

Health Reform Alert

DOJ and FTC Issue Policy Statement on Antitrust Enforcement of ACOs

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The Department of Justice (DOJ) and the Federal Trade Commission (FTC) (together, “the antitrust agencies”) have raised as many antitrust questions as they have answered with their March 31, 2011, Proposed Statement of Antitrust Enforcement Policy Regarding Accountable Care Organizations Participating in the Medicare Shared Savings Program (“Policy Statement”). Although the Policy Statement is styled as a mere statement of antitrust enforcement policy for accountable care organizations (ACOs), similar to earlier enforcement statements, in fact it is issued in support of a proposed regulation from the Centers for Medicare & Medicaid Services (CMS), regarding the Medicare Shared Savings Program and ACO provisions of the Patient Protection and Affordable Care Act (PPACA). As such, the antitrust agencies clearly have taken on a much more significant role in the regulatory review process of a sister agency than previously. That regulatory entanglement can be seen in provisions of the Policy Statement that attempt to reconcile the contradictory goals of reducing antitrust uncertainty for ACOs in order to facilitate participation in the Medicare Shared Savings Program, while sending a strong enforcement message that the antitrust agencies will not tolerate ACOs that acquire the ability to exercise market power in commercial markets. The results are highly technical rules intended to allow ease of application, but which, as discussed below, raise many questions as to their meaning and likely application. Comments on the proposed Policy Statement are due on or before May 31, 2011, which is within 60 days of publication in the *Federal Register*.

Purpose of Antitrust Review of ACOs

Although the antitrust agencies published their Policy Statement as a separate document for notice and comment, CMS provided its own explanation for the role of antitrust review in the Medicare Shared Savings Program. In CMS’ proposed rule, it identified three reasons for its incorporation and reliance on the antitrust agencies’ Policy Statement: (i) ACOs that do not face significant antitrust risk are likely to complete the three-year commitment that CMS requires without disruption of the program due to antitrust challenge, (ii) ACO-versus-ACO competition is likely to improve the clinical quality of care that Medicare beneficiaries receive and (iii) ACOs exercising market power in the private market are likely to prefer private pay patients over Medicare patients and, thus, to limit access by Medicare patients to their services. The antitrust agencies, in turn, explained that they issued their Policy Statement “to maximize and foster opportunities for ACO innovation” and “both to clarify the antitrust analysis of newly formed collaborations among independent providers . . . and to coordinate the antitrust analysis with the CMS.”

Framework of the ACO Antitrust Policy Statement

Applicability. The Policy Statement applies only “to collaborations among otherwise independent providers and provider groups, formed after March 23, 2010, that seek to participate, or have otherwise been approved to participate, in the Medicare Shared Savings Program.” It does not apply to mergers.



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General Approach. Not surprisingly, given the nature and detail of the requirements for an ACO to receive CMS approval, the Policy Statement declares that the antitrust agencies will review the legality of those ACOs using the more nuanced “rule of reason” test rather than examining whether to summarily condemn ACOs as mere price-fixing vehicles under the strict “per se” test, so long as “a CMS-approved ACO provides the same or essentially the same services in the commercial market” and “in the commercial market, the ACO uses the same governance and leadership structure and the same clinical and administrative processes as it uses to qualify for and participate in the Medicare Shared Savings Program.”

The actual antitrust review of an ACO is a mix of (i) self-evaluation, (ii) voluntary submission to the antitrust agencies and (iii) mandatory review, depending on the “size” of the ACO as determined by a defined statistical analysis set forth in the Policy Statement. Moreover, the Policy Statement is arguably ambiguous as to which agency—the DOJ Antitrust Division or the FTC—will conduct the review. The Policy Statement states that it could be either, by requiring an ACO to submit requests for review to both agencies, who “will then determine which Agency will be the reviewing Agency” through a newly established joint “ACO Working Group.” No criteria are provided as to how the work will be divided between the agencies. Indeed, Commissioner Rosch of the FTC dissented in part from the Policy Statement “because of the statement’s *suggestion* that the formation of ACOs will be reviewed by both the FTC and the DOJ.” Clearly, at least Commissioner Rosch has left open the possibility that the ACO Working Group will determine that the FTC conducts all reviews.

The Policy Statement describes three paths for review. The agencies deem some ACOs to pose so little antitrust risk that they do not require, or even have the opportunity for, agency review, and, thus, fall within a “safety zone.” ACOs that are outside the safety zone have two potential avenues of antitrust review. Voluntary review is available for those of “intermediate” size; for those whose size is deemed “dominant,” mandatory review is necessary before they may participate in the Medicare Shared Savings Program.

Safety Zone. Some ACOs can avoid agency review if they limit their participation so as not to exceed an agency-declared 30 percent cap, or “safe harbor.” With some important exceptions (discussed below), the agencies do not require review of an ACO where “the independent ACO participants (e.g., physician group practices) that provide the same service (a “common service”) . . . have a combined share of 30 percent or less of each common service in each participant’s [Primary Service Area or “PSA”], wherever two or more ACO participants provide that service to patients from that PSA.” The PSA for each service is defined as “the lowest number of contiguous postal zip codes from which the [ACO participant] draws at least 75 percent of its [patients]” for that service.

