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Submitted electronically at:

<https://ftcpUBLIC.commentworks.com/ftc/acoenforcementpolicy>

May 31, 2011

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

Dear Mr. Clark:

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

The Association of American Medical Colleges (AAMC) is a not-for-profit association representing all 134 accredited U.S. and 17 accredited Canadian medical schools; nearly 400 major teaching hospitals and health systems, including 62 Department of Veterans Affairs medical centers; and nearly 90 academic and scientific societies. Through these institutions and organizations, the AAMC represents 128,000 faculty members, 75,000 medical students, and 110,000 resident physicians. The AAMC appreciates the opportunity to comment on the FTC/DOJ notice, *Proposed Statement of Antitrust Enforcement Policy Regarding Accountable Care Organizations Participating in the Medicare Shared Savings Program* (the “Proposed Statement”).

The AAMC supports the decision by the Federal Trade Commission (FTC) and Department of Justice (DOJ) to create a safety zone for accountable care organizations (ACOs) that participate under the Centers for Medicare & Medicaid Services’ (CMS) Medicare Shared Savings Program (MSSP). We also support the Agencies’ decision to use a rule of reason analysis for a commercial ACO that uses “the same governance and leadership structure and the same clinical and administrative processes as it uses to qualify for and participate in the Medicare Shared Savings Program.” However, as described below, we have significant concerns with a number of other provisions of the Proposed Statement.

According to the Proposed Statement, “the key issue is whether the ACO, on balance, will provide consumers with high-quality, cost-effective care or, instead, increase price and reduce consumer choice and value.” (page 10) Although the AAMC agrees with this statement, we are very concerned that the FTC and DOJ will adopt a regulatory approach that is extremely

burdensome for providers; sets unrealistic time frames for review; and employs an analysis that fails to acknowledge that the driving force behind ACOs is that they are designed to use a team-based approach to deliver coordinated care and must also be financially integrated, risk-bearing entities. Entities and physicians that wish to establish ACOs are engaging in the type of behavior identified by CMS as being necessary to embark on a path that will lead to a health care system that focuses on delivering quality care, reducing spending, and improving the health of populations. **The AAMC believes that antitrust concerns are best addressed through guidance, and if necessary, enforcement, rather than by forcing ACOs to undergo a complicated and costly analysis made even more difficult because it must occur before they begin operating. Without significant revisions and clarifications to the Proposed Statement, we believe that it will function as a potentially insurmountable barrier to ACO formation.**

Duration of Rule of Reason Analysis for ACOs

Among the AAMC's concerns is that the rule of reason analysis will apply only for the duration of the ACO's participation in the MSSP. Given the large investment of money, time and other resources, the considerable financial risk that must be borne to become a participant in the MSSP, and the likelihood that the intention of these entities is to continue to operate after their participation in the MSSP ends, FTC and DOJ should continue to use the rule of reason analysis even after the ACO completes its agreement with CMS. Doing so will not lessen the Agencies' ability to protect the public against anticompetitive behavior that may arise. As the Proposed Statement acknowledges, and as is equally true after participation in the MSSP ends:

. . . if it appears that an ACO's formation **or conduct** may be anticompetitive, one of the Agencies may investigate the ACO and, if appropriate, take enforcement action at any time during the ACO's participation in the Shared Savings Program." (emphasis added; page 10)

Application of the Antitrust Enforcement Policy

According to the Agencies, the Proposed Statement will apply only to "collaborations among otherwise independent providers and provider groups" formed after March 23, 2010. The AAMC believes that, regardless of the date the ACO was formed, the antitrust analysis should focus exclusively on the organization and its attributes, which, in this case, will include compliance with extensive CMS requirements. We believe further that all ACOs participating in the MSSP should be subject to identical standards with respect to antitrust review. There is no reason to believe that ACOs that existed prior to the date of enactment of the Affordable Care Act were not (or could not have been) organized in a manner to avoid raising antitrust concerns or that they should be subject to heightened scrutiny because of the date of their formation.

If the Agencies choose to retain this requirement, the AAMC requests a clarification regarding the meaning of the phrase "formed after March 23, 2010." For example, will an ACO that was

Mr. Donald S. Clark
May 31, 2011
Page 3

formed as a legal entity prior to March 23, 2010, but did not begin functioning as an ACO until after that date meet that criterion?

