May 31, 2011

Via Electronic Mail

Federal Trade Commission
Office of the Secretary
Room H-113 (Annex W)
600 Pennsylvania Avenue, N.W.
Washington, D.C. 20580

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

Dear Sir or Madam:

I'm an antitrust attorney in Washington, D.C. I appreciate the opportunity to submit these comments about the Proposed Statement of Antitrust Enforcement Policy Regarding Accountable Care Organizations Participating in the Medicare Shared Savings Program (the Policy Statement). These comments reflect only my own individual views and not necessarily those of my law firm, any of its attorneys, or any of its clients.

I've divided this comment into nine parts: (1) General Comments, (2) Applicability of the Proposed Statement, (3) Ancillarity of Joint Negotiations, (4) The Safety Zone and Exclusivity Generally, (5) Market Definition, (6) Market Share Calculations, (7) Mandatory and Voluntary Agency Antitrust Review, (8) Provider Exclusion, and (9) Time and Cost.

1. General Comments

A. Overall, the drafters of the Policy Statement have done an excellent job covering some complicated antitrust subjects in a succinct and understandable manner. Unless the per se rule applies to the conduct in question, antitrust analysis, including that of provider-controlled contracting networks such as accountable care organizations (ACOs), is a notoriously fact-specific task. The drafters were asked to craft a relatively short and succinct statement of antitrust analysis and enforcement for which one size would fit all. This means that, inherently, the analysis will result in more of both false negatives and false positives than if ACOs were subjected to full-scale antitrust investigations. But given the decision to issue a Policy Statement positing a "streamlined analysis" to all ACOs to which the Policy Statement applies, this problem is inevitable. In reviewing the Policy Statement, I discovered that criticizing it is relatively easy but that formulating specific improvements within the necessary brevity, clarity, and uniformity constraints of a document of this type is much more difficult.

B. Although the Policy Statement will not, as a technical matter, apply to ACOs or other types of provider-controlled contracting networks that choose not to participate in the Medicare Shared Savings Program (SSP), but choose to contract only with

commercial insurers, the Policy Statement may have its greatest practical effect on the latter. I believe that there will be many fewer ACOs that participate in the SSP than the agencies and CMS predict unless CMS drastically revises its proposed ACO regulation to decrease its burdensomeness and increase the participants' likely financial return on their investment. On the other hand, there seems to be substantial interest among providers in forming ACOs or ACO-like organizations to work with commercial insurers to develop and implement new and innovative forms of health-care delivery and reimbursement. Thus, I believe it important the Policy Statement identify the circumstances, if any, in which the agencies' analysis of networks not participating in the SSP might differ from the analyses of those that do participate.

C. Related to this, the relationship, if any, between Statement 8 and particularly Statement 9 of the DOJ/FTC *Statements of Antitrust Enforcement Policy in Health Care*, which I assume continues to apply to provider-controlled contracting networks not participating in the SSP, is not clear. ACOs are clinically integrated multi-provider networks as defined in Statement 9. The agencies should consider broadening the Policy Statement to cover all clinically integrated multi-provider networks (and perhaps risk-sharing networks as well), and reissuing the Policy Statement as a new Statement 9 rather than as an independent, stand-alone policy statement. At the least, the analysis and standards in the Policy Statement and in Statement 9 should be consistent, absent a compelling reason otherwise. If the Policy Statement is to be free-standing, Statement 9 should be amended so that, absent a compelling reason, the same guidelines apply to those networks participating in the SSP and those that do not. Otherwise, I believe there will be a good deal of confusion about the applicability of Statement 9 to different types of networks and confusion about the degree to which, as a practical matter, the principles of the Policy Statement apply to networks not participating in the SSP.

D. The Policy Statement should explicitly specify the types of conduct by ACOs to which it applies. It clearly applies to, and I believe it was meant to apply to, ACO joint negotiations of prices with commercial health plans. But as written, it can be read to apply to any type of potentially anticompetitive conduct in which an ACO might engage. The Policy Statement notes, for example, that "the Agencies will provide rule of reason treatment to an ACO" if the ACO meets the CMS eligibility requirements for participation in the SSP, but without describing the types of conduct subject to rule of reason analysis. I doubt, for example, that the agencies would apply the rule of reason to a horizontal market-allocation agreement of any type between two ACOs.

E. The Policy Statement should explicitly define "ACO participant," identifying, in particular, the types of providers required to calculate ACO market shares. It's clear that physicians, hospitals, and ambulatory surgery centers are "ACO participants." And the Policy Statement provides that the term includes "otherwise independent providers and provider groups that constitute the ACO." But what providers "constitute" the ACO? What about providers such as DME suppliers, home-health agencies, hospices, and the many other types of providers that an ACO might include, or with which it might contract, to provide a full continuum of care?

