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Medical Association of Georgia

Building a Better State of Health Since 1849

May 27, 2011

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

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

Dear Secretary Clark:

The Medical Association of Georgia appreciates the opportunity to provide comments to the Federal Trade Commission (FTC) and the Department of Justice (DOJ) on the proposed Statement of Antitrust Enforcement Policy regarding Accountable Care Organizations (proposed FTC/DOJ ACO policy) participating in the Medicare Shared Savings Program. Although this letter responds specifically to the proposed FTC/DOJ's ACO policy, it is important to realize that the FTC/DOJ proposal is inextricably linked to the Centers for Medicare & Medicaid Services' (CMS) proposed rule on the Medicare Shared Savings Program. **We urge you to consider the MAG's recommendations for significant modifications to both proposals given that, if not properly developed, the ACO requirements and antitrust clearance process could have a significant and negative impact on the ability of physicians, hospitals, and other eligible ACO entities to successfully form and participate in ACO models.**

One of CMS' stated goals for the ACO program is to "raise the likelihood of preserving alternatives in the market, ultimately leading to the emergence of better procedures and treatments."[1] Physician-led ACOs are a necessary option because "the savings generated by ACOs in many cases are expected to result from reduced inpatient admissions,"[2] and this requires physician leadership outside of a hospital. Accordingly, it is important that the antitrust rules create a level playing field that does not favor hospitals over physician led ACOs.

[1] CMS Proposed Rule on the Medicare Shared Savings Program, p.19630.
[2] *Id.* at p.19537.

Unfortunately, the proposed clinical integration rules unnecessarily require resources that many physicians do not have but that hospitals do possess. If this issue is not adequately addressed, the ACO policy will have the unintended consequence of encouraging and facilitating hospital consolidation of physician markets by acquiring physician practices. Hospitals are already increasing their acquisitions of physicians and physician group practices, which have, in some markets, given hospitals significant market power over both facility and physician markets. More importantly, because each such acquisition is small, this consolidation occurs under the radar of antitrust enforcement. It is critical that the FTC/DOJ set forth clear and common sense antitrust rules concerning the formation of ACOs so that physicians can pursue integration options that are not hospital driven. Physicians should not have to become employed by a hospital or sell their practice to a hospital in order to participate in ACOs or other innovative delivery models.

We support the following FTC/DOJ proposals: (a) the FTC/DOJ ACO policy to apply the rule of reason to ACOs; (b) the establishment, in principle, of a safety zone with respect to the issue of market power; and (c) a 90-day expedited review process for ACOs that seek and/or are required to obtain FTC/DOJ approval.

We are concerned, however, with the Primary Service Area (PSA) methodology set forth in the proposed FTC/DOJ ACO policy for determining whether an ACO falls within a safety zone, or falls within the class of ACOs that require antitrust review. We believe the PSA methodology set forth in the proposed FTC/DOJ ACO policy for evaluating market power is biased towards finding market power where none exists. Such a methodology loses any ability to single out potentially problematic ACOs and, by creating a false impression of market power, will chill the development of many ACOs. Overall, we believe that the current methodology will essentially render safety zone protection meaningless. Finally, the current PSA analysis will impose substantial costs on physicians trying to form an ACO that will, in and of itself, probably deter the formation of many ACOs. We are also concerned about the negative treatment in the proposed FTC/DOJ ACO policy of exclusivity requirements, which can be an important arrangement for ACOs. Finally, while we support the 90-day expedited review process, we have concerns that the disclosure obligations are overbroad. This is particularly important given that the current market screen will almost certainly place the large majority of ACOs into the mandatory reporting category.

I. *FTC/DOJ eligibility requirements for participating in the Medicare shared savings program*

The Proposed ACO Policy applies to collaborations made after March 23, 2010, among independent providers seeking to participate in the Medicare Shared Savings Program and who provide the same or essentially the same services in the commercial market. The proposed FTC/DOJ ACO policy would also apply to various ACO initiatives undertaken by the Innovation Center of CMS, but only if these ACOs are "substantially clinically or financially integrated."