Application of this PSA share test will require careful statistical analysis using data that CMS promises to make available. Indeed, as discussed below, ACOs exceeding the 30 percent threshold have reason to apply the test carefully, because if the share exceeds 50 percent, an ACO may have to obtain prior approval from an antitrust agency to participate in the Medicare Shared Savings Program.

Using an example of two groups of orthopedic surgeons, Practice Group (PG) A and PG B, the antitrust agencies specify that the 30 percent cap must not be exceeded by the combined share for each practice group’s preexisting PSA, not for merely for the ACO as a combined entity. “The ACO’s share of orthopedic surgery in PSA A would be the total Medicare allowed charges for claims billed by the ACO’s orthopedic surgeons (which are PG A’s and PG B’s total allowed charges for claims billed by orthopedic surgeons for Medicare beneficiaries in PSA A’s zip codes) divided by the total allowed charges for orthopedic surgery for all Medicare beneficiaries in PSA A.” The same approach would apply to PSA B.

Additional limits apply to qualify for the safety zone. “Any hospital or ambulatory surgery center (“ASC”) participating in an ACO must be non-exclusive to the ACO to fall within the safety zone, regardless of its PSA share.” While the Policy Statement declares that nonexclusivity is satisfied if “a hospital or ASC is allowed to contract individually or affiliate with other ACOs or commercial payers,” the practical application of this limitation will need to be considered carefully. The agencies do not specify, for example, what happens if a hospital or ASC fails to participate in other ACOs, or whether there is any review beyond the express terms of the ACO participation agreement.

It is worth noting, moreover, that, in two circumstances, ACOs can still qualify for the safety zone, even if their PSA share exceeds 30 percent. First, if an ACO exceeds the cap merely because it includes one or more preexisting practice groups whose share exceeds 30 percent, but the ACO does not add any other participant who provides the same service as the preexisting practice group, there are no “common” services, and the safety zone applies. The Policy Statement illustrates the point this way: “For example, 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 and the ACO falls within the safety zone regardless of its share, subject to the dominant provider limitation, described below.” Where the PSA share of such a single provider is “dominant,” i.e., where it exceeds 50 percent, the “dominant provider” must be nonexclusive and “cannot require a commercial payer to contract exclusively with the ACO or otherwise restrict a commercial payer’s ability to contract or deal with other ACOs or provider networks.”

Second, even where a “common service” exceeds 30 percent, an “ACO may include one physician per specialty from each rural county (as defined by the U.S. Census Bureau) on a non-exclusive basis” or a “Rural Hospital on a non-exclusive basis” and still qualify for the safety zone. A rural hospital is either a sole community hospital or a critical access hospital. Sole community hospitals and critical access hospitals are defined by reference to specific criteria and Medicare reimbursement methodologies. The antitrust agencies do not explain how they came to view this special rule as necessary, but one can readily envision a circumstance where, for example, inclusion of a rural hospital that is necessary for the ACO’s purposes would entail inclusion of physicians employed by the hospital, thus triggering a potential loss of the safety zone.

Intermediate ACOs. An ACO in the intermediate world, i.e., greater than 30 percent share but less than 50 percent share, can run the risk of submitting its proposed ACO to the antitrust agencies for review with the hope of receiving “further certainty regarding the application of the antitrust laws to its formation and planned operation.” The “risk” is that if the reviewing agency states that it “is likely to challenge or recommend challenging the ACO if it proceeds,” CMS will not accept the ACO into the Medicare Shared Savings Program. Naturally, if the agency states a present intent not to challenge, then the ACO has received “further certainty” that the agency will not do so. The agencies promise “expedited review” of ACOs seeking their views, committing to complete the review within 90 days of receiving a rather extensive and not fully defined list of “necessary documents and information.” It is noteworthy that the information expected includes a calculation for each “combined service” regardless of whether the share of the combined service exceeds the 30 percent safe harbor cap, suggesting that the agency review may extend beyond the service line that disqualified the ACO from the safe harbor. Furthermore, the ACO must submit all the information that would satisfy CMS’ ACO application process. The 90-day clock does not begin to run until the agency determines that it has received all the information it expects.

An ACO in the intermediate world can also obtain “further certainty” by avoiding “five types of conduct” specified by the antitrust agencies. The Policy Statement declares that such an ACO “is highly unlikely to present competitive concerns” if it avoids the following—

- preventing or discouraging commercial payers from directing or incentivizing patients to choose certain providers, including providers that do not participate in the ACO
- 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), including providers affiliated with an ACO participant (e.g., an ACO may not require a purchaser to contract with all the hospitals in the same network as the hospital that belongs to the ACO)
- with an exception for primary care physicians, contracting with other ACO physician specialists, hospitals, ASCs or other providers on an exclusive basis, thus preventing or discouraging them from contracting outside the ACO, either individually or through other ACOs or provider networks
- 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, if that

information is similar to the cost, quality, efficiency and performance measures used in the Medicare Shared Savings Program

- sharing among the ACO's provider participants competitively sensitive pricing or other data that they could use to set prices or other terms for services they provide outside the ACO.

