Antitrust Compliance and Clinical Integration
Assessing Anti-Competitiveness of Healthcare Provider Collaborations,
Minimizing Risk of Agency Challenges

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Antitrust and Clinical Integration

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Program Overview*

1. Antitrust Overview

2. Clinical Integration, Ancillarity and ACOs

3. Market Power and Competitive Effects

4. Questions & Answers

* This presentation was prepared from public sources. The views expressed herein may or may not reflect those of the Federal Trade Commission.
The Purpose of Antitrust Law

• Prevent *private* business practices that *unreasonably* restrain competition.

• For the benefit of consumers:
  – Lower prices;
  – Better quality; and
  – Increased choice, selection, convenience, and innovation.
Provider Price Negotiations: *Antitrust Concerns*

1. Price-Fixing/Cartels

Agreements among competitors on price, or other terms of dealing, without meaningful integration of the members’ activities.

2. Monopolization

Integrated group, with substantial market power, engages in anticompetitive conduct to achieve or maintain its market power.
Guidance

Formal Guidance

• ACO Policy Statement (2011)
• Clinical Integration Workshop (2008)
• Collaboration Guidelines (2000)
• Health Care Statements (1996)

Advisory Opinion Letters

• Norman PHO (2013)
• TriState (2009)
• GRIPA (2007)
• SHO Advisory Opinion Letter (2006)
• MedSouth (2002) and “Follow Up” Letter (2007)
Clinical Integration

• An active and ongoing program to evaluate and modify the practice patterns of providers and create a high degree of interdependence and cooperation to control costs and ensure quality.

• The goal is to create a meaningful prospect of jointly improving efficiency in the delivery of care; controlling costs; better managing utilization, and otherwise improving the quality of care.

• Agreements on price must be “reasonably necessary” to realize efficiency, cost and quality goals.
FTC/DOJ 2004 Report

• What do providers plan to do together from a clinical standpoint?

• How do providers expect to accomplish these goals?

• What basis is there to think that providers will actually seek to accomplish these goals?

• What results can reasonably be expected from undertaking these goals?

• How does joint contracting with payers contribute to accomplishing the clinical goals?
Some Lessons
… from MedSouth to Norman PHO …

• Clinical integration and successful provider network joint ventures take many forms.

• Provider focus must be on quality, not quantity.

• There are no guarantees. A given program may or may not be easy, inexpensive, or attractive to payers and consumers.

• “Ancillarity” is a key part of the antitrust inquiry.
Advisory Opinion Letters

- Sets forth staff’s enforcement intentions or recommendations regarding specific conduct.
  - Analysis is based on the requesting party’s factual representations.
  - Extensive market or technical analysis must not be necessary.
  - Request must relate to proposed conduct – *i.e.*, *not* hypothetical questions or ongoing conduct.
Accountable Care Organizations

• SSP specifies that groups of providers
  “... meeting [specified] criteria ... may work together to manage and coordinate care for Medicare ... beneficiaries;” and may receive payments for shared savings if the ACO meets certain quality performance standards.”

• The SSP is similar to traditional clinical integration programs – i.e., in terms of goals and means.
ACO Policy Statement

• Applies to collaborations among otherwise independent providers that:
  – Meet CMS’ eligibility criteria and participate in SSP; and
  – Operate in commercial markets.

• Does not apply to:
  – Mergers; or
  – Traditional (non-SSP) network joint ventures.
ACO Analysis

• ACO may qualify for Safety Zone where:
  – Combined shares $\leq 30\%$ for each common service in each participant's primary service area ("PSA"); and
  – Hospitals and ASCs must be non-exclusive.

• ACOs that fall outside the Safety Zone:
  – Will be analyzed under rule of reason*
  – May seek expedited, 90-day review
Clinical Integration: Why and How?

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Clinical Integration – Why?

