



CPI Antitrust Chronicle

May 2011 (1)

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I. INTRODUCTION

On March 31, 2011, the Federal Trade Commission (“FTC”) and the U.S. Department of Justice (“DOJ”) released a joint Proposed Statement of Antitrust Enforcement Policy Regarding Accountable Care Organizations Participating in the Medicare Shared Savings Program (the “ACO Statement” or “Statement”).² The ACO Statement incorporates a market-share based “safety zone,” a feature common to both the Antitrust Guidelines for Collaborations Among Competitors (2000)³ and the Statements of Antitrust Enforcement Policy in Health Care (1996).⁴ Unlike these prior guidelines, however, the ACO Statement requires *mandatory* agency review if a certain threshold is met. Because CMS (the U.S. federal agency that administers health insurance programs such as Medicare) will not approve ACOs that the antitrust enforcement agencies determine are subject to challenge, careful up-front attention to antitrust risk will be of vital importance to providers in navigating successfully the requirements for establishing ACOs.

II. LENDING A HELPING HAND: AUTOMATIC INTEGRATION UNDER THE ACO STATEMENT

As applied to physician network joint ventures, the safety zones of the *Competitor Collaboration Guidelines* and *Health Care Statements* require (1) sufficient clinical and financial *integration* of the joint venture; and (2) a small *market share*. The ACO Statement provides importance guidance on the first requirement—needed to avoid *per se* invalidation for price-fixing⁵—by tying sufficient “integration” to the CMS criteria for participation in the Shared Savings Program.⁶ Although the *Competitor Collaborations Guidelines* and *Health Care Statements* provided examples of permissible conduct and a direction to share “substantial financial risk,”⁷ parties could not predict with certainty what the agencies would deem to be *unintegrated*, and

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² PROPOSED STATEMENT OF ANTITRUST ENFORCEMENT POLICY REGARDING ACCOUNTABLE CARE ORGANIZATIONS PARTICIPATING IN THE MEDICARE SHARED SAVINGS PROGRAM (2011) [hereinafter “ACO Statement”], available at www.justice.gov/atr/public/guidelines/269155.pdf.

³ ANTITRUST GUIDELINES FOR COLLABORATIONS AMONG COMPETITORS (2000) [hereinafter “Competitor Collaborations Guidelines”], available at www.ftc.gov/os/2000/04/ftcdojguidelines.pdf.

⁴ STATEMENTS OF ANTITRUST OF ANTITRUST ENFORCEMENT POLICY IN HEALTH CARE (1996) [hereinafter “Health Care Statements”], available at www.justice.gov/atr/public/guidelines/0000.pdf.

⁵ See *Arizona v. Maricopa County Medical Society*, 457 U.S. 332, 356 (1982).

⁶ See ACO Statement, *supra* note 2, at 2-5.

⁷ See Health Care Statements, *supra* note 4, at 64 (“arrangements [must] involve the sharing of substantial financial risk among a network’s physician participants . . . to come within the safety zones.”).

therefore outside the safety zone. Indeed, under some circumstances, the FTC has rejected physician joint ventures on the basis of insufficient integration.⁸ By contrast, if a proposed ACO follows CMS guidelines for integration, the problem of *per se* invalidity may be avoided. This potentially enables the ACO to seek joint negotiations with private payors by the integrated providers subject to the market-share thresholds and other factors discussed below.

III. GIVING THRESHOLDS TEETH: MANDATORY REVIEW AND PITFALLS IN MARKET SHARE CALCULATIONS

Although the ACO Statement makes it easier for joint ventures to determine if they meet the safety zone's integration requirement, the Statement's structure significantly raises the stakes for assessing correctly the second requirement: the market-share threshold. The central role played by market shares under the ACO Statement makes the accurate determination of shares, and thus the up-front involvement of experienced antitrust counsel, of critical importance to structuring ACOs.

Under the Statement, if a proposed ACO exceeds 50 percent market share in any service provided by two or more participants, the ACO's formation is subject to *mandatory review* by the antitrust agencies. Although time will tell under what circumstances the agencies will disallow proposed ACOs subject to mandatory review, the Statement indicates that a 50 percent share in any service is a "valuable indication of the potential for competitive harm."⁹ By contrast, proposed ACOs with *less* than 30 percent market share in *all* services provided by two or more participants may achieve safety zone status, which results in no obligation to contact the agencies, and the ACO is deemed "highly unlikely to raise significant competitive concerns."¹⁰ Proposed ACOs with between 30 percent and 50 percent share may either proceed with caution or may voluntarily seek agency review.

