COMMENTS OF THE AMERICAN BAR ASSOCIATION SECTIONS OF ANTITRUST LAW AND HEALTH LAW ON THE PROPOSED DOJ/FTC STATEMENT OF ANTITRUST ENFORCEMENT POLICY REGARDING ACCOUNTABLE CARE ORGANIZATIONS IN THE MEDICARE SHARED SAVINGS PROGRAM/ CMS PROPOSED RULE ON MEDICARE SHARED SAVINGS PROGRAM: ACCOUNTABLE CARE ORGANIZATIONS

May 31, 2011

The Sections of Antitrust Law and Health Law of the American Bar Association ("ABA")[1] are pleased to submit these comments on the Proposed Statement of Antitrust Enforcement Policy Regarding Accountable Care Organizations Participating in the Medicare Shared Savings Program ("Proposed Antitrust Statement"), issued by the U.S. Department of Justice ("DOJ") and the Federal Trade Commission ("FTC") (collectively referred to as "the Antitrust Agencies") on March 31, 2011.[2] These comments also address sections related to antitrust considerations contained in the proposed rule ("Proposed ACO Rule") issued by the Centers for Medicare & Medicaid Services ("CMS") on the Medicare Shared Savings Program: Accountable Care Organizations.[3] The views expressed herein are being presented on behalf of the Antitrust Law Section and Health Law Section and have been approved by both of the Sections' respective Councils. They have not been approved by the House of Delegates or the Board of Governors of the American Bar Association and, accordingly, should not be construed as representing the policy of the American Bar Association.

I. INTRODUCTION

The Section applauds the efforts by the DOJ and FTC to work together and, in an unprecedented way, with CMS, to consider the role of competition and antitrust enforcement with respect to the new Medicare Shared Savings Program ("SSP"), scheduled to become operational in January 2012. Under the SSP, groups of providers who participate in approved Accountable Care Organizations ("ACOs") can receive additional Medicare payments to the extent they meet certain quality standards and their efforts result in savings to the Medicare program. While ACOs will not negotiate with CMS with respect to their Medicare

[1] The Antitrust Law Section assembled a working group led by Robert Leibenluft of lawyers and economists consisting of Mark Botti, Meg Guerin-Calvert, Arthur Lerner, Toby Singer and Greg Vistnes to prepare these comments. All of the working group members have worked at the FTC or DOJ where they had significant responsibility for health care antitrust enforcement matters. After the comments were completed, they were approved by the Councils of both the Antitrust Law and Health Law Sections. References to "the Section" in these comments refer to both the Antitrust Law and Health Law Sections.

[2] Notice, 76 Fed. Reg. 21,894 (April 19, 2011).

[3] CMS Proposed Rule on Medicare Shared Savings Program: Accountable Care Organizations, 76 Fed. Reg. 19,528 (proposed April 7, 2011) (to be codified at 42 C.F.R. § 425)

reimbursement, it is anticipated that many ACOs will negotiate with commercial health plans (including Medicare Advantage plans) for reimbursement under those plans.

The Section appreciates that the Antitrust Agencies and CMS are facing a challenging task. By their very nature, ACOs are intended to increase the degree of coordination among health care providers in furnishing care, and some of these providers are likely to be independent, competing individuals or entities. The Antitrust Agencies note that while ACOs may result in innovative collaborations that can increase quality and reduce costs, under some circumstances they may reduce competition to the detriment of consumers and market efficiency. Antitrust review must strike the right balance so that it can curtail efforts that are likely to cause anticompetitive harm, while not deterring collaborations that will prove beneficial. The task is made more difficult in that ACOs are being created to participate in a novel Medicare program which is untested, and whose rules and requirements are still being developed. It is unclear how many entities will seek to qualify as ACOs under the SSP and, of these, how many will seek to negotiate with commercial health plans where they could have an impact on competition beyond the Medicare program. Moreover, the approach taken by the Antitrust Agencies with respect to ACOs under the SSP could have important implications for the antitrust review of collaborative efforts involving clinical or financial integration by health providers that do not participate in the SSP. Finally, the Antitrust Agencies must balance the need to give guidance to the provider community and to CMS, regarding their antitrust analysis, while at the same time providing such guidance in a timely fashion, not burdening providers with unnecessary information requests, and not deterring collaborations that have little risk of anticompetitive effects or giving inappropriate encouragement to arrangements that do pose significant risk of anticompetitive harm. These various considerations may conflict with each other, and the Section recognizes that there are no easy and obvious solutions.

The Antitrust Agencies and CMS are to be commended for examining these significant questions in the Proposed Antitrust Statement and the antitrust aspects of the Proposed ACO Rule. As described below, the Section believes there are a number of areas in which the reasons for the approach chosen or the substance of the approach itself should be clarified or further explained. In addition to specific reasons for providing clarification, the Section believes clarification generally would assist the health care industry to make better decisions regarding whether, and how, to participate in the SSP and would engender public confidence in the substance and procedures announced by the Antitrust Agencies and CMS. We also suggest alternative approaches the Antitrust Agencies and CMS may wish to consider in their review process.

II. THE PROPOSED ANTITRUST STATEMENT'S OVERALL APPROACH TO THE ANTITRUST REVIEW OF ACOS

A. The Mandatory Review Process

The Proposed Antitrust Statement sets forth the process for implementing the Proposed ACO Rule's mandate that certain ACOs obtain favorable Antitrust Agency review in order to become eligible for the SSP. Unlike the self-executing safety zone and the opportunity for expedited agency review for other ACOs in the Proposed Antitrust Statement or similar safety zones and review opportunities in the *DOJ/FTC 1996 Statements of Antitrust Enforcement in*

Health Care ("*Health Care Policy Statements*"), this mandatory review serves as the substantive gating requirement for participation in the program of another agency, i.e. CMS's, SSP. The mandatory review breaks new ground with respect to the Antitrust Agencies' historical law enforcement approach to antitrust enforcement, essentially vesting the agencies with authority to block an ACO's entry into a government program on the basis of expressed law enforcement intentions with no apparent recourse for the ACO through judicial or administrative adjudicative processes.

Many of the issues that the Section raises in these Comments arise because of the mandatory and expedited nature of the proposed review and its effect on participation in the SSP. The Section believes that the Antitrust Agencies should consider whether extending the voluntary approach suggested for ACOs between a 30% and 50% Primary Service Area ("PSA") share to ACOs above that threshold could achieve many of the same goals as the proposed mandatory review framework, without some of its disadvantages. Under such an approach, those ACOs that wish more certainty about the antitrust implications of their proposals could obtain that certainty by requesting review, and those ACOs that prefer not to incur the burden imposed by the requirements for antitrust review would be subject to the existing antitrust process. The Antitrust Agencies could investigate, and challenge as appropriate, ACOs if and when their conduct with respect to either Medicare or commercial health plans raises antitrust concerns. As outlined below, the process could include mandatory submission of prescribed antitrust screening information with a protocol for CMS to obtain Antitrust Agency guidance.

We recognize that the proposed review process is not simply aimed at providing more certainty to ACOs about their potential antitrust risks; CMS and the Antitrust Agencies also wish to address concerns that allowing some ACOs to form and participate in the SSP may enable them to accrue market power and engage in anticompetitive conduct with respect to both the Medicare program and commercial health plans that would be difficult to remedy. Accordingly, they may wish to go beyond a wholly voluntary approach and subject some, or even *all,* ACOs that seek to participate in the SSP to some sort of prior review.

