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May 31, 2011

Mr. Donald S. Clark
Secretary
Federal Trade Commission
Room H-113 (Annex W)
600 Pennsylvania Avenue NW
Washington, DC 20580

RE: Proposed Statement of Antitrust Enforcement Policy Regarding ACOs Participating in the Medicare Shared Savings Program, Matter V100017

Dear Secretary Clark:

I appreciate the opportunity to submit written comments to the Federal Trade Commission (FTC) and the Department of Justice (DOJ) on the Proposed Statement of Antitrust Enforcement Policy Regarding Accountable Care Organizations Participating in the Medicare Shared Savings Program, as published in the Federal Register (Vol. 76, No. 75, p. 21894) on April 19, 2011. I regret that I was out of town and unable to participate on the panel at the FTC's Workshop on May 9.

Summary of Comments

The Proposed Statement includes four major elements that are very positive and should remain key parts of any final version of the Statement:

- It expands the number of situations in which collaborations of independent providers will be evaluated under the rule of reason, rather than treated as *per se* violations of antitrust law;
- It defines a safe harbor in which such collaborations will be exempted from antitrust investigations or actions, which will help encourage small-scale collaborations among providers that can improve the quality and reduce the costs of care;
- It explicitly discourages several important types of anticompetitive conduct by provider organizations; and
- It provides for an expedited review of provider collaborations whose size causes concerns about anticompetitive effects.

On the other hand, there are also several aspects of the Proposed Statement that are very problematic and need to be significantly revised before it is finalized:

- Its criteria for granting rule of reason treatment are too narrowly defined;
- It only attempts to address the anticompetitive effects of new collaborations of independent providers, ignoring and potentially encouraging or strengthening other types of providers which could cause equal or greater problems for competition in specific healthcare markets;
- It uses a new statistical test (PSA share) to define "market power" that will likely have significant numbers of false positives, as well as imposing significant administrative burdens on providers; and
- It relies on measures based on Medicare patients to assess the competitive impacts of providers in the commercial market.

Each of these concerns is explained in more detail below, along with suggested remedies.

Using Rule of Reason Treatment for Collaborations of Independent Providers

Despite overwhelming evidence of the improved care and lower costs that can result from having several small independent physicians collaborating with each other to share resources and coordinate care, under current law, if they jointly price their services in order to support their collaborative efforts, they are viewed as having committed "naked price fixing" and a *per se* violation of antitrust law. The notion that two independent physicians jointly providing and pricing their services automatically creates a threat to consumers, even if they are in a large metropolitan area, is absurd on its face, particularly since if those two physicians choose to abandon their independent practices and joint the payroll of a large group or hospital which jointly provides and prices its services, there would be no antitrust problem at all. It is likely that the primary impact of the current policy is to discourage more coordinated care among small providers rather than to discourage genuinely anti-competitive collusions.

Consequently, it is appropriate and long overdue to have collaborations of small independent providers evaluated, by default, under the rule of reason. The Proposed Statement takes an important step in this direction, but it should go even further in two respects:

- First, rule of reason treatment is only provided to organizations if they use, in the commercial market, the "same governance and leadership structure and the same clinical and administrative processes" that they use to meet CMS's requirements under the Shared Savings Program. However, not all of the requirements imposed by CMS for participation in the Shared Savings Program may be necessary to enable the ACO to achieve lower costs or better quality for patients, and ACOs may need to have somewhat different structures and processes for dealing with commercial patients. Consequently, **the Statement should permit ACOs to justify the existence of some differences in their structures and processes in commercial markets without automatically losing their rule of reason treatment**.
- Second, the Proposed Statement would only grant rule of reason treatment "for the duration of [the ACO's] participation in the Shared Savings Program." It is unlikely that independent providers will be willing to form collaborations if there is a threat that they will suddenly be prosecuted for *per se* violations if the ACO program is not continued in three years or if the providers are forced to drop out simply because they find the

financial aspects of the Shared Savings Program unworkable. If the standards of the Shared Savings Program were sufficient to justify rule of reason treatment while the ACO participated in that program, then they should be adequate to justify rule of reason treatment on an ongoing basis. **Consequently, the second-to-last sentence in section III of the statement should be modified to read "This rule of reason treatment will apply to the ACO ~~for the duration of its participation in the Shared Savings Program~~ as long as its structure and clinical processes remain substantially the same."**

