VIA Electronic Submission to http://www.regulations.gov

June 6, 2011

Centers for Medicare & 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 or Madam:

Thank you for the opportunity to submit our comments on CMS' Proposed Rule on Accountable Care Organizations ("ACOs") and the Medicare Shared Savings Program ("MSSP"). As CMS considers promulgating a Final Rule establishing ACOs, the National Community Pharmacists Association (NCPA) appreciates the opportunity to share our perspectives.

NCPA represents the interests of America's community pharmacists, including the owners of more than 23,000 independent community pharmacies, pharmacy franchises, and chains. Together they represent a $93 billion health-care marketplace, have more than 315,000 employees including 62,400 pharmacists, and dispense over 41% of all retail prescriptions. NCPA members are the primary providers of drugs and pharmaceutical supplies to millions of Americans.

NCPA members also provide valuable preventive care services to Medicare beneficiaries, especially various disease management services, Medication Therapy Management ("MTM") and Diabetes Self-Management Training ("DSMT")[1]. Community pharmacist provided services promote efficient medication utilization, avoid dangerous medication interactions, avoid disease complications, avoid costly hospitalizations and promote better health outcomes. In addition, community pharmacists play a vital role in coordination of care, often caring for their patients as they are undergoing a transition of care. It is also important to note that community pharmacists see their patients more often than any other healthcare provider. The average community pharmacy patron visited a community pharmacy 2.45 times per month in 2008.[2] Accordingly,

[1] Also known as Diabetes Self-Management Education ("DSME").
[2] Independent Pharmacy Satisfaction Report. Wilson Rx and Boehringer Inglelheim.

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community pharmacists have an important role to play in promoting quality and generating savings with ACOs.

As you review our comments below, NCPA encourages you to keep a few overarching concepts in mind as you further develop the ACO concept:

- Pharmacists are accessible suppliers of drugs and medical supplies. However, community pharmacists also provide valuable health care services, which promote the dual goals of ACOs – cost savings and health care quality improvement. NCPA requests that the Final Rule elaborate on the role for and promote the inclusion of pharmacists within ACOs.

- There are many services that pharmacists offer their patients that are not currently reimbursed by Medicare today. NCPA maintains that independent community pharmacists can play a vital role in helping ACO's provide the best patient care leading to a better alignment of incentives for all stakeholders. NCPA is requesting that CMS make clear that community pharmacists are eligible to be ACO participating providers for the important services they provide and to have those services linked with or aligned with ACO shared savings.

Participation by Community Pharmacists in ACOs

NCPA strongly urges CMS to expressly provide that ACOs be authorized to pay for and share savings with ACO participant community pharmacists for certain services that they provide outside of Part B fee-for-service ("FFS") services, especially MTM and disease management services. Under the Proposed Rule, ACO participant pharmacists should already be eligible for ACO participation and shared savings related to the provision of DSMT services because those services are provided under Part B FFS. NCPA supports this approach, but seeks clarity on the ability of pharmacists to contribute to comprehensive disease management activities within an ACO, which would include other valuable community-pharmacy based services that do not fall under the Part A/B FFS system.

Substantial evidence exists to demonstrate that pharmacists provide valuable preventive services, such as DSMT and MTM, which decrease health care expenditures for Medicare beneficiaries and improve the quality of the health care outcomes for those beneficiaries. In a position statement, the American Diabetes Association (ADA) has noted that multiple studies have found that Diabetes Self-Management Education "is associated with improved diabetes knowledge and improved self-care behavior, improved clinical outcomes such as lower A1C, lower self-reported weight, improved quality of life, healthy coping, and lower costs." The ADA also cited studies finding that "diabetes education is associated with increased use of primary and preventive services and lower use of acute, inpatient hospital services. Patients who participate in diabetes education are more likely to follow best practice treatment recommendations, particularly among the Medicare population, and have lower Medicare and commercial claim costs."[3] Other studies provide similar support in terms of DSMT associated cost savings[4] and DSMT associated positive diabetes health outcomes.[5]

[3] American Diabetes Association, Standards of Medical Care in Diabetes-2011, Diabetes Care, Volume 34, Supplement 1, January, 2011, at S22.

ACO participant community pharmacist provided DSMT services, as FFS services, appear to be eligible for shared savings under the existing Proposed Rule. However, it is unclear whether similar non-FFS services provided by ACO participant community pharmacists are also eligible for shared savings. NCPA contends that such services, particularly MTM services, should be eligible for ACO reimbursement, given the positive health outcomes and cost savings demonstrated by MTM.

