The FTC-DOJ Antitrust Enforcement Policy
For ACOs in the Aftermath of Public Comment

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With the close of the public comment period on the accountable care organization (ACO) antitrust enforcement policy statement proposed by the Department of Justice and the Federal Trade Commission, it is probably fair to say that the public comments overall were supportive of the idea that the agencies should have such a policy, but had many disagreements with the methodological approach taken in the document.

More than 100 public comments were submitted and they are predictably wide-ranging. With no pretense of distilling every such comment, this article discusses nine major themes that seem to have broad support or otherwise present questions of interest.

2 The DOJ and FTC are referred to herein as the “agencies.”
3 The public comments reflect little disagreement with the substantive antitrust standards, but on the other hand, there was relatively little in the policy statement that could be considered groundbreaking from a substantive antitrust standpoint.
4 All of the comments referenced in this article may be accessed online through the index-page link at the end of the article.
The Policy Statement Summarized.

The policy statement applies to ACOs that are (a) formed as collaborations (but not mergers) among otherwise independent providers and provider groups, (b) after the effective date of the Patient Protection and Affordable Care Act (the “health reform act”), i.e., March 23, 2010, that (c) seek to participate, or have otherwise been approved to participate, in the Medicare Shared Savings Program (“SSP”).  The true focus of the policy statement, however, are those ACOs that also intend to contract with commercial health insurance plans.

ACOs that meet the Medicare SSP requirements for governance, leadership structure, and clinical and administrative processes will be treated by the agencies as “clinically integrated,” and accordingly their activities will be evaluated for antitrust purposes under the “rule of reason” (a facts-and-circumstances analysis).  This means that the agencies will not presumptively treat the collective pricing and negotiation activities of qualified ACOs as per se unlawful price-fixing or market allocation agreements.

In order to assess the antitrust risks of an ACO, the policy statement establishes a rubric that, first, adopts simplifying assumptions for defining the relevant product and geographic markets in which to assess competitive effects and, second, divides the universe of ACOs into three levels of concern based on market share.  The policy statement relies on Medicare payment methodology to define product markets—that is, a physician’s “product market” is defined by the Medicare Specialty Code (MSC) for her practice, outpatient “products” are classified by outpatient service categories as defined by Medicare, and inpatient “products” are defined by major diagnostic category (MDC).  Geographical markets are defined by each provider’s “primary service area” (PSA), defined by the contiguous ZIP codes from which the provider obtains 75 percent of its patients.

Using these criteria to determine market share, ACOs are grouped in the following categories:

- An ACO meets the agencies’ “safety zone”—and therefore presumptively presents no antitrust risks—if it meets three criteria: (1) the ACO participants in combination do not provide than 30 percent of any relevant service (product) in any single ACO provider’s PSA, subject to certain defined (and limited) exceptions for providers in rural areas; (2) no hospital or ASC participating in the ACO is exclusive to the ACO; and (3) if the ACO includes a “dominant provider” (one with more than a 50 percent market share of any service that no other ACO participant provides), the dominant provider has a nonexclusive relationship with the ACO and the ACO does not restrict any payer’s ability to contract with other networks (through an exclusivity clause or otherwise).
- If an ACO (other than with respect to providers who qualify for a rural exception) has a greater than 50 percent share of any service in any single provider’s PSA, it must obtain clearance from the agencies before it may be approved for participation in the Medicare SSP.
- ACOs that do not meet the safety zone requirements but are not subject to mandatory review may (but are not required to) obtain review from the agencies.  ACOs that seek voluntary review but receive an adverse determination from the agencies will be precluded from participating in the Medicare SSP.

In regard to the latter category, the policy statement identifies five categories of conduct (“suspect categories”) that the agencies believe would be indicative of competitive concerns: (1) preventing or discouraging commercial payers from directing or incentivizing patients to choose certain providers (e.g., “anti-steering” clauses in payer contracts); (2) tying sales (either explicitly or implicitly through pricing policies) of the ACO’s services to the commercial payer’s purchase of other services from providers outside the ACO (and vice versa); (3) contracting with physician specialists, hospitals, ASCs, or other providers (but not primary care physicians) on an exclusive basis; (4) restricting a commercial payer’s ability to make provider cost, quality, efficiency, and performance information available to its enrollees; and (5) sharing competitively sensitive pricing or other data among the ACO’s provider participants, i.e., that could be used to fix prices or other terms for services provided outside the ACO.

The agencies’ determination upon review that an ACO presents no competitive concerns (and an ACO’s ability to rely on the safety zone) is effective only for as long as the ACO meets the CMS criteria and continues to participate in the Medicare SSP, and only to the extent there are no “significant changes” in the ACO’s circumstances (presumably meaning, e.g., additions or substitutions to the provider panel).