For example, must the common-services PSA market shares of these providers be 30 percent or less for the safety zone to apply to the ACO? If any of their common-service PSA market shares exceed 50 percent, must the ACO obtain a positive review letter from one of the agencies as a condition of participation in the SSP? What are the product market or markets for calculating those shares? What measure or universe is used to calculate their market shares? From where does the necessary data come? Does the Policy Statement apply to providers that merely contract to provide goods and services through the ACO, or only to those that are owners? Although the proposed CMS regulation does define "ACO participant," its definition is nebulous, and it is not clear whether the Policy Statement definition of "ACO participant" is identical to the CMS regulation definition.

F. The Policy Statement should identify with more clarity the specific functions and responsibilities of the FTC/DOJ ACO Working Group. Is the Working Group nothing more than a "think tank"? Are these the attorneys responsible for assessing ACOs and drafting agency review letters? Regardless of how well crafted the Policy Statement is, numerous questions relating to its applicability, interpretation, and process will arise. Thought should be given to establishing an informal procedure through which one function of the Working Group is to provide informal advice and to answer questions about interpretation and compliance with the Policy Statement. Based on the questions, the Working Group could issue periodic releases or a "frequently asked questions"-type of document to guide the public.

2. Applicability of the Proposed Statement

A. As presently drafted, the Policy Statement applies only to those collaborations formed after March 23, 2010. The Policy Statement should be amended to apply to all collaborative networks participating in, or applying to participate in, the SSP. As I understand it, the rationale for exempting those collaborations formed prior to the trigger date is that if there were an antitrust problem with them, the agencies would be aware of it—e.g., a payer would have complained. But this is not necessarily so. It is the ability to exercise market power, not merely its actual exercise, that concerns the antitrust laws. That a network hasn't yet exercised whatever power it might have, or that no one has complained about it if it has, is not a strong indication that it can't or won't do so in the future.

There are numerous reasons why no complaint may have surfaced about a network with market power. The network may have formed only recently; it may have no contracts; large payers may have successfully fended off its demands for supracompetitive reimbursement; or the health plan may have received something in return (including, e.g., some type of partial or complete exclusivity harming its competitors) in return for supracompetitive reimbursement. That a previously formed network hasn't generated antitrust concern in the past is not a sufficient reason for exempting it from coverage by the Policy Statement. Those networks formed before and after the March 23 date should be subject to the same rules, burdens, and constraints. The potential antitrust concern with both is the same.

B. Likewise, single-entity ACOs—those that don't constitute "collaborations" because, for example, a hospital acquired sufficient providers to comprise its own ACOs—should not be exempted from the streamlined rule-of-reason analysis of the Policy Statement or and the mandatory-review requirement. Single-entity ACOs have the same (and perhaps greater) probability of exercising market power as ACOs formed through collaboration among otherwise independent providers.

It is true that in some situations, divestitures might be necessary for a single-entity ACO to obtain a positive agency review letter and thus to participate in the SSP. As a technical matter, divestiture would likely be easy. The most common situation would be that where a hospital would be forced to divest a physician or physician practice that it previously acquired. Because physician acquisitions involve relatively little integration or "scrambling of the eggs," divestiture would be easy—no more difficult than the divestiture of outpatient facilities that the FTC required in its enforcement action against Carilion. Admittedly, divestiture could work a serious practical hardship on the physicians subject to it, but the effect of the ACOs market power should trump the concern about physician hardship. The need for divesture would suggest that the acquisition should have been investigated and challenged when it occurred.

In sum, single-entity ACOs can raise the same market-power concerns as collaborative ACOs, and thus the rules of the game should be the same for both. Otherwise, I believe hospital-driven ACOs comprised of their employed physicians will have an unjustified advantage over collaborative ACOs and will have even greater incentive to acquire physician practices in transactions escaping agency scrutiny where scrutiny is warranted.

3. Ancillarity of Joint Negotiations

A. The Policy Statement establishes, in effect, a conclusive presumption that an ACO's joint negotiations with commercial insurers is an ancillary restraint if the ACO meets the CMS eligibility requirements to participate in the SSP. The rationale is that the CMS eligibility criteria are "broadly consistent with the indicia of clinical integration that the Agencies previously set forth in the Health Care Statements." In truth, the CMS eligibility requirements go much beyond the requirements for a clinically integrated network. See Proposed CMS Reg. § 425.5. The only subsections of the regulation that are directly connected to a sufficient clinical integration program for antitrust purposes are § 425.5(d)(9)(iv) through (viii). The remaining eligibility requirements are surplusage.

