Antitrust Regulatory Issues and Government Guidance for Prospective ACOs

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Accountable Care Organizations ("ACOs")

- Health reform law provides for provider-sponsored ACOs in Shared Savings Program ("SSP") under fee for service Medicare program
- CMS originally proposed antitrust pre-screening mechanism to deny participation to ACOs hitting antitrust risk threshold that do not get favorable advance review from FTC or DOJ
- FTC and DOJ proposed new policy guidance
- CMS final rule abandons mandatory prior antitrust review. 76 Fed. Reg. 67,806 (Nov. 2, 2011)
- Antitrust agencies issue revised final guidance, including new "safety zone" -- Statement of Antitrust Enforcement Policy Regarding Accountable Care Organizations Participating in the Medicare Shared Savings Program, 76 Fed. Reg. 67,026 (Oct. 28 , 2011)
- CMS will give antitrust agencies aggregate claims data on allowed charges and fee-for-service payments for ACOs accepted into the SSP and copies of SSP applications of ACOs formed after March 23, 2010.

New FTC-DOJ enforcement policy on ACOs

- FTC-DOJ guidance applies to all Medicare ACOs, including those that wish to contract with commercial payers, regardless of date of formation
- New “safety zone” for ACOs meeting specific standards
- Safety zone applicability tied to provider membership relative to provider participation thresholds in defined “Primary Service Areas” (“PSAs”).

Antitrust Issues – Clinical Integration

- Prior antitrust guidance indicated that providers could avoid application of "per se" rule against price-fixing for joint negotiations with payers if they are (1) financially integrated via risk sharing or (2) clinically integrated and price negotiation by the provider network is reasonably necessary for venture to work.
  - Under 1996 policy statement, clinical integration is shown by implementing an ongoing program to evaluate and modify practice patterns by provider participants and creating a high degree of interdependence and cooperation among providers to control costs and ensure quality.
- New Enforcement Policy confirms that satisfaction of CMS's requirements to be an ACO under the SSP would be sufficient to defeat per se pricing treatment of joint price negotiations by the ACO with commercial payers:
  - [I]f a CMS-approved ACO provides the same or essentially the same services in the commercial market, . . . [t]he [CMS] integration criteria are sufficiently rigorous that joint negotiations with private-sector payers will be treated as subordinate and reasonably related to the ACO's primary purpose of improving health care services. . . . [T]he Agencies will provide rule of reason treatment to an ACO if, in the commercial market, the ACO uses the same governance and leadership structure and the same clinical and administrative processes.

New Safety Zone

- The Agencies will not challenge Medicare ACOs that fall within a new "safety zone," absent extraordinary circumstances.
- To qualify, every independent ACO participant (e.g., each physician group, individual practitioner, or hospital) that provides the same service ("common service") must have a combined share of 30% or less of each common service in each participant's Primary Service Area, wherever two or more ACO participants provide that service to patients from that PSA.
  - PSA is the "lowest number of postal zip codes from which the [ACO participant] draws at least 75 percent of its patients."
  - PSA to be score separately for each independent provider
  - in ACO. CMS to make Medicare data available for calculations.

New Safety Zone

- Hospitals and ambulatory surgery centers must be "non-exclusive" to the ACO to be in the safety zone, regardless of PSA share.
  - To be non-exclusive, the provider must be allowed to contract individually or affiliate with other ACOs or commercial payers.
  - Exclusivity will be assessed based on practical realities, rather than simply by nominal phrasing of organizational documents or contracts.
- "Dominant provider limitation" if an individual provider in the ACO has a share in a PSA greater than 50% of any service that no other ACO participant provides to patients in the PSA.
  - Where the limitation applies, the provider must be non-exclusive to the ACO in order to qualify for the safety zone.
- Rural exception permits inclusion of one physician or group in any specialty regardless of share

Suspect behavior?

- Agencies flag four types of conduct that may be OK, but where present could raise potential competition concerns:
  - Use of "anti-steering," "anti-tiering," "guaranteed inclusion," "most-favored-nation," or similar clauses to discourage payers from directing or incentivizing patients to choose certain providers
  - Tying, expressly or via pricing policies, ACO's services to payer's purchase of other services from providers outside the ACO venture (and vice versa)
  - Contracting on an exclusive basis with providers
  - Restricting a payer's ability to make cost, quality, efficiency, and performance information available to enrollees, if it is similar to information used in Medicare Shared Savings Program
- When might any of these actions itself be an antitrust violation?

Review process

- Agencies will provide process for expedited voluntary requests for review
- For ACOs that do not qualify for safety zone, agencies will consider a range of information suggesting that PSA shares may not reflect actual market power
- They will also consider pro-competitive justifications

Determining PSA share levels

- To perform the PSA calculations, an ACO must: (1) identify each service provided by two or more independent ACO participants; (2) collect patient zip code data from those participants; (3) collect coding or billing data from those participants (which may or may not be in the same computer file as the zip code data); and (4) match the zip codes to the Medicare Specialty Codes ("MSCs") (in the case of physicians), outpatient treatment categories (in the case of outpatient facilities), or Major Diagnostic Categories ("MDCs") (in the case of hospitals).
- Then the ACO must match Medicare fee-for-service allowed charges (physicians), Medicare fee-for-service payments (outpatient facilities), or inpatient discharges (hospitals) to the zip codes and specialty codes or categories.