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FTC/DOJ Final Policy on Accountable Care Organizations: Important Antitrust Issues Remain Uncertain for Healthcare Collaborations

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The Federal Trade Commission (FTC) and Department of Justice (DOJ) (together, the Agencies) issued their final "Statement of Antitrust Enforcement Policy Regarding Accountable Care Organizations Participating in the Medicare Shared Savings Program" (Policy Statement) on October 20, on the same day that the Centers for Medicare and Medicaid Services (CMS) issued extensive regulations governing the formation, registration, and operation of accountable care organizations (ACOs). The Policy Statement outlines in general terms the standards the Agencies will apply in analyzing the legality of ACO formation and conduct under the antitrust laws. ACOs formed pursuant to the CMS regulations are not subject to mandatory antitrust review by the Agencies, but the Agencies have committed to an expedited process for the review of any ACO that voluntarily requests such a review. The Policy Statement also (a) outlines the standard that will be applied in the review by the Agencies (the Rule of Reason), (b) defines a "safe harbor" for ACOs that are below certain market share thresholds, and (c) outlines some conduct by ACOs that would be problematic from the Agencies' perspectives.

The Policy Statement, however, leaves many important questions unanswered:

- How will the Agencies apply the Rule of Reason standard to ACOs, and what level of detail will they require from ACOs to establish the existence of efficiencies from integration and the "reasonable necessity" of integration to achieve those efficiencies? The Agencies have historically been skeptical of the need for integration by healthcare professionals, and have brought many antitrust challenges to healthcare collaborations. Earlier this week, for example, the FTC opposed a proposed New York law that would authorize collective negotiations by healthcare providers with certain health insurers.

- How aggressively will the Agencies pursue post-formation challenges to ACOs (and other healthcare collaborations)? The Policy Statement notes that the Agencies will receive and review data from CMS about the operation of ACOs, including the prices they charge.

- What role will the state attorneys general play? All but one of the states have their own antitrust laws, and state attorneys general have been particularly aggressive in enforcing those laws in the healthcare industry. Although the states have no role in the Medicare system, ACOs organized to also operate in relation to Medicaid or the private market (i.e., Pioneer ACOs) need to consider state antitrust laws and their potentially differing enforcement.

Accountable Care Organizations

The Patient Protection and Affordable Care Act (PPACA), enacted in March 2010 as part of the Obama administration's healthcare reform law, established the Medicare Shared Savings Program (Shared Savings Program) to encourage the formation of ACOs. ACOs are groups of healthcare providers (e.g., physicians, hospitals) that are clinically integrated and jointly offer services to patients across a variety of specialties and in a variety of institutional settings.[1] CMS has responsibility for implementing the Shared Savings Program. In March 2011, CMS issued a proposed rule detailing eligibility criteria for ACOs, and the Agencies issued a proposed joint policy statement (Proposed Statement) detailing the enforcement of antitrust laws regarding ACOs; both proposals were made available for public comment, and both generated a significant number of comments. Last week, CMS issued its final rule concurrent with the Agencies' release of the Policy Statement.

Final Policy Statement

The final Policy Statement eliminated a proposed mandatory review mechanism, and also broadened the scope of its application to all ACOs that are eligible and intend, or have been approved, to participate in the Medicare Shared Savings Program. The final Policy Statement otherwise does not substantially differ from the Proposed Statement. A more detailed explanation of the major elements of the Policy Statement follows:

- **Elimination of Mandatory Review**

  Initially, the Agencies had proposed a mandatory review for any ACO applicant having a 50% or greater share of any common service that two or more independent ACO participants provide to patients in the same primary service area (PSA).[2] The proposed mandatory review process was widely criticized by various healthcare organizations, claiming that ACO applicants would be subject to undue costs and burdens and that the Agencies would exceed their traditional roles as enforcers and become regulators.

  Despite eliminating the mandatory antitrust review, the Agencies cautioned that they will still "vigorously monitor complaints" about an ACO's formation and will take enforcement actions wherever appropriate, "aided by data and information from CMS that will assist the Agencies in monitoring the competitive effects of an ACO." Although ACOs that would have been subject to a mandatory review under the Proposed Statement no longer have a legal obligation to notify the Agencies of their formation, such ACOs are still at risk of post-formation investigations and enforcement actions.

  Given that the Agencies' Proposed Statement stated that a "50 percent share threshold for mandatory review provides a valuable indication of the potential for competitive harm from ACOs

1. Pursuant to CMS regulations, in order to participate in the Shared Savings Program, ACOs must meet several eligibility requirements, including operating through a formal legal structure, having a mechanism for shared governance, and having at least 5,000 Medicare beneficiaries. As an incentive to form ACOs under the Shared Savings Program, ACOs are eligible to share in the Medicare savings by receiving shared-savings payments from CMS, so long as certain quality measures and cost savings thresholds are met.