If a voluntary approach is deemed insufficient, we suggest that the Antitrust Agencies at least consider a mandatory *notice* requirement, perhaps limited to ACOs that meet certain criteria (e.g., exceeding some threshold that is a proxy for market share), in lieu of the proposed mandatory review approach. As the Proposed Antitrust Statement now stands, all ACO applicants are required to determine whether they trigger the mandatory review requirement in any common service that two or more independent ACO participants provide. A mandatory notice requirement could require the submission of a filing containing a limited but sufficient amount of information to flag potential antitrust issues, *without having the gating effect of requiring a favorable antitrust agency letter as a precondition for approval as an ACO*. With this option, CMS could obtain Antitrust Agency input or advice regarding specific ACOs about which it may have concerns, or one of the Antitrust Agencies on its own could initiate a more extensive review of an ACO based on the preliminary information it has received. If a specified threshold were met, input from an Antitrust Agency could be made mandatory. But failure to obtain a favorable letter would not itself be an *automatic* basis for denial of participation in the SSP. A variant of this option would be to allow an ACO that believes it would receive an unfavorable letter at the end of the 90-day expedited review period to request additional time to try to address the Agency's concerns; such a request for additional time would not preclude the

consideration of its application by CMS, which could be undertaken at the same time. The goal of these alternatives would be to still give the Antitrust Agencies the opportunity to review ACOs before they are approved to participate in the SSP, but under a process that may be less burdensome to many ACOs and which would provide greater flexibility for the Agency review.

If CMS and the Antitrust Agencies ultimately conclude that a favorable antitrust review letter should be a prerequisite for many ACOs (i.e. all that fall within the mandatory review requirement as proposed), we encourage them to explain why that route is most appropriate, as compared to other alternatives. In so doing, the Antitrust Agencies and CMS should explain their consideration of the relative likelihood of erroneous determinations that may occur in the mandatory review process. We discuss below some of the factors that may increase the cost and uncertainty of the agency review process. The inherent and potentially significant risk of agency error may chill ACO formation, depriving CMS of the participation of ACOs that would otherwise serve the purposes of the SSP. Alternatively, that same risk of agency error may lead to the approval of ACOs that acquire and exercise market power, insulating harmful ACOs from antitrust review. The agencies should explain how they have reviewed and reconciled these concerns.

B. Rule of Reason

The Proposed Antitrust Statement takes a significant step by equating an ACO's organization and operation in accordance with CMS SSP requirements with the concept of clinical integration identified in the *Health Care Policy Statements*, thus assuring approved ACOs that the Rule of Reason test will apply to their negotiations with customers in commercial markets, even where there is no risk sharing. From issuance of the *Health Care Policy Statements* to the present day, significant public debate and discussion has arisen regarding what constitutes sufficient clinical integration. The Proposed Antitrust Statement will provide guidance for existing provider collaborations as well future collaborations for which ACO eligibility is not sought or obtained.

The Proposed Antitrust Statement asserts that "[t]he Agencies have determined that CMS's proposed eligibility criteria are broadly consistent with the indicia of clinical integration that the Agencies previously set forth in the *Health Care Policy Statements* and identified in the context of specific proposals for clinical integration from health care providers." But the Proposed ACO Regulation does not identify specific integration criteria to be applied to determine if an ACO has the statutorily-required "processes to promote evidence-based medicine and patient engagement, report on quality and cost measures, and coordinate care, such as through the use of telehealth, remote patient monitoring, and other such enabling technologies."[4] Instead, ACOs are afforded flexibility to identify the means they are using to meet this broad statutory mandate. CMS will then approve or deny applications based on its review of their particular proposals. In light of the absence of specific criteria for these key clinical integration activities in the CMS regulations, the Antitrust Agencies might wish to clarify their conclusion. The implication appears to be that the Agencies are deferring to CMS, as the payer of services, to determine whether there has been meaningful clinical integration and that, at least initially, CMS may accommodate a range of approaches from ACO applicants.

[4] 76 Fed. Reg. at 19546-47.

The importance of clarifying this deference question is underscored by the treatment of the concept of "ancillarity" in the Proposed Antitrust Statement. Ancillarity is a significant aspect of the *Health Care Policy Statements* and is discussed at some length in several FTC staff advisory opinions.[5] Ancillarity essentially addresses why joint negotiation by clinically-integrated groups of providers is reasonably necessary to achieve their legitimate goals. These earlier Antitrust Agency statements treated ancillarity as a separate and significant inquiry in the review of a clinically integrated provider collaboration, whereas the Proposed Antitrust Statement appears to assume the ancillarity conclusion:

> [I]f a CMS-approved ACO provides the same or essentially the same services in the commercial market, the Antitrust Agencies have determined that the integration criteria are sufficiently rigorous that joint negotiations with private-sector payers will be treated as subordinate and reasonably related to the ACO's primary purpose of improving health care services.[6]

Why is ancillarity assumed for an approved ACO, particularly where its program details and its achievement of "meaningful integration" will not be known until CMS reviews the application? If the explanation is deference to CMS, the Antitrust Agencies should address whether similar deference would be given to clinical integration programs not participating in the SSP that are endorsed by private payers. Clarifying this point would give useful guidance to provider collaborations that may be similar in clinical integration approach to ACOs approved under the SSP, but which are not participating in the program.

Provider collaborations not participating in the SSP also would benefit from a better understanding of the requirement that an approved ACO use in its commercial activities "the same governance and leadership structure and the same clinical and administrative processes as it uses to qualify and participate in the Shared Savings Program to obtain rule of reason treatment under the Proposed Antitrust Statement. It would be useful for the Antitrust Agencies to explain what elements of CMS' governance and leadership structure requirements they believe are relevant to whether an ACO should receive rule of reason treatment, and why those elements are required when operating in the commercial payor context. For example, the Proposed ACO Rule requires that ACO participants control at least 75% of the ACO's governing body, that each ACO participant have appropriate proportionate control over governing body decision making, and that the governing body include a Medicare beneficiary representative.[7] It would be helpful for entities that wish to form clinically-integrated arrangements outside of the SSP to know whether the Antitrust Agencies are looking to similar criteria in their arrangements and the relevance of that criteria to their analysis.

---

[5] *See, e.g.*, *Tristate Health Partners, Inc*., Staff Advisory Op. at 24-28 (April 13, 2009), *available at* http://www.ftc.gov/os/closings/staff/090413tristateaoletter.pdf; Greater Rochester Independent Practice Association, Inc. Advisory Opinion from FTC Staff (September 17, 2007), at 16-24, *available at* http://www.ftc.gov/bc/adops/gripa.pdf.

[6] 76 Fed. Reg. at 21896

[7] Proposed 42 C.F.R. § 425.5(d)(8).

