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FTC/DOJ Remove Mandatory Antitrust Review for MSSP-Participating ACOs in Final Policy Statement

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On October 20, 2011, the Federal Trade Commission and Department of Justice issued a final policy statement on accountable care organizations (ACOs) participating in the Medicare Shared Savings Program (MSSP). Significantly, the Agencies eliminated mandatory antitrust review of certain ACOs seeking to participate in the MSSP, but declined to adopt other stakeholder recommendations.

Introduction

On October 20, 2011, the Federal Trade Commission (FTC) and Department of Justice (DOJ and, with the FTC, an Agency, and, collectively, the Agencies) issued a final "Statement of Antitrust Enforcement Policy Regarding Accountable Care Organizations Participating in the Medicare Shared Savings Program" (Policy Statement). The final Policy Statement differs from the Policy Statement the Agencies proposed in March 2011 in a couple of key respects, but does not incorporate many other comments that stakeholders submitted in response to the proposed Policy Statement. Most significantly, the Agencies eliminated mandatory antitrust review prior to participation in the Medicare Shared Savings Program (MSSP) for accountable care organizations (ACOs) with a combined primary service area (PSA) share in excess of 50 percent in any common service. In its place, the Agencies implemented a process for "newly formed" ACOs to seek expedited voluntary antitrust review.

Background

The Policy Statement provides that the Agencies will apply rule of reason—and not *per se*—analysis to an ACO's joint contracting activities with commercial payors, so long as the ACO meets the U.S. Centers for Medicare & Medicaid Services' (CMS') requirements for participation—and participates—in the MSSP, and uses the same governance structures and clinical processes to serve patients in Medicare and commercial markets. The Policy Statement also creates a safety zone providing that the Agencies will not challenge, absent extraordinary circumstances, an ACO comprising independent ACO participants providing a common service that possess a combined share of 30 percent or less of each common service in each participant's PSA. View FTC/DOJ Issue Joint Proposed Statement of Antitrust Enforcement

Policy Relating to ACOs for an in-depth summary of the key provisions of the proposed Policy Statement, most of which were retained in the final Policy Statement.

Changes: The Good and the Bad

Elimination of Mandatory Review Lowers Burden on ACOs

The most significant difference between the proposed and final Policy Statement is the elimination of mandatory Agency antitrust review as a prerequisite for participation in the MSSP, which, under the proposed Policy Statement, was required for ACOs with a PSA share in excess of 50 percent in any service common to independent ACO participants. This revision removes a burdensome and broad production of information to the Agencies.

Availability of Voluntary Expedited Review Is Useful, but Agency Selection Could Be Outcome Determinative

Having eliminated mandatory antitrust review, the final Policy Statement provides that "newly formed" ACOs seeking further antitrust guidance may voluntarily request from the Agencies an expedited 90-day antitrust review prior to participation in the MSSP. Newly formed ACOs are ACOs that, as of March 23, 2010, "had not yet signed or jointly negotiated any contracts with private payors" and have not yet participated in the MSSP. Both an ACO's request letter and the Agency's response will be made public consistent with confidentiality provisions pertaining to competitively-sensitive information. An ACO must submit its request to both the FTC and DOJ, who will determine which Agency will review the request (although they have not disclosed how they will allocate requests between them). Although the Policy Statement notes that it has been the Agencies' practice to share with each other their proposed business review and staff advisory opinion letters before issuing them in final form to ensure application of consistent standards of antitrust review, this dual-Agency review system would seem to increase the likelihood of inconsistencies in antitrust analyses and, with differences between the Agencies in their approach to antitrust enforcement, the decision as to which Agency will review a particular ACO could play a significant role in the outcome of the review.

Expansion of Applicability of Policy Statement Provides Certainty of Rule of Reason Treatment to More ACO Collaborations but Leaves Purely Commercial ACOs Without Safe Harbors

