Antitrust Enforcement Agencies Issue Final Guidance on ACOs

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The federal antitrust agencies issued the final statement of their antitrust enforcement policy regarding Accountable Care Organizations participating in Medicare’s Shared Savings Program on October 20, 2011.1

The statement departs in two significant ways from the proposed statement released in March 2011 by the Federal Trade Commission and the Department of Justice’s Antitrust Division.

First, and most significantly, the agencies will not require any ACO to submit to mandatory review by the antitrust agencies as a condition to entry into the Shared Savings Program. The statement issued in March proposed to require review for ACOs combining providers with shares of 50% or more in overlapping services within their primary service areas (PSAs).

Second, the guidance in 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 earlier statement proposed to limit applicability to collaborations formed after March 23, 2010 (the date the Patient Protection and Affordable Care Act was enacted).

The final policy statement, issued on the same day CMS issued its final rule on ACOs,2 confirms the federal antitrust enforcement agencies will apply the so-called “rule of reason” to combinations of providers meeting CMS eligibility criteria for ACOs participating in the Shared Savings Program rather than the considerably more harsh “per se” rule of illegality reserved for provider collaborations that do not involve significant financial or clinical integration.

ACOs with groups of providers who offer common services that cumulatively account for no more than 30% of those services within their PSAs fall within a “safety zone.” Such ACOs “are highly unlikely to raise significant competitive concerns.” Therefore, the agencies state, they will not challenge these ACOs under the antitrust laws, “absent extraordinary circumstances.”

ACOs that do not qualify for the safety zone “may be procompetitive and legal.” But, “not all ACOs are likely to benefit consumers.” According to the final policy statement, “under certain conditions ACOs could reduce competition and harm consumers through higher prices or lower quality of care.”

The effect of the final policy statement is to place the responsibility squarely on the shoulders of each ACO and its antitrust advisors to determine the legality under the antitrust laws of ACOs

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1 The policy statement can be found here: www.ftc.gov/os/fedreg/2011/10/111020aco.pdf
2 The final rule can be found here: www.ofr.gov/OFRUpload/OFRData/2011-27461_PI.pdf
that fall outside the safety zone. Newly formed ACOs that want guidance from the antitrust agencies may request a statement as to the agencies’ enforcement intentions through an expedited, 90-day review process detailed in the policy statement. No ACO is required to obtain such input, however, before applying for entry to the Shared Savings Program and commencing operations. ACOs that choose to skip a review by the antitrust agencies are provided with advice on how to operate so as to minimize the possibility of a later antitrust enforcement action.

The balance of this paper provides more detail on the final policy statement.

Applicability of the Policy Statement

The policy statement applies to “collaborations among otherwise independent providers and provider groups that are eligible and intend, or have been approved, to participate in the Shared Savings Program.” The agencies recognize many ACOs will provide services to commercially insured patients as well. The policy statement provides a framework under which the agencies will analyze CMS-qualified ACOs when they provide services in the commercial market.

The policy statement does not apply to single, integrated entities, nor does it apply to mergers.

“Rule of Reason” Treatment for Price Negotiations by Qualifying ACOs with Commercial Payors

Under standard antitrust principles, otherwise competing providers who jointly negotiate contracts with commercial payors are fixing prices in violation of Section 1 of the Sherman Act, unless the providers are either clinically or financially “integrated.” In antitrust jargon, such joint negotiations are a “per se” violation of Section 1. In the event the providers are “integrated,” however, their collaboration is judged under the more lenient “rule of reason.” As the agencies explain in the final policy statement, a rule of reason analysis examines both the efficiencies that flow from the collaboration and its anticompetitive effects. The arrangement is unlawful only if, on balance, the likely anticompetitive effects outweigh the efficiencies.

The antitrust agencies have provided a great deal of advice elsewhere on what constitutes sufficient financial or clinical integration to escape per se treatment and bring an arrangement under the rule of reason. In particular, the “Statements of Antitrust Enforcement Policy in Health Care,” issued by the two federal antitrust agencies in 1996, provide detailed guidance on how providers might integrate.3 Both the Federal Trade Commission and the Department of Justice have issued advice letters that discuss adequate financial or clinical integration in specific factual circumstances. Speeches from enforcement officials have further illuminated the criteria the agencies consider to determine when integration is present.

