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A Not So Modest Proposal? The FTC/DOJ Proposed Statement of Antitrust Enforcement Policy Regarding Accountable Care Organizations Participating in the Medicare Shared Savings Program

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On March 31, 2011, the Federal Trade Commission and the Antitrust Division of the Department of Justice (the "FTC and "DOJ" or the "Agencies") issued a Proposed Statement of Antitrust Enforcement Policy Regarding Accountable Care Organizations Participating in the Medicare Shared Savings Program. ("Proposed Statement).[2] The Proposed Statement offers guidance concerning how the Agencies will review for antitrust compliance combinations of physicians, hospitals, and other providers into Accountable Care Organizations ("ACOs") created pursuant to the Medicare Shared Savings Program of the Patient Protection and Affordable Care Act and the Health Care and Education Reconciliation Act of 2010 (the "Affordable Care Act").[3] The thrust of the Medicare Shared Savings Program is that providers who form ACOs that lead to reduced costs for Medicare will share in any savings they helped create.

At a glance, it may not be apparent how a program to incentivize health care providers to lower Medicare costs could implicate the antitrust laws. Indeed, if an ACO chooses to contract only with the Medicare program, one would anticipate very little interest on the part of the Agencies. However, providers have made clear that they are unlikely to form ACOs unless they might also use them for their commercially-insured patients;[4] because ACOs by their very nature involve competitors acting in concert, extending their reach to the commercial setting raises antitrust concerns and inevitably attracts the attention of the FTC and DOJ.

The Proposed Statement arises out of tight coordination between the Agencies and the Center for Medicare and Medicaid Service ("CMS"). One of the Proposed Statement's major accomplishments is to confer automatic Rule of Reason treatment on any ACO that has met certain eligibility criteria[5] for the Medicare Shared Savings Program[6] laid out in the CMS Notice

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[2] 76 Fed. Reg. 21894; Press Release *available at* http://www.ftc.gov/opa/2011/03/aco.shtm.

[3] The Proposed Statement applies only to combinations of providers formed after March 23, 2010.

[4] *See* Fed. Trade Comm'n & Dep't of Health and Human Serv., Workshop Regarding Accountable Care Organizations, and Implications Regarding Antitrust, Physician Self-Referral, Anti-Kickback, and Civil Monetary Penalty (CMP) Laws (Oct. 5, 2010).

[5] The eligibility criteria an ACO must meet in order to participate in the Shared Savings Program are: (1) a formal legal structure that allows an ACO to receive and distribute payments for shared savings; (2) a leadership and management structure that includes clinical and administrative processes; (3) processes to promote evidence-based medicine and patient engagement; (4) reporting on quality and cost measures; and (5) coordinated care for beneficiaries.

of Proposed Rulemaking, Medicare Program; Medicare Shared Savings Program: Accountable Care Organizations ("CMS Proposed Rule").[7] This represents a remarkable development, both because it pegs the Agencies' antitrust analysis to standards created by a different agency and because so much of the Agencies' prior evaluation of clinically integrated networks involved assessing whether or not the Rule of Reason was appropriate under a given set of circumstances. The removal of doubt regarding whether to apply the Rule of Reason seems to have shifted the emphasis forward such that the bulk of the Proposed Statement focuses on which ACOs need to undergo antitrust analysis in the first instance.

The Proposed Statement breaks potential ACOs into three different classes based upon their perceived potential to exercise market power: depending on whether the combined share of any services that are offered by more than one of an ACO's participants in their respective Primary Service Area ("PSA") is less than 30 percent, greater than 50 percent, or between 30 and 50 percent, an ACO's regulatory burden will vary from minimal to rather heavy.

Understanding this screening mechanism depends upon understanding two concepts, PSA share and common services. PSA share—a construct imported from the Stark II laws—refers to an ACO participant's share in the lowest number of contiguous zip codes from which it draws at least 75 percent of its patients for a particular service. The Proposed Statement defines a common service as one offered by more than one ACO participant. Thus, if an ACO features two physician groups that both offer, among other services, cardiology, then their combined share of cardiology services—their common service—in their respective PSAs must be calculated for antitrust review purposes. Notably, ACO participants' respective shares of services only offered by one participant are irrelevant to the antitrust analysis.