Comments and Observations

Public comment on the policy statement covers a wide range of issues and concerns, but considered as a whole, the common thematic concerns are the following:

Is It Appropriate for the Antitrust Agencies to Act as Regulators?

Perhaps the most significant aspect of the policy statement is the mandatory review provision (and what many perceive to be the virtually mandatory review requirement for ACOs that fall in between the safety zone and mandatory review criteria).  This requirement takes the agencies beyond their traditional role of antitrust enforcement into the realm of regulating participation in a federal program.  Because of wide ranging concerns about the apparent rigidity, validity and practicality of the criteria set forth in the policy statement (not to men-
tion the de facto delegation of clinical integration criteria to CMS), the agencies’ regulatory role has been called into question. In this regard, many commenters have criticized the absence of any appeal mechanism to challenge an agency determination. This is a serious issue in light of the fact that the agencies have absolute control over an ACO’s ability to participate in the SSP and other federal agencies performing similar adjudicatory roles are required by the federal Administrative Procedure Act to adhere to minimum due process standards.

A number of commenters have proposed that either the agencies abandon mandatory review altogether (and instead follow the voluntary review approach taken in the agencies’ 1996 enforcement policy statements) or replace the mandatory review requirement with a notification requirement for ACOs that exceed the 50 percent threshold. In either case, agency review would not be a prerequisite for participation in the Medicare SSP, but presumably any subsequent investigation or action by an agency with respect to an ACO would permit CMS to exercise discretion as to whether to terminate the ACO from participation in the SSP.

**Is the Compliance Burden Excessive?**

A closely related concern pertains to the effort that any ACO must expend to determine whether it is subject to mandatory review (or whether it qualifies for the safety zone), as well as the effort that apparently would be required to present a case to the agencies for approval in a mandatory review situation.

Economists David Argue and John Gale have published a paper demonstrating the burden of the market share calculations. They estimate that an ACO with only two providers of each type (hospital, ASC, and physician group)—assuming that each provider provides a full range of services (25 MDCs per hospital, 31 outpatient categories per ASC, and 55 MSCs per physician group)—would be required to make 284 separate market share calculations in order to determine its position in the policy statement rubric. Many ACOs could be expected to have significantly more providers and therefore a geometrically larger calculation burden. Because of this, some commenters have recommended that the agencies assess an ACO’s market using geopolitical boundaries rather than on a provider-by-provider (PSA by-PSA) basis.

The agencies indicate that an ACO subject to mandatory review will be expected to provide, among other things, the ACO’s formational documents, its provider participation agreement provider payment arrangement documents, documents “discussing” the ACO’s business strategies and competitive plans, supporting information for its PSA-based market share calculations, a description of the ACO’s safeguards against intramural disclosure of competitive information, information concerning the principal commercial health plans with which the ACO is contracting or expects to contract, and the identity of competing ACOs. Commenters have requested that the agencies specify their requirements in more detail, particularly with respect to the ACO’s business plans, so as to minimize the potentially significant burden of searching for any and all documents that may have been created over a long planning and organizational cycle for the ACO.

**Will the Required Market Share Calculations Actually Be Useful?**

This question has two aspects. First, the policy statement itself recognizes that readily available data and information will be insufficient for most ACOs to make the required market share calculations. Some of the gaps in information will be addressed by more detailed data to be made available by CMS. However, that information will be in the form of Medicare fee-for-service allowed charges by physician specialty and outpatient care category by ZIP code, and in states where hospital discharge data are not reported, the policy statement recommends using Medicare fee-for-service allowed charges as market share measures for hospitals as well.

However, as the comments indicate, Medicare data have significant limitations for this purpose. Notably, Medicare data will not provide a necessarily accurate picture of utilization for services that are not used (or not used to a significant degree) by the over-65 population, such as obstetrics and pediatrics. More generally, in many geographic areas, Medicare data will not accurately portray relative provider market shares for the commercial population, and this is a concern given that competition in the commercial patient market is in fact the primary focus of the policy statement. Geographic proximity to a retirement community, for example, might well suggest, based on Medicare discharges, that a hospital has a high market share, when in fact that hospital might not have a comparably high share of commercial patients.