III. SUBSTANTIVE STANDARDS OF THE PROPOSED ANTITRUST STATEMENT

A. Applicability Only to Entities Formed After March 23, 2010

The Proposed Antitrust Statement applies 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 SSP. Elsewhere, in Section I, the Antitrust Agencies explain that the Statement seeks to clarify the antitrust analysis of "newly formed collaborations among independent providers" that seek to become ACOs in the SSP. Footnote 7 defines "newly formed competitor collaborations" as those formed "in whole or in part after March 23, 2010."[8] CMS and the Antitrust Agencies should explain and clarify their discussion for the disparate treatment of entities formed before and after March 23, 2010.

First, it appears that the Proposed ACO Rule at § 425.5(d)(2) does not carve out entities formed before March 23, 2010 from the mandatory antitrust review requirement. If CMS intends to exclude pre-existing ACOs from the mandatory review requirement, that intent should be clearly stated; otherwise the rationale for carving out such entities from the Proposed Antitrust Statement is unclear. On the other hand, if all ACOs meeting the specified screening threshold are subject to the mandatory review requirement, the Antitrust Agencies should make clear what procedures and standards would govern attempts by the pre-existing collaborations to obtain the required favorable antitrust review letter -- presumably, the standards would be the same as those applicable to entities formed after March 23, 2010 but this should be clarified.

Second, the rationale for the carve-out should be better explained. It appears that CMS and the Antitrust Agencies may believe that prior antitrust review is not necessary as a requirement for participation in the SSP for ACOs that already are operating in commercial health plan markets. But it is not apparent that an entity's *formation* before or after March 23, 2010 would be a meaningful indicator of its antitrust character or likely impact on the marketplace. For example, a more relevant test might be tied to whether the entity has entered into health plan contracts and made its presence known in the privately insured health care marketplace.

Similarly, if the intent is to exempt from mandatory prior review entities that have been operating and dealing with commercial health plans prior to applying to participate in the SSP, it might be preferable to tie the carve-out to any entity that has been operating for a specified period of time (e.g., two years) prior to submitting its application, rather than to a specified date. Such a change would better address collaborations that have formed since March 23, 2010 and which may contract with commercial health plans prior to applying to participate in the SSP until some time after 2012.

Third, if entities formed before March 23, 2010 are exempted from the mandatory antitrust review requirements, it is unclear why other aspects of the Proposed Antitrust Statement

[8] In addition, the documentation required to be submitted with a request for a mandated antitrust review under Section IV(B) should include "[d]ocuments 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." It is not clear what is intended by this requirement and how it should be construed.

should not apply to them. Thus, for example, the Antitrust Agencies should explain why the safety zone should not apply to a pre-existing organization if it is accepted into the SSP program and is otherwise indistinguishable from newly-formed organizations. Similarly, the Agencies should indicate whether they would subject pre-existing entities to rule of reason treatment in connection with their conduct in the commercial market if they use the same governance and leadership structure and the same clinical and administrative processes as they use to qualify for and participate in the SSP.

Finally, the terms of the carve-out from the Proposed Antitrust Statement leave many unanswered questions. The Proposed Antitrust Statement does not explain what is meant by the phrase "collaboration . . . formed after March 23, 2010." Does it refer to the date an entity's articles of organization or incorporation or similar document is filed with its domiciliary state? Does it refer to the date it actually becomes "collaborative" – e.g., signs participation agreements with health care providers or begins to employ certain clinical or administrative processes to improve care, as opposed to an earlier date when it may have existed as a legal entity, but did not have the requisite character of being a collaboration of independent providers? What is the meaning of the "in whole or in part" language in footnote 7? If a pre-existing competitor collaboration creates a new corporate affiliate after March 23, 2010 to be the applicant for the SSP, would that new entity be considered a newly-formed entity? Would it matter if the provider contracts relied upon by the new ACO entity were held by the pre-existing competitor collaboration entity (such as an IPA, or a PHO) that contracted as an intermediary with the new ACO legal entity? If a competitor collaboration legal entity existed prior to March 23, 2010 but signs new provider contracts for the SSP or adds new providers to meet Medicare requirements after that date, would that indicate that the entity was newly formed, or formed "in whole or in part" after March 23, 2010?

In short, considerable additional guidance is needed in order for the industry to understand the applicability of the Proposed Antitrust Statement, particularly if it is intended to be consistent with CMS requirements as to whether an entity must undergo a particular form of antitrust review in order to be approved to participate in the SSP. The need for clarity and precision on this aspect of the Proposed Statement and the Proposed ACO Rule is essential in that the Proposed Statement serves not only as guidance intended to inform and educate, but also provides the mechanism under the Proposed ACO Rule for satisfying a mandatory requirement for entry into a particular type of government contract.

B. Use of Primary Service Area Shares in Setting Screens for the Safety Zone and Mandatory Antitrust Review

At the heart of the Proposed Antitrust Statement is a screening methodology to identify three categories of ACOs: (1) those that qualify for the safety zone; (2) those that must undergo a mandatory review; and (3) the remaining ACOs that fit into neither of the preceding two classes and can seek a voluntary review. The Section realizes that developing an appropriate screening methodology is a challenging task because, by its very nature, it must depend on shares of what is at best only a proxy for the relevant product and geographic markets. Such a proxy ideally should reflect the competitive dynamics of the market, use readily available information, and be straightforward to calculate and interpret.

In establishing a screening methodology, it is important to consider two types of possible errors. A "false positive" error occurs when a competitively-benign ACO undergoes *excessive* antitrust scrutiny, either by falling outside the safety zone or by triggering a mandatory review. The costs of a false positive error include not only the ACO's costs of completing the review application itself, but also the legal and planning costs associated with the necessary analysis. A false positive may chill formation of ACOs and hence participation in the SSP. A "false negative" error occurs when an anticompetitive ACO is subjected to *insufficient* antitrust scrutiny, either by falling within the safety zone or by avoiding a mandatory review. A false negative error may also allow the formation of ACOs that acquire or create market power in commercial markets (as well as having non-price anticompetitive effects with the SSP), that otherwise may have been deterred or blocked. The harm from the operations of an anticompetitive ACO could be very large. The harm to an individual ACO applicant that is competitively benign facing costs to determine applicability of the screening mechanism, and perhaps falling outside the safety zone or having to seek a mandatory review, is less. In the *aggregate*, however, the costs imposed on competitively benign ACO applicants and the possibility that some may be deterred from applying also may be very substantial. In developing criteria for its screening tests, the Antitrust Agencies must balance the likelihood and downsides of both false positives and false negatives, taking into account the aggregate effect of each of these potential outcomes. This balance is likely to be different for the safety zone (where the disadvantages of a false positive is not that severe)[9] than it is for mandatory review (where the consequences of failing to obtain a favorable letter from the Antitrust Agencies is much more substantial).

The Proposed Antitrust Statement relies on shares of PSAs for both the safety zone and mandatory review screening tests. 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 the service." This approach calls for ACOs to make multiple calculations of the geographic area from which the ACO draws 75% of its patients.

The Antitrust Agencies should clarify their adoption of the PSA methodology in light of their prior rejection of similar statistical methods based on patient origin data for determination of market power issues in hospital merger matters. The Antitrust Agencies should clarify why PSAs are appropriate as a screen for potentially anticompetitive consolidations in the formation of ACOs, yet not appropriate as a reliable method for defining relevant geographic markets for hospital mergers under the antitrust laws. Does the Proposed Antitrust Statement indicate that, going forward, the Antitrust Agencies will be more receptive to use of patient origin statistical analysis in hospital mergers? Or, is the proposed methodology for determination of PSAs distinguishable in some significant way from the analyses the Agencies have previously disfavored?