• The delivery and reimbursement environments are changing, seemingly at warp speed
• Emphasis on value in terms of cost and outcomes, not the number of procedures and tests
• Health-care reform:
  – Lower reimbursement, both governmental and commercial
  – Financial incentives based on cost and quality
Clinical Integration and the Antitrust Laws

- CI and value-based delivery of care induce, if not require, concerted action among often competing providers
- The antitrust laws prohibit certain concerted action
- Is there a disconnect between the antitrust laws and this new environment as some argue?
  - Does concerted action resulting in higher prices from greater market power further the goals of health-care reform?
  - Is concerted action resulting in market power likely to generate higher quality?
Clinical Integration and the Antitrust Framework

• “Naked” horizontal price-fixing agreements are per se unlawful under Sherman Act § 1
• Actions by provider-controlled contracting networks (IPAs, PHOs, ACOs, etc.), including joint negotiations, result from “agreements”
• Price fixing agreements are agreements that directly affect prices competing sellers charge
• Ergo, network joint negotiation of price terms in payer contracts results in price-fixing agreements
The Framework

• But – “ancillary,” as opposed to “naked,” price fixing agreements are subject to rule-of-reason analysis

• What’s the difference?
  – Naked:
    – Little or no integration or interdependence among providers; no reason for agreement other than supra-competitive prices
  – Ancillary:
    – Subordinate to a larger endeavor
    – Integration to achieve significant efficiencies
    – Price fix “reasonably necessary” to achieve those efficiencies
The Framework

• Key points:
  – Joint price negotiations must be ancillary or subordinate to efficiency achievement, not vice versa
  – CI, done right, can turn joint negotiations from naked to ancillary restraints

• Crucially important early question for clients considering CI:
  – “What are your reasons for considering clinically integrating?”
    • Improve quality and efficiency in service delivery?
    • Aggregate bargaining power to force higher reimbursement?
      – If the second, high probability venture will fail
      – Over 50 FTC and DOJ challenges; last one filed by DOJ Sept. 2013
A Digression: Messenger Arrangements

- Network is merely a conduit for payer offers, individual provider acceptances, rejections, and counteroffers
- Operated lawfully, can’t aggregate provider bargaining leverage to increase reimbursement
  - Difficult to run lawfully
- Can’t negotiate prices and then messenger offers
- Numerous FTC enforcement challenges
- Generally, not worth the time and effort
Clinical Integration – Step 1: The Integration Requirement

Favorite client question: “How much integration is enough? (Read: “How little can we get away with and still fix prices?”)

– Wrong question; suggests the CI, not the price fixing, is ancillary

– In any event, no black-and-white answer; requires an educated, but subjective, judgment

  • Enough so that significant efficiencies are probable
    – Efficiency: Anything benefitting consumers that the providers couldn’t generate individually

  • Good discussions in the FTC Staff Advisory Opinions, but no magic answer because there isn’t one
Clinical Integration – Indicia

• No “cookie-cutter” approach, but FTC Advisory Opinions, speeches, and 2004 FTC/DOJ *Dose of Competition* report help identify important characteristics

• See FTC/DOJ ACO *Antitrust Statement*:
  – Structure including clinical and administrative processes
  – Processes to promote evidence-based medicine and patient engagement
  – Reporting and reviewing quality and cost measures
  – Coordinated care for patients

• In general:
  – Provider development and implementation of the program
  – Interdependence among participating providers in caring for patients
  – Strong provider commitment to improving quality, efficiency, cost, and resource use
  – Significant provider financial and time commitment to the program
  – Ultimately, demonstrably beneficial results
Clinical Integration – Indicia

• More specifically:
  – Selective choice of participating providers based on interest in, and history of, providing high-quality care, and on network need
  – Development and implementation by network providers of practice protocols sufficient to cover network specialties and sufficient to improve quality and utilization
  – Development by network providers of network quality and efficiency goals and benchmarks above current levels
  – A system, preferably electronic, by which providers exchange relevant patient information, such as notes, test results, procedures, and prescriptions
  – Development and implementation of a system, preferably electronic, by which providers report compliance with protocols,
Clinical Integration – Indicia