Primary Service Area Analysis

The road to the “safety zone” is via the primary service area (PSA) share analysis. Before submitting an application to CMS for participation in the MSSP, an ACO must know the PSA shares for all services. This may mean that virtually every ACO, except those that employ physicians, will be required to conduct a PSA analysis. In addition, depending on the result of the PSA analysis, the ACO may then have to seek expedited FTC/DOJ review prior to submission of an application to CMS. The AAMC is concerned that this will be burdensome, costly, and may be impossible to complete by the January 1, 2012 start of the MSSP proposed by CMS. In addition, by requiring every ACO to do a service-by-service analysis, the focus remains on the individual components of the health care system, rather than on the ACO as a new type of delivery system that is clinically integrated and delivers care through a team-based approach. **The AAMC strongly urges FTC and DOJ to implement an approach that is better designed to encourage the development of ACOs.**

The Proposed Statement states that “the higher the PSA share, the greater the risk the ACO will be anticompetitive.” (page 6) The PSA analysis was developed for the purpose of the Proposed Statement and has never been tested to determine its validity as a proxy for market power. This test is inconsistent with the market definition process used in other industries, and the AAMC is unaware of any economic or legal analysis that supports the conclusion that high PSA shares indicate a greater risk of anticompetitive behavior. If the purpose of the PSA is to provide a quick screen to identify which ACOs raise concerns about their market power, the AAMC suggests modifications should be made so that the screening can be done quickly and economically. **Should the requirement for a PSA analysis be retained, the AAMC requests that the Agencies provide an explanation as to why it is considered to be a proxy for market power.**

The PSA analysis could be replaced by a more traditional market analysis that would be a less costly, more reasonable, and potentially more reliable screen for determining whether an ACO may be anti-competitive. It also would be preferable to conduct the analysis at a geographic level, or a geographic subdivision level, rather than by zip code. FTC and DOJ should explore the feasibility of having CMS, the agency that collects all of the relevant data, perform the relevant calculations. At a minimum, CMS could provide the numerators and denominators to the ACOs, allowing them to more readily calculate each PSA share.

According to the Proposed Statement, “[t]he safety zone for physician and other provider services (regardless of whether the physicians or other providers are hospital employees) does not differ based on whether the physicians or other providers are exclusive or non-exclusive to the ACO . . .” The AAMC requests that the Agencies clarify the antitrust concerns for non-

Mr. Donald S. Clark
May 31, 2011
Page 4

exclusive physicians, as non-exclusivity could be considered an indicator that it will be difficult to exercise market power.

90-Day Mandatory Review

Given the complexity of the mandatory Agency review, the 90 days proposed for its completion may be unrealistic, particularly if sufficient staff is not assigned to this task. The review is likely to be complicated further by the fact that the final regulations will not be issued by CMS for at least several months, yet the start date for the ACO participation in the MSSP is January 1, 2012. **The AAMC strongly suggests that FTC and DOJ consider making the review voluntary and that the process be streamlined, including prompt notification to an ACO of preliminary findings.** If the 90-day review requirement is retained, the AAMC requests clarification regarding when the 90-day period begins (*i.e.*, when the “clock starts”).

Other Issues

The AAMC also requests clarification about what will happen in the event that the final CMS regulation for ACO participation in the MSSP is substantially different from the proposed rule. In that case, will FTC and DOJ feel compelled to revisit whether the changes would be any less “broadly consistent with the indicia of clinical integration”? **The AAMC urges the FTC and DOJ to rely on CMS’s decisions regarding the final requirements for participation in the MSSP.** Regardless of the specific criteria adopted by CMS, the program will rely on extensive data collection and monitoring throughout its entirety.

Finally, the AAMC asks that FTC and DOJ clarify whether the Statement will apply to entities, such as Pioneer ACOs, that participate under the auspices of CMS’s Center for Medicare and Medicaid Innovations.

If you have questions, or need additional information, please contact Ivy Baer, Director and Regulatory Counsel, of my staff at 202-828-0499 or at ibaer@aamc.org.

Sincerely,

Darrell G. Kirch, M.D.
President and CEO