In light of the mandatory review requirement, an accurate up-front predication of how the agencies will assess market shares will be essential. This is particularly true for "common services" for which ACOs and their counsel must collect and analyze data. The ACO Statement offers the following example to illustrate the concept of common services, which can place a proposed ACO in either the safety zone or the mandatory review category depending upon market-share calculations:

If two physician group practices form an ACO and each includes cardiologists and oncologists, cardiology and oncology would be *common services*. If, on the other hand, one physician group practice consists only of cardiologists and the other only of oncologists, then there are no *common services*

Although this example is clear, other service categories may prove less obvious. For example, proposed ACOs will need to determine which "outpatient categories" (to be defined by CMS)

⁸ See FTC, In re Suburban Health Organization Inc. Advisory Opinion (2006) (FTC rejects joint venture due to insufficient clinical integration), available at <http://www.ftc.gov/os/2006/03/SuburbanHealthOrganizationStaffAdvisoryOpinion03282006.pdf>; North Texas Specialty Physicians v. FTC, 528 F.3d 346 (5th Cir. 2008) (joint venture rejected due to lack of financial integration and insufficient clinical integration). Compare FTC, In re TriState Health Partners Inc. Advisory Letter (2009) (sufficient clinical integration found to justify joint contracting without financial risk), available at <http://www.ftc.gov/os/closings/staff/090413tristatealetter.pdf>.

⁹ ACO Statement, *supra* note 2, at 8.

¹⁰ *Id.* at 6.

are provided by each participant on the basis of procedure codes in order to determine whether any category will trigger mandatory review.¹¹

Determining the scope of the geographic market may present similar complexities. Under the ACO Statement, after identifying common services, a proposed ACO must determine market share for each participant's provision of each common service within the participant's Primary Service Area ("PSA").¹² A PSA 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."¹³ Thus, an ACO may achieve safety zone status only if, after consideration of each common service, there is no more than a 30 percent combined share of *each* such service in *each* participant's PSA. In computing multiple, potentially-overlapping PSA shares, ACOs must pay careful attention to the selection of zip codes and consequent effects on market share. Because each geographic market must be computed separately for each service provided by two or more participants, a practice focused largely on one service may have a very different map for another service. Further, PSA shares must be computed from alternate data (rather than Medicare fee-for-service allowed charges) when the service is rarely used by Medicare beneficiaries.¹⁴

IV. PRACTICAL GUIDANCE FOR CLEARING THE ANTITRUST HURDLE

The ACO Statement makes it particularly important to get the analysis described above right. If the DOJ or FTC determines that it is "likely to challenge or recommend challenging the ACO if it proceeds," the proposed ACO will not be approved by CMS for the Shared Savings Program.¹⁵ The reviewing agency may, alternatively, *condition* its approval upon the proposed ACO's written agreement to "take specific steps to remedy concerns raised by the Agency."¹⁶ The following practical steps may help ACOs avoid the significant pitfalls of getting the antitrust analysis wrong while seeking to maximize potential efficiencies in the Shared Savings Program:

A. Identify "Dominant Providers" and Rural Areas in Potential ACO

"Dominant Providers" are defined under the ACO Statement as participants with greater than 50 percent share in of any service in the participant's PSA.¹⁷ Importantly, under the "Dominant Provider Limitation," a Dominant Provider may be part of a proposed ACO, and still obtain safety zone treatment, as long as no other ACO participant provides that same service to patients in the Dominant Provider's PSA, meaning that there is no overlap in geography with that Dominant Provider's PSA. On the other hand, joining into an ACO even a *single* physician who provides a common service within the Dominant Provider's PSA will trigger *mandatory* agency review.

Similarly, the "Rural Exception" allows proposed ACOs to gather providers from rural counties and qualify for the safety zone, even if the inclusion of these physicians causes an ACO's share of a common service to exceed 30 percent in a participant's PSA. Although the definition

¹¹ *See id.* at 12 n.41.

¹² *Id.* at 7.

