

June 6, 2011

Centers for Medicare and Medicaid Services  
Department of Health and Human Services  
Attention: CMS-1345-P  
P.O. Box 8013,  
Baltimore, MD 21244-8013

**Re: CMS-1345-P; Medicare Program; Medicare Shared Savings Program: Accountable Care Organizations; Proposed Rule**

Dear Sir/Madam:

The Health Care Reform Pharmacy Stakeholders, as represented by the undersigned organizations, appreciate the opportunity to comment on the Centers for Medicare and Medicaid Services (CMS) proposed rule *Medicare Shared Savings Program: Accountable Care Organizations* as published in the Federal Register (FR) on April 7, 2011 (76 FR 19528). Our organizations represent pharmacists practicing across the spectrum of health and patient care settings. These comments reflect our collective organizations' interests in reorganizing the health care system to better ensure that patients have access to high quality, patient-centered, team-based care.

We support CMS in the development of accountable care organizations (ACOs). Our organizations commend the aims of this proposed rule which are: better care for individuals; better health for populations; and lower growth in expenditures. ACOs represent an important step towards increased quality and decreased costs for Medicare fee-for-service (FFS) beneficiaries. However, for CMS to promote the development of successful ACOs, we recommend CMS address the following: clarification of pharmacists' role in ACOs, concerns with administrative requirements, inclusion of pharmacists in data sharing, and the proposal's quality provisions.

**Background**

As the medication expert on the health care team, pharmacists will serve as vital partners to ACOs by working with physicians and patients on safe and effective medication use. In 2006, 71 percent of physician visits resulted in at least one prescription medication.<sup>1</sup> The proper use of medication is especially important considering the treatment of chronic disease costs the health care system over \$1 trillion dollars annually.<sup>2</sup> Reportedly, 32 percent of adverse events leading to hospitalization are due to medications, and only 33 to 50 percent of patients with chronic conditions adhere to their prescribed medication therapies.<sup>1</sup> Data suggest that Medicare beneficiaries with multiple chronic illnesses see on average 13 different physicians, fill 50 prescriptions each year, account for 76 percent of all hospitalizations and are 100 times more likely to have a preventable hospitalization than those with no chronic illnesses.<sup>3</sup>

Pharmacists should be part of all integrated care models, including ACOs. The Institute of Medicine has suggested that while only 10 percent of total health care costs are spent on medications, their ability to control disease and impact overall morbidity, productivity and costs, when used appropriately, is enormous.<sup>3</sup> Pharmacists can play an important role in achieving desired therapeutic outcomes while promoting cost-effective medication use when their services are utilized appropriately.<sup>1</sup>

### **The Important Role of Pharmacists in the ACO**

Studies have shown that integrating pharmacists into multi-disciplinary care models has positively impacted patient outcomes and appropriate medication use. Pharmacists are well trained in pharmacotherapeutics and are uniquely positioned to help patients optimize appropriate medication use, reduce medication-related problems and errors, and improve health outcomes through the delivery of patient care services, health promotion and education, health screenings and immunizations, and disease prevention and mitigation.

Similar to the patient-centered medical home (PCMH) concept, the ACO model requires the coordination of care and communication across multiple providers, including pharmacists.<sup>4</sup> Pharmacists in community settings, hospitals and managed care organizations already work closely with prescribers under collaborative drug therapy management agreements in 43 states and are authorized “to initiate, modify, or continue drug therapy for a specific patient” in most of those states with CDTM agreements.<sup>5</sup> Coordinating care for thousands of patients will most likely require ACOs to organize patient care through other providers, and pharmacists should be a part of the ACO’s health care team. Incorporating pharmacists within the ACO health care team will be essential to achieving CMS required quality improvement benchmarks.

Organizations across diverse care settings are already implementing pharmacy services, including medication therapy management (MTM), care transitions, discharge planning and medication reconciliation within their settings to help manage medication use issues and avoid adverse drug events. MTM services should be provided to hospitalized patients as well as to patients visiting a clinic or a primary care office, in addition to community settings. Medication management is especially important in medical homes that treat patients with multiple chronic conditions.<sup>6</sup> Pharmacists as part of an ACO could select or recommend initial medication therapy, reconcile medications, review patients’ medications, recommend any medication changes to the patient’s physician and counsel patients on their new medication regimens and be available to answer patients’ questions.

Pharmacists can help patients better manage their medications and chronic conditions, thereby reducing hospitalizations and rehospitalizations. Pharmacists’ participation in ACOs will help ACOs reach CMS-determined clinical and financial performance targets that will show improved patient results and lower health care costs. For more information on the essential role that pharmacists will play in successful ACOs, please see the recently published documents:

- *Pharmacists' Role in Accountable Care Organizations*, available at: <http://www.ashp.org/DocLibrary/Advocacy/PolicyAlert/ACO-Policy-Analysis.aspx>
- *Pharmacists as Vital Members of Accountable Care Organizations*, available at: [www.amcp.org/aco.pdf](http://www.amcp.org/aco.pdf).

