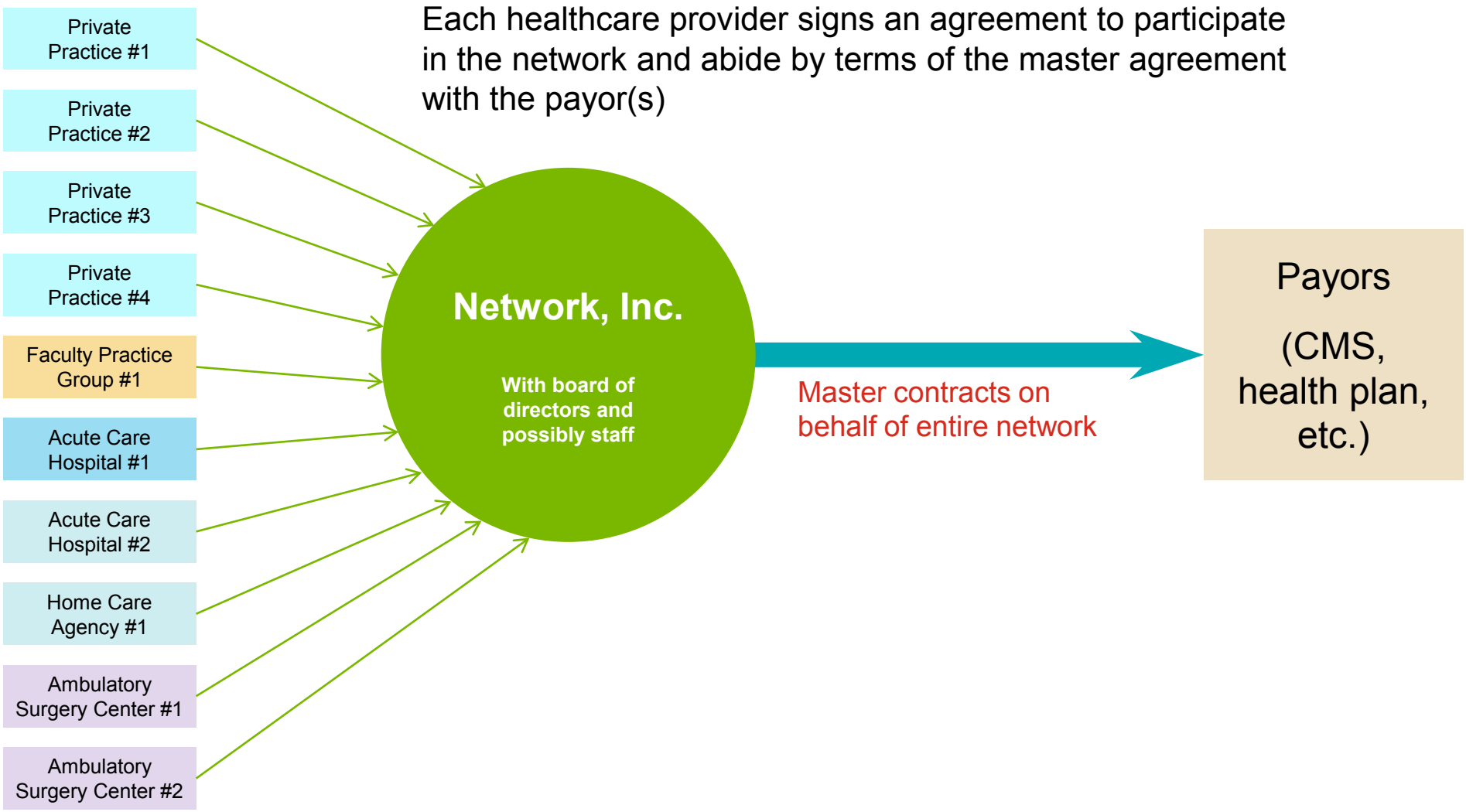
Basic Purpose of Entities

- Basic purpose of all of the above:
  - Create an entity that assembles a network of healthcare providers
  - Aim to enhance quality for benefit of patients
  - Network attempts to be more efficient and reduce healthcare costs
  - Network entity acts as “middleman” between payors and the healthcare providers

Other Terminology

- Do not confuse entity itself with description of new business terms
- Value-based payment (VBP)
  - A set of payment terms that move away from purely fee-for-service claims payment
  - Adds features related to quality metrics, shared savings, shared losses, capitation/population-based payments, etc.
- Accountable care organization (ACO) has another meaning
  - A group of providers who pursue the triple aim and are paid on a VBP basis (a description of one party to the new type of contract)
  - Thus “ACO” can also mean the nature of the contractual arrangement between providers and CMS, the state Medicaid agency or a health plan
    - Regardless of whether the provider entity entering into that contractual arrangement is legally formed as an IPA, ACO, CIN, PHO, HCC, etc.

