May 31, 2011

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

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

Dear Sirs:

The Texas Medical Association (TMA) appreciates this opportunity to comment on the Federal Trade Commission (FTC) and Department of Justice (DOJ) Proposed Statement of Antitrust Enforcement Policy Regarding Accountable Care Organizations Participating in the Medicare Shared Savings Program.

TMA is a private voluntary, nonprofit association of Texas physicians and medical students. TMA was founded in 1853 to serve the people of Texas in matters of medical care, prevention and cure of disease, and improvement of public health. Today, its mission is to "Improve the health of all Texans." Its almost 46,000 members practice in all fields of medical specialization. It is located in Austin and has 119 component county medical societies around the state.

Consistent with its mission, TMA has a keen interest in advocating for laws and regulations promoting both increased quality and efficiency in the delivery of healthcare. TMA recognizes that accountable care organizations (ACOs) in the Medicare Shared Savings Program (MSSP), as envisioned by Congress, under Section 3022 of the Patient Protection and Affordable Care Act (PPACA), are directed towards this end.

Many potential challenges, however, are presented in transforming the theory behind ACOs into practice. TMA acknowledges that, among those potential challenges, are considerations regarding the application and enforcement of federal antitrust law to ACOs. TMA, therefore, appreciates the FTC and DOJ's efforts in drafting the proposed Enforcement Policy Statement for ACOs participating in the MSSP and in appropriately seeking and considering stakeholder responses on this issue. TMA respectfully offers the

following comments on the proposed Enforcement Policy Statement, as published in the Federal Register on April 19, 2011.

I. Physician-Specific Bright-Line Anti-trust Safety Zone

First, TMA appreciates the high level of complexity involved in devising an appropriate antitrust analysis and enforcement scheme for ACOs participating in the MSSP. The FTC and DOJ are charged with the difficult task of drafting enforcement policies that are flexible enough to encourage provider participation in the MSSP, yet stringent enough to protect consumers and facilitate competition in the marketplace.

TMA appreciates the FTC and DOJ's drafting of a MSSP ACO-specific safety zone, as presented in the proposed Enforcement Policy Statement.[1] TMA believes that an ACO-specific safety zone is necessary to provide a level of certainty to ACO participants regarding combinations/activities in the marketplace that will not be challenged, absent extraordinary circumstances. The safety zone in the Enforcement Policy Statement was presumably drafted with such an intent.[2]

The safety zone framework established in the proposed Policy Statement, however, is drafted for *general* application to ACOs participating in the MSSP (with only minor modifications based upon provider types participating in the ACO). More specifically, the safety zone provides that an ACO will fall within the proposed safety zone if:

> independent ACO participants … that provide the same service … have a combined share of 30 percent or less of each common service in each participant's [Primary Service Area] PSA, wherever two or more ACO participants provide that service to patients from that PSA.[3]

If a hospital or ambulatory surgical center participates in an ACO, it must be non-exclusive to the ACO to fall within the safety zone, regardless of PSA share.[4] For physicians and other providers, exclusivity or non-exclusivity to the ACO is not a factor in safety-zone qualification.[5]

TMA strongly contends that the proposed safety zone, with its broad application to *all* ACO participants, fails to adequately accommodate *physician-only* ACOs participating in the MSSP. Physician-only ACOs already face significant financial barriers to market entry, given the substantial start-up costs necessary to form an ACO.[6] The added

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[1] *See* 76 Fed. Reg. 21897.
[2] *Id*.
[3] *Id*.
[4] *Id.*
[5] *Id*.
[6] The Centers for Medicare and Medicaid Services (CMS) itself estimates the aggregate cost for start-up investment and first year operating expenditures for MSSP ACOs to range from $131 million to $263 million, assuming 75 to 150 ACOs participate in the MSSP. *See* 76 Fed. Reg. 19633. Physician practices are highly unlikely to independently have the financial resources to create an ACO or to offer significant capital investments in ACOs.

difficulties and expense associated with calculating PSA and market share will further discourage market entry by ACOs comprised solely of physician groups.

TMA, therefore, urges the FTC and DOJ to draft a physician-specific bright-line antitrust safety zone that will permit physicians to act together in a manner that is clearly anticipated by the PPACA. Such a safety zone is critical to providing physicians with the flexibility necessary to create ACOs that will appropriately address local public health conditions and issues, as well as to clarify the application of otherwise nebulous antitrust law so that physicians have a level of certainty that their actions fall within the confines of the law. The narrower the antitrust safety zone is for small and solo physician practices, the greater the obstacle to innovation in ACO structure.

