ACOs & Antitrust

January 27, 2011

Jane Willis
Ropes & Gray
Jane.Willis@ropesgray.com
617.951.7603

Timothy McCrystal
Ropes & Gray
Timothy.McCrystal
617.951.7278

Introduction

1. Objectives of this presentation:
    1. Provide overview of key antitrust principles and apply them to Accountable Care Organizations
    2. Provide overview of current and likely future FTC and DOJ thinking about ACOs

Key Underlying Principles

A. Antitrust analysis regarding cooperative behavior, like provider collaborations, can be broken down into three "boxes"

1. Some conduct is almost always **illegal** (**red** light)
2. Some conduct is almost always **legal** (**green** light)
3. Some (most) conduct is in a "**yellow** light" zone where the answer turns on the facts

Key Underlying Principles (cont.)

4. Antitrust doctrine is something of a continuum:

   a) **Red** light = ***per se* illegal**

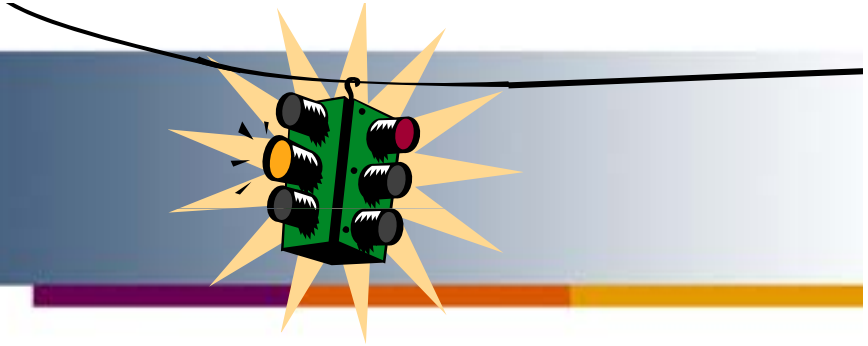
   b) **Yellow** light:

      i. May be presumptively **unlawful**, but certain facts can make this **lawful** (this is called the "**quick look" rule of reason**)

      ii. The type of conduct where a lot of analysis is needed to conclude that the conduct is **legal or illegal** under the **rule of reason**

   c) **Green** light: facts quickly lead you to the conclusion that the conduct is **reasonable**.

ACOs: Yellow Light



A. ACOs are considered a type of joint venture

1. Many joint ventures are considered pro-competitive
2. It's the *restraints* that can raise antitrust issues (moving from green light to yellow light, and sometimes even red)
   a) Agreement on pricing/joint contracting
   b) Dividing up patients, services, territories

Yellow Light: DOJ/FTC Guidance

B. Guidance: how do we know what the DOJ/FTC will consider red/yellow/green in health care context?

1. 1996 Health Care Statements

   a) Describes generally agreements/arrangements that are pro-competitive and anti-competitive

   b) Focuses mostly on physicians

2. Advisory Opinions

   a) Very fact-specific

   b) Difficult, burdensome process

Yellow Light: DOJ/FTC Guidance

3. To engage in joint contracting (or have other significant restraints), the DOJ/FTC take the position that:

a) The parties must be substantially financially and/or clinically integrated (since 2002, FTC has recognized that clinical integration alone can be enough)

b) Joint contracting must be necessary to realize those efficiencies

c) Providers must not have combined presence of more than 25/30 percent (exclusive/non-exclusive)

Yellow Light: Clinical and Financial Integration

A. What is financial integration?

1. Sharing of "substantial financial risk"
2. May include:
   a) Providing services to a health plan at a capitated rate
   b) Providing designated services or classes of services to a health plan for a predetermined percentage of premium or revenue from the plan
   c) Significant financial incentives for provider participants, as a group, to achieve specified cost-containment goals

Yellow Light: Clinical & Financial Integration

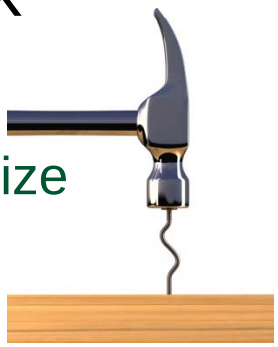
B. What is clinical integration?

A provider joint venture, controlled by physicians (including primary care and specialists), in which systems and procedures have been established that promote greater interdependence and joint responsibility such that physicians work in coordinated fashion to pool infrastructure and resources and implement guidelines/protocols to furnish higher quality care more efficiently

Yellow Light: Clinical & Financial Integration

C. Key elements of a clinically integrated network

1. Participants



a) Primary care and broad range of specialists to maximize efficiencies

b) May commence with relaxed participation criteria and gradually adopt more stringent requirements with experience

c) Look to providers who will further efficiencies of network

Yellow Light: Clinical & Financial Integration

2. Provider interaction
   a) May require referrals within the network, where feasible
   b) Sharing of clinical data among participants through common IT systems
3. Infrastructure
   a) Development of information system
      i) May include lab, clinical and radiological records, treatment plans, clinical guidelines support, on-line prescriptions and prescription information, patient satisfaction surveys
   b) Education of providers in use of information system

ACOs: Overview

A. Intended to provide coordinated or integrated provider care to a group of patients in an effort to reduce costs and improve quality
   1. Goal is to pay providers in a way that encourages providers to work together, discourages supplier-induced demand, and rewards high quality of care