### **Clarification of Pharmacists' Participation in ACOs**

In developing and implementing a framework for management and coordinated care for beneficiaries through ACOs, our organizations feel strongly that all health care providers, in all practice settings, that can positively impact the costs of care while meeting quality benchmarks should be included. The proposed rule generally lists, in Section 425.5 (FR Pg. 19641), providers and suppliers (such as ACO professionals and hospitals) eligible to form ACOs that may participate in the Shared Savings Program. We concur it may be impracticable to list all possible healthcare professionals in this section. However because of the impact pharmacists can have in driving down costs while improving quality, our organizations recommend that CMS clarify in the Final Rule that pharmacists are among those healthcare professionals eligible to serve as full members in ACOs participating in the Shared Savings Program.

Ensuring pharmacists role in ACOs will further secure the success of this program. Pharmacists have demonstrated time and again their ability to improve medication therapy outcomes while reducing costs. For example, pharmacist-provided care can reduce “drug expenditures, hospital readmissions, lengths of hospital stay, and emergency department visits.”<sup>7</sup> As a clinical expert working as part of an interdisciplinary team, pharmacists can assess whether medication use is contributing to unwanted effects and can help achieve desired outcomes from medication use.<sup>1</sup>

### **Administrative Requirements May Limit ACO Development**

The proposed rule contains extensive administrative requirements in Section 425.5 (FR Pg. 19641) that may limit the formation of ACOs. Our organizations appreciate the challenges CMS had in drafting this rule to counter potential fraud, waste and abuse issues; however, we are concerned these requirements may be overly burdensome for many potential ACOs. We understand from national dialogue that the current proposal presents challenges that may prevent organizations from participating. Much of the success of ACA implementation is based on the uptake of the ACO concept and the willingness to take on risk. Our organizations encourage CMS to consider the unintended consequences on potential ACOs that may not have the accounting, administrative, and legal resources necessary to meet these CMS application and approval requirements and to work with all stakeholders to incorporate changes that ease administrative burdens.

### **Timely Availability of Data Elements**

The proposed rule details data sharing requirements between CMS and ACOs in Section 425.19 (FR Pg. 19652). These data reports will be necessary for ACOs to make sound business decisions. There is concern however that a stringent timeline is not required of CMS to produce such reports. We believe the current aggregate data reports called for in Section 425.19 should be obtainable and not delayed until all claims have been fully adjudicated and closed out. This process could delay availability of important data for months. For business decisions to be made in an effective way, data must be made available even if such data are not perfect. This concern can be addressed through striking the words “when available” from Section 425.19(b)(2) (FR Pg. 19652) and adding the following language (bolded below) so this Section would read:

*These aggregate data reports will **contain the most current data and include,**~~when available,~~ the following information:*

- (i) Financial performance.*
- (ii) Quality performance scores.*
- (iii) Aggregated metrics on the assigned beneficiary population.*
- (iv) Utilization data at the start for the agreement period based on historical beneficiaries used to calculate the benchmark.*

### **Inclusion of Pharmacists in Data Sharing**

Including pharmacists in ACOs is a necessary element to fully achieve the intent of the ACO program. To be effective, pharmacists must have access to electronic information. Our organizations encourage CMS and the Office of the National Coordinator for Health Information Technology to ensure the Pharmacist/Pharmacy Provider EHR (PP-EHR) is integrated with other certified healthcare EHRs. This system would support the exchange of clinical information while at the same time leverage existing interoperability specifications, utilize existing standards and support data flow that could be tested.

### **Gradual Phase-in of Quality Provisions**

We are concerned with the impact the number of measures in the initial year could have on ACO formation. The proposed rule requires ACOs to report on 65 measures in the first year of the program (in five key domains). As such, our organizations recommend CMS consider gradually phasing-in these quality measures. We also recommend that CMS continue to recognize the importance of incorporating quality measures that will encourage ACOs to focus on areas that may not directly translate to shared savings.