Because, as a technical matter, the Policy Statement applies only to ACOs participating, or seeking to participate, in the SSP and ACOs must comply with all the eligibility requirements, this surplusage has no effect on them. But it seems clear that, as a practical matter, clinically integrated networks choosing not to participate in the SSP will rely heavily on the Policy Statement in assessing their own antitrust risk and in determining whether they are sufficiently clinically integrated so their joint negotiations

will not constitute per se violations. This is especially true because neither Statement 8 nor 9 provide detailed guidance about the elements that a sufficient clinical integration program might include. Clearly, clinically integrated networks need not meet all the CMS eligibility requirements. Accordingly, it would be helpful if the Policy Statement were more specific in delineating the eligibility requirements that a network, whether it be a network participating in the SSP or not, must be meet for its joint negotiations to avoid per se condemnation. At the same time, the Policy Statement could reemphasize that compliance with those eligibility requirements is not the only method to achieve sufficient clinical integration.

B. As noted before, the Policy Statement should specify the types of conduct to which the rule of reason will apply based on sufficient clinical integration.

C. As to the sufficiency of the ACO's integration to justify rule-of-reason analysis, the characteristics cited in § 425.5(d)(9)(iv) through (viii) of the proposed CMS regulation are those that should constitute sufficient clinical integration. They fairly mirror the characteristics set forth in the *Health Care Statements*, the four FTC Staff Advisory Opinions discussing clinical integration, the FTC's follow-up letter to MedSouth, various speeches by agency officials, and the description of clinical integration provided in the FTC and DOJ *Improving Health Care: A Dose of Competition*. Although the CMS regulation's description of the criteria are not particularly detailed, leaving much discretion to ACOs as to how to comply with them, it would be impossible to provide more specificity in the context of a relatively succinct policy statement or regulation.

D. Well-established antitrust law principles require that to justify price-fixing agreements embodied in joint negotiations, providers in a provider-controlled contracting network must not only partially integrate their delivery of care in ways likely to achieve significant efficiencies, but their joint negotiations must be reasonably necessary for the network to achieve those efficiencies. The Policy Statement recognizes this principle, noting that "the agreement [must be] reasonably necessary to accomplish the procompetitive benefits," but it provides no explanation why the joint negotiations of every ACO complying with the CMS eligibility requirements sustains the "reasonably necessary" requirement.

The FTC Staff Advisory Opinions discussing clinically integrated networks spend significant space discussing circumstances under which joint contracting by clinically integrated networks can be reasonably necessary for the network's success in improving quality and lowering costs. It would be helpful if the Policy Statement provided some truncated discussion of this. I suppose that ACOs participating in the SSP should not look a gift horse in the mouth, but clinically integrated networks choosing not to participate in the SSP will look to the Policy Statement for guidance even though it technically does not apply to them. Thus, it would be helpful if the Policy Statement provided them with some guidance about the circumstances under which their joint negotiations may be "reasonably necessary," especially since Statements 8 and 9 provide no guidance on that issue.

E. The Policy Statement provides that "The Agencies will provide rule of reason treatment to an ACO if, in the commercial market, the ACO uses the same . . . ." What about the Medicare "market"? Although the government fixes prices in the market, non-price competition remains. Perhaps the Policy Statement could provide: "The Agencies will apply the rule of reason to ACO contracting activities with Medicare, and it will apply the rule of reason to the joint negotiation of contract terms with commercial insurers if the ACO uses the same or equally effective clinical, administrative, reporting, and monitoring processes as it uses to qualify for participation in the Shared Savings Program."

4. The Safety Zone and Exclusivity Generally

A. Including a safety zone based on market share is wise, and, all else equal, a 30 percent market-share threshold seems reasonable. The Supreme Court and lower courts have indicated that, all else equal, it would be highly unusual for a firm with less that 30 percent of a properly defined relevant market to have market power.

B. Please see 1.E. above. The Policy Statement needs to specify the types of providers whose market shares must be 30 percent or less for the safety zone to apply. Does it apply to every type of provider that provides common services through the ACO or just to physicians, hospitals, and ambulatory surgery centers?

C. The Safety Zone provides, as Statement 8 of the *Health Care Statements* does, that "the Agencies will not challenge ACOs that fall within the safety zone, absent extraordinary circumstances." Again, the Policy Statement should indicate what specific types of ACO conduct is protected by the safety zone. Is safety zone protection limited to the ACO's joint negotiations or does it apply to any activity in which the ACO might engage?

D. Although it would be impossible to delineate, before the fact, all the situations that might constitute "extraordinary circumstances," if the agencies have ideas about circumstances that might meet that description, the Policy Statement should disclose them. "Extraordinary circumstances" is not a self-defining phrase. For example, if true, the agencies might want to clearly state that even ACOs with initial safety-zone protection are subject to retroactive examination and that an "extraordinary circumstance" might include clear direct proof that the ACO has actually increased prices significantly as a result of market power gained through the ability to negotiate prices jointly on behalf of its participants.

