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# Proposed Antitrust Guidance for Accountable Care Organizations From the Federal Trade Commission and Department of Justice

By Douglas Ross

The federal antitrust agencies issued detailed guidance at the end of March for health care providers and payors considering forming Accountable Care Organizations so as to participate in Medicare's Shared Savings Program. The guidance is contained in a proposed statement of antitrust enforcement policy with respect to ACOs.[1]

If the proposed statement becomes final, it will require an ACO wishing to participate in the Shared Savings Program to engage in a detailed analysis of the shares the ACO's providers hold within their service areas. If any of those shares exceed 50%, the ACO must seek clearance from the federal antitrust agencies before it submits an application to the Centers for Medicare and Medicaid Services (CMS) to participate in the Shared Savings Program.

The policy statement, issued on the same day CMS issued its proposed regulations on ACOs, provides a ''safety zone'' for ACOs with shares under 30%. If the statement becomes final, these ACOs may submit applications directly to CMS without having to seek antitrust clearance. ACOs with shares falling between 30% and 50% may seek an antitrust review, if they want certainty the federal agencies will not later prosecute them, but will not be required to do so.

The policy statement signals significant changes in how the antitrust enforcement agencies do business. The Federal Trade Commission and the Department of Justice's Antitrust Division historically have been law enforcement agencies, not regulatory bodies. Firms operating in competitive markets are free to contract with each other, form joint ventures, and even merge, without first having to seek permission from the antitrust enforcers. The antitrust laws provide the rules of the road firms must follow in a free market. If a firm violates those rules – or threatens to do so – it is up to the antitrust agencies to file an enforcement action to stop the violation.

The Hart-Scott-Rodino premerger notification program is no exception to this rule. While firms engaging in certain mergers must give advance notice of their plans, when the proscribed waiting period expires they are free to complete the merger. If an antitrust agency objects, it must file an enforcement action and persuade a neutral tribunal to block the transaction.

Once the proposed policy statement becomes final, however, the FTC and DOJ will sit as regulatory agencies, granting or withholding permission to ACOs to participate in the Shared Savings Program.

Although the policy statement provides criteria for participation in the Shared Savings Program, the antitrust agencies recognize ACOs seeking to participate in that program are likely to provide services for commercially insured patients as well. Accordingly, the agencies provide that for the duration of an ACO's participation in the Shared Savings Program they will review ACO activities in commercial markets under the so-called ''rule of reason,'' so long as the ACO uses the same governance and leadership structure and the same clinical and administrative processes in the commercial market as it uses to qualify for the Shared Savings Program.

The practical effect of this is to permit an ACO that qualifies to participate in the Shared Savings Program to contract with commercial payors without running the risk the agencies later will determine the ACO was engaged in ''per se'' unlawful price fixing.

Before a group of providers forms an ACO to avail themselves of this more lenient antitrust treatment, however, they will want carefully to consider the cost and complexity of the process required to obtain anti-

[1] Proposed Statement of Antitrust Enforcement Policy Regarding Accountable Care Organizations Participating in the Medicare Shared Savings Program, 76 Fed. Reg. 21894 (April 19, 2011).

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trust review and balance this against the potential benefits afforded by antitrust clearance. The proposed policy statement does not answer all questions providers may have as they navigate this process. The agencies have invited comments on the proposed statement through May 31, 2011. Providers and others with comments or questions they would like the agencies to consider before the statement is finalized, therefore, should consider filing comments.

### *Overview of the Policy Statement*

If it becomes final, the policy statement will apply to ACOs formed after March 23, 2010, among otherwise independent providers that seek to participate in, or have otherwise been approved to participate in, Medicare's Shared Savings Program. The statement does not apply to an ACO composed entirely of providers within a single health system.

Because the policy statement differentiates among ACOs according to their shares of certain services in defined areas, and requires that some ACOs obtain mandatory clearance from the antitrust agencies before proceeding, ***every*** ACO seeking to qualify to participate in the Shared Savings Program established by CMS must clearly understand the process set forth in the policy statement to measure shares.

To conduct the required share analysis, every ACO first must determine which services are provided by two or more competing providers, or groups of providers.[2] The ACO then will calculate, for each such service, the share of ***all*** ACO providers within ***each*** provider's primary service area (''PSA'').[3] The statement defines a PSA as the lowest number of contiguous zip codes from which the provider draws a least 75 percent of its patients for a particular service.

So, as an example, if an ACO were to include two otherwise independent groups of oncologists, 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.

### *Mandatory Agency Review of ACOs Creating Shares Greater Than 50%*

ACOs that combine two or more competing providers with an aggregate share of more than 50%, should the policy statement become final, will have to apply to the antitrust agencies for clearance before CMS will qualify them to participate in the Shared Savings Program.