We seek clarification from the FTC/DOJ as to why collaborations created before March 23, 2010, will not be evaluated under the proposed FTC/DOJ ACO Policy. We do not see any

plausible rationale for the March 23, 2010, cut-off date. Organizations trying to form ACOs should not be subject to a different antitrust analysis simply because they were created before March 23, 2010. The analysis should focus on the merits of the organization and whether it complies with the statutory requirements for an ACO.

II. *Clarification is needed on the proposed Medicare shared savings program two-sided risk model*

The FTC/DOJ have failed to acknowledge that participation in the Medicare ACO program is an undertaking of meaningful financial integration, rendering the need for compliance with FTC/DOJ prescriptions on clinical integration unnecessary for avoiding the *per se* prohibition against price fixing. As a result, when CMS required various types of clinical integration in its proposed regulations, it did so under an erroneous assumption that this was the only way physicians could avoid the *per se* prohibition against price fixing. CMS' confusion is expressed by its statement that:

> It is in the public interest to harmonize the eligibility criteria for ACOs that wish to participate in the Shared Savings Program with the similar antitrust criteria on clinical integration...the certainty created by harmonizing our eligibility criteria with antitrust requirements will help to ensure that an ACO organization participating in the Shared Savings Program will not subsequently face an antitrust challenge that its conduct is per se illegal, which could prevent the ACO from fulfilling the three years of its agreement under the Shared Savings Program.[3]

CMS cited and interpreted the FTC's advisory letters to MedSouth, Inc., Greater Rochester Independent Practice Association, Inc., and Tristate as necessitating their overly burdensome clinical integration requirements in all circumstances. CMS apparently did not evaluate or understand the FTC/DOJ Health Care Guidelines and the FTC/DOJ's many advisory letters concerning financial risk-sharing.

Under the proposed Shared Savings Program, ACOs will have to engage in risk-sharing. Each will at some point have the obligation of paying money to the Medicare program if it does not meet its cost saving targets. It is hard to predict the possible exposure any ACO could face, but just as the savings could be large, the losses could also be large. Further, given that the ACO's participants will have to contribute substantial time and money to make the ACO viable, the added risk of loss takes on even more importance. This is especially true with physicians, many of whom do not have a large amount of capital available to them. Overall, ACO participants will share financial risk, and the ACO will be financially integrated.

Physicians should have the ability to experiment with a variety of organizational approaches aimed at reducing medical costs, and it is inappropriate to mandate prescriptions for clinical integration. **The FTC and DOJ should clarify the requirements for adequate financial integration and declare that arrangements prompted by the need to participate successfully**

[3] CMS Proposed Rule on the Medicare Shared Savings Program, p.19542.

in a two-sided Shared Savings Program are not subject to the *per se* rule against price fixing.

III. *Application of the rule of reason to ACOs participating in the Medicare shared savings program*

The proposed FTC/DOJ ACO policy states that ACOs participating in the commercial market in addition to their participation in the Shared Savings Program will be analyzed under the rule of reason, if they use the same governance and leadership structure and the same clinical and administrative processes required by the CMS Shared Savings Program. **MAG strongly supports the application of the rule of reason to ACOs. MAG believes, however, that ACOs should continue to receive rule of reason treatment even if they no longer participate in the Shared Savings Program.**

In order to access the Shared Savings Program, physicians forming an ACO will have to create an organization that lowers medical costs while at the same time maintaining or increasing the level of care. To achieve these objectives, the ACO will have to create treatment protocols and set quality benchmarks. The ACO will also have to monitor the quality of the medical services it offers, and will have to create reports that quantify this information. Further, if the ACO wants to compete in the commercial market, it will have to offer a product that is valuable to consumers and commercial health insurers.