The Basic Concept of an Intermediary Contracting Entity



3 Separate Concepts

1. Entity formation
2. Antitrust compliance
3. The operational and clinical steps necessary to build a successful, ongoing network entity
   - Includes tools for care coordination, network recruitment, quality measurement, quality improvement, data mining and analytics to identify problems in advance, improved clinical practices, patient engagement, etc.

Agenda

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Entity Formation Issues

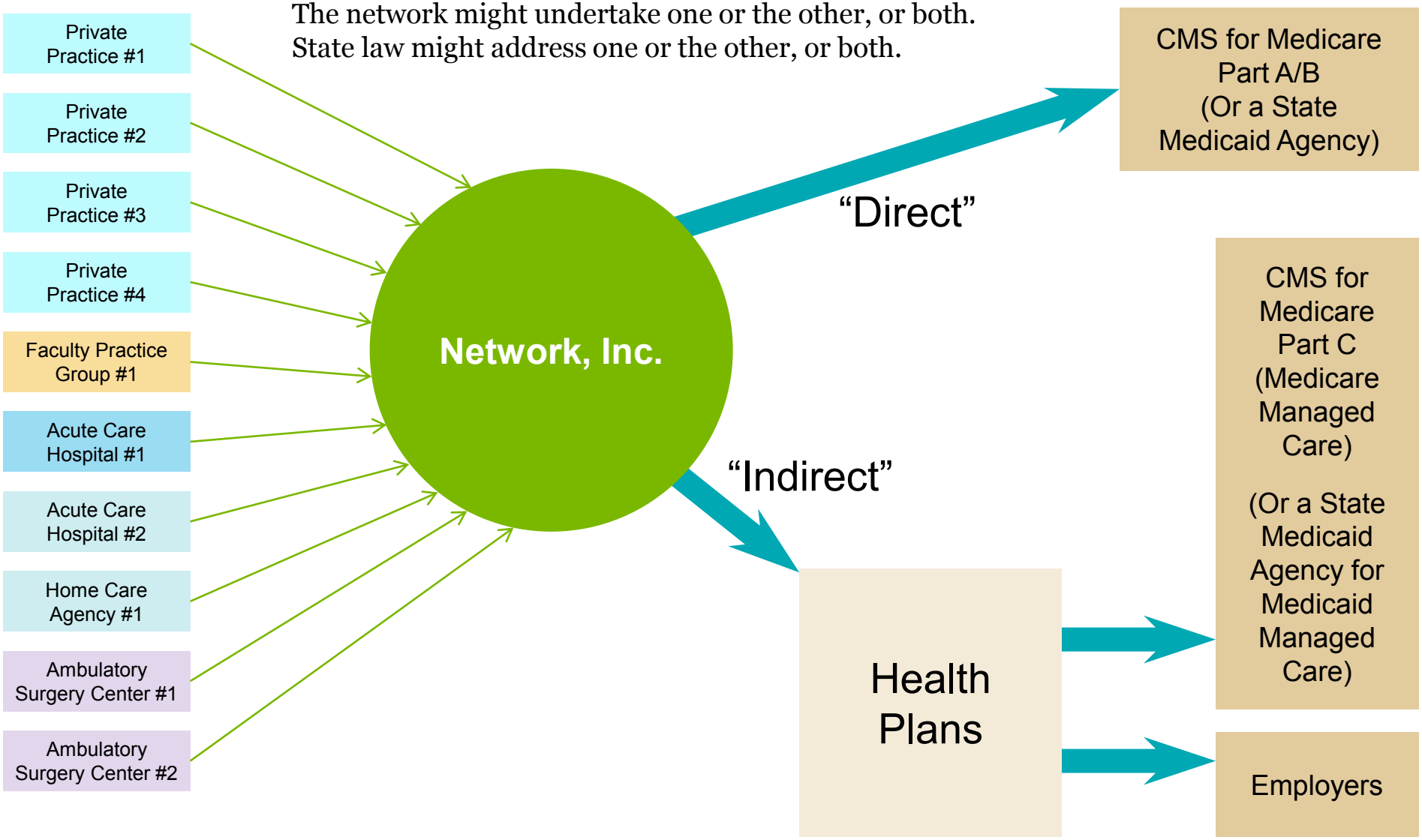
- Typically handled at the state level
- May be not-for-profit corporations, business corporations, limited liability companies, etc.
- Some states require regulatory review or approval
  - New York limits IPAs to contracting only with a defined class of payors (Art. 44 health plans), and state must prior approve formation documents
  - Some states review formation of ACOs if entity is formally called an “ACO” (NY for example)
  - Massachusetts requires risk-bearing provider organizations (RBPO) to apply for either risk certificates or waivers, and supply actuarial certifications
  - Other states have various references, such as Colorado, Utah, Maryland, Texas, Minnesota, New Jersey, etc.
- IRS typically will not grant tax-exempt status to network entities
  - If not-for-profit, often are taxable not-for-profits

