2016 Antitrust in Healthcare Conference

PROVIDER AFFILIATIONS SHORT OF FULL-FLEDGED Mergers

May 12, 2016

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BASS BERRY & SIMS
Clinical Integration

• The primary source of authority is Statement 8 of the 1996 DOJ and FTC “Statements of Antitrust Enforcement Policy in Health Care,” as well as several Advisory Opinions and other statements from the FTC.

• Clinical integration is a process designed to achieve efficiencies in the provision of health care through organized, cooperative activity among physicians and/or other providers.

• Clinical integration was introduced by the DOJ and FTC in 1996 as a form of provider collaboration that can be the basis for joint negotiations with payors by the provider participants; successful use avoids “per se” liability under Sherman Act, Section One.

• It is a program; there is no requirement for a formal corporate structure.
Clinical Integration

• Clinical integration is defined in Statement 8 as an “active and ongoing program to evaluate and modify practice patterns by the group’s physician participants and create a high degree of interdependence and cooperation among the physicians to control costs and ensure quality.”

• Statement 8 states joint negotiations of payor contracts by clinically integrated competing physicians will be analyzed under the Rule of Reason so long as the joint negotiations are reasonably necessary to accomplish the venture’s efficiencies.

  • There is no safety zone, however.

• Under the Rule of Reason, market power concerns may arise at 30-35% market share if an exclusive network; apparently much higher shares tolerated if non-exclusive.
Clinical Integration

- Statement 8 provides the following as examples of activities that a clinical integration program may include:
  - establishing mechanisms to monitor and control utilization of health care services that are designed to control costs and assure quality of care;
  - selectively choosing network physicians who are likely to further these efficiency objectives (including disciplining selected physicians who fail to follow the clinical integration program); and
  - the significant investment of capital, both monetary and human, in the necessary infrastructure and capability to realize the claimed efficiencies.
Clinical Integration

• Statement 8 makes clear these examples are not the only types of arrangements that can evidence sufficient integration to warrant Rule of Reason analysis; the Agencies will consider other arrangements that also evidence such integration.

• In all cases, the Agencies’ analysis will focus on substance, rather than form, in assessing a network's likelihood of producing significant efficiencies.

• The goal of clinical integration should be to create a meaningful prospect of:
  • Improving efficiency in the delivery of care;
  • Controlling costs;
  • Better managing utilization; and/or
  • Improving the quality of care.
Clinical Integration

*Structural and Operational Components*

- Physician-led committee infrastructure, e.g., Specialty Advisory Groups, Mentor’s Committee, and Quality Assurance Committee;
- Significant computer capabilities including hardware and software interfaces that connect all participating physicians and related personnel and any related hospital or clinics --
  - Clinical support system, e-prescribing, and EMRs,
  - Data collection, outcomes measurement, utilization management and performance reporting and protocol compliance, and
  - Exchange of relevant patient information, such as notes, test results, procedures, and prescriptions.
Clinical Integration

Structural and Operational Components

• Dedicated employees --
  • E.g., Medical Director, Medical Informatics Officer, Director of Q.A.;

• Financial contribution by all physicians – membership fees, contributions to computer infrastructure, and “sweat equity” by committee participation, protocol design and creation, and peer review.
Clinical Integration
Protocols and Benchmarks

- Development and implementation of clinical protocols sufficient to cover many network specialties, including a broad spectrum of diseases and disorders;
- Development of evidence based quality and efficiency goals and benchmarks above current levels;
- A formal program for review of individual physician performance, considering protocol compliance and network benchmarks;
- A formal program for identifying providers failing to apply the protocols or achieve network benchmarks;
- A corrective action program for those providers; and
- Sanctions for failing to meet the benchmarks, including expulsion.
Clinical Integration
Advisory Opinions & Other Statements

• In re Norman Physician Hospital Organization (Feb. 13, 2013)
• In re TriState Health Partners, Inc. (April 13, 2009)
• In re Greater Rochester Independent Practice Association (Sept. 17, 2007)
• In re Follow-Up to 2002 MedSouth, Inc. Advisory Opinion (June 18, 2007)
• In re Suburban Health Organization (March 28, 2006)
• In the Matter of North Texas Specialty Physicians (December 1, 2005)
• In the Matter of California Pacific Medical Group, Inc. (April 5, 2005)
• In re MedSouth, Inc. (Feb. 19, 2002)
Clinical Integration

*In re Norman Physician Hospital Organization*

- Latest clinical integration advisory opinion by the FTC and only one issued since enactment of Affordable Care Act and issuance of FTC/DOJ Joint Policy Statement regarding ACOs.