Setting up an ACO is, therefore, a substantial undertaking. CMS has estimated that an ACO's start-up costs for the first year will likely exceed $1.5 million. Given the experience of Independent Practice Associations (IPAs) that have formed clinical integration programs, the start up costs for an ACO will probably be much higher. In addition to the monetary costs, setting up an ACO will also require substantial involvement by the participating physicians. Physicians will have to implement health IT systems, learn and apply the treatment protocols, and comply with all of the ACO's reporting requirements. This is not a trivial undertaking. These will be particularly difficult changes given that physicians typically practice in small firms with a wide range of practice patterns. According to the AMA Physician Practice Information survey (2007-2008), 78 percent of office based physicians in the U.S. are in a practice with nine physicians or less. The majority of those physicians are either in a solo practice or in a practice of between two and four physicians.[4]

Balanced against these costs and the changes physicians will have to make to their practices is the very real financial risk that the ACO will not earn enough to fully recoup the start-up costs and the general costs associated with running such an organization. These financial risks will weed out unserious efforts at integration. This financial risk also gives physicians participating in an ACO a strong incentive to work with the ACO in achieving the cost reduction targets and quality benchmarks. Indeed, these financial risks are as substantial, and probably more substantial, than the financial integration discussed in the FTC/DOJ Health Care Guidelines. The physicians participating in a new ACO will quickly realize that the ACO's success will

[4] Kane, Carol K. "The Practice Arrangements of Patient Care Physicians, 2007-2008: An Analysis by Age Cohort and Gender." Policy Research Perspectives No. 2009-6. (Chicago, IL: American Medical Association, December 2009).

depend on what each and every member of the ACO does, and how the members interact with one another. This type of incentive structure in a joint venture merits rule of reason treatment.

Most physicians will not want to participate in an ACO that only participates in the Medicare program. For a large number of physicians, it simply will not make financial sense for them to join an ACO that does not operate in the commercial market. Physicians understand that they cannot limit to Medicare patients the changes they will have to make within their practices. There is no reason, therefore, to limit the ACO's activities to the Medicare market. Further, given the costs associated with starting and running an ACO, physicians will want a broader source of potential revenue than what is offered by the Shared Savings Program. We think it is highly doubtful that most physicians will view the risks in forming and participating in an ACO worthwhile if the ACO cannot operate in the commercial market.

Applying the rule of reason to ACOs is also consistent with current antitrust doctrine and the policy set forth in the FTC/DOJ Competitor Collaboration Guidelines. One unmistakable trend in antitrust law is the narrowing scope of the *per se* prohibitions. Many types of conduct that were once squarely within a *per se* prohibition are now subject to the rule of reason. Courts, economists and antitrust attorneys have largely recognized that the broad application of *per se* prohibitions stifled many procompetitive undertakings, all to the detriment of consumers. While the *per se* prohibitions are easy to apply, they can impose significant costs on consumers by condemning and deterring collaborative activities that actually enhance competition and consumer welfare. For this reason, courts are now applying rule of reason tests to many types of conduct that were once considered *per se* unlawful. The benefit of this approach is that courts can now analyze both the procompetitive and anticompetitive aspects of a collaboration. The *per se* prohibitions are now largely confined to naked anticompetitive restraints, such as price fixing, that are not part of a potentially procompetitive joint venture or collaboration.

For example, the strict application of the *per se* rule to ancillary restraints in joint ventures that was announced in *United States v. Topco Associates, Inc*., 405 U.S. 559 (1972) has largely been rejected. A joint venture that has the ability to create procompetitive efficiencies is not condemned out of hand because it has a price restraint. The FTC/DOJ have played an important role in the narrowing of the *per se* prohibitions. The FTC/DOJ Competitor Collaboration Guidelines are essentially based on a rejection of the stilted analysis announced in *Topco* and the broad application of *per se* prohibitions. The FTC/DOJ's decision to evaluate ACOs under the rule of reason is, therefore, entirely consistent with the narrowing of the *per se* prohibitions and the FTC/DOJ Competitor Collaboration Guidelines**.**

MAG, however, does not agree that the rule of reason should only apply during the ACOs participation in the Shared Savings Program. Physicians would be discouraged from developing or participating in an ACO, if that ACO were only subject to the rule of reason for three years and then became potentially subject to *per se* condemnation. More importantly, limiting rule of reason treatment in such a way does not seem to make any sense. If the economic substance of an ACO merits rule of reason treatment in year one, it should have rule of reason treatment in year four. To have a different rule is to either imply an arbitrary enforcement policy or is some type of assertion that the ACO was never really entitled to rule of reason

treatment. Either option sends a terrible message to the market. Under such an arrangement, physicians are being asked to invest substantial money and effort into an organization to which the FTC/DOJ might later apply an entirely different set of rules, or in an organization that the FTC/DOJ fundamentally view as problematic from an antitrust perspective.