The specter of antitrust enforcement hinders small and solo physician practice (hereinafter "small practices") participation in ACOs, as it is recognized that cooperative action must be taken for the implementation of ACOs, yet the government has previously expressed distrust of coordinated physician activities. Small practices have limited resources and those resources should be devoted to creating health care delivery systems and protocols that will achieve the goals of ACOs, rather than having to dedicate capital to legal representation and ongoing compliance programs.

The current FTC series of advisory letters on antitrust and clinical integration that may allow practices to avoid enforcement (via a rule of reason analysis) is complex and unworkable for small practices seeking to participate in or establish an ACO. Indeed, it is widely acknowledged (even by the government itself) that "what constitutes clinical integration is still uncertain."[7] Given the coordinated goals of ACOs and Congress' intent for broad-reaching physician participation in ACOs, this uncertainty must be eliminated. The general safety zone for ACOs, as currently drafted in the proposed Enforcement Policy Statement, represents a respectable first step towards providing much-needed clarity in this area, yet remains unworkable for small practices. The creation of a common sense bright-line *physician-specific* safety zone will facilitate coordination among physicians and provide the certainty necessary to encourage physician participation in the MSSP.

Furthermore, to encourage the establishment and investment in ACO organizations by small practices, any broad bright-line physician-specific antitrust safety zone must also be applicable to physician activity in the private insurance market. Therefore, TMA strongly supports the proposed Enforcement Policy Statement's assurances that participation in the MSSP will permit an ACO to engage in combined activity in the commercial market (with rule of reason treatment) if the ACO uses the same governance and leadership structure and the same clinical and administrative processes as it uses to qualify for and participate in the MSSP.[8] The Policy Statement's assurances regarding commercial market activity are desirable, because they reduce the administrative burdens of discerning which patient carries which type of coverage. Additionally, they serve to promote ACO formation in general, which the government should favor since the goals

[7] Remarks of J. Thomas Rosch, Commissioner, US Federal Trade Commission, Sept. 3, 2008.
[8] *See* 76 Fed. Reg. 21896.

of ACOs (i.e., appropriate care, provided at the right time, in the right place of service) are laudable in *all* professional interactions (i.e., in private insurance arrangements, as well as government programs).

Finally, it is important for the FTC and DOJ to note that hospitals or hospital systems need not be included in a physician-specific bright-line antitrust safety zone. The PPACA expressly permits the establishment of ACOs by physicians *only*.[9] In contrast, hospitals are permitted to participate in the MSSP, but only in concert with physicians.[10] TMA strongly asserts that this eligibility framework is an expression of Congress' preference for physician-practice ACOs. Such a framework, therefore, warrants special accommodation of physician-specific ACOs from an antitrust perspective.

Given that: (1) ACOs with hospitals are likely to enjoy greater resources and (2) hospital systems have a much larger presence in their market, hospital-participating ACOs do not need the same level of antitrust accommodation as ACOs established solely by physicians, especially physicians in small practice. Hospitals simply do not face the same operational challenges and coordination challenges as physicians. It is imperative that this important distinction be recognized by the FTC and the DOJ in the development of their final ACO Enforcement Policy Statement.

II. Hospital-Participating ACO Safety Zones

Next, TMA supports the Enforcement Policy Statement's pronouncement that the safety zones and other ACO-specific guidance contained within the Statement, including provisions for streamlined analysis, are inapplicable to mergers.[11] As the Statement provides, merger transactions should continue to be evaluated under the Agencies' *Horizontal Merger Guidelines*.[12] Mergers pose a significant antitrust threat and should, therefore, be subject to a heightened level of antitrust scrutiny.

However, despite the proposed Enforcement Policy Statement's assurances that mergers will be evaluated separately, TMA has concerns about hospitals developing significant or comparable market power under the aegis of the proposed ACO antitrust safety zone.