E. The Policy Statement provides that an ACO's safety-zone protection lasts only "for the duration of its participation in the [SSP]." This provision should be modified or deleted. An ACO's termination from participation in the SSP can result for numerous reasons, only some of which are related to its effect on competition. For example, an ACO may discover at the end of its contract with CMS that the costs of participation in the SSP outweigh any return and decide not to re-enlist, but want to continue its clinical

integration program with commercial insurers. Section § 425.14 of the CMS regulation itself provides some 16 grounds on which CMS can terminate an ACO's participation, and about half of them have nothing to do with an ACO's clinical integration program or effect on competition.

The rationale for terminating safety-zone protection when an ACO no longer participates in the SSP may be that CMS will no longer monitor the ACO's actual performance in improving quality and lowering costs. But this is not a sufficient reason for terminating the ACO's safety-zone protection. Statement 8 of the *Health Care Statements* provides two safety zones without requiring an independent monitor of network performance. The Policy Statement's safety zone should remain in place for as long as the ACO's common-services market shares remain at or under 30 percent and the ACO continues its clinical integration program in substantially the same form and with substantially the same processes that were sufficient to meet the CMS SSP eligibility requirements. Since, as a technical matter, the Policy Statement would no longer apply to the ACO, perhaps Statement 9 could be revised to reflect this.

F. The Policy Statement provides that the safety zone remains in effect "unless there is a significant change to the ACO's provider composition." If the agencies have any ideas of circumstances that constitute a "significant change," the Policy Statement should disclose them because ACOs and their counsel will have no clue of its meaning. For example, if the meaning is limited to situations in which the change increases one of an an ACO's market share above 30 percent, the Policy Statement should say so. If "significant change" has a broader meaning, it is impossible to decipher what it encompasses or what standards the agencies will apply in making that determination.

G. The Policy Statement's definition of exclusivity needs slight clarification. It provides that "[i]n a non-exclusive ACO, a hospital or ASC is allowed to contract individually or affiliate with other ACOs or commercial payers." Does this mean that the ACO may prohibit participants from contracting with payers through other types of contracting networks, such as IPAs and PPOs, or does the Policy Statement mean to subsume them within the term "ACOs" (keeping in mind that the Policy Statement's definition of "ACO" is limited to an organization that participates in the SSP)?

The above definition mentions only hospitals and ASCs. The Policy Statement needs to clarify that when it uses the term "non-exclusivity," regardless of the type of provider, it means that the provider is free to contract with payers through all contracting mechanisms; and that when it states that a provider "must be non-exclusive to the ACO," it means that the provider must be free to contract with payers through all other vehicles, not just that the provider must be free to contract with other ACOs (if that is the intent of the Policy Statement). Some confusion may result here because § 425.5(c)(2) and (3) of the CMS regulation appears to adopt the latter meaning of exclusivity—i.e., that exclusivity or non-exclusivity refers only to the ability of a provider to contract with other ACOs, not its ability to contract with payers through other methods, such as directly or through an IPA or PHO.

H. For an ACO to enjoy safety-zone protection, all hospitals and ASCs must participate in the ACOs on a non-exclusive basis. Since this requirement is in the context of a safety zone rather than in the context of determining whether the ACO actually has market power, and since exclusivity is an important factor in determining whether a network has market power, this requirement seems appropraite. This is true even though, in most situations, a 30 percent market share would indicate sufficient alternative providers for payers seeking to build networks. But safety zones should be conservative, and the Policy Statement clearly provides that "ACOs outside the safety zone are not presumptively unlawful" and "frequently may be procompetitive and lawful." (I would substitute "are" for "may be.") In the context of a safety zone, an abundance of caution is appropriate.

I. The more difficult issue relating to exclusivity may be determining when a hospital (or any provider) is exclusive to the ACO, and the agencies should tread cautiously here. Statement 8, to which the Policy Statement refers, provides, in part, that "[i]n an 'exclusive' venture, the network's [providers] . . . do not in practice, individually contract or affiliate with other network joint ventures or health plans." The agencies should not assume that merely because an ACO participant rejects an invitation to contract with payers through other means, or, as a factual matter does not contract with payers other than through the ACO, that the participant is de facto exclusive to an ACO. Doing so would force providers to participate in relationships that are unfavorable for reasons unrelated to competitive concerns. For example, it could force providers to contract with payers that, aware of the non-exclusivity requirement, could use it as leverage to force providers to accept non-competitively low contract offers. Even though it may be easy for providers to create pretextual legitimate justifications for not contracting outside of the ACO, the agencies should grant ACO participants significant leeway to make their own decisions about whether and with whom they will contract.

