The Role of Competition in Integrated Delivery: ACOs, Federal and State Antitrust Law, the State Action Doctrine, and Clinical Integration
Roadmap

- NJ Medicaid ACO Overview
- Antitrust Concerns: Any Exceptions?
  - NJ Antitrust Law
  - Federal Antitrust Law:
    - MSSP Federal Safe Harbor
    - State Action Exception
    - Clinical Integration
NJ Medicaid ACO Overview

S. 2443, P.L.2011, CHAPTER 114 (approved Aug. 18, 2011)

Statutory Objectives

- increase access to care in defined regions
- improve health outcomes and quality as measured by objective metrics and patient experience of care
- reduce unnecessary and inefficient care without interfering with access.
NJ Medicaid ACO Overview
S. 2443, P.L.2011, CHAPTER 114 (approved Aug. 18, 2011)

Key Features:

- Non-profit with governing board
- Regional collaboration and shared accountability
- 100% hospitals/75% primary care providers
- Quality Improvement and Gainsharing Plan
- Community involvement
- Electronic prescribing and EHRs
- Non-exclusive to other ACOs (but only 1 Medicaid ACO per geographic area)
Antitrust Concerns

- Collaborating competitors
- Huge market share
- No risk sharing
- Exclusive Medicaid ACO in region
NJ Antitrust Law

- Clear intent in statute to exempt from state antitrust law:
  - “The Legislature, therefore, intends to exempt activities undertaken pursuant to the Medicaid ACO Demonstration Project that might otherwise be constrained by State antitrust laws”
Federal Antitrust Law

- Sherman Antitrust Act
  - Section 1 makes illegal every contract, combination, or conspiracy in restraint of trade

- Do any exceptions apply?
MSSP Federal Safe Harbor

- Medicare Shared Savings Program
  - some similarities to NJ Medicaid ACOs
- FTC/DOJ Final Statement of Antitrust Enforcement Policy Regarding ACOs Participating in the MSSP (10/20/2011)
  - Federal Safe Harbor
    - PSA – 30%
  - hospitals and ASCs must be non-exclusive to the ACO
MSSP Federal Safe Harbor

- Does not include NJ Medicaid ACOs
  - Formally: Only applies to collaborations among otherwise independent providers and provider groups that are eligible and intend, or have been approved, to participate in the MSSP
  - Substantively: far exceed PSA market share percentage cap
State Action Exception

- **Midcal elements:**
  - State must articulate a clear and affirmative policy to allow the anticompetitive conduct
  - State must provide active supervision of anticompetitive conduct undertaken by private actors

State Action Exception

- Statute seems to satisfy 1st element
  - “The Legislature, therefore, intends . . . to provide immunity for such activities from federal antitrust laws through the state action immunity doctrine”

- Focus on active supervision requirement
State Action Exception

What constitutes active supervision?

“requires that state officials have and exercise power to review particular anticompetitive acts of private parties and disapprove those that fail to accord with state policy.”

State must exercise sufficient independent judgment and control

State Action Exception

- FTC’s Report of the State Action Task Force:
  - develop an adequate factual record, including notice and opportunity to be heard
  - Issue written decision on the merits
  - Perform “a specific assessment – both qualitative and quantitative – of how the private action comports with the substantive standards established by the state legislature”
Applicability of the State Action Exception to NJ Medicaid ACOs

- Some features of oversight in legislation:
  - Clear intent for state oversight
  - Certification & Gainsharing Plan approval processes
  - Data reporting
  - Public comment
  - Annual review

- What will regulations require?
- How will State implement oversight?
Ways to Distinguish State Action Guidance

- This is NOT collective bargaining over reimbursement rates; only shared savings
- Clinical integration
- Quality overlay – emphasis on measuring and improving
- Consumer input
- Medicaid not Medicare, so less risk of creep into commercial markets
Clinical Integration

Substantial clinical integration

likely to produce significant efficiencies that benefit consumers

agreements reasonably necessary to realize procompetitive benefits of integration

Rule of Reason Review
Clinical Integration: Rule of Reason

“A rule of reason analysis evaluates whether the collaboration is likely to have anticompetitive effects and, if so, whether the collaboration’s potential procompetitive efficiencies are likely to outweigh those effects. The greater the likely anticompetitive effects, the greater the likely efficiencies must be for the collaboration to pass muster under the antitrust laws.”