State Law Considerations

- State laws vary in the ACO or network issues they address
- State laws could relate to
  - Entity formation
  - Relationship to the state Medicaid program
  - Level of financial risk that is permitted to be assumed
  - Other issues
- To more precisely evaluate state laws, it may help to distinguish between two different situations the state laws often address
  - "Direct" ACO or other network entity issues in contracts with CMS or the state Medicaid program
    - No health plan involved as middleman
  - "Indirect" ACO or other network entity issues in contracts with health plans
  - Whether "direct" or "indirect," the goals and operational methods of the ACO or network entity may well be the same, but the regulatory context might be very different

Direct ACOs and Indirect ACOs

Informal terms to distinguish two situations.
The network might undertake one or the other, or both.
State law might address one or the other, or both.



Agenda

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Antitrust Issues–Basics

- Key antitrust statute is Section 1 of the Sherman Act
  - Prohibits agreements that unreasonably restrain competition
- Some agreements ***per se*** illegal
  - Don't need to demonstrate actual anticompetitive impact
  - Agreements between competitors to fix prices, allocate service or product markets, allocate customers, allocate geographic territories, boycott particular customers or suppliers
- All other agreements considered under **rule of reason**
  - Need to analyze actual competitive impact of agreement and take into consideration procompetitive efficiencies

Antitrust Issues–Provider Collaborations

- All provider collaborations are in effect agreements between independent parties that are subject to Section 1
  - The "agreement" is the participating provider agreement itself
  - Collaborations between competing or potentially competing providers are potentially subject to *per se* liability
- Principal antitrust concern is "price-fixing"
  - Provider networks typically want to engage in collective price negotiations with payors and enter into agreements covering services of entire group
    - Join together to collectively negotiate fee schedules, or other compensation from payors
    - Join together to collectively negotiate medical necessity and other clauses in a payor contract that significantly impact compensation from payors
  - If the agreement to jointly negotiate is between competing providers without more, this could be a *per se* illegal price-fixing agreement

Antitrust Issues–Other Potential Concerns

- Market allocation
- Tying agreements
- Imposition of anti-steering or anti-tiering requirements
- Group boycotts
- Exclusivity
- Exchange of competitively sensitive information
- “Spillover” effects

Antitrust Issues–Competitors

- Which participating providers in the network compete with which other participating providers in the network?
- Do the providers compete in the same market?
  - Are the providers substitutes from a patient/payor perspective?
  - Define the healthcare services to be offered and the geographic markets where those services are offered
- Not all providers compete
  - Different services
    - Orthopedists do not compete with obstetricians
  - Different regions
    - Primary care physicians in one region do not compete with primary care physicians 150 miles away

Antitrust Issues–Competitors

- Competition is not always obvious:
  - There may be overlaps with other specialty classifications
    - Example: PCPs may provide many of the same services as a cardiologist
  - Multispecialty practices and federally qualified health centers may cloud the picture because they often contain a wide variety of providers and specialists
  - Use of telemedicine may create competition despite the fact the other providers are at a distant location
  - The fact that certain providers are friendly to each other, and may even refer patients to each other, does not mean they do not (in theory) compete with each other
  - Hospitals may be part of physician competition if the hospital employs primary care physicians or specialists who compete with private practice physicians in the surrounding community
  - Competition may exist between all types of providers–not just physicians
    - Hospitals compete with other hospitals, or with ambulatory surgery centers that deliver some of the same institutional services

Agenda

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Entity formation issues

Antitrust issues

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Managing Antitrust Risks

- Options:
  - Integration
  - Single entity
  - Messenger model

Managing Antitrust Risks–Integration

- All programs aimed to achieve efficiencies–cost savings, quality improvements, etc.
- Types:
  - Financial integration
  - Clinical integration
  - Hybrid models
- Will avoid "per se price-fixing" concern where joint contracting is ancillary and necessary to the efficiency goals of integration
  - Not the primary purpose
- Significant agency guidance on when integration permits joint contracting
  - 1996 Healthcare Statements
  - 2011 Medicare Shared Savings Program (MSSP) ACO Guidance
  - Advisory opinion letters
- Nothing since 2013 (Norman PHO letter)

Financial Integration

- A network of otherwise independent providers **share financial risk** in such a way that each member has an economic incentive to ensure that the network as a whole generates efficiencies that benefit consumers
- Financial integration is not an end in itself; the goal is to create a meaningful prospect of
  - Improving efficiency in the delivery of care
  - Controlling costs
  - Better managing utilization, or
  - Improving the quality of care
- If "substantial" financial integration, will be judged under rule of reason
  - Substantial means both upside and downside risk
  - No clear guidance on exact level of risk that is enough
    - 15% common benchmark
    - What about 10%? 5%?