In the proposed FTC/DOJ ACO policy, the FTC and DOJ claim that they have "determined that CMS' proposed eligibility criteria are broadly consistent with the indicia of clinical integration that the Agencies previously set forth in the Health Care Statements and identified in the context of specific proposals for clinical integration from health care providers." Unless the ACO experiences some type of fundamental change in its organization or operation, stripping the ACO of rule of reason treatment is inconsistent with the FTC and DOJ's above quoted conclusion. **MAG strongly urges the FTC/DOJ to extend the application of the rule of reason to ACOs for as long as the ACOs remain in existence.**

IV. *Market analysis for ACOs: the 30 percent safety zone and the dominant provider limitation*[5]

Given that all ACOs will receive rule of reason treatment, the antitrust analysis shifts to determining whether a proposed ACO has the ability to injure competition. The first, and most important, indicator on whether an ACO could injure competition is whether the ACO has market power. Here, the proposed FTC/DOJ ACO policy sets forth a uniform approach for making an initial determination concerning market power. The proposed model would require an ACO to identify PSAs for its participating physicians, and then calculate the market share that each participant has in its PSA. According to the Proposed Policy, "[t]he higher the PSA share, the greater the risk the ACO will be anticompetitive."

The proposed FTC/DOJ ACO policy then sets forth various thresholds that control the analysis. First, the proposed policy establishes a safety zone for ACOs. An ACO whose participants have a market share of 30 percent or less in each of the ACO's PSAs is deemed not to raise any antitrust concerns. The ACO does not have to contact the FTC or DOJ and can require exclusive dealing arrangements with its participants. Second, there is a "rural exception[6]" to the 30 percent threshold, which applies if the ACO has a non-exclusive relationship with "one physician" in a "rural county." Finally, the proposed policy establishes a 50 percent threshold that triggers a mandatory "Antitrust Agency Review," which involves the submission of various types of documents to the FTC or DOJ by the ACO and some type of heightened (but undefined) antitrust

[5] Dominant Provider Limitation: This limitation applies to any ACO that includes a participant with a greater than 50 percent share in its PSA of any service that no other ACO participant provides to patients in that PSA. Under these conditions, the ACO participant (a dominant provider) must be non-exclusive to the ACO to fall within the safety zone. In addition, to fall within the safety zone, an ACO with a dominant provider cannot require a commercial payer to contract exclusively with the ACO or otherwise restrict a commercial payer's ability to contract or deal with other ACOs or provider networks.

[6] Rural Exception: An ACO may include one physician per specialty from each rural county on a non-exclusive basis and qualify for the safety zone, even if the inclusion of these physicians causes the ACO's share of any common service to exceed 30 percent in any ACO participant's PSA for that service. Likewise, an ACO may include rural hospitals on a non-exclusive basis and qualify for the safety zone, even if the inclusion of a rural hospital causes the ACO's share of any common service to exceed 30 percent in any ACO participant's PSA for that service.

evaluation. The overall goal of this process it to provide a "streamlined analysis" that will supposedly weed out the ACOs that raise a risk of exerting market power to the possible detriment of consumers.

It seems that the PSA model, set forth in the proposed FTC/DOJ ACO policy, was meant to be a screen designed to identify the ACOs needing a more thorough market analysis. If the PSA model is in fact a screen, it needs to satisfy two basic requirements. **First, the PSA model should be inexpensive and easy to apply. Second, the PSA model should not generate a high percentage of false positives concerning market power.** If the PSA test as currently structured fails either condition, it will significantly deter the formation of ACOs by physicians and will result in anything but a streamlined process.