2. The boundaries of a PSA are determined by the geographically contiguous zip codes that represent 75% of the ACO participant's Medicare-allowed charges.

with high PSA shares," it is likely that ACOs that meet or exceed that threshold—although no longer subject to a mandatory pre-formation review—will nevertheless receive heightened antitrust scrutiny before and after consummation.[3]

- **Voluntary Review**

  The Policy Statement makes a voluntary 90-day expedited antitrust review available to all ACOs formed after March 23, 2010. Given the threat of post-formation antitrust scrutiny, it can reasonably be expected that many ACO applicants with high PSA shares will seek a voluntary review in order to avoid more costly and burdensome potential post-formation scrutiny from the Agencies. If the Agencies provide negative feedback to an ACO, that ACO can adjust its structure or dissolve. A positive response from the Agencies in response to a voluntary review could help reduce the likelihood of a successful antitrust challenge by private parties post-formation.

  Prior to entering the Shared Savings Program, the ACO applicant may submit a request for review to the Agencies, who will promptly notify the applicant whether the FTC or DOJ will conduct the review. In order to begin the 90-day review period, the ACO applicant must then submit to the reviewing agency a variety of documentation, including (1) the ACO application and all supporting documents, (2) documents discussing business strategies and competition, (3) certain competitive and market information, and (4) information related to restrictions that prevent ACO participants from obtaining information regarding prices that other ACO participants charge to private payers that do not contract through the ACO.

  In addition, the ACO applicant may submit additional information and documents pertaining to market power (or lack thereof), pro-competitive justifications, and an explanation as to why the ACO would not be anticompetitive or might be pro-competitive. Within 90 days after receiving all documents and information, the reviewing agency will advise the ACO that the formation of the ACO (1) does not likely raise competitive concerns or does not do so conditioned on the ACO's written agreement to take specific steps to alleviate the agency's concerns, (2) potentially raises concerns, or (3) likely raises competitive concerns.

- **Antitrust Safety Zone**

  Absent extraordinary circumstances, such as evidence of collusion, the Agencies will not challenge ACOs that meet CMS eligibility criteria so long as they meet certain share thresholds within an antitrust "safety zone." With certain exceptions,[4] the antitrust safety zone applies to ACO participants that provide the same service (a "common service") and have a combined share of 30 percent or less of each common service in each participant's PSA, wherever two or more ACO participants provide that service to patients from that PSA. Higher shares of physician practices may still fall within the safety zone if they are in rural areas. This safety zone generally accords

3. Indeed, the FTC's statement in opposition to New York Senate Bill S. 3186-A (NY Healthcare Act) cited to its Proposed Statement as an example of antitrust guidance for healthcare collaborators.

4. Hospitals and ambulatory surgery centers participating in an ACO must be nonexclusive to the ACO in order for a safety zone to apply to that ACO, regardless of PSA share. The Policy Statement further broadens the antitrust safety zone to include certain ACOs that exist in rural areas by allowing such ACOs to include one physician group or physician group practice per specialty from each rural area on a nonexclusive basis, even if the inclusion of such physicians causes the ACO's share to exceed 30% for a common service in any ACO participant's PSA. Similarly, an ACO may include certain rural hospitals on a nonexclusive basis and qualify for the safety zone even if the inclusion causes the ACO's share in a common service to exceed 30% in any ACO participant's PSA.

with the share thresholds recognized in the courts as sufficient to create "market power"—a necessary predicate to any antitrust challenge under the Rule of Reason. ACOs that fall within this safety zone can be reasonably confident that their formation will not be challenged by the Agencies, though it is not clear how state attorneys general will treat such ACOs, as discussed below.

- **Rule of Reason**

  The activities and formation of ACOs that do not fall within the "antitrust safety zone" will generally be evaluated by the Agencies under the Rule of Reason, which weighs the potential anticompetitive effects of collaboration against its potential pro-competitive effects, such as enhancing efficiency.

  The Policy Statement notes that the Rule of Reason will be applied by the Agencies "if providers are financially or clinically integrated and the agreement is reasonably necessary to accomplish the pro-competitive benefits of the integration." The Policy Statement acknowledges, moreover, that CMS's ACO eligibility requirements are generally consistent with the type of clinical integration the Agencies have accepted in the past. However, the failure of the Policy Statement to affirmatively endorse those attributes as sufficient indicia of pro-competitive integration that would meet the Agencies' standards (or to explain situations in which ACOs approved by CMS might nonetheless have their agreements challenged as not "reasonably necessary" for integration) leaves open the possibility that some ACO actions or agreements might be challenged as per se unlawful antitrust violations.

  The Policy Statement also leaves unanswered many questions about how the Rule of Reason might be applied in the context of ACOs. The Policy Statement points to the healthcare guidelines and statements previously issued by the Agencies for an articulation of their policy in the area, but notes that they will rely on future data provided by CMS to "determine whether the CMS eligibility criteria have required a sufficient level of clinical integration to produce cost savings and quality improvements" to meet the Agencies' standards (and the Rule of Reason). Thus, it remains uncertain how the antitrust laws will be applied by the Agencies to healthcare collaborations.

