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Applying FTC/DOJ Guidance: Is this the End or Just the Beginning?

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Presentation overview

- What are the principal antitrust concerns raised by ACOs?
  - Note: “ACOs” refers here generally to a wide range of possible collaborations among health care providers
- The DOJ/FTC Statement on ACOs
- Some common questions – and answers
- Practical guidance for reducing antitrust risk

Antitrust concerns raised by ACOs

- Principal concern: agreements among competitors regarding prices to commercial health plans
- Two main issues
  1. Is there sufficient integration (financial or clinical) to avoid allegation of naked “price-fixing” and qualify for “rule of reason” treatment?
  2. Does collaboration have market power?
     - >30-40% market share in any relevant market
     - Ability to raise prices above competitive levels
- Other potential antitrust issues
  - Foreclosing rival ACOs (too many providers in the ACO)
  - Excluding providers from the ACOs (too few providers in the ACO)

The DOJ/FTC *Statement of Antitrust Enforcement Policy Regarding ACOs under the MSSP*

DOJ/FTC ACO Statement – key provisions

- Agencies will apply Rule of Reason treatment to ACOs in the commercial market
  - for duration of participation in MSSP
  - if the ACOs use the same clinical and administrative processes
- Mandatory review is NOT required for ACOs with high PSA shares in any overlapping service line
  - But CMS will share claims data and ACO applications with DOJ/FTC
- Antitrust “safety zone” available to certain ACOs with low shares for each service in overlapping PSAs
- Expedited 90-day voluntary review for newly formed ACOs
- Identifies five types of conduct that increase antitrust concerns

Antitrust safety zone

- 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

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.

Conduct that ACO providers should avoid

- Sharing competitively sensitive information regarding conduct outside the ACO
- Dominant providers should avoid:
  1. Preventing efforts by payers to steer patients
  2. Tying sales of ACO services to commercial plans to purchase of other provider services
  3. Contracting with non-PCPs on exclusive basis
  4. Restricting payers from making cost, quality, efficiency & other info available

Expedited 90-day voluntary review

- Available to ACOs formed after 3/23/2010
- Application to be submitted to both agencies, but will be reviewed by only one
- Agencies will form a joint working group to collaborate and discuss issues arising out of ACO reviews
- Within 90 days of receiving required info and documents, agency will indicate whether ACO:
  - is not likely to raise competitive concerns (perhaps conditioned on written agreement to take certain steps)
  - potentially raises competitive concerns
  - likely raises competitive concerns
- Agency response will be made public

Information requested for expedited review

1. Application to CMS and all supporting documents, sample participation agreements, financial arrangements, bylaws and operating policies
2. Documents discussing:
   a. ACO's business strategies, plans to compete in Medicare and commercial markets, and likely impact on prices, cost or quality
   b. Level and nature of competition among ACO participants, and competitive significance of ACO and ACO participants

Information requested, *cont'd*

1. Information sufficient to show:
   a. Common services that two or more ACO participants provide to patients in the same PSA and identity of those participants
   b. PSA of each ACO participant, and either PSA share calculations or other data to show current competitive significance of the ACO or its participants
   c. Restrictions that prevent ACO participants from obtaining information regarding prices that other ACO participants charge private payers that do not contract through the ACO
   d. Identity, including point of contact, of five largest private payers, actual or projected, for the ACO's services
   e. Identity of other existing or proposed ACOs in any market in which the ACO will provide services

Information requested, *cont'd*

- ACO is invited to submit other documents or information that it believes may be helpful to the Agency in assessing likely impact on competition
  - Evidence ACO is not likely to have market power in the relevant market
  - Any substantial procompetitive justification for why the ACO needs its proposed composition to provide high quality, cost-effective care
  - If relevant, an explanation as to why the ACO engaging in any of the four types of "suspect" conduct would not be anticompetitive or might be procompetitive

Observations re DOJ/FTC ACO Statement

- More clarity on how to get to Rule of Reason
  - Automatic for CMS-approved ACOs
  - Much more fulsome examples of what a qualified CI program looks like
- Few ACOs are likely to meet safety zone requirements
- Unlikely that many ACOs will seek voluntary expedited review
- Focus will switch to market power concerns
  - DOJ/FTC view non-exclusivity as one way to reduce such concerns
  - Warning to “dominant” ACOs about engaging in the 4 “no-nos”

Some common questions – and answers

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 ACO 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 ACO that is over-inclusive
  - Will more likely have market power in payer negotiations
  - Could foreclose the development of rival ACOs

  Therefore – need to consider justification for more inclusive panels
- Under-inclusive ACOs raise possibility of private litigation
  - But excluding providers based on objective performance criteria could be an important predicate for a successful ACO
  - 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 ACO 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 ACO
  - 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 ACO 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

What about payer reactions?