- A formal program for review of individual physician performance, considering protocol compliance and network benchmarks
- A process to maximize in-network referrals
- Willingness to work with payers to potentially incorporate their ideas in the program
- A formal program for identifying providers failing to apply the protocols or achieve the network’s benchmarks
- A corrective action program for those providers
- Sanctions for providers consistently failing to meet the network’s benchmarks, including potential exclusion
Clinical Integration – Step 2: Need for Joint Price Negotiations, i.e., “Ancillarity”

• Given sufficient integration, the question becomes whether joint price negotiations are “reasonably necessary” for the network integration to achieve its proposed efficiency and cost benefits
  – An admittedly amorphous standard
  – What’s not sufficient: That providers won’t participate unless they can fix prices. See FTC Staff Advisory Opinion Letter to Norman PHO, p. 17
Clinical Integration – Ancillarity

• No pat answer to when joint negotiations are ancillary
  – May be several answers, depending on the specific facts
• Most helpful discussions are FTC Staff Advisory Opinions to TriState Health Partners, pp. 24-28, and GRIPA, pp. 16-24:
  – Broadly, for network to generate maximum efficiencies, it’s important that all providers participate in all contracts, and
  • Only way for this to happen is for the network to mandate that all providers participate in all contracts, and
  • Only way for this to happen is for the network to negotiate contracts for all its providers
Clinical Integration – Ancillarity

• Why is it important for all providers to participate in all contracts?
  – Maximizes the number of patients subject to the efficiency benefits of the program
  – Maximizes providers’ use of the protocols, accustoming them to the program’s system of integrating care and thus maximizing its achieving its benefits
  – Increases degree of in-network referrals, thus increasing the program’s amount of patient information and thus the effectiveness the program
  – Provides greater incentive for providers to contribute their time and effort to the program
  – Provides for a consistent and readily identifiable network, unlike messenger arrangements
  – Provides transaction-cost efficiencies for both payers and providers through single-signature contracting
Clinical Integration – Practical Reminders

1. After a time, the program must show results
2. Do CI for the right reason, and ensure documents and discussions show this
3. Ensure the CI is a program payers want to buy; it can’t be crammed down their throats
4. CI can improve reimbursement lawfully if payers are willing to pay for quality improvements
5. But CI is expensive and time consuming with no guaranteed financial return
6. It’s helpful to include some financial incentives (e.g., P4P) in the program.

7. FTC hasn’t taken a hard line on the ancillarity question—four approvals, one disapproval.

8. Remember that ancillarity is just the first antitrust hurdle; it doesn’t mean that the joint negotiations are per se legal.
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Clinical integration: Market power and competitive effects

Strafford Webinar on
“Antitrust Compliance and Clinical Integration”
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Antitrust questions raised by clinically integrated networks (“CINs”) (also includes ACOs)

- Principal concern: agreements among competitors regarding prices to commercial health plans
  - Additional concern is foreclosing development of rival CINs/ACOs
- Two main questions
  1. Is there sufficient integration (financial or clinical) to avoid allegation of naked “price-fixing” and qualify for “rule of reason” treatment?
     - Sufficient integration?
     - Ancillarity (are agreements related and reasonably necessary to achieve legitimate goals) ?
  2. Under the Rule of Reason, will anticompetitive effects outweigh procompetitive benefits?
- Market power is directly relevant to the Rule of Reason analysis
  - But as a practical matter, it likely will also affect the extent of scrutiny given to the integration question: networks with higher market shares likely will be more closely scrutinized since they have more potential for anticompetitive effects.
Rule of reason analysis

• What are the type of agreements at issue?
  – Agreements on price?
  – Exclusivity?
  – Any agreements unrelated to the venture?

• What is nature of possible competitive harm?
  – Collusion – e.g. higher prices due to agreements on price or spillover effects
  – Exclusion – e.g. hindering ability of competition from rivals

• Consider shares in relevant product and geographic market

• Is entry timely, likely and sufficient?