Apart from issue of data limitations, public comments have focused on the potential “false positive” issue arising from the use of proxies for product and geographic markets. That is, there is a risk that under the agencies’ methodology, high market shares of ACO participants may be more apparent than real. Hospital services are a good example this problem with respect to product market definition. The universe of inpatient hospital services is divided into 25 MDCs. Within each MDC, there is an average of 25 DRGs. Thus, two hospitals that each provide cardiac services would be classified as “competitors” on an MDC basis, even though they might not compete significantly at the DRG level (e.g., one may be a significant provider of cardiac surgical services while the other may only provide medical services).
The reliance on primary service areas as a proxy for geographic markets poses similar issues. The agencies acknowledge that the 75 percent PSA definition may not reasonably approximate actual geographic markets. Although a number of commenters indicate that the use of ZIP code patient origin data may be the only realistic choice for the agencies to use as an “quick-look” initial screen, they point out that the agencies themselves do not actually rely on this type of market definition in making enforcement decisions in health care. There seems to be consensus, however, that a 75 percent threshold is too narrow in any event, as, by definition, it means that the provider in question is obtaining 25 percent of its patients from outside the putative “market,” which ordinarily would be considered too economically significant to a health care provider to exclude from a competitive analysis.22

The consensus of public comment around these issues seems to be that many ACOs will be required to expend time and resources explaining why the competition defined by the agencies’ rubric doesn’t really exist (or, at least, is not as extensive as it appears), but rather is an artifice of the agencies’ methodology.

Are the Criteria Too Rigid?

Like all regulatory “safe harbor” pronouncements, the policy statement is conservative and, from a practical standpoint, one would not expect the agencies to cover every “what-if” circumstance in the document. However, many comments note concern over the apparent rigidity of the text. This is particularly evident with respect to the caveat that an agency’s clearance advice will be effective only for so long as there are no “significant changes” in the ACO’s provider network composition. For most IPAs, PHOs, or health plans, providers come and go on a regular basis. But absent some materiality standard, there is concern that ACOs will be required to constantly interact with the agencies on a regulatory basis as their networks change and evolve.23

The concern with rigidity also arises in regard to exclusivity and the suspect categories of behavior, as discussed below.

Is Exclusivity Always Bad?

Many commenters have challenged the agencies’ negative outlook on exclusivity. Exclusivity is treated negatively both in the safety zone and in the identification of suspect categories of behavior. The agencies make a point of noting that when they say “nonexclusive” they mean nonexclusive in fact, not just the absence of a contractual restriction.

There is a widely held consensus that the presumption against provider exclusivity, especially hospital exclusivity, is (at a minimum) too rigid and ill-advised.24 For example, it is expected that most ACOs will be formed around hospitals, and that hospitals will make significant investments in the formation and operation of the networks. Effectively requiring a hospital to participate in a competing ACO therefore is a deterrent to making the investment in the first place, and certainly would deprive the ACO (and the public) of the benefits of competition between ACOs. It also has been noted that exclusivity can be means to promote efficiency in terms of care coordination and resource alignment.25

One commenter has pointed out that the agencies logically should bifurcate their concerns about exclusivity between requirements that a provider contract exclusively with a particular ACO (and not participate in other ACOs) and requirements that a provider contract with payers only through the ACO (and not contract with any payer outside of the ACO).26 The former circumstance rarely presents a competitive concern in the absence of the second, and thus it makes no sense to focus on the former as a disqualifying factor.

How Suspect Are the Suspect Categories?

Within the categories of suspect behavior, there is a fair amount of gray area that the agencies have not acknowledged in the policy statement.27 This is significant because several of the five categories recur frequently in provider-payer contract negotiations, notably with respect to the collection and dissemination of provider performance data and in regard to the imposition by payers of limited provider networks.

The agencies understandably would like to assure that consumers have relevant information relating to ACO providers, as market information is a foundation of competition. To that end, the agencies state, “Restricting a commercial payer’s ability to make available to its health plan enrollees cost, quality, efficiency, and performance information to aid enrollees in evaluating and selecting providers in the health plan . . .” is likely to present competitive concerns. With some reason, however, providers have an abiding concern over the way in which commercial payers collect, process and present provider performance data. To the extent that the agencies are suggesting that an ACO could not refuse to contract with a payer that would not agree to objectively reasonable criteria to govern the data collection and reporting process, that would appear to be an unreasonable, and even counter-productive, position.26

The agencies also state that competitive concerns will be presented if an ACO, “prevent[s] or discourag[es]” commercial payers from directing or incentivizing patients to choose certain providers, including providers that do not participate in the ACO, through ‘anti-steering,’ ‘guaranteed inclusion,’ ‘product participation,’ ‘price parity,’ or similar contractual clauses or provisions.” Again, it is by no means clear that it is always or even generally anticompetitive for a provider network to require contractual assurance against arbitrary or capricious exclusion from commercial networks.28

How Does the Policy Statement Relate to Enforcement Decisions?