  The Agencies have historically been skeptical of collaborations among healthcare professionals and organizations, and have brought numerous challenges to physician organizations and other collaborations. For example, the FTC responded earlier this week to a New York Senator's request to review the proposed NY Healthcare Act, which would permit healthcare providers to negotiate certain fee-related contract provisions with health plans that have significant a market share. Under the proposed act, the New York Attorney General would have 60 days to conduct a substantive investigation of the competitive impact of the proposed agreement.

  In its response, the FTC noted that it has "consistently challenged such collective negotiations by independent, competing healthcare providers" because of their harmful effects upon competition, including higher prices and less innovation. The FTC further noted that competing providers would have access to each other's competitively sensitive information, which could lead to collusion regardless of whether an agreement with a health plan is ever reached.

- **Activities to Avoid for ACOs with High PSAs**

  The Policy Statement details conduct that ACOs with high PSA shares should avoid in order to reduce the potential for antitrust scrutiny. Notably, these types of conduct were also listed in the Proposed Statement for those ACOs below the mandatory review threshold and outside of the safety zone. Accordingly, it is unclear to what degree avoiding this conduct will protect ACOs with PSA shares above 50% from antitrust scrutiny:

  (1) The use of certain "antisteering," "antitiering," "guaranteed inclusion," "most favored nation," or similar contract provisions.

  (2) Tying sales of the ACO's services to the private payer's purchase of other services from providers outside of the ACO, including those providers affiliated with an ACO participant.

  (3) Contracting on an exclusive basis with ACO physicians, hospitals, ASCs, or other providers that may prevent or discourage those providers from contracting with private payers outside of the ACO, either individually or through other ACOs or analogous collaborations.

  (4) Restricting a private payer's ability to make available to its enrollees certain information about the ACO's cost, quality, and efficiency.

- **Firewalls for All ACOs, Regardless of PSA Shares**

  The Policy Statement also warns ACO participants, regardless of PSA shares or market power, not to share competitively sensitive pricing or other data that they could use to set prices or other terms for services they provide outside the ACO. ACO participants should therefore implement firewalls in order to prevent the dissemination of competitively sensitive information.

- **State Attorneys General**

  The Policy Statement addresses only the enforcement policies of the federal antitrust authorities—the FTC and DOJ. All but one of the states and the District of Columbia also have separate antitrust laws enforced by the states' attorneys general. ACOs that intend to operate in commercial or Medicaid markets, in addition to Medicare, thus must also consider state law and enforcement in addition to the federal antitrust laws and agencies. Many state attorneys general have been particularly active in healthcare markets.

  For instance, Pennsylvania's attorney general recently filed a complaint against the Urology of Central Pennsylvania Inc. (UCPA), an entity formed six years ago when five independent urology practices in Harrisburg, Pennsylvania merged into a single entity. The merger was not reportable to the Agencies pursuant to the Hart-Scott-Rodino Act. The attorney general's action alleged that the merger was anticompetitive in that it gave UCPA an increased ability and incentive to raise prices, and it permitted UCPA "to collectively bargain with area health plans to obtain increases in reimbursement rates for urology services and ancillary services." The parties entered into a settlement whereby UCPA agreed to a series of conduct remedies and fines.

  This case highlights the potential for state antitrust scrutiny of ACOs. Given there is no preemption provision in the PPACA that relates specifically to antitrust, there is a clear potential that the states

will apply their own antitrust laws, possibly with different or more severe antitrust scrutiny than that set out in the Policy Statement.

Key Takeaways for ACO Applicants

- Consider Voluntary Review – An expedited voluntary review will be cheaper and less burdensome than a post-consummation investigation, and any agency concerns identified in the review will be easier to remedy. Given the Agencies' expressed skepticism about ACOs with shares in any PSA in excess of 50%, such ACO applicants should strongly consider taking advantage of the voluntary expedited review process. Additionally, other ACO applicants not within the antitrust safety zone should also consider a voluntary review, depending on PSA shares and other competitive considerations.

- Implementation of Firewalls – All ACOs, regardless of PSA shares, must implement firewalls to prevent the dissemination of competitively sensitive information between competitors. Even those ACOs within the antitrust safety zone are not exempt from antitrust scrutiny if there is evidence of collusion.

- Avoid Potentially Anticompetitive Practices – ACOs not subject to the antitrust safety zone should avoid potentially anticompetitive practices such as those described in the Policy Statement.

- Consider State Laws and Attorneys General – As illustrated by the action brought by Pennsylvania against UCPA, state attorneys general can be expected to investigate and seek action against healthcare collaborations in certain instances.

- Implementation of Internal Controls – Certain internal controls, in addition to firewalls, may reduce antitrust risk.

- Provider Collaboration for Collective Bargaining – The FTC has expressed hostility towards providers collectively bargaining with competing healthcare providers. Prior to implementing a collaborative collective bargaining effort, providers should consult with antitrust counsel.

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