J. The Policy Statement's warnings about exclusivity are understandable and justified. But there should be some recognition in the Policy Statement that exclusivity, depending on the circumstances, can have procompetitive effects by promoting continuity of care, providing participants with greater incentive to work on behalf of the network, preventing free-riding, and generating a larger, more robust data bases for performance monitoring and evaluation. Thus, with respect to C.3, relating to exclusivity, the agencies should consider limiting this warning to specific common-services markets in which the ACO's market share exceeds 30 percent. In the mention of physician exclusivity in the safety-zone discussion, the Policy Statement might explain that the reason the safety zone does not differentiate between exclusive and non-exclusive physician participation in ACOs is that under certain circumstances, particularly when an ACO's market shares are low, exclusivity can be procompetitive.

K. I believe few, if any, ACOs will be able to comply with the Rural Exception requirements and, at the same time, include the number of physicians in the necessary specialties needed to provide adequate care to its Medicare beneficiaries and commercial-insurer enrollees. It seems unlikely to me that one physician per specialty per county will provide anything close to adequate access and coverage. The single-physician

requirement also raises some practical problems—e.g., multi-physician practices' having to agree on and decide which physician will participate.

A better, although certainly not optimal, approach would be to revise the Rural Exception to also provide safety-zone protection if all the ACO's shares of common services are 45 percent or less and require that all physicians other than those "upon which beneficiary assignment is dependent" in the language of § 425.5(c)(2) of the CMS regulation, participate in the ACO on a non-exclusive basis.

L. The "Dominant Provider Limitation" should remain in the Policy Statement, but I think it can be shortened and clarified as follows: "The safety zone does not apply to any ACO (not subject to the Rural Exception) that includes any ACO participant with a market share greater than 50 percent in its PSA of any service that no other ACO participant provides to patients in that PSA (a "dominant provider"), unless (1) the dominant provider participates in the ACO on a non-exclusive basis, and (2) the ACO does not restrict any commercial insurer's ability to contract with providers other than through the ACO."

5. Market Definition

A. General.

(1) Everyone recognizes that factors such as Medicare Specialty Codes (MSCs), Major Diagnostic Categories (MDCs), and Primary Service Areas (PSAs) constitute actual relevant product and relevant geographic markets only by coincidence. Everyone also recognizes, however, that use of these variables is meant to serve, as one FTC economist put it, as "a quick screen that is not a substitute for . . . market definition" to streamline the ability to estimate ACO market shares.

(2) Nevertheless, important consequences flow from these quick, but admittedly inaccurate, screens. The most important of these is the requirement, discussed in the next section, that, based on "market" shares determined in large part through these screens, the CMS regulation and the Policy Statement require some, if not most, ACOs to obtain an antitrust review letter from one of the agencies that may prohibit them from participating in the SSP. Given the admitted inaccuracy of the market surrogates, large numbers of false positives and false negatives will inevitably result. The penalties for a false positive—e.g., a negative review letter and rejection from the SSP—are significant. Thus, a small degree of inaccuracy may be acceptable, but a large degree is not.

B. Product Market.

(1) The Policy Statement uses MSCs as surrogates for physician-service product markets. These, while not perfect, provide a relatively close surrogate for actual product markets. CPT codes would provide even more accuracy, but calculating PSA market shares based on CPT codes would be an administrative nightmare, if possible at all. Thus, MSCs seem adequate for purposes here. I do question, however, why the primary

care physician category includes geriatric medicine practitioners, whose patient base and the maladies they treat differ markedly from those of internists, family-medicine practitioners, and general practitioners.

(2) On the other hand, MDCs likely present a very inaccurate picture of hospital market shares. There are only 25 MDCs, representing all inpatient services provided by hospitals, with an average of 25 DRGs in each MDC. MDCs seem much too broad to serve as reasonable surrogates for hospital product markets because they include so many non-substitutable services. In most situations, they will lead to overly broad product markets. For example, two hospitals participating in an ACO might provide totally different services in the same MDC and have a low MDC market share, while, at the same time, each may have a high market share in substitutable services within the MDC—perhaps more than the important 50 percent threshold. Typically, the inaccuracy will be to the benefit of the ACO. But situations can arise, based on the hospitals' volumes and revenues from different services, where the market-share calculation would result in an inaccurately high MDC share. I lack the knowledge necessary to provide an alternative but believe there must be other groupings of hospital services that would provide a more accurate surrogate.

(3) CMS has not identified the categories for other types of services. Thus, it's not possible to comment on them.