Financial Integration—Safety Zones

- Antitrust safety zones for physician networks–very low
  - Exclusive physician networks: participants constitute 20% or less of each physician specialty in the relevant geographic market
  - Nonexclusive physician networks: participants constitute 30% or less of each specialty
    - Must be viable competing networks or a managed care plan with adequate participation; physicians in network must actually participate in other networks/plans and earn substantial revenue from them
- Outside safety zones
  - Judged under rule of reason if integration likely to produce significant efficiencies that benefit consumers and price agreements are reasonably necessary to achieve the efficiencies
  - In effect, closer scrutiny of effectiveness of the arrangements and the degree of financial risk in cases where a large proportion of practitioners in a region are involved—i.e., high market shares

Examples of Financial Integration—1

- 1980s-era approach of fee-for-service payments from a fee schedule are made by the health plan, with 20% of each claim payment initially withheld
  - Year-end performance metrics (such as whether total cost of care is or is not within a pre-determined budget) determine whether some or all of the withheld funds are subsequently paid to the billing provider, or possibly a bonus in addition to the withheld funds is paid
  - Because withheld funds may not be paid at year-end, they are "at risk"
  - Return of 20% of fee that was initially withheld is "at risk" based on collective performance of the entire network → network is "financially integrated"

Examples of Financial Integration—2

- Full-risk capitation where health plan pays network entity a fixed fee of $100 per member per month
  - Commonly referred to today as “population-based payments”
  - Network entity pays participant’s fee-for-service claims. Network entity may set own fee schedule. Network entity may pay downstream capitation to PCPs, etc.
    - Might utilize initial withhold from claims payments
  - All risk of financial gain or loss is held by the network entity, not by the health plan
  - Availability of sufficient funds for network entity to pay all claims is based on collective performance of the entire network → “financially integrated”

Examples of Financial Integration—3

- ACA-type fee-for-service
  - Payor pays standard fees from payor's existing FFS schedule
  - If aggregate claims payments for the calendar year are less than the payor projected, the payor will share a % of the savings with the network entity.
  - Payor makes lump sum payment at year end to the network entity.
  - Computation may include $ addition or $ deduction based on quality of care scores.
  - The network entity decides how that lump sum receipt will be allocated to downstream participating providers.

Examples of Financial Integration—3 (cont.)

- Some contracts are upside only—no risk of loss if spend more than target
  - Example Track 1 of CMS Medicare MSSP program
  - This is NOT financially integrated
- Some contracts have both upside and downside risk
  - Network entity makes payment to payor if aggregate claims costs exceed spending target
  - Example CMS NextGeneration ACO—and certain payment tracks under MSSP
  - Appears to qualify as financially integrated if risk is "substantial
  - Not clear what constitutes "substantial;" 1%? 5%? 10%?

Clinical Integration

- "[A]n active and ongoing program to evaluate and modify the practice patterns by the network's physicians and create a high degree of interdependence and cooperation among the physicians to control costs and ensure quality." (DOJ/FTC Healthcare Statements, 1996)
- Deliberately open-ended definition; analysis focuses on substance, not form
  - May include (1) mechanism to monitor and control utilization to control cost and assure quality; (2) selective choice of network participants; (3) significant investment of capital, monetary and human
- The goal is to create a meaningful prospect of
  - Jointly improving efficiency in the delivery of care
  - Controlling costs
  - Better managing utilization
  - Otherwise improving the quality of care
- Any agreements on price must be "reasonably necessary" to realize the efficiency, cost and quality goals

Beware of Alternative Meanings

- The term “clinically integrated” is sometimes used in other contexts
  - Those other uses should not be confused with the antitrust definitions
- Today’s healthcare innovators seek to achieve the “triple aim”
  - Improving the experience of care, improving the health of populations, reducing the per capita cost of healthcare
- The term “clinical integration” is sometimes used in healthcare reform discussions to describe the key tools that are assumed to be necessary to attain the triple aim:
  - Care coordination, evidence-based medicine, data analytics, smooth handoffs from one care setting to the next (acute care to LTC, acute care to community settings, etc.) and other operational and clinical improvements