As has been broadly reported, many organizations are speeding to meet a perceived call by government and the marketplace to consolidate. For example, in the Houston, Texas market, Memorial Hermann Healthcare System is already consolidating medical and hospital services in the quest to be considered an ACO.[13] According to an American Hospital Association (AHA) case study on the Memorial Hermann effort, more than 2,000 physicians responded to a request to participate in a "clinically integrated" network. That network would comprise almost 20% of physicians if it were confined to Harris County, Texas (as TMA has information that approximately 10,000 physicians

[9] *See* 42 USC 1395jjj(b)(1)(A).
[10] *See* 42 USC 1395jjj(b)(1)(D).
[11] 76 Fed. Reg. 21895.
[12] *Id*.
[13] *See* http://www.aha.org/aha/content/2011/pdf/aco-case-mem-hermann.pdf; last accessed 5/27/2011.

practice in that county). Memorial Hermann has a 34% share of the health care market in Houston by its own admission.[14]

According to the Bureau of Labor Statistics, the Houston Metropolitan Statistical Area has the highest health care cost per consumer unit among selected southern cities.[15] TMA asserts that consolidation in the name of the MSSP participation would potentially be detrimental to certain markets.

Further, TMA urges the FTC and DOJ to be mindful of protecting competition for both physicians who will choose to participate in ACOs, as well as physicians who will choose to remain independent from ACOs.[16] Small practices are independent by choice and should not be driven from the market by the presence of a large ACO. In Texas, 58% of all physicians practice in groups of one to three physicians. Seventy-two percent (72%) of all Texas physicians practice in groups of one to eight physicians. When Texas physicians were asked about the factors they considered when entering practice for the first time or when changing their practice setting, 74% and 60% of those physicians, respectively, chose "personal control of clinical decisions" as a very important factor in their decision.[17] These physician perspectives on medical practice should be acknowledged by and incorporated into the framework developed by the FTC and DOJ.

To address the foregoing concerns, TMA contends that more narrowly-tailored antitrust safety zones are necessary when a hospital is a participant in an ACO. Thus to quality for the safety zone, TMA suggests that the PSA combined share of each common service be reduced from the current percentages when a hospital is an ACO participant. Furthermore, TMA has concerns that rural hospitals may exercise market power to the detriment of physicians who choose not to participate in the rural hospital's ACO. TMA, therefore, recommends that the dominant provider safety zone be rendered unavailable to ACOs with hospital participants, as the danger of market power and the associated rise in prices is contrary to the purpose of ACOs. Such a modification to the proposed Enforcement Policy Statement would be consistent with the FTC and DOJ mandate to preserve competition.

In addition to the aforementioned safety zone modifications, TMA encourages the FTC and DOJ to take proactive measures to preserve competition and access-to-care by preventing hospital-participating ACOs from utilizing marketplace-limiting contract provisions (e.g., restrictive covenants and so-called "clean sweep" provisions). In the past, hospitals have exploited their market power in other markets.[18] Indeed, in at least one market, it has been reported that "[h]igher priced hospitals are gaining market share at the expense of lower priced hospitals, which are losing volume."[19] To slow or limit

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[14] *Id*, page 3.
[15] *See* http://www.bls.gov/cex/2009/msas/south.pdf; last accessed 5/27/2011
[16] TMA represents both physicians who will participate in ACOs and physicians who will remain independent.
[17] Source: Texas Medical Association 2010 Survey of Texas Physicians.
[18] *See* Martha Coakley, *Examination of Health Care Cost Trends and Cost Drivers* (2010); available at: http://www.mass.gov/Cago/docs/healthcare/final_report_w_cover_appendices_glossary.pdf
[19] *Id. p. 5.*

such consolidation, the Enforcement Policy Statement should include a prohibition on all hospital-associated ACOs utilizing marketplace-limiting contract provisions. Physician privileges at an ACO-associated hospital should not be conditioned on the physician's participation in the ACO, nor should the physician's privileges at the hospital automatically cease upon the termination of the physician's agreement with an ACO. The use of marketplace limiting contracts is contrary to the purpose of an ACO as a method of promoting community-based care and only serves to eliminate potential competitors from a service area.

III. Availability of Data for Safety Zone Assessment

Next, as previously mentioned in Section I. above (regarding the need for a physician-specific safety zone), the determination of the Primary Service Area (PSA) and market share in a PSA is a very daunting task. Indeed, it is likely to be well beyond the capabilities of an ACO comprised of small physician groups. If the FTC and DOJ continue to pursue the current framework for safety zone qualification based upon PSAs and market share for physicians, TMA urges the FTC and DOJ, in consultation with the Centers for Medicare and Medicaid Services (CMS), to provide the necessary information to applicant physicians for the purpose of calculating the PSA for the proposed ACO. Furthermore, when applicant physicians rely upon the CMS-supplied data, TMA strongly recommends that the FTC and DOJ permit remediation without penalty in any instances in which the calculation is incorrect due to inaccuracies contained within the CMS-supplied information.

