

May 31, 2011

Federal Trade Commission  
Office of the Secretary  
Room H-113  
600 Pennsylvania Avenue, NW  
Washington, D.C. 20580

*Re: Proposed Statement of Antitrust Enforcement Policy Regarding Accountable Care Organizations Participating in the Medicare Shared Savings Program—MatterV100017*

Dear Sir or Madam:

Thank you for the opportunity to submit our comments on the above-referenced Proposed Statement of Antitrust Enforcement Policy that will apply to Accountable Care Organizations (ACOs) participating in the Medicare program under Section 3021 or 3022 of the Affordable Care Act. The National Community Pharmacists Association (NCPA) represents America's community pharmacists, including the owners of more than 23,000 community pharmacies, pharmacy franchises and chains. Together, these employ over 300,000 full-time employees and dispense nearly half of the nation's retail prescription medicines.

### **Pharmacists as Integral Members of Collaborative Care Models**

Pharmacists are increasingly gaining recognition for the integral role that they play in encouraging preventative care and promoting wellness, given their subject matter expertise and access to the communities in which they serve. Allowing pharmacists to collaborate and negotiate with insurers to deliver patient care services and serve as patient advocates in exchange for adequate reimbursement for these activities will ensure that more consumers—both in Medicare ACOs and in private plans—will have access to this type of innovative care, resulting in a reduction in overall healthcare costs.

Medications have an integral role in the treatment of chronic medical conditions. Evidence suggests that a significant number of hospital readmissions are due, at least in part, to prescription drug therapy problems that could be avoided through collaborative management of increasingly complex drug regimens. Pharmacists in the community—who may already be managing a patient's drug therapy along with the patient's prescribers—are in a unique position to help integrate the new, post-hospital medications into a patient's existing drug therapy and to monitor post-discharge adherence.

## **Proposed Tiered System for Antitrust Scrutiny Based on Providers Market Share Will Require Each Provider to Accurately Assess His/Her Market Share to Estimate Potential Antitrust Liability**

NCPA appreciates the efforts expended by the FTC and DOJ in establishing the tiered approach to antitrust enforcement and the creation of a “safety zone” for those ACOs considered unlikely to raise significant competitive concerns. In order to qualify for the safety zone, independent ACO participants who provide a common service must have a combined share not in excess of 30% for any common service in each participant’s common primary service area. Under this market share approach to antitrust scrutiny, it will be imperative that each individual provider is able to accurately assess and calculate his or her own market share percentage in specific defined geographic areas in order to be able estimate his or her own potential antitrust liability.

## **Prior NCPA Comments Spoke to the Need for Specific Antitrust Guidance Pertaining to Solo or Small Groups of Allied Health Care Providers**

NCPA submitted comments in December 2010 in response to a Request for Information that specifically sought input as to what steps could be taken to ensure that “groups of solo and small practice providers” could actively participate in the Medicare Shared Savings Programs and the ACO models tested by the Center for Medicare and Medicaid Innovation (CMMI). In light of the fact that many independent community pharmacies are located in very rural and/or very urban areas not typically served by chain pharmacies, the participation of these providers is crucial to ensure beneficiary access to these services. Prior NCPA comments focused on the fact that in order for independent community pharmacists to be able to actively participate in the envisioned ACOs and other collaborative care models, these practitioners need to be able to collaborate with one another in order to form provider networks that can realistically compete on an equal footing with pharmacy networks made up of chain pharmacies (such as Walgreens or CVS Caremark). If pharmacists are unable to band together to participate with ACOs, those ACOs may be limited to simply dealing with corporate chain pharmacies that dominate the market.

Although pharmacists are mentioned in the context of participation in ACOs in federal healthcare reform, neither pharmacists nor other types of allied health care providers are specifically mentioned in any of the various portions of the actual ACO proposed regulations. In the past, the majority of helpful FTC guidance that has been issued to health care providers on the topic of navigating potential anti-trust concerns in collaborative care models has been virtually limited to physicians and hospitals. Also, the 1996 FTC/DOJ *Statements of Antitrust Enforcement Policy in Healthcare* only seem to allow provider collaboration when providers can integrate to help control utilization; however, since pharmacies dispense and do not prescribe they are unable to meet this threshold requirement under the FTC guidelines. The proposed Statement of Antitrust Enforcement Policy currently under discussion also seems to be focused primarily on physicians and hospitals despite the fact that the stated goal for ACOs is to encourage a collaborative model of care delivery that involves the full continuum of care. Given the fact that effective patient care necessarily involves the collaboration of all types of health care providers—not simply physicians and hospitals-- NCPA would recommend that more detailed or specific guidance be offered to allied health care providers, including pharmacists, who may be interested in participating in ACOs.

Another important issue is the ability of community pharmacies in rural areas to participate in ACOs. The rural exception in the proposed notice recognizes the difficulty of meeting the safety zone test in more sparsely populated rural areas. However, as proposed, it would only offer special accommodation for the participation by rural hospitals and physicians. Yet a rural community is also likely to have a small number of pharmacies as well, which will make it difficult to stay within the safety zone for participation in a rural ACO. The proposed notice only provides an allowance for physicians and hospitals in a rural area to meet the safety zone test under certain circumstances but does not take into account that pharmacists are also likely to face the same issues in rural areas in staying within the safety zone. NCPA would recommend that the rural exception be modified to include a similar exception for pharmacies located in a rural area that participate in an ACO.

**NCPA would recommend that the FTC/DOJ allow individual pharmacists and similar groups of ancillary healthcare providers to collaborate with one another to form provider networks that could collectively negotiate with ACOs**

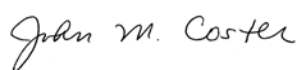
CMS has expressed interest in pursuing measures to ensure that ACOs are in fact “patient centered”. A widely accepted component of “patient centered” healthcare is the principle of patient choice. Many patients view their hometown community pharmacist as a long-term partner in the maintenance of their medical conditions and overall healthcare. If independent pharmacies are not permitted to collaborate in order to provide services that are able to compete with the large pharmacy chains, many Medicare beneficiaries may be effectively forced to abandon their relationship with their community pharmacist in order to maintain access to services. As noted earlier, independent community pharmacies many times are found in very rural areas or very urban areas—or places in which chain pharmacies are not well represented. In addition, many patients in these settings have extremely limited access to virtually all health care providers. If independent pharmacies were able to collaborate in order to participate in ACOs, CMS could effectively increase patient access.

**Conclusion**

In conclusion, NCPA would recommend that the FTC provide a greater range of safe harbor provisions that would specifically allow pharmacists and other groups of allied health professions to collaborate in order to participate in ACOs. Collaborative healthcare models need the active participation of all types of health care providers and caregivers who practice in a variety of settings. Accountable Care Organizations involving only the collaboration of highly regimented corporate entities will not be able to provide effective healthcare services to all members of the community.

As you gather information from all interested stakeholders, NCPA respectfully urges you to consider these issues. We appreciate the opportunity to share our concerns and recommendations with you.

Sincerely,



John M. Coster, PhD., RPh.  
Senior Vice President, Government Affairs  
Director, Center for Community Pharmacy Advocacy