In order to obtain clearance from an antitrust agency, the proposal requires an ACO applicant to submit prescribed information to both antitrust agencies at least 90 days before the ACO's application to CMS otherwise would be due.[4] The FTC and DOJ will determine which agency will review each application. The reviewing agency may request more information but will respond within 90 days of an application either providing antitrust clearance or refusing to do so.

### *Antitrust ''Safety Zone''*

The policy statement, should it become final, will establish an antitrust safety zone for ACOs that combine providers with shares so long as they do not exceed 30% in any overlapping service.

If an ACO includes hospitals or ambulatory surgery centers, those facilities must be free to contract with other ACOs or payors if the applicant ACO wants to qualify for the safety zone. This does not mean an ACO cannot contract with a hospital or ASC on an exclusive basis – it may do so. But if it does, the ACO will not qualify for the safety zone. This holds true no matter how many other hospitals or ASCs compete within the same PSA.

The policy statement relaxes the rules, slightly, in rural areas. An ACO in a rural area can include one physician per specialty, per rural county (as defined by the Census Bureau) so long as that physician is included on a non-exclusive basis – and even if the inclusion of the provider takes the ACO over the 30% threshold. A similar exception applies for ''Rural Hospitals,'' defined as a sole community hospitals or critical access hospitals under CMS regulations.

Some providers, of course, will join an ACO with a pre-existing share within their relevant service area greater than 50%. If only one such provider, per service, is included, under the statement's ''dominant provider limitation,'' an ACO may still qualify for the safety zone so long as the provider is included on a non-exclusive basis.

Except as set forth in the rural exception and the dominant provider limitation, an ACO may 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.

### *Guidelines for ACOs Falling between the 30% and 50% Thresholds*

An ACO with a share in any service line above 30% cannot qualify for the safety zone. But if none of its shares exceeds 50% it need not apply for clearance from the antitrust agencies before seeking to qualify in the Medicare Shared Savings Program.

What is an ACO in this in-between position to do?

The policy statement indicates such an ACO may apply for clearance to the antitrust agencies if it wishes to obtain certainty from them they will not take action against the organization. Any ACO following this path must submit the same information as would an ACO that is required to obtain antitrust clearance, and the agencies again promise to respond within 90 days.

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[2] Physician services are defined by a physician's specialty, as defined by Medicare Specialty Codes. Hospital inpatient services are identified by Major Diagnostic Categories. Outpatient services are defined by categories to be identified by CMS.

[3] Shares would be calculated for hospitals by using all payor discharge data for the relevant MDCs. Physician shares would be calculated using Medicare fee-for-service allowed charges. Outpatient services would be measured by Medicare fee-for-service payment data. For services not captured in Medicare payment data, such as pediatrics, obstetrics and neonatal care, ACO applicants would be directed to use ''other available data.''

[4] The required information includes (1) the application and supporting documents to CMS for participation in the Shared Savings Program; (2) ''documents or agreements relating to the ability of the ACO participants to compete with the ACO''; (3) documents discussing the ACO's business strategies or plans to compete and the ACO's impact on quality or price; (4) documents showing the ACO's formation; and (5) information about the ACO's share calculations, proof of restrictions on exchanging price information among ACO participants, payor contacts, and the identities of other ACOs in the market.

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But an ACO in this position is not required to seek antitrust clearance. The policy statement advises ACOs in the middle zone that do not want to seek an antitrust review to consider avoiding certain specified types of conduct to minimize the likelihood of a subsequent antitrust investigation. Such ACOs should not:

1) Include ''anti-steering'' (or similar) clauses in commercial payor contracts. The agencies state the ability of a payor to steer patients to certain providers, including providers that do not participate in the ACO, is important if payors are to offer differentiated products.

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

3) Contract with ACO participants on an exclusive basis, with a stated exception for primary care physicians.

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

5) Share competitively sensitive pricing information among ACO participants.

### *The Importance of Qualifying as a CMS-Sanctioned ACO for ACOs that Wish to Contract with Commercial Payors*

If a provider network, such as an ACO, includes competing providers of the same service, price negotiations with commercial payors likely are ''per se'' violations of Section 1 of the Sherman Act,[5] unless the network is ''integrated.'' The antitrust agencies issued guidance 15 years ago on how provider networks could integrate and so avoid per se liability.[6] The earlier guidance contains detailed advice on how providers might integrate – either financially or clinically – in order to avoid per se condemnation of their price negotiations under the antitrust laws.[7]

Financial integration is by now well understood. The 1996 Statements[8] and subsequent business review and staff advice letters from the antitrust agencies[9] provide dozens of specific examples of financial integration. The question of how to integrate clinically has generated more controversy, however. 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 Statements, 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.[10]