IV. Rural Exception – Physician Issues

Next, TMA supports the inclusion of a rural physician exception in the Enforcement Policy Statement. However, TMA recommends that the exception be broadened. As currently drafted, the rural exception provides that:

> an ACO may include one physician per specialty from each rural county (as defined by the U.S. Census Bureau) on a non-exclusive basis and quality 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.[20]

TMA contends that this exception is unrealistic in its expectations and fails to take into account the realities of the practice of medicine. More specifically, it is important to note that physicians rely on other physicians for providing patients with an appropriate continuity of care. Under the rural exception, as currently drafted, TMA is unable to discern whether a physician could take a vacation or utilize other specialists for call coverage when he or she is otherwise unavailable for patient care. To deliver high quality care, more than one physician per rural county per specialty is necessary. The exception must, therefore, be expanded as necessary to make allowances for continuity of care.

[20] 76 Fed. Reg 21897.

V. Rural Exception – Hospital Issues

Next, TMA urges the FTC and DOJ to empower physicians to keep patients out of the local rural hospital by eliminating the exception for rural hospitals with PSA shares greater than 30% in the proposed Enforcement Policy Statement. TMA does not agree with the supposition implicit in the rural hospital exception that there will be multiple ACOs in a rural area that would give effect to the mandate that a rural hospital be a non-exclusive participant in a rural ACO. Rural markets will generally be able to support a single ACO (as the concept is now envisioned in proposed regulations). Thus, there is no real protection possible other than to exclude a rural facility from ACO participation.

Patients *must* receive the right care at the right time and in the least expensive places of service. Physician offices and other non-hospital based health care provider locations are less expensive than hospital emergency room and in-patient settings. Hospital care is only a limited – albeit expensive – component of the continuum of care that a patient receives. Successful ACOs will reduce in-patient care at hospitals. Yet, "rural communities rely on their hospitals as critical components of the region's economic and social fabric. These hospitals are typically the largest or second largest employer in the community, and often stand alone in their ability to offer highly-skilled jobs."[21] Simply put, rural hospitals already exert great influence in their local community and the ACO MSSP should not be utilized to allow such hospitals to amplify their market presence. Thus, TMA strongly recommends that the rural hospital exception be eliminated.

VI. Allowance for Winding Down

Finally, TMA notes that the applicability of the Enforcement Policy Statement is generally limited to ACOs that are approved for and actively participating in the MSSP. The Enforcement Policy Statement expressly provides that only those ACOs formed after March 23, 2010, that seek to participate, or have otherwise been approved to participate in, the MSSP are governed by the Statement.[22] Similarly, the Statement provides that commercial ACOs are only governed by the Enforcement Policy Statement "during the duration of [their] participation in the Shared Savings Program."[23] As currently drafted, there is *no* provision or accommodation in any of the guidance for the possibility that the shared savings arrangement with the government will be terminated. TMA urges the FTC and DOJ to include a specific safety zone to permit an ACO that is otherwise compliant with the safety zone criteria (yet is terminated from the MSSP) to wind-down without fear of an antitrust enforcement action.

VII. Conclusion

[21] AHA, The Opportunities and Challenges for Rural Hospitals in an Era of Health Reform , (April 2011) at [www.aha.org/aha/trendwatch/2011/11apr-tw-rural.pdf*] Citing* Doeksen, G.A., and Schott, V. (2003). *Economic Importance of the Health Care Sector in a Rural Economy. Rural and Remote Health,* 3. Access at http://www.rrh.org.au.

[22] 76 Fed. Reg. 21895.

[23] 76 Fed. Reg. 21896.

Once again, TMA thanks you for the opportunity to provide these comments. If you should have any questions or need any additional information, please do not hesitate to contact me or the following staff of the Texas Medical Association: Lee A. Spangler, JD, TMA Vice President, Division of Medical Economics; or Kelly Walla, JD, LLM, TMA Associate General Counsel at TMA's main number 512-370-1300.

Sincerely,

Asa C. Lockhart, MD, MBA, Chair
Ad Hoc Committee on Accountable Care Organizations