The applicability of the final Policy Statement is no longer limited to collaborations formed after March 23, 2010 (the date on which the Patient Protection and Affordable Care Act was enacted), but rather applies to all collaborations of otherwise independent providers and provider groups that are eligible and intend, or have been approved, to participate in the MSSP. This revision will provide the certainty of rule of reason treatment to a greater number of ACOs. Yet, the Policy Statement still does not apply to ACOs whose programs are substantially similar to ACOs participating in the MSSP, but provide services to commercially insured patients only. Those organizations will not have the benefit of the safe harbor, which could discourage or deter the formation of potentially efficiency-enhancing collaborations. One could expect, though, that the analytical framework of the Policy Statement will nevertheless be instructive for ACOs participating only in the commercial marketplace. Similarly, a footnote to the Policy Statement indicates that "the analytical principles underlying the Policy Statement also would apply to various ACO initiatives undertaken by the Innovation Center within CMS as long as those ACOs are substantially clinically or financially integrated," but comes short of expressly applying the Policy Statement to ACOs participating in programs through the Center for Medicare & Medicaid Innovation, such as the Pioneer ACO program.

Two other clarifications about the Policy Statement's applicability are noteworthy. Large, vertically integrated health systems can take comfort in the guidance that the Policy Statement does not apply to single, fully integrated entities. Moreover, the final Policy Statement addresses confusion as to what entities constitute ACO participants by defining an ACO participant as an independent physician solo practice, a fully integrated physician group practice, an inpatient facility or an outpatient facility. Stakeholders should be aware that the Policy Statement's definition of ACO participant may differ from CMS's.

PSA Shares May Not Accurately Predict Market Share or Market Power

The final Policy Statement retained the proposed method of calculating physician PSA shares based on Medicare fee-for-service allowed charges. While the selection of this measure of shares reflects the limitation of available data, shares based on Medicare revenues may not accurately predict the market share of collaborating physicians who provide a common service, as not all participating physicians may participate in Medicare and, even if they do, they may not share the same payor mix.

Medical providers interested in establishing an ACO should work diligently to assess antitrust risk, especially when PSA shares exceed 30 percent. A relatively low 30 percent safety zone

means that many ACOs will not be insulated from Agency review. And even if they do fall within the safety zone, ACOs must remember that the Policy Statement does not shield them from a state challenge or private challenge.

Rural Exception

The Agencies also expanded the rural exception from one physician per specialty from each rural county to one physician *or integrated physician group practice* per specialty from each *rural area*. This change eliminates the impracticality the proposed Policy Statement created of having to choose only one physician—and not all physician members—of an integrated group practice. Under the rural exception as revised, an ACO may include on a non-exclusive basis one physician or one physician practice per specialty from each rural area and still otherwise qualify for the safety zone, so long as the physician or group practice's primary office is in a ZIP code that the WWAMI Rural Health Research Center of the University of Washington has classified as "isolated rural" or "other small rural."

For physician groups to qualify for the rural exception, the group practice must have been an integrated group practice as of the date of the final Policy Statement. The Agencies also changed the geographic definition from a rural county (as defined by the U.S. Census Bureau) to a rural area, which is any county containing at least one zip code that the WWAMI Rural Health Research Center of the University of Washington has classified as "isolated rural" or "other small rural."

The Agencies also added a third category of rural hospitals that are eligible for the rural exception. In addition to a sole community hospital and a critical access hospital, any other acute care hospital located in a rural area that has no more than 50 acute care inpatient beds and is located at least 35 miles from any other inpatient acute care hospital may also be eligible for the exception. The rural exception provides that an ACO may include rural hospitals on a non-exclusive basis and still qualify for the safety zone, even if the inclusion of a rural hospital causes the ACO's share of any common service to exceed 30 percent in any ACO participant's PSA.

Conclusion

Although the Agencies eliminated mandatory antitrust review for certain ACOs prior to participation in the MSSP, the Agencies state they will "vigilantly" monitor complaints about an ACO's formation or conduct and take appropriate enforcement action.

The Policy Statement identifies five categories of conduct that, under certain circumstances, may raise competitive concerns and, therefore, are likely to draw Agency scrutiny. Irrespective of PSA shares, the Agencies caution against the exchange of competitively sensitive information among ACO participants that could facilitate collusion among ACO participants in the sale of competing services outside of the ACO. The Agencies further recommend that ACOs with high PSA shares or other indicia of market power avoid:

- Preventing or discouraging commercial payors from steering patients to other providers
- Tying sales of the ACO's services to the payor's purchase of other services from providers outside the ACO
- Contracting with ACO participants on an exclusive basis
- Restricting a payor's ability to disclose to its beneficiaries cost and quality data.

ACOs should, therefore, be mindful of the competitive implications of their contracting activities in the marketplace.