We are concerned that the PSA model as it is currently structured will fail both of the above mentioned conditions. First, the PSA model will impose significant costs on physicians trying to form ACOs. Second, the PSA model may create many false positives. Taken together, the PSA model imposes significant additional costs on the ACO formation process, while possibly creating so many false positives that it loses any meaningful ability to act as a screening device. **We believe that the FTC and DOJ should replace the PSA model with a more traditional market definition analysis, possibly drawing guidance from the market analysis set forth in many of the business review letters issued to IPAs by the FTC. If that is not a realistic option, the FTC and DOJ should modify the PSA model in a way that reduces the implementation costs and substantially reduces the risk of false positives.**

A. *Cost issues*

Under the proposed FTC/DOJ ACO policy, every ACO participant will have to perform a zip code analysis. Specifically, the ACO will have to add up on a zip code by zip code basis the Medicare allowed charges for claims billed by the ACO's physicians. The ACO will then have to organize this data by Medicare specialty code. Each physician's specialty will be determined by what the physician designated on his or her Medicare enrollment application. The ACO will then have to aggregate this data for each of the practice groups participating in the ACO. Thus, an orthopedic group with three orthopedic physicians will have one PSA that will be built by looking at the patient draw patterns of each of the group's physicians.

This zip code information is the basic building block for an ACO participant's PSA. In order to build a PSA, the ACO will have to determine which geographically contiguous zip codes represent 75 percent of the ACO participant's Medicare allowed charges. Once these PSAs are built, the ACO will have to determine each ACO participant's markets share in its PSA.

In order to evaluate its compliance with the thresholds in the proposed FTC/DOJ ACO policy, the ACO will have to determine, for each Medicare specialty code, the number of its participants that draw patients from the ACO's PSAs. Under the proposed FTC/DOJ ACO policy, this does not require an actual overlap of the PSAs of two or more ACO participants that practice under the same Medicare specialty code. For example, assume that two of the ACO's participants practice orthopedic surgery, with Participant A having PSA 1 and Participant B having PSA 2. Also assume that no overlap exists between PSA 1 and PSA 2. Under the proposed policy, the

ACO would have to determine if Participant B has drawn any of its patients from any of the zip codes that make up Participant A's PSA (and vice versa). If Participant B has a 2 percent share of the Medicare allowed charges in Participant A's PSA, then the ACO would have to combine Participant A and B's market shares to evaluate the application of the 30 percent safety zone. If Participant A had a 50 percent share of its PSA (PSA 1), and Participant B had a 2 percent share of PSA 1, the ACO would fall within the mandatory reporting requirement.

We believe that building PSA's will impose substantial costs on most, if not all, ACOs. The cost of building PSAs will not be uniform among physicians or physician groups. The primary issue is whether physicians already have in electronic form the data needed to build the required PSAs. We have not had the time to perform a study evaluating this issue, but we suspect that most physician practices do not have the base data in an electronic format. While the larger physician group practices may have the ability to build PSAs from their current billing databases, this is not necessarily true of the many other smaller group practices or solo-physician offices. Building such a database from scratch for a large number of physicians would cost a significant amount of money, take an extended period of time, and require a large organizational effort.

We do not know if the FTC and DOJ have conducted any surveys addressing the cost issue. If the FTC and DOJ have conducted such surveys, we would ask that the FTC and DOJ share the results. If not, we strongly recommend that the FTC and DOJ conduct such surveys. **If building PSAs is a lengthy and expensive process, imposing such an obligation on newly formed ACOs will undermine the FTC and DOJ's stated policy of having a streamlined review process. It will also undermine Congress' intention of encouraging the formation of ACOs.**

Knowing the costs associated with building PSA shares for ACO participants is also critical to evaluating the usefulness of the PSA model from a cost-benefit perspective. The PSA model is not a traditional market power test. It appears that if the PSA test indicates the possible existence of market power, the relevant ACO will have to then conduct a more rigorous market share analysis. We cannot determine at this time how much of the work on building PSAs will transfer to a more rigorous market power analysis. It appears, however, that a significant risk exists that ACOs may have to incur duplicative costs with respect to the market power issue.