[9] In general, the downsides of a high threshold for the safety zone (i.e. one that might result in relatively more false positives), are not severe if it only results in causing some ACOs to lack the certainty of the safety zone, but such ACOs still are reasonably confident that they will not be subject to an antitrust challenge. It is important, however, that the Antitrust Agencies continue to emphasize that the safety zone thresholds are being set very conservatively, and that many (perhaps most) ACOs that do not qualify for the safety zone are still likely not to raise antitrust concerns. This is especially important in light of the proposed safety zone tests because it seems likely that very few ACOs will meet the requirement that *every* common service have a combined share of 30 percent or less.

Historically, the Antitrust Agencies have expressed concerns regarding the predictive accuracy of statistical analyses of patient origin data. A similar concern over the accuracy of the PSAs as a predictor of potential antitrust problems thus appears to arise in connection with the proposed safety zone and mandatory review for proposed ACOs. The Antitrust Agencies should explain the basis for choosing this methodology, particularly given their historical reservations about such an approach.

Our further comments concerning the proposed use of PSAs as a screening tool address the following issues: (1) use of the 75% threshold in defining the PSA; (2) use of PSAs instead of relevant market shares for defining the safety zone threshold; (3) use of the 30% and 50% share thresholds for determining safety zone and mandatory reviews; (4) the burden of using the PSA approach and how that might be reduced; (5) the contiguous zip code requirement and multi-site providers; and (6) consideration of geopolitical areas for use as an alternative screening tool.

(1) The "75%" PSA. The 75% statistic is used by the Department of Health & Human Services to identify hospitals' geographic areas for purposes of an exception to Stark Law proscriptions for physician recruitment activities. The Antitrust Agencies should explain why this same 75% PSA threshold was chosen over some other number to establish an antitrust review screening threshold. Did the Antitrust Agencies, for example, consider a 90% or a 60% PSA? How would moving in one direction or the other increase or decrease the risk of either a false positive or a false negative error? In particular, a higher percentage (e.g., 90%) will result in a broader geographic region that will likely result in lower ACO shares. That broader market is, in turn, likely to result in more false negatives. In contrast, a lower percentage (e.g., 60%) will result in a narrower geographic region that will likely result in higher ACO shares. Those lower shares, in turn, increase the likelihood of false positives. These relationships may not always hold, however. At least in some cases, it is possible that defining a broader geographic region will make it appear that two ACO participants are competing whereas they would not appear to be competitors in more narrowly-defined geographic markets.[10] Similarly, in some cases the smaller geographic region could eliminate any apparent overlap between ACO participants, and thus reduce calculated shares.[11]

The Antitrust Agencies acknowledge that the 75% PSA threshold may not reasonably approximate actual geographic markets for physicians and hospitals Instead, it appears intended to serve as a winnowing tool to help identify ACOs that pose no serious antitrust concerns, and therefore may be provided safety zone treatment without further analysis if specified conditions are met, and to identify those ACOs that warrant mandatory review. We encourage the Antitrust Agencies to explain the extent to which they have determined that the 75% threshold is well-suited for that purpose, both generally, and across the various lines of services to which it will

[10] Consider, for example, an ACO that includes two large physician clinics located 15 miles apart. If the geographic region were limited to a 10-mile radius, there would be no overlap between the two physician clinics, and the ACO would qualify for the safety zone. If, however, the geographic region were extended to a 15-mile radius, the two physician clinics would overlap, and the resultant shares might be quite high—high enough, in fact, that not only would the ACO be denied safety zone treatment, it would likely be subject to mandatory review.

[11] Take the reverse of the above, for example: if the geographic region is reduced from 15 miles to 10 miles, the apparent overlap between the two ACO participants disappears.

be applied. If the 75% PSA significantly diverges from the correctly-defined geographic market, its predictive utility is reduced, and as the variance increases, the risks of false positives and false negatives increase. We note, for example, that many court decisions in hospital merger cases use a broader PSA than the merging parties' 75% service area in their geographic market conclusions; moreover, in recent years, the FTC, DOJ, and academic researchers have criticized the use of patient-flow data for determining relevant geographic markets for antitrust purposes.[12]

The Section believes that the Antitrust Agencies are likely to have the data necessary to compare what they believe to be the correctly-defined geographic market in certain hospital or physician cases with the areas that would be specified under the PSA approach. We understand from public statements by Antitrust Agency staff that the Antitrust Agencies have not performed this type of comparison, but we recommend that the Antitrust Agencies conduct the analysis in assessing the implications of adopting a 75% PSA approach. We also encourage the Antitrust Agencies to re-evaluate the utility of whatever screening test they ultimately adopt as they obtain more experience evaluating ACOs through future ACO reviews in which the relevant geographic markets are actually determined.

(2) Use of PSAs instead relevant markets to define the safety zone threshold**.** The Antitrust Agencies should explain why they have chosen to use PSAs for defining the safety zone instead of relevant markets. The latter approach was taken with the *Health Care Policy Statements*. We understand that the proposed approach provides greater certainty for applicants, but the Antitrust Agencies should explain why, on balance, the PSA approach is preferable.

(3) PSA Shares. The Section requests that the Antitrust Agencies also explain their choice of 30% PSA shares and 50% PSA shares for the safety zone and mandatory review thresholds. Because PSAs are not expected to correspond to actual antitrust relevant geographic markets, there is no reason that the PSA share criteria should necessarily correspond to similar market share criteria used in other Antitrust Agency policy statements. In particular, there is no necessary correspondence between the Proposed Antitrust Statement 30% "PSA share" and the *Health Care Policy Statements'* 30% market share criteria for a safety zone for physician network joint ventures given that the *Health Care Policy Statements* market share criteria is explicitly based on shares in the correctly-defined antitrust relevant market. For example, if there is a likelihood that the 75% PSA calculation will yield a geographic region that often overstates the true size of the actual relevant geographic market for some or all services, and thus can be expected to understate the market shares in a correctly-defined market, then the Proposed Antitrust Statement likely should prescribe lower share criteria than might be the case if the market were a correctly-defined relevant market. The Antitrust Agencies should explain why they chose the 30% PSA share and the 50% PSA share, what alternatives they considered, and why they rejected those alternatives.

[12] *See, e.g.*, Greg Werden, *The Limited Relevance of Patient Migration Data in Market Delineation for Hospital Merger Cases*, 8 J. Health Econ. 363 (1990); Cory Capps, David Dranove, and Mark Satterthwaite, *Competition and Market Power in Option Demand Markets*, 34 Rand J. Econ. 737 (2003); Robert Town and Gregory Vistnes, *Hospital Competition in HMO Networks*, 20 J. Health Econ. 733 (2001); *In re Evanston Northwestern Healthcare Corp.*, No. 9315, 2007 WL 2286195 at *66 (F.T.C. Aug. 6, 2007) ("We should view patient origin data with a high degree of caution . . . .").