Beware of Alternative Meanings

- While network entities, payors and governments may use the term “clinically integrated,” they are often using it in colloquial fashion to describe the steps they believe will achieve healthcare reform
  - They are not using the term in the more legalistic, antitrust law use of that term
  - However, there are similarities
  - In some cases the package of improvements used by the network entity for healthcare reform purposes may in fact be the same as the package required to qualify under the antitrust definition
  - But that is not true by definition
    - So one should be careful not to automatically assume that a network entity’s description of itself as “clinical integrated” is sufficient to meet the DOJ/FTC definition of that same term

Alternative Meanings–State Definitions

- Some states have their own definition and own purposes
  - The state regulatory definitions and documentation may (or may not) be the same as the antitrust uses of that term
  - For example, the New York state ACO licensing process defines "clinical integration" and requires the applicant to document to the state health department's satisfaction that the network providers are clinically integrated
    - 10 NYCRR Part 1003.2 (f), 1003.3 (b)(2) and 1003.4 (i)
  - Again, one should be careful not to automatically assume that a regulator's standard as "clinically integrated" is sufficient to meet the DOJ/FTC definition of that same term
  - On the other hand, to the extent the state regulatory definition is similar to the antitrust definition, a network entity that has been issued a state license may be able to point to the state's regulations (and the network entity's state license)
    - May be persuasive talking point in any discussions with DOJ/FTC

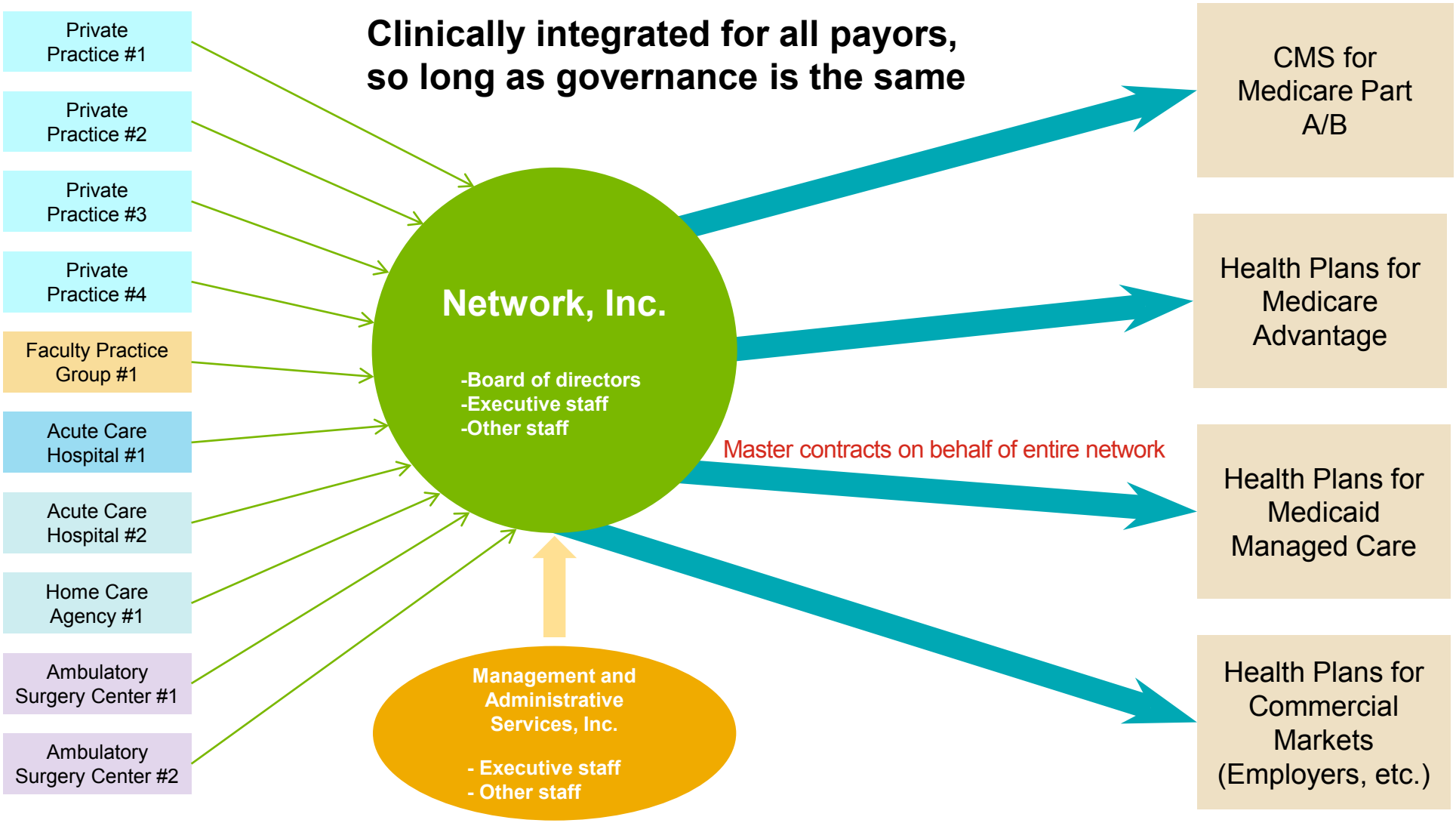
Clinical Integration–How to Get Comfortable