• What are likely efficiencies, and could they reasonably have been accomplished with less restrictive means?
The relevance of market shares

- Antitrust challenge requires plaintiff to prove relevant product and geographic markets
- Lack of evidence of market power makes anticompetitive harm unlikely
- What is market power?
  - Ability to raise price above competitive levels
  - Could be reflected by
    - high market shares (>30-40%), plus barriers to entry
    - evidence of supra-competitive “quality-adjusted” prices
Proving market power with physician services

• A difficult task
• Challenging problems in defining
  – Product markets
  – Geographic markets
• Entry barriers may be low
• Also difficult to prove a quality-adjusted price increase
• And always a very fact-specific inquiry
  – For this reason, DOJ/FTC guidance necessarily is of limited utility
DOJ/FTC 1996 Health Care Statements

• “Safety zone” for financially integrated physician networks where the share of physicians with hospital staff privileges in the relevant geographic market for each physician specialty account for
  – 20% or less if network is exclusive
  – 30% or less if network is non-exclusive

• By its terms, does not apply to clinically-integrated networks or those involving non-physicians

• But same concepts should apply
DOJ/FTC MSSP ACO Statement

• Antitrust “safety zone” available to certain ACOs with low shares for each service in overlapping PSAs

• Combined share must be 30% or less for each common service in each participant’s PSA wherever there is an overlapping service
  – PSA is the lowest number of contiguous zip codes that account for 75% of the ACO participant’s patients for that service
  – Each fully integrated physician group, outpatient facility and inpatient facility will have its own PSA
  – Assess each different physician specialty, MDC, or outpatient category as defined by CMS
  – This is a short-cut to approximate product and geographic market definition

• Exclusivity
  – All participating hospitals or ASCs must be non-exclusive
  – Safety zone for physicians is same whether or not they are exclusive, except it will affect rural exception and dominant provider limitation
ACO antitrust safety zone, cont’d

• Rural exception
  – ACO can still qualify for safety zone even if it exceeds 30% threshold if it has only one physician or group practice per specialty for each county that contains an “isolated rural” or “other small rural” zip code, even if including such providers cause it to exceed the threshold
  – Such providers must be non-exclusive

• Dominant participant limitation
  – If a single ACO participant has a PSA share of greater than 50%, ACO participant must be non-exclusive to the ACO
  – ACO cannot require a private payer to contract exclusively with the ACO or restrict payer’s ability to contract or deal with other ACOs or provider networks.
ACO antitrust safety zone, \textit{cont’d}

• Safety zone is of limited utility

• Designed to provide a mechanical approach for estimating market shares that could be used by ACO applicants
  – Cumbersome to employ
  – Often will not reflect market realities

• Conservative because it is a safety zone
  – Thus, unlikely to shed much guidance in close cases

• But could be a useful starting point
FTC Advisory Opinions

• Illustrate that physician shares can be much higher than safety zone limits where network is non-exclusive

• Examples
  – FTC Advisory Opinion re TriState Health Partners (2009)
    • TriState physicians represented 64% of the physicians at the only hospital in Washington County and half or more of the physicians in a large number of specialties in the hospital and TriState’s PSA
    • No other IPAs or PHOs in the county
  – FTC Advisory Opinion re Norman PHO (2013)
    • PHO physicians account for majority of patient discharges in Norman and McClain counties and includes the only hospital in Norman, OK
    • Health plans lack practical alternatives to the PHO or its members to serve patients in the immediate Norman area
Practical advice for addressing market power concerns

• Question must be considered from vantage point of health plan
  – If the CIN participants did not contract with the plan, to whom else could the plan turn and still have a viable network?
  – Need to be considered for each specialty/service line

• May be necessary to limit membership so that plans (and other networks) will have available a sufficient number of non-participating providers outside the CIN

• Some market share concerns may be inevitable
  – With certain subspecialists
  – In rural areas
  – Where a “dominant” hospital is part of the CIN

• Try to address with non-exclusivity

• No “black and white” simple analysis – in close cases, could require extensive economist input

• But antitrust risk also will depend on what value the CIN brings to the market and how it deals with payers
Conduct that CINs should avoid

• Sharing competitively sensitive information regarding conduct outside the CIN

• Dominant providers who are part of a CIN should avoid:
  – Precluding members from joining other CINs or ACOs
  – Preventing efforts by payers to steer patients
  – Tying sales of CIN services to purchase of other provider services
  – Restricting payers from making cost, quality, efficiency & other info available
Some common questions – and answers
How long does clinical integration normally take?