In an effort to offer guidance regarding the share calculation, the Proposed Statement mandates that an ACO calculate its share of outpatient services using allowed Medicare fee-for-service payments (which CMS has stated it will make public) and recommends that, for inpatient services, ACOs use state-level all-payer data to determine share of inpatient discharges. For services not often used by Medicare beneficiaries, such as pediatrics, obstetrics, or neonatal care, providers are left to their own devices to find data to measure PSA share of those services—the Proposed Statement suggests as a "reasonable" data source the "number of actively participating physicians within a specialty and within the PSA."[8] While confusion persists regarding exactly how to conduct this share calculation, what is clear is that gathering the necessary information likely presents a heavy burden for providers interested in forming ACOs.

Once an ACO calculates its PSA share for any combined services, it can then obtain a clearer picture of the process it must undertake with respect to a potential antitrust review. If the PSA share does not exceed 30 percent, the Agencies pledge in the Proposed Statement not to challenge an ACO, absent "extraordinary circumstances." Thus, such ACOs fall into a so-called Antitrust Safety Zone, and the participants have no obligation to contact the Agencies for antitrust review. Of note for hospital or ambulatory care participants, in order to qualify for the

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[6] The Proposed Statement notes that, though the CMS eligibility requirements relate only to the Medicare Shared Services Program, the Agencies will use the same criteria for evaluating ACOs in the commercial market.

[7] Released the same day as the Proposed Statement, 76 Fed. Reg. 19528, *available at* http://edocket.access.gpo.gov/2011/pdf/2011-7880.pdf.

[8] The Proposed Statement offers no suggestions about how to obtain the necessary information.

Antitrust Safety Zone, in addition to having a PSA share of less than 30 percent, each must have a non-exclusive relationship with the ACO.

The Antitrust Safety Zone can also extend to an ACO with rural counties in its PSA. Such an ACO may include one physician per offered specialty from each county or one rural hospital per county and fall within the Antitrust Safety Zone, even if the inclusion of such physicians or hospitals raises the ACO's PSA shares for common services above 30 percent, as long as the ACO contracts with the physician and/or hospital on a non-exclusive basis.

In contrast to ACOs that have less than a 30 percent combined PSA share, those whose participants exceed a combined share of 50 percent in any common service are obliged by the CMS Proposed Rule and the Proposed Statement to submit to an antitrust review. In fact, an ACO whose share exceeds 50 percent for any common service cannot participate in the Medicare Share Savings Program absent a letter from one of the Agencies stating "it has no present intent to challenge or recommend challenging the ACO under the antitrust laws."[9] An ACO in this situation must file a request for expedited antitrust review with both Agencies, which will then decide between them which agency will handle the review for that particular ACO. The Proposed Statement is silent about what factors might influence the decision of whether the DOJ or the FTC conducts the review of a given ACO.[10]

Though the Agencies express a shared emphasis on handling the antitrust review in an expedited fashion, the Proposed Statement includes an extensive list of documents—completely distinct from those required for the CMS application—that the Agencies must receive from the ACO to assure such expedited review. These documents include:

1. the application submitted to CMS and all supporting documents;
2. documents or agreements relating to the ability of the ACO participants to compete with the ACO or relating to incentives to contact with insurers through the ACO;
3. documents discussing the ACO's business strategies or plans to compete in the Medicare and commercial markets;
4. documents showing "the formation of any ACO or ACO participant that was formed in whole or in part, or otherwise affiliated with the ACO, after March 23, 2010"; and
5. information sufficient to demonstrate: (a) the ACO's PSA share calculations for each common service, (b) any restrictions that "prevent ACO participants from obtaining information regarding prices that other ACO participants charge commercial payers that do not contract through the ACO," (c) the identity of the five largest commercial health plans or other payers for the ACO's services, and (d) the identity of any other known ACOs that will compete in the ACOs PSA.