- How to gain comfort that there are no antitrust problems?
  - Review DOJ/FTC guidance and come to own conclusion
    - OK if fall within safety zones; more difficult if do not
  - Seek informal FTC guidance
    - Off-the-record, but puts you on agency radar
  - Seek formal advisory opinion
    - Information burden
  - Apply for state-action protection
    - Some states (e.g., New York, Tennessee, North Carolina) have Certificate of Public Advantage (COPA) process for collaborations that meet state healthcare goals
  - Add financial integration

Clinical Integration–Medicare ACO Policy Statement

- Applies to ACOs that are eligible and intend, or have been approved, to participate in the MSSP
  - Also applies to other ACO initiatives from CMS Innovation Center (Pioneer ACO, NextGen ACO)
  - Also applies to Medicare ACOs that participate in commercial markets
  - Guidance does not formally apply to non-Medicare ACOs, but an ACO with the same features is likely to satisfy clinical integration standards

DOJ/FTC Medicare ACO Guidance Extends to Other Payors as Well



Clinical Integration–Medicare ACO Policy Statement

- Confirms that FTC and DOJ will apply rule of reason analysis to Medicare ACOs
  - CMS eligibility criteria broadly consistent with indicia of clinical integration that FTC/DOJ have previously advised on
  - MSSP ACOs likely to be genuine arrangements to reduce costs of providing healthcare
  - CMS monitors MSSP ACO results
- No mention of financial risk sharing

Clinical Integration–Medicare ACO Policy Statement

- Safety zones
  - Combined shares of not more than 30% for each common service
    - "Market and "Service" defined based on physician specialties, CMS definitions of major diagnostic categories for inpatient and outpatient facilities–not necessarily market reality
  - Hospitals, ambulatory surgery centers and "dominant participants" must be non-exclusive
  - Physicians may be exclusive unless they have more than 50% market share
    - Rural exception
  - Complex and data-intensive exercise, particularly for physicians
  - Safety zones very conservative
    - Advisory opinions show that shares can be much higher if network nonexclusive –e.g., TriState Health Partners–covered 64% of physicians in region

Clinical Integration–Medicare ACO Policy Statement

- ACOs that fall outside safety zones will be analyzed under rule of reason
  - FTC unlikely to challenge unless ACO has very high market share and engages in certain "bad" conduct
  - Guidance sets out types of conduct to avoid
    - Preventing commercial payors from directing or incentivizing patients through steering and tiering
    - Tying sales of ACO services to commercial payors purchase of other services outside ACO
    - Exclusive contracting with physicians, hospitals, ambulatory surgery centers, etc.
    - Restricting a payor's ability to make cost, quality and other information available to enrollees
  - Offers expedited (90-day) voluntary antitrust review for Medicare ACOs–no examples yet
  - Fall back on principles in FTC advisory opinions from 2002–2013

Clinical Integration–Some Key Features from FTC Advisory Opinions

- Selective choice of participating providers
- Development and implementation by network providers of
  - Clinical protocols addressing a substantial number of conditions covered by network
  - Network quality goals and efficiency goals and benchmarks
- Creation of organizational infrastructure to facilitate provider collaboration, ensure practice pattern transparency and monitor compliance with clinical guidelines
- Network infrastructure
  - Implementation of electronic health information technology to share clinical information
  - Development of system, preferably electronic, to monitor physician compliance
- Formal program for physician performance reviews, corrective action program and sanctions for consistently failing to meet benchmarks
- Process to maximize in-network referrals

Clinical Integration–When Is There 'Enough'?