As currently written, the PSA test must be applied to any independent ACO participants that provide a common service. It would be helpful to clarify whether "ACO participant" in this context applies only to providers who are eligible to earn portions of any shared savings or who are at risk for any penalties under the SSP, or whether it also would extend to providers who are under contract with the ACO but who are not eligible or at risk. In prior evaluations of certain provider arrangements, the Antitrust Agencies have taken the position that a risk-bearing provider collaboration may subcontract with any number of other providers as long as it retains the economic incentive to bargain for lower fees and to control the utilization of the subcontracted providers.[13]

We also note that that the Proposed Antitrust Statement indicates that shares will be based on Medicare fee-for-service allowed charges. In some instances, for example, where providers (either those in or outside of the ACO) obtain a disproportionately large share of their revenues from Medicare Advantage or from commercial payers, Medicare fee-for-service charges may substantially understate their competitive significance. The Antitrust Agencies should indicate if their methodology will provide some way of address such anomalies.

(4) The burdens of the PSA approach and how they might be reduced. Under the Proposed Antitrust Statement, every ACO applicant must consider undertaking the PSA analysis of every common service offered by independent ACO participants to determine whether it is eligible for the safety zone and, even more importantly, determine whether or not it is subject to mandatory antitrust review. We believe this will be a very considerable burden for most ACOs.

To perform the PSA calculations, an ACO must: (1) identify each service provided by two or more independent ACO participants; (2) collect patient zip code data from those participants; (3) collect coding or billing data from those participants (which may or may not be in the same computer file as the zip code data); and (4) match the zip codes to the Medicare Specialty Codes ("MSCs") (in the case of physicians), outpatient treatment categories (in the case of outpatient facilities), or Major Diagnostic Categories ("MDCs") (in the case of hospitals). Then the ACO must match Medicare fee-for-service allowed charges (physicians), Medicare fee-for-service payments (outpatient facilities), or inpatient discharges (hospitals) to the zip codes and specialty codes or categories.

This undertaking could be quite complex; it will be time-consuming and entail considerable costs. There are 55 MSCs, 25 MDCs, and 31 outpatient treatment categories -- 111 in all --for which an ACO must potentially perform PSA calculations. With the exception of ACOs whose participants are all already under common ownership and control or who are absolutely confident that their common services will not trigger mandatory review, *every* ACO must evaluate each of its independent providers to see to what extent, if any, there are overlapping services in *any* of the 111 different services lines.

The burden will be greatest for those ACOs that include participants with the largest number of independent practices. The burden will also be great for those ACOs that provide the most comprehensive range of services -- these are the ACOs that may have the most potential for

[13] *See e.g. Health Care Policy Statements* at 77-78; *United States et al v. Health Care Partners, Inc. et al,* (D. CT. 1995) ,*Competitive Impact Statement, available at http://www.justice.gov/atr/cases/f0300/0386.wpd.*

achieving the benefits intended by the program.[14] Moreover, many physicians' offices do not have the data systems necessary to easily compile the required information. In many cases, the data will have to be compiled from the different information systems used by the participants, which may or may not lend themselves to easy comparison. In fact, the smaller offices will have to incur the greatest cost, because they are the least likely to have ready access to the information.[15]

Even once the PSAs are identified, ACO applicants face additional costs. They must still calculate PSA shares. Although CMS is making the Medicare data available to provide the information necessary to calculate aggregated charges in each PSA (the denominator only), performing the calculations on the data (even assuming that the data are sufficiently clean and error free to begin with) will entail costs. And for specialties for which only limited Medicare data is available—most notably obstetrics and pediatrics. Those ACO participants may be required to come up with another way to measure shares on their own (i.e. determine both the numerator and denominator for the share calculations). The Proposed Antitrust Statement suggests that a physician head count could be used for this purpose, but that is not easily accomplished. Identifying all of the physicians in the 75% PSA in specific specialties will be a substantial task in many locations. Indeed, in the areas with the highest number of physicians (and therefore presumably the areas where the ACOs' shares are likely to be lower), the difficulty will be the greatest. The issues extend beyond identification of physicians, to issues related to specialty (e.g., neonatologists may just be listed as pediatricians), timeliness of the data, and whether the physicians are in active practice and may have offices in multiple locations.

The Section asks whether the Antitrust Agencies have fully explored the likely burden that the proposed PSA calculations would impose on the typical ACO and, if the PSA approach is pursued, how such burdens can be reduced. We recognize that the Antitrust Agencies propose to ease the burden of computing PSA *denominators* by making CMS data available. But this does not address the considerable burden of determining where there are overlaps, collecting all of the requisite data, calculating the PSA *numerators*, and performing the ultimate PSA shares calculations. We believe that a concerted effort on the part of CMS and the Antitrust Agencies to make *numerator* data available to each ACO participant would considerably ease the burden to ACO applicants and would assure more reliable and comparable information for the Antitrust Agencies to review.

For example, the Section suggests that CMS and the Antitrust Agencies consider collecting the necessary data, calculating appropriate algorithms, and developing a secure electronic portal whereby any proposed ACO could conduct its required screening analysis using the CMS/Antitrust Agencies portal. An ACO could submit the Taxpayer Identification Numbers of its physician groups, relevant IDs for ASCs or other entities (with secure log-in required), and

[14] We note that the examples given in the Appendix to the Proposed Antitrust Statement -- hospitals with only two overlapping services and a hospital that doesn't provide outpatient services -- while illustrative of the calculation likely understate complexity and scope of the required calculations

[15] A presumably unintended effect of this data requirement may be to encourage physicians in small practices who are interested in ACO participation to merge their practices with much larger organizations.

the CMS algorithm would calculate each 75% PSA, each numerator, and each denominator. The result could be a report that would provide the relevant data to the ACO so that the ACO could verify the data to the extent it desired. The report could also identify the ACO's PSA shares for each service line.

While we appreciate that this may require dedicated resources at CMS to develop and maintain the database and software, having this done centrally at CMS would undoubtedly reduce the overall costs of obtaining the data and increase the likelihood of reliable and consistent data-reporting to the Antitrust Agencies. The approach would also allow the ACOs readily to determine which, if any, common services exceeded thresholds (and by how much), and allow the ACO potentially to reconfigure or address potential antitrust concerns. It would facilitate the use of a standardized report format for CMS filings, which could assist the Antitrust Agencies in their screening. Standardization of the reporting process could also be helpful to the Antitrust Agencies in evaluating the reliability and efficacy of the PSA approach in their screening process. Even if this broad undertaking by CMS and the Antitrust Agencies is not practical, the Section believes that great benefit would be achieved if CMS could make ACO participant data directly available to the ACO that is planning to apply for SSP participation so that it could calculate its own numerator and denominator.

In short, the Antitrust Section is concerned that the PSA calculations may impose very serious burdens on ACOs and could have the effect of discouraging ACOs from applying to participate in the SSP. Providing data from a central and reliable data source, such as through a CMS portal, could greatly ease that burden.

(5) The contiguous zip code requirement and multi-site providers. The Proposed Antitrust Statement indicates that the PSA for which market shares are to be calculated should be a set of geographically-contiguous zip codes. The requirement that zip codes be contiguous, in some cases, can make the determination of the PSA much more complex: rather than rely on a relatively mechanical algorithm to define the PSA, additional human intervention will be necessary to ensure contiguity and to make judgment calls about what constitutes contiguity in the case of, *e.g.* "touching zip corners" or non-contiguous zip code regions (*e.g.*, an island or peninsula in which the closest zip code lies across a body of water).