- The structure of Norman PHO was comprised of:
  - Norman Physicians Association (280 PCPs and specialists in 38 areas), and
  - Norman Regional Health System which operates hospitals and family medical centers in Norman, Oklahoma.
Clinical Integration

*In re Norman Physician Hospital Organization*

- Proposed clinical integration program:
  - Significant number of clinical guidelines and continuous reassessment of their appropriateness;
  - Significant time and financial investment in EMR to enable physicians to use quality parameters in treating patients, streamline prescriptions and reduce errors, facilitate physician-to-physician communication, and enable data collection to evaluate performance;
  - Physicians required to use EMR and make their data available;
  - Set eligibility criteria and selectivity on which physicians can join;
  - Physicians must commit significant time to development of guidelines;
  - Ongoing financial contribution; and
  - Penalties for noncompliance, including expulsion.
Clinical Integration

In re Norman Physician Hospital Organization

- Limited spillover anticompetitive effects:
  - Antitrust compliance training;
  - Control of flow of competitively sensitive information.
- Expected benefits identified, but not quantified.
- Non-exclusive network:
  - Physicians had to participate in contract;
  - But payors could choose to contract with just certain physicians.
- Joint contracting ancillary to goals of clinical integration:
  - Necessary to maintain consistent panel of providers with shared commitment to clinical integration.
  - However, this does not support a rationale that physicians need to receive higher rates in order to be incentivized to participate.
# Agency Guidance

## Proposed Clinical Integration Compared

<table>
<thead>
<tr>
<th>Name</th>
<th>MedSouth</th>
<th>Brown &amp; Toland</th>
<th>NTSP</th>
<th>SHO</th>
<th>GRIPA</th>
<th>TriState</th>
<th>Norman</th>
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<tbody>
<tr>
<td>Exclusive or Nonexclusive?</td>
<td>Non</td>
<td>Non</td>
<td>Non</td>
<td></td>
<td>Exclusive</td>
<td>Non</td>
<td>Non</td>
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<tr>
<td>Multi-specialty?</td>
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<td>Yes</td>
<td>Yes</td>
<td>Yes</td>
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<tr>
<td>Implemented Clinical Protocols?</td>
<td>Yes</td>
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<td>No</td>
<td>Yes</td>
<td>Yes</td>
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<td>Protocols cover substantial amount of conditions covered by group?</td>
<td>Yes</td>
<td>Yes</td>
<td>No</td>
<td>No</td>
<td>No</td>
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<tr>
<td>Authority to Discipline Physicians?</td>
<td>Yes</td>
<td>Yes</td>
<td>No</td>
<td>No</td>
<td>No</td>
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<td>Healthcare IT System Implemented?</td>
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<td>No</td>
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<td>Yes</td>
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<td>Sharing of Clinical Information?</td>
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<td>No</td>
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<td>Yes</td>
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<td>Monitoring of Performance?</td>
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<td>No</td>
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<td>Yes</td>
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<td>In-network referrals?</td>
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Single Entity?

• If a collaboration of otherwise competing or potentially competing entities can be deemed a single entity, then there is no plurality of actors required for a Sherman Act, Section One violation.

• *Maricopa County* (1982) held “single-entity status applies [to] partnerships or other joint arrangements in which persons who would otherwise be competitors pool their capital and share the risks of loss as well as the opportunity for profit.”

• *Copperweld* (1984) held parent and wholly-owned subsidiary comprise a single entity, because they have a complete “unity of interest”; objectives are “common, not disparate”; actions guided by “single corporate consciousness”; and subsidiary subject to momentary assertion of control by parent.