[9] The only exception to this rule would be if the ACO falls under the Rural Exception discussed above; in that case, even if the ACO's common services PSA share exceeds fifty percent, it nonetheless would be exempt from the above review, as long as it contracts with rural providers on a non-exclusive basis.

[10] The Proposed Statement does note that the Agencies intend to establish a joint Working Group to "collaborate and discuss issues arising out of the ACO reviews" to "ensure efficient, cooperative, and expeditious review."

An ACO must also warrant that it has undertaken a good faith search for such documents and has provided all responsive material. In addition, the Agencies reserve the right to request additional information and documents as needed.

If the ACO submits all the required documents above within 90 days of the CMS deadline to submit ACO applications, the Agencies pledge in the Proposed Statement to, in 90 days or fewer, inform the ACO whether or not it is likely to face a challenge under the antitrust laws.[11] Assuming the Agencies inform the ACO that it is not likely to face such a challenge, the Proposed Statement makes clear that that advice from the agencies will be in effect for the duration of the CMS approval (3 years) absent significant changes[12] in provider composition.

When an ACO possesses a combined share in its common services of between 30 and 50 percent, it is neither eligible for the Antitrust Safety Zone nor does it trigger automatic antitrust review. An ACO in this circumstance has the choice of requesting expedited antitrust review—in which case it would follow the same procedures as an ACO subject to mandatory review—or of eschewing preliminary review and beginning operations without assurances from the Agencies regarding the likelihood of a challenge.

The Proposed Statement acknowledges that ACOs in this middle share range "may frequently be procompetitive" and offers a list of conduct that such an ACO should avoid to "reduce significantly the likelihood of an antitrust investigation." According to the Proposed Statement, the Agencies "believe that an ACO in this category is highly unlikely to present competitive concerns" if it avoids:

1. including anti-steering or similar provisions in contracts with insurers;
2. tying sales of the ACO's services to the commercial payer's purchase of other services from providers;
3. exclusive contracting with specialists, hospitals or other providers;
4. restricting insurers' right to disclose cost, quality and efficiency data to its members; and
5. sharing "competitively sensitive pricing" or other data among the ACO's participants.

As for the substance of any actual antitrust review undertaken, as mentioned above, the Agencies will employ the Rule of Reason, which involves determining whether an ACO may have significant anticompetitive effects and whether there exist substantial enough pro-competitive benefits to outweigh those anticompetitive effects. And while any ACO that meets the CMS eligibility criteria can be assured that the Agencies will not declare it *per se* illegal, the Proposed Statement does not provide any further instruction regarding how the Agencies will apply the Rule of Reason. Prior FTC advisory opinions related to clinical integration suggest that the presence or absence of market power, exclusivity of contracting, and the degree of clinical integration will drive the analysis.

Interestingly, while the Proposed Statement takes pains to present the Rule of Reason analysis as contingent on meeting the CMS eligibility criteria, it say nothing about a

[11] It remains unclear whether the time in which the Agencies are deciding which of them will review a given ACO is included within this 90 day time period.

[12] The Proposed Statement does not endeavor to grapple with what constitutes a significant change and confusing definitions in the CMS Proposed Rule only serve to cloud the picture.

collaboration among competing providers that does not meet the CMS eligibility criteria. Presumably, such a collaboration, for example an ACO-like arrangement that chooses not to participate in the Medicare Shared Services Program, is not guaranteed Rule of Reason treatment in any potential antitrust review and thus faces a greater risk if challenged.

In conclusion, the Proposed Statement endeavors to articulate clear guidelines for an ACO to obtain antitrust approval that do not unduly hamper the development of ACOs as the cost-saving, quality-of-care-improving mechanisms envisioned by the Affordable Care Act. The jury is still out on whether or not the Proposed Statement met that goal. The Agencies will accept public comments on the Proposed Statement until May 31, 2011.