Requiring contiguous zip codes also may pose problems when an ACO participant provides services in multiple locations. For example, in cases where a physician clinic has two offices the contiguity requirement might result in one of those offices being completely ignored in the PSA determination.[16] In other cases, requiring contiguous zip codes may require the inclusion of middle regions in which the ACO providers draw few or no patients.[17] In addition,

[16]Consider a physician clinic with a large office in Town A and a smaller office in Town B. The 75% PSA that accounts for both offices' patients might be non-overlapping circles centered around each town. Because those circles are non-contiguous, the PSA would have to build off just one of those physician offices, with the result that the 75% PSA might be one large circle around Town A that does not extend to Town B or the region in which the second, smaller office's patients come from. Thus, the smaller office would be completely ignored in the screening process defined by the PSA.

[17] Taking the example discussed above, the two non-overlapping circles around Town A and Town B that together represent a 75% PSA for the clinic could be connected by including zip codes in between those two circles.

it is not clear if CMS data would readily permit breaking down Medicare utilization data to reflect the location where particular services were rendered by a multi-site provider entity. The Section notes that the PSA concept is drawn from a Stark Law rule for hospitals, which typically occupy a single location, in contrast to some types of medical groups and other health care providers that traditionally have numerous offices, in some cases in multiple market areas.

Whether the extra burden of requiring contiguous zip codes is warranted depends on what value the Agency sees in this requirement. An explanation of that value would be helpful, in part so that ACOs can assess how to proceed in those special cases where consideration of non-contiguous zip codes can lead to anomalous results.

(5) A possible alternative: geopolitical regions. As we have described above, there are likely to be considerable burdens to the 75% PSA approach, especially if CMS is not able to provide a means for ACOs to easily calculate their PSA shares in all common services. The Antitrust Agencies should consider whether using geopolitical areas such as MSAs, cities, towns, or counties) for defining a geographic area might significantly reduce ACOs' burden of calculating market shares, while creating no greater problems (on average) associated with false positives and false negatives. If so, that alternative means of defining regions over which ACO shares are calculated for purposes of the mandatory review or the safety zone may be preferable in all or some cases.

Geopolitically-defined areas have the advantage that they would obviate the need for each ACO to calculate separate geographic areas for each independent provider for each common service and would avoid the problems noted above with constructing areas out of contiguous zip codes, including at least some of the issues raised above involving multi-site providers. Finally, geopolitical areas would be much more "user-friendly" and easier to comprehend for screening purposes than multiple PSAs for a large number of common services.

The Section notes that reliance on geopolitically-defined regions would not be without its own problems. For example, guidance would have to be given regarding how such regions should be defined, and the extent to which they should vary by different service lines. It also may not be apparent how such areas should be defined when an ACO is located near a "corner" of a geopolitical region. While neither PSAs nor geopolitical areas may closely match relevant geographic markets in many instances, to the extent PSAs reflect where patients are currently receiving services, they may be at least somewhat more empirically-based than geopolitical areas.

Fundamentally, any screening methodology that is not based on actual market analysis necessarily will have significant drawbacks. Accordingly, if the Antitrust Agencies conclude that the PSA approach, despite its limitations, is generally better than any alternatives, they might wish to consider that in particular cases, they would allow an ACO -- with prior approval from the Antitrust Agency -- to use geopolitical areas, or some other alternative, for determining whether a mandatory review is required.

Creating contiguity in this way is misleading, inasmuch as it leads to the inclusion of regions in which no ACO participants from either office compete.

IV. SAFETY ZONE NON-EXCLUSIVITY

The Proposed Antitrust Statement requires that for an ACO to fall within the safety zone, any hospital or ambulatory surgery center ("ASC") in the ACO must be non-exclusive to the ACO.[18] The same non-exclusivity requirement applies to rural hospitals or dominant providers for ACOs that seek to qualify under the rural and dominant provider exceptions. The Antitrust Agencies explain that in a non-exclusive ACO, the providers "are allowed to contract individually or affiliate with other ACOs or commercial payers." Moreover, the Antitrust Agencies note that the ACO must be "non-exclusive in fact and not just in name," and refer to the *Health Care Policy Statements* for indicia of non-exclusivity. In their discussion of non-exclusivity, the *Health Care Policy Statements* look to evidence that providers actually individually participate in, or contract with, other networks or managed care plans; evidence of their willingness and incentive to do so; and evidence that they earn substantial revenue from other networks or through individual contracts with managed care plans.

The Section is concerned that the safety zone's non-exclusivity requirements as they apply to participation with other ACOs may be too stringent. The Section understands that where an ACO is exclusive with respect to commercial plan contracting, the ACO could become the means of exercising market power, assuming it has a high share in one or more properly-defined markets of provider services. But requiring non-exclusivity -- especially with respect to hospitals that may form the backbone of an ACO and invest substantially in its formation -- may dampen their incentive to make such investments. Requiring non-exclusivity suggests that a hospital that forms its own ACO may need to participate in efforts by its rivals to form their own ACOs in order to qualify for safety zone protection. Hospitals would have legitimate reasons not to participate in such endeavors, although by not doing so they would risk being found exclusive under the Proposed Antitrust Statement and outside the safety zone.

Implicit in this aspect of the Proposed Antitrust Statement is the assumption that exclusive participation by a hospital or ASC raises antitrust concerns comparable to when a provider agrees to contract exclusively through a particular entity. Simply because Provider A – even a dominant provider -- only participates in ACO X does not mean that Provider A will not be available to contract with health plans that choose not to contract with ACO X. Focusing on one ACO to the exclusion of others is fundamentally different from a situation in which a collaboration that is the exclusive contracting vehicle for a health plan can deny access by the health plan to its providers unless the health plan contracts through the collaboration. This is not to suggest that an ACO that employs exclusivity requirements that preclude its members from participating in other ACOs could not raise antitrust concerns under some circumstances; but the concerns are likely to be more removed and less direct than with an ACO that requires exclusivity with respect to contracting with health plans.

In general, the Proposed Antitrust Statement's treatment of ACO exclusivity should be clarified to explain that in some circumstances (e.g., where the participants have low PSA shares) there is little concern about exclusivity. Indeed, exclusivity may be pro-competitive as it can

[18]In contrast, the *Health Care Policy Statements* do not limit safety zone treatment to non-exclusive networks; exclusive networks that are financially-integrated qualify for the safety zone provided their market share does not exceed 20%.

provide incentives to increase the commitment of providers to a venture and reduce the risk of free-riding.[19] And in the SSP ACO context, because Medicare beneficiaries are free to obtain care from any Medicare provider, concerns about exclusivity are significantly reduced as long as the ACO is not the exclusive contracting vehicle with health plans. If the Antitrust Agencies believe there are particular circumstances where non-exclusivity is especially important, it should explain these situations and consider more narrowly drafting any non-exclusivity requirements in the safety zone and other Proposed Antitrust Statement sections. Clarification of these issues is important not only because it will affect which ACOs are eligible for the safety zone, but because all ACOs will look to this discussion for guidance on how the Antitrust Agencies consider exclusivity in evaluating ACOs that do not meet the safety zone.