The risk of duplicative costs is reduced if the PSA model works as an effective screen for potential ACOs. However, as stated above, we believe that as currently structured, the PSA model is not an effective screen because it may result in many false positives. This will have a significant deterrent effect on the formation of ACOs. Any ACO that believes it will fail one or more of the thresholds will have to confront the very real possibility that the costs associated with building PSAs for its physicians is only the start of its antitrust compliance costs.

Given the potential cost issue, the FTC/DOJ should consider a market screen that focuses directly on the number of physicians in a community or a realistic geographic area. This approach zeros in on the options available to consumers and the possibility that other rival ACOs could form in the area. Another option for alleviating the financial burden on ACOs is for an ACO to provide a list of its participating physicians to CMS and have CMS perform the relevant calculations. Given that CMS should have all of the data needed to run PSA calculations in its database, CMS could provide the numerator and denominator to the ACO so that they can more

readily calculate their PSA. This would eliminate a tremendous amount of redundant costs. The FTC and DOJ, along with CMS, should evaluate the feasibility and cost of such an arrangement.

MAG urges the FTC and DOJ to evaluate the costs ACOs will face when trying to comply with the proposed PSA model. MAG also requests that the FTC and DOJ consider a cost-benefit analysis that addresses the potential problem of duplicative costs. Finally, MAG requests that FTC/DOJ work with CMS to determine if CMS could put in place a program that would assist the ACO with the PSA calculations.

B. *False positive problem*

The PSA model represents a stark departure from the market definition approaches set forth by the FTC and DOJ in their long standing enforcement policy statements. The PSA model is also inconsistent with the market definition principles accepted by every federal appellate court. The proposed FTC/DOJ ACO policy addresses this issue in a footnote: "[w]hile a PSA does not necessarily constitute a relevant antitrust geographic market, it nonetheless provides a useful tool for evaluating potential anticompetitive effects."[7]

We are concerned that the proposed FTC/DOJ ACO policy does not clearly articulate the role of the PSA model in the antitrust review process. The proposed FTC/DOJ ACO policy makes statements indicating that the PSA model is a good substitute for the market definition approaches used by the FTC and DOJ in the past. For example, the FTC and DOJ state that the "higher the PSA share, the greater the risk the ACO will be anticompetitive," and footnote 22 expressly refers to the PSA model as a "useful tool for evaluating potential anticompetitive effects."[8] Based on these statements, it appears that the PSA model is a substitute market power analysis and is not technically a screen for weeding out potentially problematic ACOs.

This ambiguity raises some difficulty commenting on the PSA model. **We have serious and substantial concerns if the PSA model is a new test for evaluating market power in physician markets. Such a test is contrary to existing law, and is inconsistent with the market definition process used in other industries.** Further, while the FTC and DOJ claim that high PSA shares indicate a greater risk of anticompetitive behavior by ACOs, we are not aware of any economic or legal analysis that would support such a conclusion. We firmly believe that the PSA model is biased towards creating artificially small geographic markets that overstate an ACO's ability to exert market power. If the proposed FTC/DOJ ACO policy portrays these shares as accurate indicators of market power, it will have a substantial chilling effect on the formation of ACOs. We believe that the overwhelming majority of ACOs will fall outside the safety zone as currently structured, and that a large majority will have a market share in some PSAs that exceed the 50 percent threshold and that do not fall under the Dominant Provider Limitation.

If the PSA model is a screening device, the FTC and DOJ should clearly state so. More importantly, if the PSA model is a screen, we do not believe that it is suitable screen. As currently structured, the PSA model will flag too large a percentage of ACOs as raising possible

[7] FTC/DOJ ACO policy, p.21896, footnote 22.
[8] *Id.*

market power concerns. We believe, however, that there exist some modifications the FTC and DOJ can adopt that would make the PSA model a more workable screening device as described below. Finally, if the PSA model is a screen, the FTC and DOJ should state how they will analyze ACOs that fail the PSA screen.

i. *"Common Service" test is too restrictive*

We believe that the "common service" test should be subject to a screen that weeds out insignificant overlaps on a zip code by zip code basis for ACO participants. As stated above, the PSA model as currently structured does not limit the common service test to overlaps between PSAs. As a result, an ACO could completely lose safety zone protection or fall outside the Dominant Provider Limitation because of an insignificant overlap between ACO participants offering a common service.

