American Society of Anesthesiologists

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May 31, 2011

Mr. Donald S. Clark
Federal Trade Commission
Office of the Secretary
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 American Society of Anesthesiologists (ASA), on behalf of its over 46,000 members, appreciates the opportunity to submit 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 released on March 31, 2011. In general, we are in agreement with the comments made by the American Medical Association (AMA) in their letter; however, we would like to emphasize the following points and issues.

Hospital and Facility Market Power

The majority of anesthesiologists are organized into independent practices that contract with a hospital or facility to provide anesthesia services. This model has thrived by balancing the appropriate level of clinical integration to ensure patient care coordination within the facility while minimizing the dangers of increased hospital and facility market share and the likelihood of increased costs. The noted patient safety record of anesthesiologists is testament that this model is successful and appropriate.

ASA is concerned that the proposed ACO clinical integration requirements unnecessarily require resources that many physician practices do not possess. Thus, perhaps unintentionally, the effect will be to encourage and facilitate hospital consolidation of physician markets through acquisition of physician practices, including anesthesiologists. In recent years, hospitals and facilities have rapidly increased their acquisition efforts with respect to physician practices and made a reality this notion of significant market share. In general, these efforts have escaped antitrust scrutiny, however, because each acquisition has been relatively small so as not to trigger such scrutiny by itself.

ASA agrees with the AMA that the FTC/DOJ should set forth clear and common sense antitrust rules that explicitly permit and encourage physicians to pursue ACO integration options that are not hospital-driven. Anesthesiologists should not be forced to become hospital/facility employees or sell their practices in order to provide innovative care through an ACO or other payment model. Further, finalized requirements pertaining to ACOs should preserve and encourage the ability of specialists, including anesthesiologists, to contract independently with hospitals, facilities, payers and other parties, even if such specialists are participating in a Medicare ACO.

ACO Eligibility and Applicability of FTC/DOJ Policy

The proposed FTC/DOJ policy applies to collaborations formed after March 23, 2010, in which the providers seek to participate in both the Medicare Shared Savings Program and the commercial market. The policy also applies to ACOs under the Center for Medicare and Medicaid Innovation (CMMI) if they are substantially clinically or financially integrated. While we acknowledge that March 23, 2010, is the date the Affordable Care Act was signed into law, we seek clarification on the application of this relatively arbitrary demarcation. Organizations seeking to form an ACO should receive the same antitrust analysis regardless of the ACO formation date.

Rule of Reason Analysis

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. **ASA agrees with the AMA and strongly supports the application of the rule of reason analysis to ACOs. ASA 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 incur significant investments in terms of financial and human capital resources in order to modify and create treatment protocols, establish or modify quality measures and benchmarks, and monitor and improve care quality and coordination. While CMS estimates that ACOs will initially need to invest $1.7 million to develop the organization and infrastructure required, a study released by the American Hospital Association (AHA) on May 13, 2011, estimates that cost to be $11.6 to $26.1 million.[1] It is clear that this is not a trivial undertaking and will require many physicians to fundamentally change the way they practice medicine.

In addition to these significant start-up costs, CMS proposes that ACOs withhold 25% of any shared savings to offset losses. Under the proposed rule, ACOs forfeit this withhold if they withdraw from the program or are terminated by CMS. This does not seem reflective of other CMS programs, especially the PGP Demonstration on which this proposed rule is largely based, and presents an unreasonable economic burden for the ACO, particularly small practices that may not have ample capital and those ACOs in markets currently demonstrating relative high quality and low costs. CMS also requires ACOs to assure repayment of shared losses, including establishing lines of credit, recoupment of losses from future fee-for-service payments, and obtaining reinsurance. These provisions must, at a minimum, be sufficient to account for 1 percent of per capita expenditures for the assigned beneficiaries.

Given the proposed requirements, ASA has significant concerns as to whether an ACO will earn enough shared savings to fully recoup the financial investment; however, the 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.

[1] http://www.aha.org/aha/issues/Clinical-Integration/casestudies.html

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 depend on what each and every member of the ACO does, and how the members interact with one another.

ASA, 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 the stricter *per se* condemnation. More important, limiting rule of reason treatment in such a way seems illogical; 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. **ASA 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.**

Conclusion

To ensure the success of the Shared Savings Program, it is critical for CMS and the FTC/DOJ to develop a Shared Savings Program and associated antitrust clearance process that enables the majority of physicians to develop, lead, and actively participate in ACOs. While ASA supports the application of the rule of reason to ACOs, we have serious reservations about the market power implications and their impact on anesthesiologists. As always, we welcome the opportunity to work with you on this proposed policy and all issues that impact anesthesiologists and the patients for whom we provide safe and high quality care.

Sincerely,

[redacted]

Mark A. Warner, M.D.
President
American Society of Anesthesiologists