3 The Statements can be found here: www.ftc.gov/bc/healthcare/industryguide/policy/index.htm. Examples of sharing financial risk include accepting capitation or setting a fee schedule with a substantial risk withhold. Clinical integration is evidenced by the implementation by a network of an active and ongoing program to evaluate and modify practice patterns by the network’s physician participants and the creation of a high degree of interdependence and cooperation among the physicians to control costs and ensure quality. Networks that are clinically integrated may set prices jointly, so long as such price setting is reasonably necessary to achieve promised efficiencies.
While the criteria by which financial integration is judged are broadly understood and have caused little controversy, the same cannot be said about clinical integration. Until now, the antitrust agencies have resisted setting out specific criteria required to establish clinical integration. Instead, in the years since the issuance of the 1996 antitrust enforcement advice, the FTC has issued a number of staff advice letters explaining what does, and does not, qualify as clinical integration sufficient to permit joint price setting.

In an important departure from this history, the agencies recognize that health care providers “could benefit from additional antitrust guidance in evaluating whether an ACO” is clinically integrated. Therefore, the policy statement provides that ACOs participating in the Medicare Shared Savings Program will be presumed to be clinically integrated (and so able to negotiate prices with commercial payors without running afoul of the antitrust laws) as long as they comply with the CMS eligibility criteria for participation in the Share Savings Program and participate in that program. Such ACOs also must employ in their commercial business “the same governance and leadership structures and the same clinical and administrative processes” used to qualify for and participate in the Shared Savings Program.

The antitrust agencies have deferred to CMS in this area because they consider CMS’s eligibility criteria to be “broadly consistent with the indicia of clinical integration” traditionally employed by the antitrust enforcers.

Therefore, so long as an ACO participates in the Shared Services Program and keeps the same governance and clinical structures in place as existed at the time of CMS’s approval of the ACO’s application for participation in that program, the ACO’s negotiations with commercial payors will not be considered by the antitrust agencies as per se violations of the antitrust laws.

Calculation of Shares for Determining the Applicability of the Safety Zone

The policy statement establishes an antitrust “safety zone” for ACOs in the Shared Service Program when shares of overlapping providers do not exceed 30%. ACOs falling within this safety zone are assured that “absent extraordinary circumstances” the agencies “will not challenge” either their formation or their operation.

If an ACO wishes to establish that it qualifies for the safety zone it must engage in a detailed share calculation. To conduct the required share analysis, the ACO first must determine which services are provided by two or more competing providers (or groups of providers) in the ACO. The ACO then must calculate, for each such “common service,” the share all the ACO’s providers hold of that service within each provider’s PSA.

For example, if an ACO were to include two otherwise independent groups of cardiologists, the PSA for each group would be separately determined. Then the combined shares of both groups would be calculated within each of the two PSAs.

The guidelines borrow the CMS definition of a PSA as the lowest number of zip codes from which the provider draws a least 75% of its patients for a particular service.
In order to perform these calculations:

- Physician services are defined by a physician’s specialty, as defined by the Medicare Specialty Code (“MSC”).
- Hospital inpatient services are identified by Major Diagnostic Categories (“MDCs”).
- Outpatient services are defined by categories to be identified by CMS.

Shares will be calculated for hospital inpatient services by using all-payor discharge data for the relevant MDCs when they exist at a state level. Physician shares will be calculated using Medicare fee-for-service allowed charges. Outpatient services will be measured by Medicare fee-for-service payment data for hospitals and fee-for-services allowed charges for ambulatory surgery centers. If available, an ACO can use state-level, all-payor discharge data instead. For services rarely used by Medicare beneficiaries, such as pediatrics, obstetrics and neonatal care, ACO applicants are directed to use “other available data” to determine shares.

An appendix to the Policy Statement provides detailed examples of share calculations.

The 30% Safety Zone

A safety zone applies to an ACO that combines providers with shares of no more than 30% in any common service (i.e., any overlapping service line) in each PSA where an ACO provider of such service is found.

If an ACO includes hospitals or ASCs, those facilities must be “non-exclusive” to the ACO to fall within the safety zone. This means a hospital or ASC must retain the ability to contract or affiliate with other payors or ACOs or the protection of the safety zone is lost.

- **Rural Hospitals.** An ACO may include “Rural Hospitals” on a non-exclusive basis and still qualify for the safety zone even if the shares for common hospital services exceed 30%. A Rural Hospital is defined as a Sole Community Hospital or Critical Access Hospital under CMS regulations, or any other acute care hospital in a rural area that has no more than 50 beds and is located at least 35 miles from another hospital.