- It obviously depends on a number of factors, e.g.
  - Number of providers involved
  - Degree of current integration, if any
  - Time needed to identify participants and obtain commitments and financing
  - Time providers have and are willing to spend putting the program together
  - Scope of any antitrust analysis
  - Time needed to negotiate and enter vendor contracts (e.g., IT)
  - Whether there are formal or informal interactions with the FTC or DOJ
- So there is no set time period
  - But all else being equal, plan on between a year and 18 months
Are there particular numbers and scope of coverage requirements for the clinical protocols?

• Nothing specific, but:
  – Attempt to develop protocols applicable to all specialties represented in the network
  – Attempt to develop protocols applicable to medical problems that contribute the most to costs
  – Within reason, maximize the number of protocols
Can the hospital fund a physician clinical integration program?

- This can be problematic for at least three reasons:
  - The Stark laws (but there may be ways to structure support consistent with Stark and anti-kickback law)
  - The physicians need to integrate through both financial and work contributions
  - Network control issues can arise

- Nevertheless, it may be possible to structure arrangements consistent with Stark and anti-kickback laws, and to address integration and control issues
Can employed and independent physicians be clinically integrated?

• Yes, but the FTC Staff Advisory Opinion to SHO suggests:
  – It may be difficult to clinically integrate only the employed physicians of several hospitals
  – The program should include specialists and not just PCPs
  – Some experts believe that the employed physicians, and not their employer hospitals, should be the drivers of the program
Can single-specialty physician networks be clinically integrated?

• Perhaps, but doing so is difficult
  – CI subsumes that network participants exchange information about and refer among themselves to improve the total care of patients
• This is not likely in single-specialty networks, suggesting that efficiencies may be very limited; see FTC Staff advisory opinion to SHO
• Difficult to see why joint negotiations would be necessary to achieve whatever efficiencies the network might generate
Should payers play any role in the early development of the program?

• Yes, for at least reasons:
  – They often have helpful ideas to improve the program
  – It’s important to develop a program they will want
  – It’s important to ascertain if they have concerns about providers banding together and to relieve those concerns
  – In at least one case, a large payer was willing to help fund the program’s development
When can joint negotiations begin?

- Must wait until infrastructure has been assembled and program is ongoing
- But “chicken and egg” problem
  - Difficult to retain commitment of physicians indefinitely
  - Need to engage health plans in future plans from the beginning
- Unrealistic to expect significant results at the outset
  - But if there are few achievements over time, it casts doubt over likelihood of achieving efficiencies
  - Need for ongoing efficiencies to justify continued operation
How important is evidence of cost or quality gains?

• Significant gains against relevant benchmarks are important favorable evidence
  – Need to choose appropriate benchmarks
  – Obvious source of benchmarks: Medicare ACO measures

• What about lack of gains?
  – Might be expected to some degree at start of program
  – Crucial issue is what does the CIN do to monitor evidence and improve where it is underperforming
  – If poor results persist over long period of time, question may be raised about extent of any procompetitive benefits or integration
What are the risks of including too many, or too few, providers?

• More serious antitrust risk is posed by CINs that are over-inclusive
  – Will more likely have market power in payer negotiations
  – Could foreclose the development of rival CINs
Therefore – need to consider justification for more inclusive panels

• Under-inclusive CINs raise possibility of private litigation
  – But excluding providers based on objective performance criteria could be an important predicate for a successful CIN
  – Similar to antitrust challenges of denial of medical staff privileges
    • Most such challenges are unsuccessful absent unusual circumstances
    • Steps can be taken to reduce antitrust exposure
Must the CIN be non-exclusive?