The proposed ACO policy statement signals an important departure from this prior practice. If the statement becomes final, ACOs that participate in the Medicare Shared Savings Program will automatically be deemed by the antitrust agencies as ''clinically integrated'' so long as they use ''the same governance and leadership structure and the same clinical and administrative processes'' as they used to qualify for the Shared Savings Program. In the future, an ACO that wants assurance from the agencies that it is clinically integrated need not obtain an FTC staff advice letter finding joint pricing permissible as ancillary to clinical integration. Instead it may use its participation in the Shared Savings program as proof, insofar as the antitrust agencies are concerned, of clinical integration.

The fact that there will be dual routes to clinical integration raises interesting questions. It seems almost certain CMS will not engage in the same studied inquiry the FTC used previously when it issued staff advice respecting whether a particular network was clinically integrated. What will the FTC do when a network that is not a CMS-qualified ACO seeks staff advice on clinical integration in the future? Will the FTC continue to apply the same degree of scrutiny to such requests they applied in the past, or will the antitrust agency use CMS's standards for clinical integration?

### *Observations*

The policy statement has additional implications for health care providers and antitrust law beyond those addressed above.

Not only do the antitrust enforcement agencies take on a new and unaccustomed role as regulators, the standard the policy statement uses to measure provider shares is different from the standard the agencies – and courts – use to define relevant markets and market shares. The policy statement acknowledges as much, noting a PSA is not necessarily equivalent to a relevant geographic market as that term is used in traditional antitrust analysis.

Antitrust courts have remarked frequently on the distinction. As one court observed, quoting a respected antitrust commentator, ''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.''[11] The same point has been made in the context of hospi-

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[5] 15 U.S.C. § 1.

[6] Statements of Antitrust Enforcement Policy in Health Care (Department of Justice and Federal Trade Commission, August 1996).

[7] The 1996 Statements indicated that financial risk sharing methods 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 the efficiencies

[8] Statements 8 and 9, 1996 Statements.

[9] *See e.g.*, FTC Staff Advisory Opinion to Assocs. in Neurology (Aug. 13, 1998) *available at* http://www.ftc.gov/bc/adops/ainlet.fin.shtm; FTC Staff Advisory Opinion to Phoenix Med. Network, Inc. (May 19, 1998) *available at* http://www.ftc.gov/bc/adops/phoenix.fin.shtm.

[10] *Compare* FTC Staff Advisory Opinion to Greater Rochester Indep. Practice Assoc., Inc. (Sept. 17, 2007) *available at* http://www.ftc.gov/bc/adops/gripa.pdf; FTC Staff Advisory Opinion to MedSouth, Inc. (Feb. 19, 2002) *available at* http://www.ftc.gov/bc/adops/medsouth.shtm; with FTC Staff Advisory Opinion to Suburban Health Organization, Inc. (March 28, 2006) available at http://www.ftc.gov/os/2006/03/SuburbanHealthOrganizationStaffAdvisoryOpinion03282006.pdf.

[11] *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).

tal mergers.[12] Nonetheless, for the purposes of the Shared Savings Program, the policy statement considers a PSA a proxy for an antitrust relevant geographic market. This is an understandable compromise. PSAs and PSA shares can be calculated in a relatively formulaic manner. The determination of an antitrust relevant geographic market is not nearly as easy and provokes heated disagreement in many antitrust cases. But the difference must be borne in mind, especially by ACOs that have shares above 50% of a PSA. Such ACOs may wish to argue that in a properly defined relevant geographic market their shares would be considerably less.

It also is important to recognize that the policy statement will not provide antitrust ''immunity'' to ACOs. While an ACO that applies for antitrust review and receives a letter from an antitrust agency indicating the agencies will not take an enforcement action can proceed, safe in the knowledge that those 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 will protect it only from an enforcement action by the agencies. Private parties are free to sue the ACO. And it remains to be seen whether courts will give weight to the policy statement in antitrust litigation before them. They do not have to do so.

Finally, 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 pronouncement in the policy statement that CMS's eligibility criteria ''are broadly consistent with the indicia of clinical integration,'' it remains to be seen whether CMS will apply different – and potentially looser – standards than has the FTC when it reviews clinically integrated networks.

These matters and others undoubtedly will be the subject of comments addressed to the antitrust agencies during the next month. While a final statement, therefore, will not be issued for many months, providers interested in forming a qualified ACO would do well to assume that the final statement will closely resemble the proposed policy statement and consider structuring their organizations accordingly.

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[12] *Federal Trade Commission v. Freeman Hospital*, 69 F.3d 260 (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).

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