C. Geographic Market.

(1) Geographic markets, for purposes of the Policy Statements, are the ACO participants' PSAs, defined as the contiguous zip code zones from which they draw 75 percent of their revenues from the relevant common services. PSAs are, at best, only rough indicators of actual antitrust geographic markets, and, particularly in the case of physicians, actual relevant geographic markets are likely larger than PSAs. Use of PSAs ignores the more important question in determining a relevant geographic market—more distant providers to whom payers and patients would turn if a provider, or given set of providers, attempted to exercise market power by increasing prices or decreasing quality. But given the context of the Policy Statement—as a quick screen—PSAs are probably the best choice given the feasible alternatives. In the case of physicians, MSAs, counties, etc., all else equal, seem too large, and in the case of all types of providers, fail to account for the fact that different types of providers have vastly different relevant geographic markets.

(2) The threshold percentage in defining PSAs should be increased to 85 percent. Most court decisions relying on patient-origin information in defining geographic markets in hospital-merger cases use a 90 percent threshold. That 25 percent of a provider's revenue flows from treating more distant patients is a significant indication (although far from conclusive) that the geographic market is larger than the PSA. Admittedly, 85 percent, just as 75 percent, is arbitrary, but it likely reflects a closer estimate of actual geographic markets than does 75 percent. Many hospitals define their PSA using a 75 percent threshold, but in doing so, they are not attempting to define a

relevant geographic market but only determining from where they derive a significant majority of their patients for business-planning purposes.

(3) The PSAs should be constructed based on the descending order of the zip code zones adding the largest amount of revenues to the calculation; the requirement that the zones be contiguous should be deleted. That this requirement was adopted from the Stark regulations and that certain zones happen to touch are irrelevant in defining a relevant geographic market. The important variable, if PSA are to be used as a surrogate for the geographic market, is the importance of the zone in contributing to the provider's revenues, not whether it happens to touch another zone.

6. Market Share Calculations

A. In calculating physician market shares, the Policy Statement directs ACOs to use Medicare allowed charges. These calculations will not reflect accurate estimates of commercial insurer market shares because, even excepting obstetrics and pediatrics, the mix of services consumed by the more elderly Medicare beneficiaries is inherently different from that of the commercial-insurance enrollee population and because, in many areas, Medicare beneficiaries are not randomly distributed. If there are reasonably accessible all-patient or commercial-insurer data sources, they should be used.

B. Clearly, all the necessary market-share calculations will be burdensome. Market-share calculations, however, could be substantially simplified if physician "participation percentages" were measured rather than revenues. This is the methodology of Statement 8's safety-zone "market share" calculations (i.e., the percentage "of the physicians in each physician specialty with active hospital staff privileges who practice in the relevant geographic market"), and this methodology seems to have worked well. It is true that this measure is not a true measure of market share because different physicians do different numbers of procedures and generate different amounts of revenues—i.e., they are not homogeneous. But the important issue in assessing the market power of a network is whether it includes such a large percentage of physicians in a given specialty in a given area that health plans in the area would lack sufficient alternatives if the network attempted to raise the prices of its participating providers. Participation percentages do a relatively good job of answering that question.

Moreover, the necessary data is easier to obtain and the calculation much simpler than those mandated under the Policy Statement. The difficulty would be in obtaining accurate information for the denominators of the calculations, but there are various sources of information—from Medicare, payer directories, medical societies, and city and telephone directories—that together would provide a reasonably accurate for purposes of a screen estimate.

7. Mandatory and Voluntary Agency Antitrust Review

A. The CMS regulation and Policy Statement should remove the mandatory agency antitrust review requirement and retain the expedited voluntary agency antitrust review with some modifications.

(1) Under the current version of the CMS regulation and Policy Statement, a negative letter has severe consequences—an inability to participate in the SSP, and there is no appeal from this determination. The market-share calculations, given the shortcomings of the surrogates for defining product and geographic markets, are likely not sufficiently accurate indicators of market power to justify the penalty for a negative review. The results of this "quick screen" for market power will be too inaccurate to justify barring an ACO from participation in the SSP.

(2) I believe that most ACOs will have at least one ACO market share greater than 50 percent and thus that most will require a review letter.

(3) Statements 8 and 9 do not require any type of mandatory review, and there is no indication that the absence of a mandatory review under them has resulted in contracting networks generating anticompetitive effects. The agencies remain perfectly free to investigate and, where warranted, challenge any ACO that appears to have market power, exercising their usual law-enforcement functions.

Apparently, in drafting Statements 8 and 9, the Agencies did not believe it warranted to require any network to obtain a Business Review Letter or Advisory Opinion. Why it should be necessary, then, in the case of ACOs is not clear, especially since ACOs participating in the SSP will be subjected to substantially more governmental scrutiny and oversight than networks covered by the *Statements*. And experience shows that commercial insurers are not shy about complaining to the agencies when they perceive the exercise of network market power against them.