V. MANDATORY REVIEW: PROCEDURES AND SUBSTANCE

The Proposed Antitrust Statement requires a mandatory antitrust review for any ACO that has a greater than 50% share of any PSA for any service provided by two or more independent ACO participants. The mandatory review requires the submission of a large volume of materials and contemplates agency review within 90 days. There are a number of unanswered questions relating to the Antitrust Agencies' process for evaluating the competitive effects of a proposed ACO during the 90-day time period. We address here questions concerning the following: (1) clearance to determine which Antitrust Agency will take on specific reviews; (2) a possible "quick look" review that could apply in certain circumstances; (3) issues arising under the 90-day review time frame; (4) the use of staged deadlines during the 90-day review period; (5) the scope of the initial information request; (6) impact on Medicare Advantage competition; (7) substantive standards and scope of the mandatory review; (8) appeal of an adverse review letter; and (9) availability of information on review letters.

(1) Clearance. We suggest that the Antitrust Agencies provide a fuller explanation to the public and affected persons on how they will allocate the responsibility for reviewing ACOs that are either required to or choose to submit their proposed ACO for antitrust review. Without belaboring the point, public comments from agency leadership have indicated that this has been a matter of some controversy between the Antitrust Agencies and that some within the agency leadership may view the choice of which agency will review an ACO as more than just a question of forum but rather one that could result in different outcomes. Accordingly, public confidence would be enhanced through greater transparency on the process by which the reviewing agency will be chosen and the substantive standards and approach each will take. This is especially important here because the Antitrust Agency decision could effectively bar an ACO from participation in the SSP.

In particular, the Proposed Antitrust Statement indicates that an ACO must submit requests for review to both Antitrust Agencies, which "will then determine which Agency will be the reviewing Agency" through a newly established joint "ACO Working Group." The Antitrust Agencies should clarify whether in fact they have decided that both Antitrust Agencies will have roughly equal responsibility in conducting substantive reviews, or whether that question remains

[19] *See., e.g., Health Care Policy Statements* at 78 ("For example in some circumstances exclusivity may help a network serve its subscribers and increase its physician participants' incentives to further the interests of the network").

unresolved whether only one may be the reviewer of most ACO applicants. No criteria are provided as to how the work will be divided between the Antitrust Agencies. What considerations will the ACO Working Group apply in deciding which agency will look at a given ACO? Will it turn on the location of the ACO, familiarity with the local market area or certain of the ACO participants, or some other criteria?

The Antitrust Agencies also should address how they will provide assurance of uniformity of decision across the two agencies. Historically, the two agencies have not always agreed on their approach to resolving antitrust issues. Moreover, the ACO approval determination under the Proposed Antitrust Statement will be made at different levels in each agency. A decision by the DOJ will be made by the Assistant Attorney General, consistent with its Business Review procedures, whereas a decision by the FTC will be made at the professional staff level and not necessarily submitted to the Commission. Though a decision in an antitrust case is ultimately a judicial one, either in a trial court or a court of appeals on review of an FTC decision, here, an unfavorable mandatory review letter is final bar. It is therefore important that the Antitrust Agencies' reviews be seen as based on a consistent framework and outlook; an individual ACO's opportunity to participate in the SSP should not be seen as affected by which Antitrust Agency drew that particular filing to review.

(2) "Quick-look" review. As discussed above, we believe that the current proposed approach likely will result in a number of ACOs being subject to mandatory review because they exceed the thresholds in only a few service lines or in only a few PSAs, and that in many cases it might be readily apparent that the ACOs do not present serious competitive concerns. We suggest that the Antitrust Agencies consider providing ACOs in this situation with an option to provide only a minimal filing -- e.g., just information about the services that trigger the mandatory review, or other more limited information than is specified for full mandatory review, and that the Antitrust Agencies commit to responding in a short time period (e.g., 15 days) whether a full submission would be required. If the Antitrust Agencies conclude that the normal filing is required, the 90-day clock would not start until the full submission has been made; thus ACOs would need to seek this "quick review" at an early enough stage to allow for such an occurrence.

(3) The 90-day review period. The Antitrust Agencies should clarify how they will conduct multiple comprehensive reviews in a shorter time than they have historically taken for such significant decisions in isolated matters. And if that is not possible, what are the implications of a failure to conclude the review? Will the proposed ACO be allowed to proceed? What happens to the timing if the Antitrust Agencies need supplemental information? Does the 90-day clock continue to run, or is it stopped until the additional information is submitted? The Agencies should explain whether holding strictly to the 90-day period will increase or decrease the likelihood of positive or negative errors associated with the mandatory review, which in turn will depend in part on what standard the Agencies will apply in reviewing the proposed ACO. If the review ends up taking more than 90 days, will the applicant necessarily be denied? If the record is inconclusive at the end of the 90 days, will the agencies presume the absence or the presence of market power? Depending on the answer to that question and others, to assure accuracy in the decision, CMS and the Antitrust Agencies may wish to consider extending the amount of time that the Antitrust Agencies have before reaching a determination whether an ACO filing a mandatory review should be deemed anticompetitive.

(4) Staged deadlines within the 90-day review period. Many of the comments in this section arise from a concern that both the ACO applicant and the Antitrust Agencies may lack sufficient time to join issue regarding potential antitrust concerns during the 90-day agency review period. We suggest that to assure that this occurs, the Antitrust Agencies commit to a structured review process with staged deadlines. For example, such a process might include the following:

- Day 1: Submission of ACO application and required documentation
- Day 15: Agency informs ACO applicant if there are any obvious omissions to the initial filing
- Day 30: Agency informs ACO applicant of potential issues of concern
- Day 60: Agency informs ACO applicant of likely recommendation, and any steps that it suggests be taken to reduce antitrust concerns
- Days 75-90: ACO applicant given opportunity to seek review of preliminary staff recommendation with senior Agency decision maker
- Day 90: Agency issues letter, unless ACO applicant requests additional time to resolve outstanding issues

The dates suggested above are for the purpose of illustration only. We also assume that throughout the process there would be ongoing dialogue between the agency staff and the ACO applicant. The important point is that the review would be structured, and ACO applicants would be informed of the potential antitrust concerns of the agency staff at an early stage so that they could seek to address them or, failing that, have sufficient time to seek further review with the ultimate agency decision maker.

(5) Information requirements. The Antitrust Agencies have asked for comments on the information requirements of the mandatory review. The required information includes:

- The application and all supporting documents that the ACO plans to submit, or has submitted, to CMS or that CMS requires the ACO to retain as part of the Shared Savings Program application process;
- Documents or agreements relating to the ability of the ACO participants to compete with the ACO, either individually or through other ACOs or entities, or to any financial or other incentives to encourage ACO participants to contract with CMS or commercial payers through the proposed ACO;
- Documents discussing the ACO's business strategies or plans to compete in the Medicare and commercial markets and the ACO's likely impact on the prices, cost, or quality of any service provided by the ACO to Medicare beneficiaries, commercial health plans, or other payers; and

- 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.