- Typically the views of customers are very important
- If health plans are positive
  - That is very persuasive evidence that the ACO 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 interested only in lowest unit cost
    - May have strong policy in favor of direct contracting

How are market shares relevant?

- Generally, market shares are *not* relevant to the threshold question of whether the network should be evaluated under Rule of Reason
  - But greater scrutiny likely will be given networks with high market share
- But a crucial consideration under the R of R
  - Likelihood of anticompetitive effects are related to market share
- DOJ/FTC PSA analysis is just a starting point
- Question must be considered from vantage point of health plan
  - If the ACO 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
- No “black and white“ simple analysis – in close cases, could require extensive economist input

Should an ACO seek an advisory review from the antitrust agencies?

- Cons
  - Will require substantial effort to meet agency information request
  - Exposes ACOs to agency scrutiny
  - May require ACO 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 ACO participants to move forward
- Needs to be decided on a case-by-case basis

Practical guidance for reducing antitrust risks

Ensure there is sufficient economic integration

- “Ask not how much integration is enough is needed to satisfy the antitrust enforcers. Instead, ask what integration is needed to achieve real cost-savings and quality improvements”
- Some degree of financial incentives are likely necessary to achieve real efficiencies
- Consider extent to which collaboration can enable providers achieve what they couldn’t independently
- Compare your venture to successful, fully integrated providers such as the Cleveland Clinic or Kaiser
- Will require substantial investment in infrastructure, data gathering and analysis, enforcement mechanisms, dedicated staff, time and effort
- There’s no free lunch – if an ACO promises providers they can join and nothing will change, except they will achieve higher reimbursement – that’s a red flag

Address market power concerns

- Need to analyze by each specialty and service line
- Avoid “locking up” large share of providers in any specialty or service line
- May be necessary to limit membership so that plans will have available a sufficient number of non-participating providers outside the ACO
- Some market share concerns may be inevitable
  - With certain subspecialists
  - In rural areas
  - Where a “dominant” hospital is part of the ACO
- Try to address with non-exclusivity
- Don’t raise quality-adjusted prices above competitive levels – and be able to document claims of quality improvement and/or better utilization
- Pay particular attention to next 3 slides

Avoid the DOJ/FTC "no no's"

- Sharing competitively sensitive information regarding conduct outside the ACO
- Dominant providers should avoid:
  1. Preventing efforts by payers to steer patients
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Work with health plans from the outset – they are your customers

- Health plan input is important in identifying what changes in provider practice is needed and in “validating” an ACO’s program
  - If health plans find little value in an ACO’s program, they will contract with alternative providers
  - If they can’t find alternatives, that will be used as evidence that the ACO has market power
- Easier to justify a price increase if health plans acknowledge that quality and/or utilization have improved
- Antitrust enforcers rely heavily on health plan input

Consider antitrust issues from the beginning

- Will vary considerably
  - In some situations AT issues will not be significant
  - In others, they could be key in determining who can participate and the organization's structure and conduct
- Crucial that all providers understand from the outset how the proposed arrangement will work and can benefit them
  - If goal is just to gain market clout without changes in clinical practice and efficiencies, then venture will either fail, or prompt tough antitrust scrutiny
- Antitrust issues can be dealt with
  - But important to have informed advice so that entity is neither overly conservative or clueless as to risks

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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 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 again 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 currently Co-Chair of the ABA Antitrust Section Joint Conduct Committee, and is a former chair of the ABA Antitrust Section's Health and Pharmaceuticals Committee and State Enforcement Committee. He is a member of the Board of Directors of HCI3, the parent company of Prometheus Payment Inc. and Bridges to Excellence.

EDUCATION

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