(4) Given that the agencies have only 90 days in which to respond to a request for an agency review, I question whether the agency can conduct an in-depth review and analysis of the ACO within that time. The *Health Care Statements* provide for a 90-day expedited review, yet the times from request to time of response in the three positive Staff Advisory Opinions discussing clinically integrated networks were approximately 270, 450, and 240 days. Admittedly, the response times under the Policy Statement should be substantially shorter, if for no other reason because the staff will need to spend substantially less time analyzing and discussing the ancillarity issue. Still, analyzing the market-power issue, if the examination is more than cursory, will require significant fact gathering and analysis. Ninety days is a very short period of time in which to conduct the examination and draft a reasonably accurate analysis with an adequate explanation, especially if front-office review and approval is necessary.

(5) The fact that one or a very few of an ACO's market shares exceeds 50 percent seems a poor indicator, by itself, that the ACO will be able to exercise market power,

especially if its specialty physicians and facility providers are free to contract with payers outside of the ACO. The tone of the Policy Statement's language, as written, suggests that even one market share exceeding 50 percent results in a de facto rebuttable presumption of market power, suggesting that the review letter will be negative. That language seems to place the burden of production, if not persuasion, on the ACO to produce "any information or alternative data suggesting that the PSA shares may not reflect the ACO's likely market power" or "any substantial procompetitive justification." A well-respected academic commentator has posited the same, while assuming that a 50 percent or above market share shows that the ACO has market power: "It does put the burden on those with market power to come forward with proof that there's not a problem there." I do not believe that an ACO should be rebuttably presumed to have significant market power merely because one of its common-service market shares exceeds 50 percent.

B. The agencies should consider replacing the mandatory review requirement with a notification requirement. The Policy Statement could require that any ACO with any common-service market share above 50 percent file a notification, including some or all of the information required under the mandatory-review requirement, providing the agencies the opportunity to investigate where they believe it warranted. The process would have no effect on participation in the SSP, but if the agency brought an enforcement action and there were a finding of a violation or a consent order or decree, CMS could exercise its discretion to determine whether to terminate the ACO from the SSP.

C. Regarding the antitrust agency review, whether or mandatory or voluntary:

(1) In general, the list of information that an ACO must submit to the agencies to obtain a review letter does not seem overly burdensome, and the required information is relevant to the agency's assessment of the ACO's effect on competition. The most burdensome information demanded is the CMS application, which ACOs will have to prepare in any event. It would lessen the burden, without affecting the agency's ability to analyze the ACO if the demand related to "business strategies and plans," etc., were limited to that information prepared for, prepared by, or reviewed by the ACO's governing body; and the demand for "formation" documents delineated the specific types of documents (e.g., articles of incorporation, operating agreement, bylaws, and participation agreement templates) that the ACO must produce.

(2) ACOs should be required to submit the information to only one of the agencies, which would serve as the "intake point" and which would copy and distribute the documents within the agencies as appropriate.

(3) The Policy Statement should clarify that while the agencies may request additional information, their doing so does not toll the running of the 90-day period.

(4) In the past, FTC Staff Advisory Opinions have been substantially longer and more detailed than Antitrust Division Business Review Letters. The agencies should

agree on a general structure for review letters so that regardless of the agency drafting the letter, their structure, length, degree of detail, and depth of analysis are consistent.

(5) The Policy Statement should mention some of the "rebuttal" factors that the agencies will consider in determining whether an ACO will be able to exercise market power—e.g., exclusivity, need for the providers to serve the ACO's patient population, access concerns, existence of other networks, etc.

(6) Although it need not be spelled out in the Policy Statement, it will be important for the agency staff to informally raise any competitive problems they see with the ACO as early in the review process as possible (e.g., not later than 30 days after receipt of the request letter), discuss them with the ACO, and determine whether an accommodation can be reached.

(7) Note 36 provides that if one or more of the ACO's market shares increases above 50 percent during its operation as a result of a change in its provider composition, it must obtain an antitrust agency review letter. This is a potentially burdensome requirement and may affect an ACO's ability to provide services to all its beneficiaries. The ACO need not seek a review letter if a market share increases merely because it attracts more patients, but if it attracts more patients, it likely will need more providers.

The agencies should consider modifying this requirement so that the ACO would have to request a review letter in this situation only at the end of its three-year CMS contract period if it intends to seek another CMS SSP contract. This would also require revision of § 425.5(d)(2)(D)(iii) of the CMS regulation.

(8) Note 36 also provides that an ACO must seek a review letter if its "provider composition is materially different than what was initially reviewed." This requirement appears also appears in § 425.21(a)(ii) and (iii). The initial review, as I understand it, refers to the CMS eligibility determination for participation in the SSP. But CMS and the Policy Statement should provide some indication of what "materially different" means and how they will interpret that term—i.e., the guidelines that the ACO should apply (or the agencies will apply) in making this determination. Apparently, the meaning is not limited to situations where the change in provider composition results in a market share exceeding 50 percent. If that is true, what is the antitrust concern warranting an ACO's having to spend the time and money on a review letter?