B. Patient Protection and Affordable Care Act of 2010 directs CMS to create national voluntary program for ACOs by January 2012
   1. Act also allows CMS to waive or reduce regulation of communications between organizations with respect to ACOs

Patient Protection and Affordable Care Act (PPACA)

A. The PPACA established several initiatives:

1. The Medicare Shared Savings Programs initiative (the "Medicare ACO program")
2. The Medicaid pediatric ACO demonstration project (the "Medicaid ACO program")
3. Pilot programs involving bundled payments for select conditions to promote care coordination
4. Funding of ongoing studies and implementation of innovative payment models

PPACA: Medicare ACO Program

B. Participating ACOs will be eligible for the share savings bonus if:

1. They meet the applicable quality standards and
2. The estimated average per capita Medicare expenditures under the ACO for fee-for-service beneficiaries (adjusted for beneficiary characteristics) is below a benchmark established by the Secretary by a percentage also to be established by the Secretary

PPACA: Medicare ACO program

C. In connection with the Medicare ACO program, the Secretary is given waiver authority for:

1. The Civil Monetary Penalties statute
2. Anti-kickback Statute
3. All of the Medicare-specific statutes under Title XVIII of the Social Security Act, which contains the Stark law

D. There is NO waiver authority for Antitrust

ACOs: General Structure

A. ACOs may be organized and include physicians, hospitals, nursing homes, and other organized delivery systems

B. Five types of ACOs allow for flexibility:

1. Integrated delivery systems
2. Multispecialty group practices
3. Physician-hospital organizations
4. Independent practice associations
5. Virtual physician organizations

ACOs: The Antitrust Issues

A. From an antitrust perspective, ACOs are provider joint ventures

B. Three issues

   1. Combined market share of the providers
   2. What restraints are there?
   3. Flow of competitively sensitive information

C. How much do efficiencies and pro-competitive benefits matter?

ACOs: Structure & Antitrust

A. There is no “magic bullet” structure that avoids antitrust scrutiny all together

B. If the participating providers have high market share and insurance companies are concerned, the DOJ/FTC will investigate regardless of HSR

C. However, whether an ACO requires an HSR filing can, at the margins, affect antitrust risk

ACOs: FTC's History in Health Care Antitrust

A. FTC philosophy: Antitrust improves health care in two ways:

1. By preventing/stopping anticompetitive agreements, antitrust enforcement saves consumers money
2. Enforcement preserves free competition, which spurs innovation and improves quality of care

ACOs: FTC's History in Health Care Antitrust

B. Aggressive enforcement

1. Hospital merger enforcement

a) Evanston/NW (2005)

i) Non-reportable (too small) merger in suburban Chicago

ii) Prices went up significantly post-merger

iii) FTC (full Commission, not ALJ) rejected Elzinga/Hogarty analysis

iv) FTC lost at ALJ, won on appeal to the Commission

v) Consent prevented joint negotiations

ACOs: FTC's History in Health Care Antitrust

b) Inova/Prince William (2007)

- i) Merger investigation in Northern Virginia
- ii) Controversial geographic market definition (D.C. excluded)
- iii) FTC also successfully argued that its merger challenges were subject to lesser standard than DOJ's
- iv) Parties abandoned deal

c) ProMedica/St. Luke's (2011)

- i) Consummated merger investigation in Ohio (both FTC and Ohio)
- ii) Deal signed August 2010, but assets not yet mixed (FTC seeking hold-separate order from judge)
- iii) FTC filed suit on 1/6
- iv) In general acute care inpatient services, deal is a 4-3; in obstetrical services, it's a 3-2

ACOs: FTC's History in Health Care Antitrust

2. Dozens of physician network investigations and enforcement actions over past few years

   a) Minnesota Valley Health Cooperative (2010)

      i) Un-integrated hospitals, physicians, and pharmacies agreed on price-related terms for services

      ii) Consent decree requires separate negotiations

   b) Boulder Valley IPA (2010)

      a) "Classic" IPA case: un-integrated physicians engaged in joint contracting with payors

      b) Concerned joint negotiations that took place from 2001-2006

ACOs: Current DOJ/FTC thinking

A. Lots of talk, little action
   1. Several workshops
   2. Speeches
   3. FTC/DOJ/CMS and other agencies

B. FTC/DOJ remain concerned about provider combinations:

So, the question before us today is: How can we design rules for ACOs that are flexible enough to allow the health care community to collaborate to improve quality and decrease costs – but not to fix prices or create market concentration?
- FTC Chairman Jon Leibowitz

ACOs: Future DOJ/FTC Thinking

A. Three possible outcomes:
   1. DOJ/FTC do nothing, use the health care statements
   2. DOJ/FTC create expedited review, but use health care statements for substantive analysis
   3. DOJ/FTC create new framework entirely

B. Practical considerations

CLE Information

For CLE credit, complete and return Attorney Affirmation form within 48 hours.

Email: professionaldevelopment@ropesgray.com

Fax: +1 617 235 9606

Note: A recording of today's presentation will be made available in a follow-up email.

Thank You For Participating

Time for Questions

- Please submit your questions now to ropesgrayllp@ropesgray.com
- **Note:** A recording of today's presentation will be made available.