We believe that it is improper to infer any meaningful competition between ACO participants when one of the participants receives only a small percentage of its patients from the zip codes that constitute another ACO participant's PSA. While it is difficult to quantify what constitutes an insignificant overlap, we believe that any physician receiving 10 percent or less of his or her patients from another physician's PSA does not represent the type of competitive interaction that would require a combination of their shares. While a 10 percent overlap requirement could reduce the incidence of false positives, we believe that the most appropriate model involves the common service test being triggered if the two or more ACO participants share the same PSA.

ii. *30 percent safety zone should have an exception for ACOs that face competition from other providers*

Under the proposed FTC/DOJ ACO policy, the ACO will have to calculate the market shares its participants control in each identified PSA. An ACO participant's market share of a PSA is the "total Medicare allowed charges for claims billed by the ACO's [participants operating in the PSA and offering a common service] divided by the total allowed charges for [the common service] for all Medicare beneficiaries" in the relevant PSA. If the ACO's participants control more than 30 percent of any PSA the ACO, as a whole, cannot get the protection of the safety zone.

The 30 percent safety zone as currently structured is overly restrictive because it is based on a market definition methodology that is biased towards defining small markets and, more importantly, makes no effort to evaluate the actual level of competition in the relevant PSA. First, even a 40 percent market share, for example, implies that 60 percent of the patients in the PSA are being treated by other physicians. Second, and more importantly, the zip code approach to building PSAs means that the ACO participant's share of each zip code in the PSA could vary widely. It is possible that an ACO participant will have a market share well in excess of 30 percent in only one of the zip codes making up its PSA, and then have market shares well below 30 percent in the remaining zip codes. For example, Physician A could have a 50 percent share of zip code one, and then a market share below 20 percent in the remaining zip codes that constitute Physician A's PSA. Physician A's low share of the remaining zip codes indicates that there are other viable physician alternatives to patients living in those zip codes. Thus, under the

PSA model, it is possible that one zip code could create a false impression of market power. Given that even one PSA's falling outside the safety zone strips the entire ACO of safety zone treatment, the safety zone model can lead to absurd results.

We believe that the FTC and DOJ can address this problem by making two modifications to the safety zone. First, raise the safety zone market share threshold to 40 percent. Raising the threshold will make it less likely that a big share in one zip code will result if an overall market share of over 40 percent in the PSA as a whole, at least in those PSAs consisting of three or more zip codes. Second, apply the safety zone to the ACO, even if the market share exceeds 40 percent, when the ACO participants face a competitor that draws patients from the relevant PSA and is equivalent in size to the ACO participant.

We believe that the above modifications will more properly focus the PSA model on the competitive realities ACOs will face and the options available to consumers. It will allow a larger number of ACOs to form without having to fear a costly and uncertain antitrust review process. These modifications, however, will not let ACOs that actually have market power to fall through the cracks.

iii. *Dominant provider limitation should have an exception for ACOs that face competition from other providers and is non-exclusive*

The same problems that limit the utility of the PSA market share figures, also limits the meaningfulness of the Dominant Provider Limitation. ACOs must seek approval from the FTC or DOJ if any of the ACO's participants has a PSA share of more than 50 percent, and any other ACO Participant in the same specialty draws patients from that PSA.