The safety zone for physicians applies regardless of whether they contract with the ACO on an exclusive basis or not – unless the physicians fall within either the “rural exception” or “dominant participant limitation,” in which case they must contract on a non-exclusive basis to take advantage of the safety zone.

- **Rural exception for physicians.** An ACO in a rural area that has more than a 30% share within a PSA may still qualify for the safety zone if that share is the result of including no more than one physician or pre-existing physician group practice, per specialty, from a rural area. The physician or group, however, must be included on a non-exclusive basis to qualify for the safety zone. The agencies borrow the definition of rural areas developed by the Health Research Center at the University of Washington.
• **Dominant Provider Limitation.** If a provider with a share greater than 50% is included in an ACO, the ACO will still qualify for the safety zone if the provider is non-exclusive to the ACO and no other providers of the same service are included. The ACO also may not require a commercial payor to contract exclusively with it.

Except as set forth in the rural exception and the dominant provider limitation, an ACO could require its physicians to provide their services on an exclusive basis, and still qualify for the safety zone, so long as the 30% thresholds are not exceeded.

To qualify for the safety zone, unless the rural exception applies, an ACO could not exceed 30% in any of the service lines in which it combined competing providers. While failing to qualify for the safety zone would not mean the ACO had run afoul of antitrust law, falling outside the safety zone could impose additional administrative burdens, as discussed below.

**Guidelines for ACOs outside the Safety Zone**

ACOs that fall outside the 30% safety zone “may be procompetitive and lawful.” Such ACOs, however, remain exposed to possible antitrust challenge by the enforcement agencies. The risk of such a challenge will rise with the market power held by an ACO. The policy statement does not give specific guidance as to when an ACO with a share or shares above 30% may violate the antitrust laws. Nonetheless, the agencies do provide guidance as to how such ACOs may reduce competitive concerns.

The policy statement identifies four types of conduct ACOs “with high PSA shares or other possible indicia of market power” should consider avoiding to minimize the likelihood of an antitrust challenge. Such ACOs should not:

1) Prevent or discourage commercial payors from steering patients to certain providers through “anti-steering,” “anti-tiering, “guaranteed inclusion,” “most favored nation,” or other similar contractual provisions.

2) Tie sales of the ACO’s services to a commercial payor’s purchase of other services from providers outside the ACO.

3) Contract on an exclusive basis with ACO participants. There is no exception for primary care physicians. 4

4) Restrict a commercial payor’s ability to share cost, quality, efficiency, and performance information with its enrollees.

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4 The policy statement notes that while CMS “requires the physician practice through which physicians bill for primary care services and to which Medicare beneficiaries are assigned to contract exclusively with one ACO for the purposes of beneficiary assignment, CMS does not require either those individual physicians or physician practices to contract exclusively through the same ACO for the purposes of providing services to private health plans’ enrollees.”
Voluntary Antitrust Review by the Agencies

Any “newly formed” ACO may seek, on an “expedited” basis, antitrust review from the enforcement agencies. A newly formed ACO is one that, as of March 23, 2010, had not signed or negotiated contracts with a commercial payor, and had not participated in the Shared Savings Program.

An ACO that wants a review must inform the FTC and DOJ it wants a review, using a form available on the agencies’ website. The agencies then decide which agency will conduct that review and inform the ACO. The ACO then must submit certain identified information to that agency. The required information includes: (1) the application and supporting documents submitted to CMS for participation in the Shared Savings Program; (2) documents discussing the ACO’s business strategies or plans to compete in the Medicare and commercial markets, including the ACO’s impact on quality or price; (3) documents discussing competition among ACO participants and in markets to be served by the ACO; and (4) information sufficient to show the common services offered by two or more ACO members, and the share calculations by PSA for those services, “or other data that show the current competitive significance of the ACO or ACO participants.”

Within 90 days of receiving “all” the required information, the reviewing agency will inform the ACO that the group’s formation and operation “does not likely raise competitive concerns,” “potentially raises competitive concerns,” or “likely raises competitive concerns.” The agency may condition a finding that the ACO does not likely raise competitive concerns on agreement by the ACO to take certain prescribed steps to remedy concerns raised by the agency.

All request letters and responses will be public documents. The two antitrust agencies also will establish a joint working group “to collaborate and discuss issues arising out of the ACO reviews.”

Observations

- **No mandatory reporting.** Unlike the proposed policy statement issued in March, the final statement does not require any ACO to submit anything to the antitrust enforcement agencies. This means antitrust enforcement in this area is consistent with antitrust enforcement philosophy generally: parties may form and operate a collaborative venture without first seeking permission from the government. But if they violate the antitrust laws they may be the subject of an enforcement action by those agencies.