¹³ *Id.*

¹⁴ *See id.* at 13. For this computation, the ACO Statement suggests "data on the number of actively participating physicians within the specialty and within the PSA may be a reasonable alternative for the purposes of calculating shares of physician services." *Id.*

¹⁵ *Id.* at 10.

¹⁶ *Id.*

¹⁷ *Id.* at 8.

of “rural county” is narrow, the addition of these practices may assist with achieving economic efficiencies without compromising safety zone status.

B. Review the Proposed ACO’s Internal Rules with Antitrust Counsel

Even if a proposed ACO falls within the safety zone according to its share calculations, and especially if a proposed ACO will undergo agency review (whether by mandate or by choice), a proposed ACO should consult with experienced counsel to assess whether the ACO’s internal rules create antitrust risk.

The ACO Statement expresses the same antitrust concerns articulated by the *Competitor Collaborations Guidelines* and the *Health Care Statements*. Central among these is *exclusivity* for hospitals, ambulatory surgery centers (ASCs), and Dominant Providers. For these participants, *non-exclusivity* is an explicit requirement for safety zone status, and non-exclusivity must be “in fact and not just in name.”¹⁸ In referring to the *Health Care Statements* for the “indicia of non-exclusivity,” the ACO Statement suggests considering several factors that influence competition involving healthcare services, including any limitations placed upon participating physicians’ freedom to contract outside the ACO.¹⁹ Antitrust counsel also can help assess antitrust risks stemming from ACO rules that could be construed as: (1) anti-steering provisions; (2) tying of sales to services outside the ACO; (3) prohibiting commercial payors from sharing information with enrollees; and (4) sharing among participants of pricing information for services provided outside the ACO.²⁰ As noted in the ACO Statement, proposed ACOs that fall outside the safety zone and feature such arrangements will make approval by the antitrust agencies less likely.

C. Formulate Pro-competitive Arguments to Present to the Antitrust Agencies

The ACO Statement articulates two types of arguments that a proposed ACO might advance to persuade the antitrust enforcement agencies to approve the venture: (1) show that alternate data demonstrate that high PSA shares are not reflective of the proposed ACO’s likely market power; and (2) provide justifications for why the proposed ACO *needs* the proposed PSA share to provide high-quality, cost-effective care.²¹

Parties proposing an ACO should also be prepared to conduct an in depth investigation to identify specific, pro-competitive benefits resulting from the ACO and to explain the *efficiencies* that will benefit consumers of healthcare services.²² Drawing from prior guidance, efficiency-based arguments may include: better use of existing assets; increased incentives for output-enhancing investments; attainment of scale or scope economies; lower prices via improved cost controls; facilitation of new products faster to market; and heightened quality assurance.

¹⁸ *Id.* at 7 n.28 (citing *Health Care Statements*, *supra* note 4, at 66-67).

¹⁹ See *Health Care Statements*, *supra* note 4, at 67.

²⁰ For similar concerns expressed in the *Competitor Collaborations Guidelines*, *supra* note 3, see § 3.34(a) (exclusivity); § 3.34(e) (information sharing). In the *Health Care Statements*, *supra* note 4, see 78-79 (exclusivity); 79 (information sharing); 103 (collateral agreements affecting prices outside a joint venture).

²¹ ACO Statement, *supra* note 2, at 8-9.

²² The ACO Statement and the earlier agency guidance all recognize the significance of efficiencies. See ACO Statement, *supra* note 2, at 2, 4 & 6; *Competitor Collaborations Guidelines*, *supra* note 3, at 5-6; *Health Care Statements*, *supra* note 4, at 101.

Proposed ACOs should seek to persuade commercial payors as to the mutual benefits from the formation of the ACO. Commercial and managed care payors (particularly the projected top five for each proposed ACO) will likely hold sway with the antitrust agencies as the primary “consumers” of healthcare services, and proposed ACOs will ultimately need to provide points-of-contact information at those payors to the agencies during review.

V. CONCLUSION

The ACO Statement makes early assessment of antitrust risk an important step in devising ACOs likely to achieve regulatory approval. In particular, market-share based safety zones and mandatory review requirements place a premium on sound up-front antitrust analysis. Providers contemplating ACOs accordingly should pay careful attention to antitrust in structuring ACOs in order to minimize regulatory risks and achieve business objectives.