We believe that a large majority of ACOs will fall beyond the Dominant Provider Limitation given the way the PSA model is structured. We also believe that ACOs falling outside the Dominant Provider Limitation for some Medicare specialty codes will face significant problems attracting physicians. **While the proposed FTC/DOJ ACO policy does not state that crossing the 50 percent threshold will create an insurmountable hurdle for antitrust approval, we strongly believe that physicians will view the 50 percent threshold as a bright line test for legality.**

While a 50 percent threshold might make sense if the proposed FTC/DOJ ACO policy were referring to a more traditional market definition model, it makes no sense when applied to the PSA model. **There are four modifications that the FTC and DOJ could make to reduce the deterrent effect the 50 percent threshold will create. First, by loosening the common service test, as described above, more ACOs will be able to claim the benefit of the Dominant Provider Limitation. Second, we recommend raising the threshold to 60 percent. Third, let the ACOs fall within the Dominant Provider Limitation if the ACO participants face a competitor that draws patients from the relevant PSA and is equivalent in size to the relevant ACO participants. We believe that these modifications balance, more appropriately, the FTC and DOJ's interest in flagging potentially anticompetitive ACOs while not unduly chilling the development of ACOs.**

Finally, the FTC and DOJ should allow an ACO to fall within the Dominant Provider Limitation, regardless of its market share in any PSA, if the ACO has a non-exclusive relationship with the ACO participants that have a market share of more than 60 percent. We recommend that the FTC/DOJ clearly define the meaning of non-exclusivity. Does the term mean that physicians do not have to go through the ACO in order to contract with a private payer or that a physician (e.g., specialist) is able to participate in more than one ACO, or does the term non-exclusivity cover both circumstances? While the proposed FTC/DOJ ACO policy views non-exclusivity as a relevant factor, we believe that non-exclusivity makes it extremely unlikely that the ACO could exert any type of market power. This is also consistent with FTC advisory letters that addressed the formation of IPAs that needed to include specialty groups with high market shares.

iv. *The rural safe harbor is overly restrictive*

We recommend that the "rural exception" be modified so that this exception would apply to a single physician as well as to a physician group practice. The rural exception as currently drafted could have the unintended consequence of causing the breakup of rural small group practices. These group practices offer their communities many efficiencies such as pooling of knowledge, subspecialization of function, and internal supervision of the quality of work.

V. *ACOs exceeding the 50 percent PSA share threshold—mandatory FTC/DOJ review required*

Under the proposed FTC/DOJ ACO policy, ACOs in which any participant has a greater than 50 percent share in its PSA must seek and obtain an approval letter from either the FTC or DOJ in order to participate in the Shared Savings Program. The FTC and DOJ have proposed a 90-day expedited review of those ACOs that need to seek this type of approval under the proposed policy. In order to obtain the expedited review, the ACO must first submit all of the information identified in Section IV.B. **MAG supports the concept of an expedited review process. Our concern is that item IV.B(3) seeks an undefined and extremely large category of documents. Without having a precisely delineated set of requested documents, the 90-day expedited review period becomes illusory.**

Item IV.B(3) requires that a reporting ACO produce all:

> [d]ocuments 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.

While we do not deny that such information is valuable, this request could conceivably cover every document the ACO and its organizers have created. While this information could be necessary if the FTC or DOJ were to formally investigate an ACO, this type of open ended request is not appropriate for a 90-day expedited review process. **We strongly recommend that the FTC and DOJ more precisely define the types of records they need in order to trigger the 90-day period.** The proposed FTC/DOJ ACO policy can add a provision that would allow

the FTC and DOJ to issue a second request for documents, if the reviewing agency had a market power concern and did not believe it had sufficient information. The proposed FTC/DOJ ACO policy would then allow a postponement of the 90-day clearance process pending compliance with the second request.

Conclusion

For those physicians interested in the Shared Savings Program, it is critical for CMS and the FTC/DOJ to develop an antitrust clearance process that enables the majority of U.S. physicians, including those in solo and small practices, to develop, lead, and actively participate in ACOs. While MAG supports the application of the rule of reason to ACOs, the establishment, in principle, of a safety zone with respect to the issue of market power, and a 90-day expedited FTC/DOJ review process for ACOs, the modifications to the proposed FTC/DOJ ACO policy detailed above are necessary, MAG looks forward to working with the FTC, DOJ, and CMS as this proposal is revised. Should you have any questions on this letter, please contact Mr. Donald J. Palmisano, Jr., Executive Director/CEO at dpalmisano@mag.org or 678-303-9251.

Sincerely,

E. Daniel DeLoach, M.D.
President

EDD:DJP/dg