Addressing Anticompetitive Behavior by Other Organizations

A serious weakness in the Proposed Statement is that it only addresses ACOs created through collaborations of otherwise independent providers. A group of independent physicians or other providers who wish to collaborate in the commercial market must (1) strive to meet CMS requirements in order to qualify for rule of reason treatment, (2) conduct PSA analyses to determine whether they fall into the safe harbor, and (3) submit to expedited antitrust reviews if they do not, but a similar number of physicians who are part of a single practice or who are employed by a hospital need do none of these things in order to act as a single, jointly priced entity in the commercial market.

Regardless of whether one thinks the provisions in the Proposed Statement with respect to collaborations of independent providers are too weak or too strict, they clearly create burdens and hurdles to the creation of such collaborations that do not apply to single provider entities that are identical in all other relevant respects. In many cases, the practical effect of this will not be to preserve competition by the independent entities that sought to collaborate, but to either (a) weaken their ability to compete against the larger consolidated entities by forcing them to drop their plans to collaborate or (b) encourage the independent providers to consolidate into a larger entity (or in the case of physicians, to seek employment with a larger entity) which will not be subject to the requirements at all. In either case, the result would be less competition, not more, which is completely counter to the goals of the Statement. (This is analogous to increasing criminal penalties only for robberies with firearms; the effect is as likely to be an increase in the number of robberies with knives and other deadly weapons as it is to reduce the total number of robberies, and research shows that such a shift can actually be more deadly for the robbery victims.)

Limiting the Statement just to collaborations of independent providers is implicitly based on two fallacies:

- First, it implicitly assumes that that if independent providers are precluded from collaborating, their only choice is to remain independent and compete with each other. But in fact, they also have the choice of consolidating with each other (e.g., through a merger) or joining other organizations (e.g., seeking employment with a hospital).
- Second, it implicitly assumes that precluding a collaboration of small independent providers, but allowing formation of a single consolidated entity with the same number of providers, would be desirable for competition. In fact, it is exactly the opposite: if independent providers collaborate but remain independent, the individual providers have greater ability to later withdraw and form new competitive structures than if they give up

their independence and consolidate into a single entity or seek employment with a hospital or other organization.

To solve this problem, the Statement should be expanded to include all types of large provider entities, not just collaborations of independent providers, in order to create a more level playing field between large provider organizations and collaborations of smaller providers. This should be done in two ways:

- **CMS should require that, in order to participate in the Medicare Shared Savings Program, all large provider organizations would need to go through the same type of review process defined in the Statement for collaborations of independent providers.** For example, if any ACO with a high market share (according to whatever criteria are included in the final Statement) wishes to participate in the Shared Savings Program, it would need to undergo the same type of mandatory review that is defined in the Statement for collaborations of independent providers, and it would be prohibited from participating in the Shared Savings Program if it fails that review. The FTC and DOJ would then simply need to expand the Statement so that the mandatory process would apply to any provider. To the extent that participation in the Shared Savings Program is desirable for large providers (which will depend heavily on how CMS revises the proposed regulations in many other respects), this will, in effect, give the FTC/DOJ a new tool for discouraging anticompetitive consolidations and other behavior.
- **The Statement should clearly indicate that the kinds of anticompetitive conduct that would be discouraged for collaborations of independent providers would also be discouraged for all types of providers above a certain size, regardless of whether they are participating in the Shared Savings Program or not.** (Comments about how the definitions of this conduct should be modified are included in the next section of this letter.)

Discouraging Anticompetitive Conduct

One of the very positive features of the Proposed Statement is that (in Section IV.C.) it explicitly defines five types of conduct that an ACO should avoid in order to minimize the likelihood of antitrust investigation. Although criteria based on clinical and financial integration help to ensure that providers are improving value in healthcare, they do nothing to distinguish between large clinically/financially integrated providers that engage in anticompetitive behaviors and those that do not, and so the list of discouraged behaviors in the Statement takes an important first step in making that distinction.