I believe that this requirement should be deleted. This seems especially true since § 425.21(a)(1) prohibits the ACO from adding any ACO participants with TINs (although apparently not individual physicians) during its contract with CMS.

8. Provider Exclusion

Based on their lack of need for providers or concern about their market shares, ACOs will likely exclude some providers wishing to participate. If history is any indication, this will generate significant antitrust litigation by excluded providers that sue

the ACO and its participants, alleging, for example, per se unlawful group boycotts. In narrow circumstances, it could generate an enforcement action by one of the agencies. The Policy Statement does not touch on this issue, although Statement 9 recognized the issue and addressed it. *Health Care Statements*, Statement 9.B.2.c. The Policy Statement should include a similar discussion.

Statement 9 notes that many procompetitive reasons exist for limiting participation in provider-controlled networks, and, as a result, rule-of-reason analysis is appropriate. The same is true for ACOs. Moreover, under rule-of-reason analysis, rarely will a provider's exclusion have a significant adverse effect on competition because (1) rarely will a provider need access to the ACO to remain competitively viable; (2) even if access is necessary, the loss of one competitor won't affect market-wide competition if there are enough others to ensure a competitive market; and (3) even if there are few other providers rendering the service in question, the procompetitive effects of the exclusion (e.g, excluding a poor-quality provider or ensuring that the ACO is not overinclusive) may swamp any anticompetitive effect.

ACOs need some comfort from the agencies that they have substantial leeway in selecting providers without significant antitrust risk from either government or private challenges. Thus, the Policy Statement should include some discussion of the agencies' analysis of ACO exclusion of providers. Statement 9's discussion is slightly too stringent because it fails to take into account (2) above.

9. Time and Cost

We can only speculate about the total number of ACOs that will apply to participate in the SSP, the number of those subject to the Policy Statement, the number of those that will seek an agency review letter, the hours necessary to comply with the Policy Statement, and the cost. But here is my speculation.

The Policy Statement estimates that between 300 and 800 ACOs will apply to participate in the SSP. Absent drastic revisions to the CMS regulation, that estimate seems quite high. Of these ACOs, the agencies estimate that the Policy Statement will apply to about half—150 to 400, assuming the Policy Statement does not apply to single entities or collaborations formed prior to March 23, 2010. I believe that the Policy Statement will apply to more than half of all ACOs that apply. Most applicants will be organizations formed after March 23, and most will probably constitute collaborations rather than single entities. Moreover, a larger percentage of these will probably seek agency review letters than the agencies estimate. This is not because of voluntary requests but because a significant majority of all ACOs to which the Policy Statement applies likely will have at least one ACO common-service market share above 50 percent and thus fall within the mandatory requirement.

It is not clear what activities are covered by the agencies' 30- to 50-hour time estimate and the $13,800 to $23,000 cost estimate. I assume these do not include

preparation of the CMS application, which will take an ungodly amount of time and money. If the estimates include the time and cost of calculating the ACO common-service market-shares, they are much too low. Moreover, all ACOs, not just those seeking an agency review letter, will have to spend the time and money necessary to calculate their shares and to obtain an antitrust analysis of other variables affecting the ACO's antitrust risk. One health-care antitrust economist has calculated that an ACO comprised of only two hospitals, two outpatient facilities, and two multi-specialty physician groups, based on reasonable assumptions of their common services, would have to calculate 284 ACO market shares; many will have to calculate significantly more. These will be time consuming and expensive endeavors.

The client cost of each of the three positive FTC Staff Advisory Opinions that examine clinically integrated networks was well in excess of $23,000 and the time expended was substantially more than 50 hours, even though no attempt was made to calculate accurate physician market-share figures. Admittedly, drafting the request letter for an ACO review letter will not take as long or be as complicated as those request letters because much of the time drafting them was spent discussing, in great detail, the characteristics of the client's clinical integration program and the reasons their joint negotiations would constitute ancillary restraints. Given the Policy Statement's conclusive presumption of ancillarity if the ACO meets the CMS eligibility requirements, the time and money expended on that issue should be modest. Still, I believe that the agencies' time and cost estimates are substantially too low.

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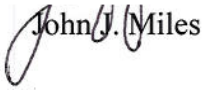
I appreciate the opportunity to comment on the Policy Statement and hope my comments are of some help. I would emphasize, as I've tried to suggest throughout these comments, that I believe the main focus of ACOs will be on the commercial insurance market. Hence, I believe it's important for the agencies to ensure that the antitrust guidance for ACOs choosing not to participate in the SSP is as clear as, and where appropriate identical with, that for ACOs participating in the SSP.

Very truly yours,



John J. Miles