There are areas in which the policy statement unquestionably is disconnected from prevailing case law and/or the agencies’ own positions in litigation. For ex-

22 See, e.g., Ettinger comments; Miles comments.
23 See, e.g., AHA comments.
24 See, e.g., AMA comments, AHA comments, ABA comments, and FAH comments.
25 See, e.g., AMA comments and comments submitted by James Langenfeld, Ph.D. (“Langenfeld comments”).
26 See ABA comments; see also Miles comments.
27 See, e.g., FAH Comments.
28 See, e.g., comments submitted by Marshfield Clinic (May 31, 2011) (“Marshfield comments”).
29 See, e.g., AMA comments.
ample, the “primary service area” approach to market definition has been rejected by federal courts and in fact is not the prevailing mode of analysis in the policies of the agencies. The policy statement also singles out certain tying arrangement (tying sales, either explicitly or through “bundled” pricing, of services provided by the ACO to services provided outside of the ACO) as conduct that is likely to be deemed anticompetitive. Here, too, courts and commentators have been unwilling to take an equivalently negative view.

To some extent perhaps, the disconnect is of no relevance, as the policy statement describes a screening process, and the determination of the reviewing agency is enforced, in the first instance, outside of the courts—i.e., by denying participation in the SSP. Presumably, if an agency went the next step in challenging an ACO, the agency would have to consider more carefully what positions it could defend in court. But the situation does again raise the question of whether a disappointed applicant to the Medicare SSP program should have readdressed if it believes that it was denied participation based on criteria that would not hold up in court.

**Does the Policy Statement Favor Some ACOs Over Others?**

Some comments express concern that the agencies have singled out ACOs that are formed as collaborations of independent providers, and do not require similar accountability from ACOs that are organizationally integrated (i.e., an ACO consisting of a single health system). It is suggested that this approach will drive ACO formation toward the system-based, physician-acquisition model.

However, one could hardly fault the agencies on this point. It has always been the case that single-entity conduct is judged differently under the antitrust laws, and purely from an antitrust standpoint—there would seem to be no reason to depart from established jurisprudence in the case of ACOs.

**What About Other Types of ACOs?**

The policy statement specifically does not address, and is not to be relied on with respect to, (1) preexisting (i.e., pre-health reform act) provider-networks, (2) networks that operate on a financial risk-sharing model (i.e., economically integrated networks), (3) networks that seek to be “clinically integrated” without meeting the criteria (or all of the criteria) of the Medicare SSP, or (4) networks that simply do not participate in, or cease participating in, the SSP. As such, the policy statement in all likelihood is technically irrelevant to a substantial majority of provider collaborations, and those networks—presumably—must continue to rely on the 1996 statements, along with the occasional staff advisory opinion on clinical integration.

Nonetheless, this dichotomy logically has led to questions from both providers and attorneys.

- Is the policy statement intended to mark any change in the agencies’ views of economically integrated provider networks (e.g., based on market shares)? Inferentially, the answer would seem to be “no,” but the existence of a separate enforcement rubric for a particular sub-class of provider networks makes the question relevant.
- Are all of the CMS criteria really relevant to the question of whether a commercial-market ACO is clinically integrated? For example, what basis is there to believe that CMS’s governance criteria for ACOs would have any nontrivial effect on the organization’s ability to be clinically integrated or on its antitrust posture generally?
- From an antitrust standpoint, what difference does it make when an ACO was formed? The agencies logically could take the position that their review is not intended to have retroactive application, but there is no reason to think that the date of incorporation could in any way affect how an ACO would compete in the future.
- If the policy statement is a logical approach to Medicare-participating ACOs that contract in the commercial market, why is it not reliable for ACOs that don’t participate in the SSP? The agencies seem to base the distinction on their willingness to rely on an ACO’s compliance with CMS participation criteria as an indicator of sufficient clinical integration. However, as noted, not all of those criteria are in fact relevant to integration, and that has left some commenters wondering why the agencies are unwilling to extend a basic set of integration principles to non-SSP-participating networks.

**Further Reading**

At last count, there were approximately 125 public comments from providers, health plans, associations, lawyers, and public interest groups. The comments may be accessed on line at [http://www.ftc.gov/os/comments/aco-comments/index.shtm](http://www.ftc.gov/os/comments/aco-comments/index.shtm). It is anticipated that the agencies will publish a response to the public comments and, potentially, a revised policy statement in sufficient time to meet the commencement date established for the SSP. As the agencies note, however, if the SSP is to commence as scheduled on Jan. 1, 2012, the agencies will need to complete their work and be in a position to accept applications for review by August 2011. But given the generally negative provider reaction to the CMS proposed ACO regulations, questions exist as to whether the SSP in fact will meet its proposed start date. A delay of the SSP might well delay a final policy statement as well.

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32 See, e.g., FAH comments; see also Miles comments.

33 See, e.g., Langenfeld comments; AMA comments.

34 See, e.g., ABA comments; FAH comments.

35 See, e.g., ABA comments; AHA comments; AMA comments.

36 See, e.g., Miles comments. In this regard, it should be noted that, although the 1996 statements discuss clinical integration, those statements do not define the criteria for integration with any specificity.