However, in order to be effective, **the Statement needs to include much greater detail on the five types of anti-competitive conduct** so that (a) they do not inadvertently preclude pro-competitive activities and (b) so that they can be used (as recommended in the previous section) more broadly than just for collaborations of independent providers in the Shared Savings Program. For example, the first statement ("Preventing or discouraging commercial payers from directing or incentivizing patients to choose certain providers…through ‚anti-steering,' ‚guaranteed inclusion,' 'product participation,' ‚price parity,' or similar contractual clauses or provisions) could help employers create desirable "tiered" benefit designs that would encourage patients to choose high-value ACOs, but it could also be interpreted by some as precluding an

ACO from requiring patients to use providers in that ACO for their care in order to ensure better coordination and management.

Although the list of anticompetitive conduct was discussed briefly at the FTC's workshops, it needs much more detailed discussion, and **it would be desirable for the FTC and DOJ to hold one or more additional workshops on anticompetitive conduct in order to inform revisions on the Statement. Moreover, it would be desirable if the FTC and DOJ would expand their expedited review process not just to applications by providers under the ACO program, but to opining on whether particular kinds of behavior by ACOs or non-ACOs in a market should be considered anticompetitive conduct.**

Defining Market Share

It would clearly be desirable to have a simple screening measure to determine which provider organizations fit into a safe harbor and which require a mandatory review. Unfortunately, the PSA Share methodology defined in the Proposed Statement is far from simple and is likely to force many provider organizations to undergo detailed reviews unnecessarily.

Under the Statement, the burden of calculating the PSA Share for a particular set of providers falls to those providers, despite the fact that making this calculation requires data on other providers that they may not have. In addition, the methodology appears to require, in effect, both expertise in linear programming and geographic information systems to determine "the lowest number of contiguous postal zip codes from which the participant draws at least 75% of its patients for that service." On top of this, since there may be many circumstances in which different combinations of independent providers are exploring collaborative efforts, multiple analyses would need to be run on each potential combination of providers to help them determine which might qualify for the Safe Harbor and which would not. All of this is not only extremely burdensome for small providers, but likely means that many providers will make errors in the calculations and there will be disagreements between providers and the FTC about whether the calculations have been made properly, which in turn will both discourage some providers from even pursuing a safe harbor and place others at risk of improperly assuming they are protected by a safe harbor when they are not. **If the PSA Share analysis is going to be required, the FTC and CMS should provide both the data and a pre-programmed analytical tool that can enable all providers to make these calculations consistently and cost-effectively**.

It would be one thing if there were evidence that this complex analysis, done correctly, would provide an accurate determination of a provider's threat to competition in a particular market, but since the methodology appears to be new and untested, there is no such evidence. Moreover, consideration of any number of hypothetical scenarios suggests that it will preclude safe harbor protection for many small providers which pose no true risk to competition. For example, if two small primary care practices located in a particular neighborhood in a large metropolitan area happen to draw their patients primarily from that neighborhood (i.e., 75% of their patients come from the zip code containing that neighborhood), and each provide care for 16% of the Medicare patients in that neighborhood, then if both practices join an ACO but remain independent, the ACO would not qualify for the safe harbor in the Statement, even though their patients could easily switch to the other primary care practices serving residents of that neighborhood or travel to a practice serving an adjoining neighborhood. If one of the

primary care practices provides care for 50% of the Medicare patients in that neighborhood, including it in the ACO would force the entire ACO to undergo mandatory antitrust review (since under CMS rules, the PCP must be exclusive to the ACO, but under the FTC policy, the PCP could not be exclusive in order for the ACO to qualify for the "dominant provider exception"). This simply makes no sense, either for the ACO (which will have to submit materials to the FTC) or the FTC (which will have to review those materials and make an unnecessary formal determination about the competitive impacts of the ACO), and it may mean that the benefits of the Safe Harbor will exist in principle, but not in reality. This clearly demonstrates that **the criterion for the safe harbor cannot be based on a zip code-level analysis; it needs to be based on whether a provider is large or small relative to a larger geographic area, such as a county or even a metropolitan area**, since a patient will often travel large distances to see a provider he or she believes delivers good care.