• *American Needle* (2010) held the inquiry is not whether two parties who allegedly have entered into an anticompetitive agreement are legally distinct entities nor whether they have organized themselves under a single umbrella or structured joint venture; the relevant question is whether the agreement joins together “independent centers of decision-making.”
Single Entity?

**Medical Ctr. at Elizabeth Place v. Premier Health Partners**

- Small acute-care hospital in Dayton, Ohio filed Section 1 claim against competing hospital network, alleging anticompetitive concerted action to prevent insurers from contracting with plaintiff.
- Defendant Premier Health comprised of four acute-care hospital systems serving Dayton who joined together under JOA.
- No formal asset combination – hospitals maintained ownership of assets.
- Contractual agreement to share profits and losses according to predetermined formulas independent of individual revenue or profitability.
- All operational, strategic, and financial decisions delegated to Premier Health.
- Chief executives at each hospital reported up to executive at Premier.
- Premier Health negotiated payor contracts on behalf of member hospitals.
- Remained separate legal entities; filed separate tax returns.
- Evidence of continuing competition for patients.
The District Court held that the previously-competing health care systems who joined together in this arrangement were a single entity incapable of conspiring with each other under Section 1.

Sixth Circuit Court of Appeals reversed in 2-1 decision.

- “Based on [evidence of anticompetitive behavior and intent], evidence of continued actual and self-proclaimed competition among the defendant hospitals, and evidence that defendants’ hospital operations were not entirely unitary, we conclude that there is a genuine issue of material fact as to whether defendant hospitals network constitutes a single entity or concerted action.”
- There was a basic disagreement between majority and dissent about how to apply American Needle and Copperweld.
- Majority relies on incomplete integration of operations, evidence of continuing competition, separate ownership of assets, and nature of anticompetitive conduct and intent to disregard significant contractual financial integration.
Single Entity?

*Partially-owned healthcare entities after Copperweld*

- 99, 90, 80, 70, 51 – okay? What about 50/50?
- For some, test is “de minimus.”
- Others, question is “control.”
  - Ownership/voting control aligned?
  - Minority rights; supra-majority votes.
- Unity of interest? Independent centers of decision-making? Pooling of capital and sharing risk of loss and opportunity for profits? Sufficient integration?
Minimizing Antitrust Risk

- Practical Tips to Minimize Antitrust Risk:
  - Press for deal structures that create as much financial integration as possible consistent with joint venturers' objectives
  - Prepare the "ancillarity case" early
  - Document procompetitive benefits of the proposed JV, from the outset and be ready to substantiate
  - Remember: procompetitive benefits are those that benefit patients and other consumers, not what benefits the JV participants
  - As always, control creation of documents by principals and consultants that discuss intent or ability to raise prices or reduce output
Minimizing Antitrust Risk

- Safeguard against "spillover" outside the parameters of the JV ("Firewalls"):
  - Strict confidentiality procedures to safeguard exchange of competitively sensitive information outside the parameters of the JV, especially plan reimbursement and current/future prices/charges
  - Formal antitrust compliance policy
  - Periodic antitrust compliance training and refreshers
  - Periodic antitrust audits
If the JV is going to depend on either clinical integration or financial integration or both, then those integration's must be built before approaching the plans.

May seem obvious—but particularly with physician oversight and self policing, real cultural barriers to clinical integration execution.

Consequences of failure are high—plans could contact enforcement authorities and defenses are not available in response to investigation. See, e.g., Southwest Health Alliances, d/b/a BSA Provider Network, 2011 WL 11798450 (FTC July 8, 2011)
Where Things Are Going

- Co-Management Agreements in physician hospital organizations—really contractual JV without necessarily exchanging or repositioning assets, or creating new corporate structures
- "Narrow Networks"—vertical integration by carriers—contracts with hospitals to select physicians and create PHOs
- Outpatient Facilities "Co-Management" Agreements – Hospitals and Private Management companies contract or create JVs to manage outpatient "Lines of Business" – antitrust issues when some facilities managed together and competing facilities managed separately – billings through hospital license or separately – unsettled antitrust issues
- Provider side healthcare management and assistance with self-insurance without necessarily obtaining insurance licenses
- Increased vertical integration – health plans buying downstream providers