Moreover, the measures related to medications that are identified in the proposal are essential to promote the provision of quality care to Medicare beneficiaries. Should CMS develop a phased in approach to implementation of quality measures, we recommend CMS consider initially including the measures for Better Care for Individuals as it phases-in other quality measures. We were pleased to see the measures related to medication management included in the proposed regulation as identified below:

- Better Care for Individuals:
  - Care Coordination/Transition
    - Measure Number 10: Medication reconciliation after discharge from an inpatient facility
    - Measure Number 11: Care transition measurement (including the medication therapy management component)
  - Care Coordination/Information Systems
    - Measure Number 22: Percentage of primary care physicians who are successful electronic prescribers under the eRx incentive program
  - Patient Safety
    - Measure Number 24: Health care acquired conditions composite
- Better Health for Populations:
  - Preventive health
    - Measure Number 26: Influenza immunization
    - Measure Number 27: Pneumococcal vaccination
    - Measure Number 30: Cholesterol Management for Patients with Cardiovascular Conditions
    - Measure Number 33: Tobacco use assessment and tobacco cessation intervention
    - Measure Number 34: Depression screening
  - At Risk Population – Diabetes
    - Measure Number 35: Diabetes composite
    - Measure Number 39: Diabetes Mellitus aspirin use (measure 39)
  - At Risk Population - Heart Failure
    - Measure Number 49: Beta-Blockers Therapy
    - Measure Number 50: Angiotensin-Converting Enzyme (ACE) inhibitor or Angiotensin Receptor Blocker (ARB) therapy
    - Measure Number 51: Warfarin therapy for patients with atrial fibrillation
  - At Risk Population - Coronary Artery Disease (CAD)
    - Measure Number 52: Coronary Artery Disease (CAD) Composite
    - Measure Number 53: Oral antiplatelet therapy prescribed for patients with CAD
    - Measure Number 54: Drug therapy for lowering LDL-Cholesterol
    - Measure Number 55: Beta-blocker therapy for CAD patients with prior myocardial infarction (MI)
  - At Risk Population - Chronic Obstructive Pulmonary Disease (COPD)
    - Measure Number 62: Bronchodilator therapy based on FEV1
  - At Risk Population – Frail Elderly
    - Measure Number 64: Osteoporosis Management in Women Who had a Fracture
    - Measure Number 65: Monthly International Normalized Ratio (INR) for beneficiaries on Warfarin

## **Conclusion**

Because pharmacists are integral members of primary care teams, our organizations strongly recommend that CMS explicitly address the role of pharmacists and pharmacists-provided medication management services in the proposed rule. In addition, we encourage CMS to reconsider the numerous administrative requirements, ensure the timely availability of data elements, include pharmacists in data sharing, and consider gradually phasing-in the proposed quality provisions.

Finally, we appreciate this opportunity to comment to the Agency as it develops integrated team-based approaches to better improve the quality of healthcare delivery under Medicare. Should you have any questions, please feel free to contact the Christopher J. Topoleski, Director, Federal Regulatory Affairs for the American Society of Health-System Pharmacists at [ctopoleski@ashp.org](mailto:ctopoleski@ashp.org) or by phone at (301) 664-8806. Thank you.

*American Society of Health-System Pharmacists*  
*American Pharmacists Association*  
*American Association of Colleges of Pharmacy*  
*American College of Clinical Pharmacy*  
*Academy of Managed Care Pharmacy*  
*American Society of Consultant Pharmacists*  
*College of Psychiatric and Neurologic Pharmacists*  
*Food Marketing Institute (FMI)*  
*National Alliance of State Pharmacy Associations*  
*National Association of Chain Drug Stores*  
*National Community Pharmacists Association*  
*Rite Aid Corporation*

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<sup>1</sup> Smith M, Bates DW, Bodenheimer T, Cleary P. Why pharmacists belong in the medical home. *Health Affairs*. 2010; 29(5):906-913.

<sup>2</sup> Pharmacy Health Care Reform Coalition. Pharmacy principles for health care reform. December 2008. [www.ashp.org/DocLibrary/News/PharmacyHealthCareReformPrinciples.pdf](http://www.ashp.org/DocLibrary/News/PharmacyHealthCareReformPrinciples.pdf). Accessed May 16, 2011.

<sup>3</sup> Patient-Centered Primary Care Collaborative (PCPCC). The Patient-Centered Medical Home: Integrating Comprehensive Medication Management to Optimize Patient Outcomes. A Resource Guide. Washington, DC: PCPCC; 2010.

<sup>4</sup> Patient-Centered Primary Care Collaborative. Better to best; Value-driving elements of the patient centered medical home and accountable care organization. [http://www.pcpcc.net/guide/better\\_to\\_best](http://www.pcpcc.net/guide/better_to_best).

<sup>5</sup> 2011 National Association of Boards of Pharmacy Survey of Pharmacy Law. Please note that New York's AB 4579 adds New York to the list of states that allow physicians and pharmacists in specified settings to engage in collaborative drug therapy management agreements, effective October 2011. In addition, pursuant to Indiana's HB 1233, collaborative practice agreements are expanded to allow for collaborative drug therapy outside of hospital settings, effective July 2011.

<sup>6</sup> Medicare Payment Advisory Commission. Report to the Congress: Reforming the Delivery System. Washington, DC, June 2008.

<sup>7</sup> Chisholm-Burns MA, Lee JK, Spivey CA et al. US pharmacists' effect as team members on patient care. Systemic review and meta-analyses. *Med Care*. 2010; 48:923-33.