Depending on how these requests are interpreted, the categories of information required to be submitted could be both overbroad and under-inclusive. Item 1, the materials to be submitted to CMS, of course is not troublesome. But Items 2 through 4 collectively could be read very broadly to require the production of all documents that relate to the indicated subject matter. This would require typical discovery or "second request"-type documentation. If, instead, the Antitrust Agencies are simply seeking contractual or organizational documents addressing these topics, the request would be more manageable; if so, the Items should be clarified. For example, Item 4 requires the proposed ACO to submit "documents showing the formation" of the ACO, which could be read very broadly to encompass planning documents generated in connection with the ACO's creation or narrowly to simply provide organizational or governance documents. (Item 4 also seeks documents showing "the formation of any ACO . . . participant," but does not explain what the formation of a "participant" is supposed to encompass).

These requirements could generate a huge amount of information. By way of example, many ACOs are likely to have a large number of documents created by consultants. They will have documents associated with planning meetings (agendas, minutes, and any handouts), and they may have files on potential physician participants, such as credentialing files. Some of this information could be entirely unnecessary for an antitrust review, such as documents concerning organizational structures considered and discarded, research on existing ACOs and similar organizations, and publicly-available information on clinical protocols and guidelines.

The Antitrust Agencies have estimated that retrieving, reviewing, and submitting the information would take 30 to 50 hours, based on their estimate of the time it takes to prepare a Hart-Scott-Rodino ("HSR") filing (39 hours). This estimate seems quite unrealistic, and that does not even include the time that is required to gather the information needed to make the PSA share calculations. Even assuming that 39 hours is an accurate estimate of how long it takes to prepare an HSR filing, the scope of the undertaking required by the Proposed Antitrust Statement is much larger than scope of an HSR filing. The HSR rules mandate the submission of limited categories of information from a limited set of individuals, and only two parties must submit that information. In contrast, the Proposed Antitrust Statement seeks information generated by or for anyone associated with the ACO,[20] and the types of documents requested in Item 4 are not limited to those that discuss particular topics. In addition, this estimate does not take into account that ACOs undergoing the mandatory review will have to pull together additional information to provide to the Antitrust Agencies to support their arguments that the ACO will not have anticompetitive effects, nor does it consider the time and effort of responding to requests for additional information and engaging in discussions with the relevant Agency during the 90-day period.

[20] *See, e.g.*, Proposed Antitrust Statement, fn. 34 ("The ACO must represent in writing that it has undertaken a good-faith search for the documents and information specified in this Policy Statement and, where applicable, provide all responsive material.").

The Antitrust Agencies could lessen the burden considerably by limiting the types of documents requested in the initial submission. For example, seeking documents that discuss certain issues (as is done in Item 3) is a better approach than the apparently broad brush of Item 4. Similarly, limiting the scope of the search for responsive documents would help. Perhaps the Antitrust Agencies could borrow from the HSR context and seek only documents prepared by or for individuals above a certain level in the ACO participants' organizations.

(6) Impact on Medicare Advantage competition. The Proposed Antitrust Statement should confirm that the Antitrust Agencies' review of the impact of ACO activity on commercial plans will include consideration of impact on Medicare Advantage plans.

(7) Substantive standards and scope of mandatory review. The Antitrust Agencies apparently intend to use their normal approach in preparing review letters -- i.e., addressing whether the agency would intend to take law enforcement action if the parties proceed with the proposed course of conduct. In the ordinary situation, if a party did proceed, and were sued, the government would have the burden of proof and the sued party would have the opportunity to defend itself. In this new mandatory review process, where a favorable review is required, the unfavorable Antitrust Agency letter will result in automatic denial of SSP participation. This leads to a number of important questions which the Section hopes the Antitrust Agencies will more extensively address in their final statement. They include the following:

- Will the unique circumstances of the Antitrust Agencies' review alter in any way their approach? Who will have the burden of proof or persuasion? In a mandatory review, must the ACO demonstrate that it is not anticompetitive in order to receive a positive letter? Or, will the Antitrust Agencies apply the traditional view that an agency must prove an antitrust violation and, if the evidence does not establish a violation, will the Antitrust Agencies permit the ACO to participate in the SSP?

- Will the Antitrust Agency review include the concept of ACO versus ACO non-price competition for Medicare patients that is one of the concerns CMS articulated in requiring antitrust review but which has not been a traditional focus of antitrust agency concern? Currently, no ACO versus ACO competition exists because ACOs are new organizations. How will the Antitrust Agencies evaluate the substantiality of any loss or gain of competition from the formation of ACOs of different sizes and compositions?

- How will the Antitrust Agencies treat efficiencies? Will the Antitrust Agencies give weight to arguably "out-of-market" efficiencies, such as shared savings benefits to the SSP, as a counterbalance to harm that might occur in the commercial markets? Alternatively, if there is a concern regarding a particular shared service, will the Antitrust Agencies credit efficiencies in the other services? What standard will the Antitrust Agencies apply in deciding whether to credit "out-of-market" efficiencies?

- What role will remedies play? Can ACOs "fix" anticompetitive concerns by providing conduct assurances? If so, how will such remedies be monitored on an ongoing basis?

(8) Appeal of an adverse review letter. Given the preclusive effect that an adverse review will have on an ACO, several questions arise regarding whether, and to whom, an adverse antitrust review can be appealed:

- Will the Antitrust Agencies provide an internal administrative review process? For example, the Antitrust Division procedures call for a letter issued by the Assistant Attorney General. Will an administrative review be afforded to other officials within the Department of Justice? At the FTC, will the staff's letter be appealable to the Director of the Bureau of Competition? To the Commission itself? Or will CMS provide an agency review process? If so, will CMS independently review the Antitrust Agency's decision not to issue a favorable letter or to issue a negative letter.

- The "gatekeeper" role of the Antitrust Agencies raises the question of whether either Antitrust Agency's decision would be governed by and subject to review under the Administrative Procedure Act ("APA"). In essence, the decision to deny an ACO's request to participate in the shared savings program could be considered an agency "order" under 5 U.S.C. § 551(6) or otherwise be considered final agency action subject to review. The Antitrust Agencies should address whether the numerous procedural and substantive issues that typically arise in matters governed by the APA are presented by the mandatory review process which involves automatic denial in the absence of a favorable agency review letter. We understand from Agency staff statements that the Antitrust Agencies believe their decisions following mandatory review are exempt from the APA.[21] The Antitrust Agencies should explain that conclusion, if it is the official position of the Agencies.

(9) Availability of information regarding review letters. CMS and the Antitrust Agencies should address the extent to which the identity of applicants for review letters or SSP participation will be public, and the extent to which information regarding such applications will be public. Consumers, payers, and others potentially affected by approval or denial of a mandatory review letter or approval of SSP participation may have a desire to assure their views are considered, while the interest of ACOs in protecting information that is truly confidential should be respected.

VI. CONCLUSION

The Proposed Antitrust Statement reflects an ambitious and challenging effort on the part of the Antitrust Agencies to work closely with CMS to address the potential antitrust issues raised by an innovative Medicare program. The ABA Antitrust Law and Health Law Sections

[21] In addition, the proposed ACO Rule states that "[t]here is no reconsideration, appeals, or other administrative or judicial review" of "[a] determination made by the reviewing antitrust agency that it is likely to challenge or recommend challenging the ACO." Proposed 42 C.F.R. § 425.15(a).

appreciate the opportunity to submit these comments to the Antitrust Agencies and hope they are helpful in their consideration of how their approach can be refined and clarified.