September 27, 2010

Centers for Medicare and Medicaid Services
U.S. Department of Health and Human Services
Office of the Inspector General
7500 Security Boulevard
Baltimore, MD 21244-1850

Re: Medicare Program: Workshop Regarding Accountable Care Organizations, and Implications Regarding Antitrust, Physician Self-Referral, Anti-Kickback, and Civil Monetary Penalty (CMP) Law.

Dear Sir or Madam:

Thank you for the opportunity to submit our comments in advance of the above-referenced workshop on Accountable Care Organizations and potential anti-trust implications. 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.

PPACA establishes a new category of health care structure—the accountable care organization (ACO) —within the Medicare program, with rules for provider participation and principles for sharing in the savings generated by this coordinated method of health care delivery. The federal legislation also specifically references the critical role that pharmacists can play in ACO's as well as in similar entities such as "medical homes", "transition of care" teams, and "medication reconciliation activities". These services have been offered for years by pharmacists in such models as the Asheville Project in Ashville, N.C. However, their inclusion as part of a government-sponsored model brings to the forefront the critical role that pharmacists can play in helping patients manage chronic conditions, reduce health risks and, in doing so, ultimately lower healthcare costs.

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, serve as a patient advocate, and assure adequate reimbursement for such services would ensure that more consumers—both in Medicare ACOs and in private plans—will have access to this type of innovative care, therefore leading to a reduction in overall healthcare costs.

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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 the failure of the patient to take medications appropriately. Pharmacists in the community may be already managing a patient's drug therapy along with the patient's prescribers. They are in a unique position to help integrate new, post-hospital medications into the patient's existing drug therapy and to help monitor post-discharge adherence.

The evidence already demonstrates the role that pharmacists can play in management of medications used in the treatment of chronic disease. For example, the Asheville Project began in 1996 as an effort by the city of Asheville, NC, a self-insured employer, to provide education and personal oversight for employees with chronic health problems such as diabetes, asthma, hypertension and high cholesterol. Patients were paired with pharmacists from one of twelve network community pharmacies. These pharmacists served as coaches to these at-risk patients and monitored medication adherence as well as encouraged and facilitated lifestyle changes.

These pharmacists were paid on a fee-for-service model patterned after a federal claims model for these clinical services—now referred to as medication therapy management or MTM. The results in terms of patient outcomes and the savings to the employer were astounding. When the project started, the city spent an average of $6,127 a year on each of its 48 diabetic employees. One year later, the claims for the group had been cut by almost forty-two percent (42%), to $3,554 per patient. The average sick time among the diabetic employees dropped more than half, from 12.6 days per employee each year to just six. Since the Asheville Project was launched, thousands of people in the Asheville area have taken control of their diabetes, cholesterol, hypertension and asthma as the model has been expanded over the years.

Lack of Existing Antitrust Guidance for Pharmacists/Allied Health Care Professionals Participating in ACOs and Other Collaborative Care Models

Although pharmacists are mentioned in the context of participation in ACOs in federal healthcare reform, the majority of helpful 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. The FTC and DOJ jointly issued the *Statements of Antitrust Enforcement Policy in Healthcare* in 1996 to provide guidance to health care providers and related entities about the agencies' enforcement policies in this area and to provide examples of types of collaboration among these providers or entities that the agencies would not challenge as violative of the antitrust laws—or those within antitrust "safety zones."

The permissible scenarios cited in the 1996 health care guidelines are primarily focused on collaborative efforts among physicians or hospitals and do not mention pharmacists, pharmacies or other types of healthcare providers. In a Statement to the Senate Judiciary Subcommittee on Antitrust, Competition Policy and Consumer Rights Regarding the Federal Trade Commission (FTC) and Department of Justice (DOJ) Antitrust Oversight, NCPA recommended that the FTC/DOJ revise the 1996 *Antitrust Enforcement Policy in Healthcare Guidelines* to include pharmacist and other types of health care provider collaboration. Despite those efforts, there has been no progress to date in the ability of pharmacists to work collaboratively and, in fact, the FTC has on numerous occasions proactively worked to prevent that from occurring by submitting unsolicited comments in opposition to prior attempts by pharmacists to act collaboratively on behalf of patients.

Critical Need for FTC Guidance for Pharmacists/Allied Health Care Providers Participating in Medicare ACOs and Other Collaborative Care Models

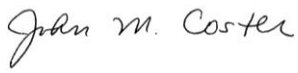
Given the fact that antitrust laws enforced by the FTC will apply to the ACOs that will operate in the new Medicare program, NCPA recommends that the FTC provide additional guidance to those allied health care providers, such as pharmacists, that are likely to be included in these entities. Such guidance could take the form of an updated *Statements of Antitrust Enforcement in Health Care* that could potentially address the role of pharmacists in ACOs and other types of collaborative care models, or the FTC could solicit input from affected parties in order to provide guidance to HHS and CMS specifically with regard to the role of pharmacists/allied health care providers in the new Medicare ACO program. This is particularly important in the case of independent pharmacies that do not have the already-existing infrastructure of regional and large chains to contract with an ACO or medical home to offer services and negotiate terms of participation.

In order to encourage participation in collaborative care models that include a variety of health care providers, such providers need to have clear guidance from the FTC as to the parameters of acceptable collaboration or those activities that would fall beneath antitrust "safety zones." In order to do so, NCPA recommends that the FTC initiate a meaningful dialogue with a variety of healthcare practitioners, including pharmacists, to gain a greater understanding as to how these providers fit into the ACO/collaborative care model and how they can contribute to improvements in patient care and lower overall costs.

Conclusion

As you gather information from all of the interested stakeholders in advance of the Workshop Regarding Accountable Care Organizations and Implications Regarding Antitrust, Physician Self-Referral, Anti-Kickback, and Civil Monetary (CMP) Laws, NCPA respectfully urges you to consider these issues. We appreciate the opportunity to share our concerns and recommendations with you. Thank you.

Sincerely,



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