- Not a safe harbor
- Some uncertainty
Clinical Integration

- DOJ/FTC Statements of Antitrust Enforcement Policy in Health Care (1996)
  - Statements 8 & 9
- TriState Health Partners, Inc. Advisory Opinion (F.T.C. Apr. 13, 2009)
- FTC/DOJ Final MSSP ACO Statement (2011)
Clinical Integration

- Indicia of Integration
  - Goals of improving quality and efficiency

- Implementing an active and ongoing program to evaluate and modify practice patterns by the venture’s providers and to create a high degree of interdependence and cooperation among the providers to control costs and ensure quality
Clinical Integration

- TriState: received favorable review
  - Mechanisms to monitor and control utilization of health care services designed to control costs and assure quality
  - Selectively choosing network physicians likely to further efficiency goals
  - Significant investment of capital (monetary and human) in infrastructure required to realize efficiencies
Clinical Integration: FTC/DOJ Final ACO Statement

- Conduct all ACOs generally should avoid:
  - Improper Sharing of Competitively Sensitive Information
    - “should refrain from, and implement appropriate firewalls or other safeguards against, conduct that may facilitate collusion among ACO participants in the sale of competing services outside the ACO”
Clinical Integration: FTC/DOJ Final ACO Statement

- Conduct that ACOs with high PSA shares or other possible indicia of market power may wish to avoid:
  - Preventing or discouraging private payers from directing or incentivizing patients to choose certain providers (e.g., “anti-steering”)
  - Tying sales of the ACO’s services to the private payer’s purchase of other services from providers outside the ACO (and vice versa)
  - Contracting on an exclusive basis with ACO physicians, hospitals, ASCs, or other providers
  - Restricting a private payer’s ability to make available to its health plan enrollees cost, quality, efficiency, and performance information to aid enrollees in evaluating and selecting providers
Clinical Integration

- FTC/DOJ Final ACO Statement:
  - “CMS’s eligibility criteria are broadly consistent with the [necessary] indicia of clinical integration”
  - Organizations meeting the MSSP eligibility requirements “are reasonably likely to be bona fide arrangements intended to improve the quality, and reduce the costs, of providing medical and other health care services through their participants’ joint efforts”
Clinical Integration

- MSSP eligibility requirements:
  - a formal legal structure that allows the ACO to receive and distribute payments for shared savings;
  - a leadership and management structure that includes clinical and administrative processes;
  - processes to promote evidence-based medicine and patient engagement;
  - reporting on quality and cost measures; and
  - coordinated care for beneficiaries.
Clinical Integration

- Indicia of Integration in NJ Medicaid ACOs:
  - express statutory objective of integration
  - Data reporting on quality
  - Not negotiating price/just sharing efficiency gains
  - Non-exclusive (except for Medicaid ACOs in same)
  - Includes range of specialists
  - Referrals within ACO
  - Electronic prescribing/EHRs
Clinical Integration

- Possible Yellow Flags for NJ Medicaid ACOs:
  - No financial investment
  - Although costs for EHR?
  - Any ability to exclude non-complying provider?
  - Exclusive Medicaid ACO in geographic region
Clinical Integration

- competitive restraints “ancillary” to the joint venture?
  - Strong argument – need market share to solve entrenched problems/improve care/realize efficiencies
- But role of market share in analysis?
  - Rule of reason balancing
  - Will need to show network is not overinclusive
  - Need safeguards to prevent anticompetitive spillover
Clinical Integration

- Extent to which Medicaid is just different:
  - Broken markets
  - Geographically contained
  - Limited duration demonstration project
  - Less risk of spillover into commercial markets
What does all this mean for Medicaid ACOs in NJ?
What does all this mean for Medicaid ACOs in NJ?

- FTC wants to encourage innovation, quality improvement, and care integration
- These are cornerstones of NJ’s Medicaid ACO Demonstration Project
  - Limited opportunity for collusion
  - Checks on quality and access
- Need to build as much into regulations as possible to address requirements of state action and clinical integration
- Some uncertainty because of market concentration and lack of risk sharing, but distinct from prior models
What does all this mean for Medicaid ACOs in NJ?

**FTC Advisory Opinions**
Health Care Division  
Bureau of Competition  
Federal Trade Commission  
Washington, D.C. 20580  
(202) 326-2756

**DOJ Business Review Letters**
Legal Procedure Unit  
Antitrust Division  
U.S. Department of Justice  
Suite 215  
325 7th St., NW  
Washington, D.C. 20530  
(202) 514-2481
Special Thanks

- Profs. Tim Greaney and John Jacobi
- SHU Law Research Assistants John Barry and Jonathan Koller
- Photos from Creative Commons