- DOJ/FTC guidance deliberately not prescriptive
  - Focus on whether network likely to generate efficiencies—"Know it when we see it"
  - Don't want to cut off opportunities for innovation that are genuinely aimed at reducing healthcare costs
- Clinical integration is a journey, not a destination
- Program needs to be assessed continually to ensure it's delivering benefits
  - Continue to develop protocols and metrics
  - Adjust as necessary

Hybrid Models–Belt + Suspenders

- Some networks qualify as both clinically integrated and financially integrated
- For example, a Medicare ACO is viewed as clinically integrated, and the ACO may also take on "substantial" financial risk in Tracks 2 and 3
  - New CMS regulations pushing Medicare ACOs to take on risk earlier in process
  - Basic track allows only two years of shared savings before moving to two-sided model
- Since the basic aims of both financial and clinical integration are the same—reduction in healthcare costs—makes sense that networks will develop both types of integration
  - A clinical integration program will provide data and coordination needed for an ACO to take on financial risk
  - A financially integrated ACO needs some sort of clinical integration efforts to achieve the system improvements that enable it to take on financial risk

Single Entity

- Some assembled networks consist solely of providers affiliated with a single health system
  - The affiliation consists of ownership or control by a common parent entity of all of the participating providers
  - Providers may be employees, or exclusive to an entity owned/controlled by the parent entity
- This is considered a single entity
  - The providers cannot compete with each other because they are all effectively part of the same entity
  - There is no basis for Section 1 liability because there is no agreement between independent competitors