- **PSAs are not antitrust relevant markets.** The policy statement expressly notes a PSA is not necessarily equivalent to a relevant geographic market used in traditional antitrust analysis and it nowhere states the calculations providers make will result in “market shares.” (The statement is careful to use the word “shares,” without the modifier “market,” throughout.) Nonetheless, for the purposes of the Shared Savings Program, the policy statement in effect considers PSAs as proxies for antitrust relevant geographic markets. As a matter of antitrust law, however, a PSA at best is only a rough approximation of a relevant geographic market. At worst it bears no resemblance at all to
a relevant geographic market, and market analysis based on PSAs can yield incorrect antitrust conclusions.⁵

- **Data Limitations.** The share calculations necessarily are limited to available data. The antitrust agencies recognize that many states collect and publish all-payer discharge data that permit, when hospital services are at issue, share calculations based on these data. But similar data generally are not available for physician services. Accordingly the statement discusses the use of Medicare data for physicians and outpatient services. But this necessarily produces shares based on Medicare revenues. Not all physicians in the same specialty see Medicare patients, however, and of those who do, not all do so in equal proportions. Consequently, share calculations based on Medicare data may be either higher or lower than calculations based on all-payer data – which, the agencies acknowledge, is preferable to Medicare data. Incomplete data (such as Medicare reimbursement data only) may lead to incorrect conclusions.

- **Safety Zones Do Not Provide Antitrust Immunity.** While an ACO that applies for antitrust review and receives a letter from an antitrust agency indicating it will not take an enforcement action may proceed safe in the knowledge that the federal antitrust agencies will not prosecute it (so long as it does not substantially change the manner in which it does business), it will have no such protection from private litigants. Similarly, if an ACO falls within the 30% “safety zone,” this protects it only from an enforcement action by the agencies. Private parties would be free to sue the ACO.

- **Uncertainty for ACOs that Are Not Qualified by CMS.** If an ACO is structured in a way that falls within the safety zone described in the policy statement, but the ACO chooses not to qualify under the Medicare Shared Savings Program and instead focuses on commercial business, it is not clear whether the antitrust enforcement agencies would scrutinize it under the guidelines set forth in the policy statement or under more traditional antitrust principles.

- **Different Criteria for Clinical Integration?** The effect of the deferral by the antitrust agencies to CMS to determine when otherwise competing providers are clinically integrated is uncertain. Despite the hopeful claims in the policy statement that CMS’s eligibility criteria “are broadly consistent with the indicia of clinical integration” and that organizations meeting the CMS criteria are “reasonably likely to be bona fide organizations” intended to improve quality and reduce costs, it remains to be seen whether, in practice, CMS’s criteria are more lenient than those the agencies would have used to test clinical integration. The possibility that CMS’s criteria will be different from – and more relaxed than – those applied until now by the antitrust agencies is a real one.

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⁵ Courts, antitrust commentators and enforcers repeatedly have warned against confusing the area from which a seller obtains its customers with a relevant geographic market. “[A] court would often be mistaken to conclude that a seller’s ‘trade area,’ or the area from which it currently draws its customers, constitutes a relevant geographic market. In fact, the ‘trade area’ and the ‘relevant market’ are precisely reverse concepts.” Bathke v. Casey’s General Stores, Inc., 64 F.3d 340, 346 (8th Cir. 1995) (quoting H. Hovenkamp, FEDERAL ANTITRUST POLICY § 3.6d, at 113-14); Federal Trade Commission v. Freeman Hosp., 69 F.3d 260, 268 (8th Cir. 1995); see also Antitrust Issues Raised by Rural, Health Care Networks, R. Leibenluft, Assistant Director, Health Care, Federal Trade Commission (February 20, 1998) (emphasis in original) available at www.ftc.gov/bc/ruralsp.shtm.
• **Information to Be Provided and the 90-Day Review Period.** The Policy Statement promises an expedited 90-day review for an ACO applying for a letter indicating the enforcement intentions of the antitrust agencies. ACOs expecting to hear definitively from an antitrust agency 90 days after they submit their applications must take great care to provide what can be a burdensome and complex amount of data in advance. Whether the agencies have sufficient staff to follow through on the promise of expedited review remains to be seen, especially as the volume – and complexity – of ACO voluntary requests is unknown and difficult to predict. Nonetheless, the burden on the agencies clearly will not be as great as it would have been had they required review of ACOs with shares over particular thresholds.