Client Advisory

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Health Care

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FTC/DOJ STATEMENT OF ANTITRUST ENFORCEMENT POLICY REGARDING ACCOUNTABLE CARE ORGANIZATIONS PARTICIPATING IN THE MEDICARE SHARED SAVINGS PROGRAM

A. Background

The FTC and DOJ's Final Statement addresses a concern expressed by physicians, hospitals and other health care providers regarding how the FTC and DOJ would evaluate the impact of ACOs participating in the Shared Savings Program and their expected interaction and negotiation with commercial payors in light of existing enforcement standards as reflected in the Statements of Antitrust Enforcement Policy in Health Care (1996), the revised Horizontal Merger Guidelines (2010), other related antitrust guidelines and the relevant advisory opinions issued by the FTC (collectively, the Antitrust Standards). In particular, providers were seeking additional flexibility so as to promote and support collaborations among otherwise competing providers, as well as additional clarity on whether ACOs would be presumed to be "clinically integrated" in light of the requirements for certification set forth under the Affordable Care Act. In response to numerous comments and criticisms voiced by individual commentators and trade associations, a number of significant changes ultimately were made. These are summarized below.

B. Summary of Final Statement

- The Final Statement applies to "all collaborations among otherwise independent providers and provider groups that are eligible and intend, or have been approved to participate in the Medicare Shared Savings Program." The Proposed Rule had only applied to collaborations formed after March 23, 2010.
- "Collaboration" is defined as a "set of agreements, other than merger agreements, among otherwise independent entities jointly to engage in economic activity, and the resulting economic activity."
- In light of the degree of clinical integration that must be achieved in order for an ACO to be certified by CMS, in addition to other requirements such as the establishment of a formal legal and governance structure, ACOs that are certified by CMS "are reasonably likely to be bona fide arrangements intended to improve the quality, and reduce the cost, of providing medical and other health care services through their participants' joint efforts."
- The Agencies therefore will apply a "rule of reason" as opposed to the "per se" analysis to a certified ACO in the commercial market if it "uses the same governance and leadership structure and the same clinical and administrative processes as it uses in the Shared Savings Program."
- The rule of reason treatment will apply to an ACO for the duration of its participation in the Shared Savings Program, which will allow the ACO to introduce and the Agencies to consider various community benefits and other factors to offset actual or perceived anti-competitive effects of the ACO's operations and practices.

C. Antitrust Safety Zone for ACOs

- ACOs that fall within the "safety zone" as described below will not be subject to challenge by the Agencies "absent extraordinary circumstances."
- Independent ACO participants that provide the same "common service" must have a combined share of 30% or less in each common service in each participant's primary service area (PSA) whenever two or more ACO participants provide that service to patients from that PSA.

- The PSA for each service is defined as "the lowest number of contiguous postal zip codes from which the ACO participant draws at least 75% of its patients for that service." While this standard does not reasonably reflect the true relevant geographic market, it is used as a "screen for evaluating potential anticompetitive effects."
- There are three major categories of services: physician specialties; major diagnosis categories for inpatient facilities; and CMS outpatient categories for outpatient facilities.
- Each ACO participant will have its own PSA, which must be calculated.
- A hospital will have a separate PSA for its inpatient services, its outpatient services and its physician services provided by physician employees.
- Hospitals or surgery centers participating in an ACO must be nonexclusive to the ACO in order to fall within the safety zone, irrespective of its PSA share.
- An ACO may still enter into exclusive arrangements, but it would not qualify for the safety zone.
- "Nonexclusive" means that the hospital or ASC is allowed to contract individually or affiliate with other ACOs or commercial payors.
- The safety zone applies to physicians and other providers irrespective of whether they are exclusive or nonexclusive to an ACO unless they fall within the rural exception or the dominant participation limitation.
- The safety zone only applies to ACOs participating in the Shared Savings Program. Otherwise, providers must comply with the more restrictive Antitrust Standards.
- Failure to fall within the safety zone does not mean that the ACO arrangement is in violation of the Antitrust Standards and applicable laws.

D. Calculation Methodology for PSA Shares of Common Services

- For physician services, first identify each service provided by at least two independent ACO participants as determined by the CMS Medicare Specialty Code.
  - "Primary care" is defined to include general practice, family practice, internal medicine and geriatric medicine as a single or common service.
- For inpatient facilities, a service is a Medicare Diagnostic Category.
- For outpatient facilities, a service is an outpatient category defined by CMS.
- Next, identify the PSA for each common service, for each participant (e.g., physician group, hospital, surgery center) in the ACO. For each common service and for each participant, the PSA is defined as the lowest number of postal zip codes from which the participant draws at least 75% of its patients for that service.
- Finally, calculate the ACO's PSA share for each common service in each PSA in which at least two ACO participants serve patients for that service.
  - Physician services: Calculate the ACO's shares of Medicare FFS-allowed charges during the most recent calendar year for which data are available.
  - Outpatient services: Calculate the ACO's shares of Medicare FFS payments during the most recent calendar year for which data are available.
  - Inpatient services: Calculate the ACO's shares of inpatient discharges using state-level all-payor hospital discharge data, where available.