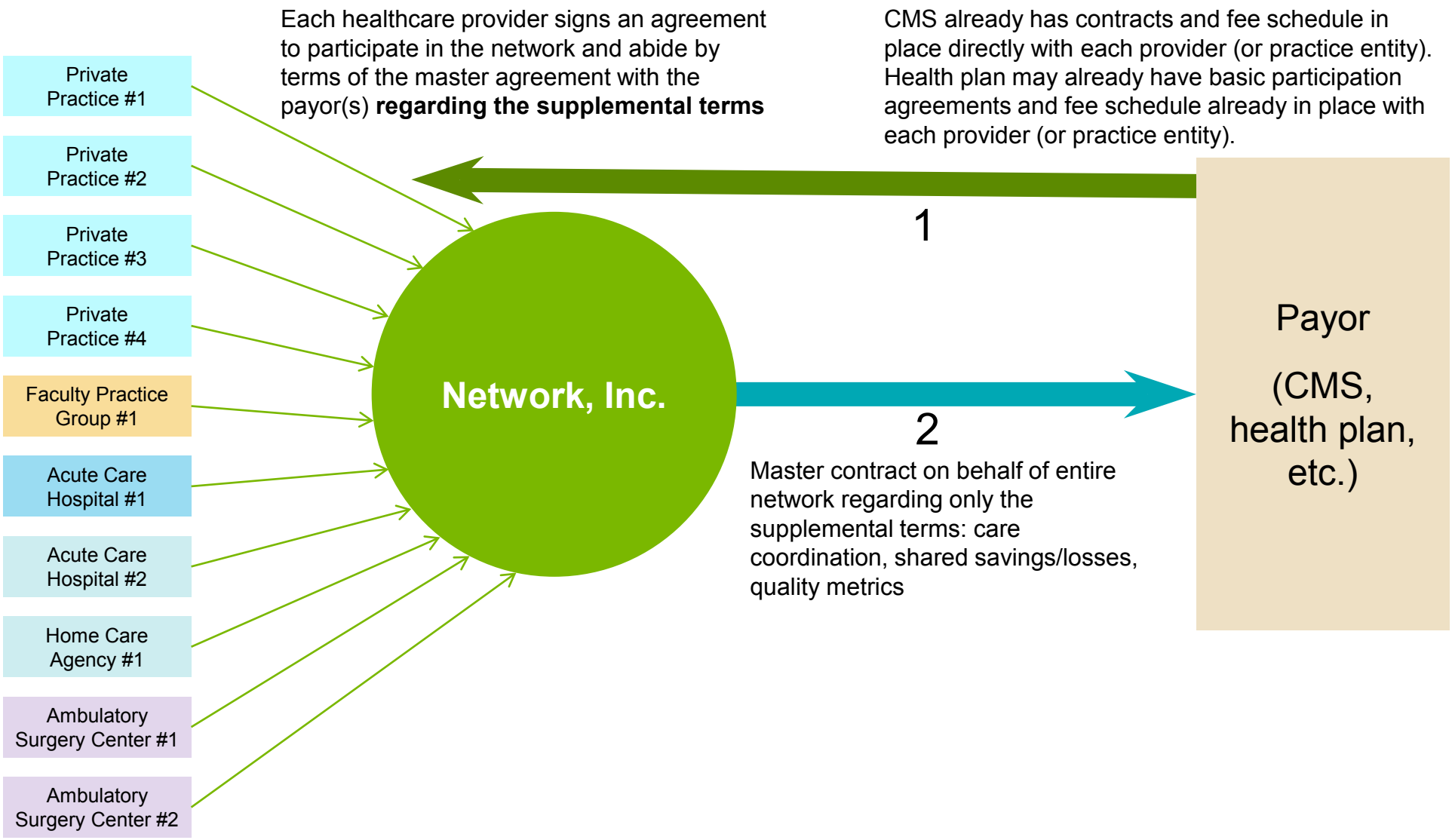
Messenger Model

- If the network entity is neither clinically integrated nor financially integrated, the only remaining option is the messenger model
  - Here there is no joint venture among the competitors. Therefore, each competitor must make its own decision in a silo without knowing what the competitors are offering or accepting.
- By definition, under the messenger model the network entity does not "negotiate on behalf of" the numerous providers
- Instead, the network entity merely relays offers and acceptances between the real parties in interest—the healthcare providers and the payor
  - Payor to provider: Will you accept a fee schedule at 110% of Medicare? Yes or No
  - Payor to provider: Will you accept the following definition of medical necessity and the prior approval process listed below? Yes or No
  - Or vice versa: Provider to payor: Will you pay me a fee schedule of 110% of Medicare? Yes or No
- Here "participation" in the network assembled by the network entity is tentative and subject to confirmation and final acceptance by each provider for each particular payor contract

ACO Twists

- Many ACOs do not negotiate payor fee schedules
  - For example, under Medicare MSSP and NextGen ACO models, CMS pays all providers at the standard, existing Medicare fee schedules, which exist regardless of the ACO arrangement
  - Many health plan VBP contracts also pay all providers at the health plan's standard, existing fee schedules, which exist regardless of the VBP arrangement
- Instead, those ACOs often negotiate only supplemental provisions regarding
  - The care coordination process
  - The addition of a supplemental shared savings (and sometimes shared losses) incentive, including the details of the necessary computations and allocations
  - The applicable quality metrics to be monitored and attained, and rewards or penalties for attaining/falling short
- While the same antitrust rules and guidance apply in these situations, it may be that antitrust officials are less likely to be concerned when the fee schedules are not being altered or renegotiated
  - Since fee schedules are typically the most obvious and important determinant of a payor's healthcare costs (although not the only factors)

Example of Negotiating Only Supplemental Terms



Summary: Decision Tree

Does the network contain providers who compete with each other? If so, need to fit into one of the boxes below.

Option 1

Clinical integration

A. MSSP ACO, or

B. Draw own conclusion from agency guidance

C. Obtain opinion from DOJ or FTC

Option 2

Financial integration

Payment models must involve a substantial level of shared financial success and shared financial losses

Could be FFS payments with withholds, or upside + downside, or full-risk capitation

Option 3

Single health system

All participating providers are owned by one health system

By definition, cannot agree not to compete with each other

Option 4

Use messenger model

Cannot collectively negotiate

Belt + suspenders if do both

Try to avoid actions identified by DOJ/FTC as of special concern:

(1) preventing or discouraging private payors from incentivizing patients to choose certain providers

(2) tying sales of ACO's services to other contracts outside the ACO

(3) contracting with providers on an exclusive basis so contracts outside the ACO are difficult to obtain

(4) restricting health plan ability to distribute provider performance ratings to consumers

Conclusion

- Entity formation and antitrust protections are two different legal issues
  - Corporate names and labels are neither dispositive nor relevant
  - Look beyond names or platitudes to evaluate compliance with antitrust requirements
- Rule of reason treatment is a welcome accompaniment to all Medicare ACOs
- The DOJ/FTC guidance is not limited to Medicare ACOs; it is very useful for similar contracts with other payors
- Attaining both clinical integration and financial integration may be a good idea
  - Makes operational sense and gives added protection from antitrust risks
- Remember state laws as well as the federal provisions
- This presentation addressed the necessary legal foundations for assembling networks
  - After this, the next step is the hard(er) work of the operational and clinical changes necessary to be successful at the triple aim
  - Such as tools for care coordination, network recruitment, quality improvement tools, data mining and analytics, improved clinical practices, patient engagement, etc.

Resources

- DOJ/FTC Statements of Antitrust Enforcement Policy in Health Care (1996) https://www.ftc.gov/sites/default/files/attachments/competition-policy-guidance/statements_of_antitrust_enforcement_policy_in_health_care_august_1996.pdf
- DOJ/FTC MSSP ACO Policy Statement (2011) https://www.govinfo.gov/content/pkg/FR-2011-10-28/pdf/2011-27944.pdf
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  - Norman PHO (2013) https://www.ftc.gov/sites/default/files/documents/advisory-opinions/norman-physician-hospital-organization/130213normanphoadvltr_0.pdf

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