In addition, any methodology that is based solely on one provider's size without also looking at the size of other providers is inherently problematic. In a market where all providers are small, having 50% of the providers form a single organization could be problematic for competition, but in a market where a large provider already has a 40-50% market share, enabling a large number of the independent providers to collaborate could be highly pro-competitive. **The methodology and thresholds used in the Statement to determine the safe harbor and mandatory review must consider the size of other providers in the local market, not just the size of the group of independent providers that is applying to be an ACO**.

It will clearly be challenging for the agencies to create a single, simple methodology that addresses the above concerns. Rather than trying to define a single, one-size-fits-all methodology to make these determinations, **the FTC and DOJ should create an alternative path that allows providers to present analyses of the markets in their own individual regions using different methodologies to justify safe harbor treatment**. Since the FTC has committed to provide expedited reviews for providers requiring mandatory antitrust reviews, and since the current PSA Share methodology could potentially send a lot of unnecessary mandatory review cases to the FTC, creating such an alternative path would not increase the FTC's workload, and could actually reduce it. In particular, **if a group of providers is located in a region that has a multi-stakeholder Regional Health Improvement Collaborative (RHIC) with access to multi-payer claims data, the FTC and DOJ should allow a group of providers to work with that Regional Health Improvement Collaborative to develop an analysis of the competitive impacts of the proposed ACO.** (For more information on Regional Health Improvement Collaboratives, see the information on the Network for Regional Healthcare Improvement website at www.NRHI.org.)

Regardless of the methodology used, the thresholds for safe harbor treatment, mandatory review, etc. in the Statement need to acknowledge that the Affordable Care Act and the Medicare Shared Savings Program regulations are specifically requiring provider organizations to have a minimum size to participate. The law requires that an ACO have a minimum of 5,000 Medicare patients, and CMS is requiring and/or encouraging even larger numbers in the Shared Savings Program regulations and the Innovation Center's Pioneer ACO program. It is quite likely that in many regions of the country, an ACO will need to include the majority of primary care physicians in order to meet the CMS size requirements, yet if those PCPs are independent practitioners, the ACO would be forced to go through a mandatory antitrust review and could be precluded from participating simply because it is large. Consequently, **either the Statement**

needs to provide special exemptions for situations in which the size of an ACO is necessary to meet Medicare minimums, or CMS needs to lower the size thresholds for participation and shared savings in order to avoid forcing providers to consolidate unnecessarily, or both.

Appropriate Measures of Performance

The Proposed Statement indicates that the FTC and DOJ will be relying on the monitoring of cost, utilization, and quality metrics by CMS to help the agencies determine whether or not the CMS eligibility criteria lead to improved quality and cost savings. However, the data collected by CMS will be focused on Medicare fee-for-service beneficiaries, and thus will not adequately address the issues that have prompted the formulation of the Proposed Statement in the first place, namely, the impact of the ACO on the commercial marketplace. Not only will the ACO serve different types of patients and provide different types of services under commercial contracts than under the Medicare ACO program, the costs of the ACO's services to commercial payers depends on both price and utilization, and the price of commercial services is typically very different than what Medicare pays. As a result, costs to commercial payers for care delivered by an ACO could go up even if costs to Medicare go down.

To adequately address this, **CMS and/or the FTC would need to require that ACOs provide data to the FTC on the costs and quality of their services to commercial patients**. The FTC could then work with state and regional organizations, such as Regional Health Improvement Collaboratives, business health coalitions, and state governments, to assess whether the ACOs have improved costs and quality for commercial patients relative to other providers in the community where the ACO is located.

Ensuring Adequate Statutory Authority

Finally, to the extent that the Agencies agree that one or more of the above recommendations are desirable but feel that there is not sufficient statutory authority to implement them, I would urge the FTC and DOJ to make that known to Congress so that it can consider appropriate amendments to the relevant statutes.

I appreciate the opportunity to submit these comments, and I would be happy to provide any additional information regarding them or to assist you in implementing them.

Sincerely,

Harold D. Miller
Executive Director

cc: Daniel J. Gilman
Michael S. Wroblewski