E. Rural Exception

- Physicians: An ACO may include one physician or physician group practice per specialty for each rural county on a nonexclusive basis even if inclusion causes the ACO's share of any common service to exceed 30% in any ACO participant's PSA for that service.
- To qualify, the practice must be treating patients as a fully integrated group as of October 20, 2011, and the number of FTE physicians does not increase during the agreement period.

- Hospitals: An ACO may include rural hospitals on a nonexclusive basis even if inclusion causes the ACO's share of any common service to exceed 30% in any ACO participant's PSA for that service.
- A rural hospital is defined as a Sole Community Hospital or Critical Access Hospital under CMS regs, or any other acute care hospital that has 50 beds or less and is located at least 35 miles from another hospital.

F. Dominant Provider Limitation

- If an ACO includes a participant with a greater than 50% share in its PSA for any service that no other ACO participant provides to patients in the PSA, the "dominant provider" must be nonexclusive.
  - To remain in the safety zone, the dominant provider cannot require a commercial payor to contract exclusively with the ACO or otherwise restrict the commercial payor's ability to contract or deal with other ACOs or provider networks.

G. Mandatory Review of ACOs Exceeding 50% PSA Share Threshold Is Eliminated in Final Rule

- Under the Proposed Rule, an ACO exceeding the 50% PSA share threshold for any common service involving two or more independent participants could not qualify for the rural exception unless it obtained a letter from the FTC or the DOJ stating that the reviewing Agency has "no present intention to challenge or recommend challenging the ACO under the antitrust laws."
- This requirement was eliminated, although the ACO can seek a voluntary expedited review.
- Under these circumstances, the Agencies will provide an expedited review of any request upon submission of the required documentation under CMS's Final Rule, which must be received by the reviewing Agency at least 90 days before the last day in which CMS will accept ACO applications for the relevant calendar year. (For a list of the documentation requirements, click here.)

H. ACOs Falling Outside Safety Zone

- If an ACO falls outside of the safety zone, it does not mean that the ACO is illegal, nor that it will be subjected to an Agency investigation.
- ACOs are not required to seek Agency review before seeking certification but can still request an expedited review.
- Providers in this category need to avoid the following types of conduct:
  - Preventing or discouraging commercial payors from directing or incentivizing patients to choose certain providers, including providers that do not participate in the ACO, through "anti-steering," "guaranteed inclusion," "product participation," "price parity" or similar contractual clauses or provisions.
  - Tying sales (either explicitly or implicitly through pricing policies) of the ACO's services to the commercial payor's purchase of other services from providers outside the ACO (and vice versa), including providers affiliated with an ACO participant (e.g., an ACO may not require a purchaser to contract with all the hospitals in the same network as the hospital that belongs to the ACO).
  - With an exception for primary care physicians, contracting with other ACO physician specialists, hospitals, ASCs and other providers on an exclusive basis, thus preventing or discouraging them from contracting outside the ACO, either individually or through other ACOs or provider networks.
  - Restricting a commercial payor's ability to make available to its health plan enrollees cost, quality, efficiency and performance information to aid enrollees in evaluating and selecting providers in the health plan, if that information is similar to the cost, quality, efficiency and performance measures used in the Shared Savings Program.
  - Sharing among the ACO's provider participants competitively sensitive pricing or other data that they could use to set prices or other terms for services they provide outside the ACO.

I. Expedited Review

- A newly formed ACO that, as of March 23, 2010, had not signed or jointly negotiated a contract with a commercial or private payor, can seek antitrust guidance through a voluntary expedited 90-day review process as long as all documentation required under the Final Statement is provided.

Comments and Recommendations

- ACOs intending to seek CMS certification need to quickly determine which providers are going to participate, whether employed, affiliated, in a joint venture or under contract.
- Market shares in each common service for each participant's PSA need to be determined.
  - Proposed methodology for calculating market shares is more of a proxy determination. If initial calculation puts an ACO outside the safety zone, the ACO can consider a more detailed market analysis for submission to the Agencies for their consideration if concerned about possible antitrust risk.
- Determine whether an ACO falls within the safety zone in each area of common service in all applicable PSAs. If not, the ACO should reevaluate whether to reduce the number of participants, accept the risk of being outside the safety zone or seek an expedited review.
- If an ACO intends to contract with commercial payors, it must maintain the same governance, leadership and other requirements for ACO certification when engaging in negotiations in order to take advantage of the proposed safety zone.
- Depending on the nature of the payor agreement, participating in "at risk" arrangements may be viewed as "financial integration," which also would trigger a rule of reason analysis.
- An ACO must be careful to avoid the high risk activity identified in this Advisory and in the Final Statement in order to mitigate against an Agency investigation, a private challenge or possible loss of ACO certification.

J. Appendix

- There is an Appendix that explains how to calculate the PSA shares for common services and gives examples. Click here to view.

Contact Us

If you have any questions about the Final ACO Rule or ACO participation, please contact your Katten Muchin Rosenman LLP attorney, or any of the following members of **Katten's Health Care Practice**.

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