While not stated as “necessary” for an intermediate ACO to pass muster, the agencies’ admonition about this conduct is a clear signal to intermediate ACOs that antitrust compliance is better achieved through avoidance of these practices.

Dominant ACOs. Lastly, “dominant” share ACOs, that is, those over 50 percent, must undergo antitrust agency review and receive a “favorable” letter, i.e., one in which an antitrust agency states it “has no present intention to challenge or recommend challenging the ACO under the antitrust laws,” in order to participate in the Medicare Shared Savings Program. Like intermediate ACOs, they must submit the not fully defined list of “necessary documents and information.” The Policy Statement advises “dominant” ACOs to avoid the five types of disfavored conduct. The 90-day clock operates in the same manner, but an additional timing requirement is imposed. A “dominant” ACO must submit all the necessary documents and information “at least 90 days before the last day on which CMS has stated that it will accept ACO applications to participate in the Medicare Shared Savings Program for the relevant calendar year.”

Changed Circumstances. The Policy Statement and CMS’ proposed regulation both make some specific references, as well as some general allusions, to the antitrust implications of changed circumstances. For example, an ACO’s PSA share may wax and wane. CMS regulations provide that if ACOs fall below a certain size, they may be drummed out of the program. That may have implications for their antitrust exposure, as well. The Policy Statement, as discussed above, declares application of the more lenient rule of reason test, but it then observes that “[t]his rule of reason treatment will apply to the ACO for the duration of its participation in the Shared Savings Program.” That observation suggests that if an ACO is disqualified, the agencies might switch modes and apply the more stringent “per se” illegal approach. Moreover, regardless of which test applies, an ACO that falls out of the program, loses the protection of the “safety zone.” Similarly, if an ACO’s share grows, it might face an additional antitrust review process, depending on the source of its growth. “[I]f . . . there is a significant change to the ACO’s provider composition such that the ACO exceeds the 50 percent threshold or is materially different than what was initially reviewed, the ACO must seek antitrust review as set forth above.” What constitutes something “materially different than what was initially reviewed” is not spelled out.

Beyond the Policy Statement – Some Preliminary Considerations

The Policy Statement only goes—and, in some ways, only could go—so far in addressing antitrust risk. For example, nothing in the Policy Statement purports to limit the general applicability of the antitrust laws. CMS’ regulation is, in fact, explicit in stating that “[n]othing in these regulations shall be construed to modify, impair, or supersede the applicability of the antitrust laws.” That means, of course, that, even for matters specifically addressed in the Policy Statement, such as the antitrust agencies’ “safety zone,” a private party is free to challenge an ACO’s formation or operation, and federal courts will make their own interpretation of how the antitrust laws apply. Indeed, the antitrust agencies point out explicitly that the “shares” of PSAs on which they base their review are not antitrust markets. The Policy Statement explicitly calls for reliance on data and a methodology for calculating PSA shares that the antitrust agencies have each disclaimed as sufficient in prior enforcement activities. ACOs would need to undertake a potentially significantly different analysis to evaluate their antitrust risk from prior suit or their antitrust risk from agency challenge if they were stripped of their safety zone.

Some antitrust implications of ACOs appear simply not to have been addressed by the Policy Statement or are otherwise unclear. For example, CMS draws a somewhat unclear distinction between ACO participants and suppliers. The former are those that form and govern an ACO; the latter appear to be providers that contract to provide services to the ACO. The Policy Statement speaks only of “participants,” without defining the term or making reference to the CMS-defined use of the terms. If the Policy Statement were read to say that “participant” for its purposes is the same as “participant” as used in the CMS proposed regulation, then it would grant significant flexibility to ACOs to comply

with the antitrust guidelines, while ensuring ACO beneficiaries broad access to care. On the other hand, one group of providers subcontracting with another and then negotiating with commercial payers can raise antitrust issues that would need to be independently evaluated.

Similarly, the Policy Statement specifies that an intermediate or dominant ACO may not “tie” the sale of an ACO service to a commercial payer to some service outside of the ACO. But what of a tying arrangement within ACO? Even if a dominant or significant ACO participant is not exclusive, that would not foreclose an ACO from “tying” the purchase of that dominant or significant participant’s services to the purchase of some other ACO participant’s services. Put another way, the antitrust Policy Statement appears to contemplate that an ACO may engage in “all or nothing” contracting within the ACO. That may well have antitrust implications that are not addressed by the antitrust agencies.

Finally, the antitrust agencies and CMS are silent on whether an intermediate ACO or a dominant ACO has any recourse if an agency letter excludes it from the Medicare Shared Savings Program. Will an ACO essentially declared anticompetitive and barred from the program have a right to appeal that determination? If so, to what court and on what record? The Policy Statement is silent on whether CMS intends to vest the antitrust agencies, whichever one ultimately reviews an ACO’s request for expedited review, with unfettered discretion to decide whether the ACO can participate in CMS’ program.

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