• Antitrust concern – facilitates ability of providers to leverage market power
• But even non-exclusive networks can raise antitrust concerns
  – “Spillover” effects
  – Possible trend to *de facto* exclusivity
• Exclusivity can create greater potential for efficiencies
  – Need for PCP exclusivity
  – Assures full commitment to the CIN
  – Should not raise serious antitrust concerns if market share is relatively small (e.g. < 20% share)
• Some providers could be non-exclusive, and others exclusive
• Some providers could start on non-exclusive basis, but take on exclusivity later as need for commitment increases and some providers drop out (so market share is smaller)
What if prices go up?

- Generally a crucial antitrust question is the impact on prices
- Need to differentiate between prices going up for all providers vs raising prices of lower-reimbursed providers to that of better-reimbursed CIN participants
- But consumers may benefit even if unit prices go up if price increases are more than offset by:
  - Quality improvement
  - Reduced utilization
- So more relevant question is whether “quality adjusted price” has gone up or “overall value” has declined
- But these issues are difficult to evaluate
- CMS comparative data will be increasingly important for CINs that participate as MSSP ACOs
What about payer reactions?

Typically the views of customers are very important.

If health plans are positive
  - That is very persuasive evidence that the CIN is achieving significant efficiencies.

If health plans are negative
  - Need to understand why
  - Possible explanations
    • May not understand or be skeptical of claimed benefits of the program
    • May be primarily interested in lowest unit cost and skeptical about quality claims
    • May have strong policy in favor of direct contracting
Should a CIN seek an advisory review from the antitrust agencies?

• **Cons**
  – Will require substantial effort to meet agency information request
  – Exposes CIN to agency scrutiny
  – May require CIN to agree not to engage in certain conduct
  – In a close call, may be difficult to get a “green light;” if not a close call, then may be unnecessary
  – Does not provide immunity from challenges by State AGs or private plaintiffs

• **Pros**
  – Will provide fair degree of antitrust comfort
  – Could persuade risk-averse CIN participants to move forward

• **Needs to be decided on a case-by-case basis**
Will the agencies provide any guidance short of a formal opinion?

• Agency staff are usually willing to meet and discuss a proposed program informally
  – Staff may have helpful input in tweaking the program in a positive manner
  – Staff comments and/or criticisms may help the parties develop a more acceptable program
  – But this advice is “off the record” and does not constitute agency approval of the program
  – The meeting provides the agency with notice of what the parties intend and may result in follow-up
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Bob Leibenluft's practice is devoted entirely to health and antitrust matters, including counseling and litigation regarding antitrust issues in the health, medical device, and pharmaceutical industries.

Upon completing law school, Bob worked as an attorney advisor in the Federal Trade Commission (FTC)'s Office of Policy Planning, concentrating on health and antitrust matters. In 1981, he joined Hogan & Hartson (now Hogan Lovells) and became a partner in the firm in 1989. He practiced health law at Hogan & Hartson until January 1996 when he rejoined the FTC as Assistant Director for Health Care in the FTC’s Bureau of Competition. As head of the Health Care Division, Bob supervised a 25-30 person staff engaged in the review of mergers, acquisitions, and joint ventures involving hospitals, physicians, and other healthcare providers, as well as conduct in the healthcare and pharmaceutical industries. While at the FTC, Bob supervised the 1996 revisions of the FTC and DOJ *Statements of Antitrust Enforcement Policy in Health Care* in which the Agencies first addressed clinical integration. He rejoined Hogan & Hartson in September 1998.

Bob is an inaugural fellow of the American Health Lawyers Association, where he previously served as a Vice-President and member of the Board of Directors. He is a former Chair of the ABA Antitrust Section Joint Conduct Committee, Health and Pharmaceuticals Committee and State Enforcement Committee. He is Chair of the Board of Directors of HCl3, the parent company of Prometheus Payment Inc. and Bridges to Excellence. Bob is also an adjunct law professor at the George Washington University School of Law where he teaches a course on Antitrust in the Health Care Sector.

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