For example, a 2010 study by Oliveira and others examined MTM outcomes over a ten year period in a large integrated health care system. Among positive results from the study, for a subset of diabetes patients, the study showed that 42.7% reached all diabetes goals through MTM, including an A1c of less than 7%, blood pressure of less than 130/80 mmHg, LDL-C less than 100 mg/dL, no tobacco use, and daily aspirin use. Only 19 patients were achieving all of these goals at baseline, demonstrating an absolute increase in goal achievement of 25.4%. The study also demonstrated that over the 10 year study there was a pharmacist-estimated cost savings to the health system of about $86 per encounter. Stated differently, there was an estimated return on investment of $1.29 per $1 spent in MTM costs. For patients that participated, there was a patient satisfaction rating of greater than 95% on all survey points.[6]

A second MTM example is a 2009-2010 study in Connecticut, which also demonstrated the quality and cost savings benefit of pharmacist-provided MTM services. In the study, a group of pharmacists provided MTM services to 88 Medicaid patients. Through MTM, the pharmacists were able to identify 917 drug therapy problems, with 73.8% being due to an unnecessary drug being used or an additional drug being needed and 26% being due to a lack of adherence. The pharmacists also reported 63 cases in which medications did not comply with

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[4] Robbins JM, Thatcher GE, Webb DA, Valdmanis VG. Nutritionist visits, diabetes classes, and hospitalization rates and charges: the Urban Diabetes Study. Diabetes Care 2008;31:655–660; Duncan I, Birkmeyer C, Coughlin S, Li, Position Statement care.diabetesjournals.org DIABETES CARE, VOLUME 34, SUPPLEMENT 1, JANUARY 2011 S51; QE, Sherr D, Boren S. Assessing the value of diabetes education. Diabetes Educ 2009;35:752–760; Costs and Benefits Associated with Diabetes Education, Suzanne Boren, PhD; Karen Fitzner, PhD; Pallavi Panhalkar; James Specker. Publication date: 2009 The Diabetes Educator; An Assessment of Patient Education and Self Management in Diabetes Disease Management, Karen Fitzner, PhD; Deborah Greenwood, Med, APRN, BCADM, CDE; Hildegarde Payne, RN, MA, CDE; John Thomson, Lana Vukovijak, MA, MS; Amber McCulloch; James Specker, Population Health Management, Volume 11, 2008; Assessing the Value of Diabetes Educators and Diabetes Self-Management Education/Training, Ian Duncan FSA FIA FCIA MAAA; Solucia Inc.; Christian Birkmeyer, MA, Solucia Inc; Suzanne Austin Boren, PhD, University of Missouri; Karen Fitzner, PhD, American Association of Diabetes Educators. Poster NIH Disparities Conference, Dec 16-20, 2008, Washington DC.

[5] Brown SA. Interventions to promote diabetes self-management: state of the science. Diabetes Educ. 1999;25(6 suppl):52-61; Norris SL, Engelgau MM, Naranyan KMV. Effectiveness of self management training in type 2 diabetes: a systematic review of randomized controlled trials. Diabetes Care. 2001;24:561-587; Norris SL, Lau J, Smith SJ, Schmid CH, Engelgau MM. Self management education for adults with type 2 diabetes: a meta analysis on the effect on glycemic control. Diabetes Care. 2002;25: 1159-1171; Norris SL. Self-management education in type 2 diabetes. Practical Diabetology. 2003;22:713; Gary TL, Genkinger JM, Guallar E, Peyrot M, Brancati FL. Meta analysis of randomized educational and behavioral interventions in type 2 diabetes. Diabetes Educ. 2003;29:488-501; Deakin T, McShane CE, Cade JE, et al. Review: group based education in self-management strategies improves outcomes in type 2 diabetes mellitus. Cochrane Database Syst Rev. 2005;(2): CD003417; Renders CM, Valk GD, Griffin SJ, Wagner EH, Eijk van JThM, Assendelft WJJ. Interventions to improve the management of diabetes in primary care, outpatient, and community settings: a systematic review. Diabetes Care. 2001;24:1821-1833.

[6] Ramalho de Oliveira D, Brummel AR, Miller DB. Medication therapy management: 10 years of experience in a large intergrated health care system. *J Manag Care Pharm*. 2010;16(3):185-95.

current evidence based guidelines. As a result of MTM, 80% of the 917 drug therapy problems were resolved by the pharmacist after four consultations, and 78% of the therapy problems were resolved without the patient having to make an appointment with their primary care provider. In terms of cost savings, pharmacist interventions resulted in an estimated annual savings of $1,123 per patient due to discontinuing unnecessary drugs and substituting generics for brands when appropriate. An additional $472 in annual savings was attributed to fewer hospital and emergency room expenses. The total savings were approximately 2.5 times the cost of the fees for the pharmacists and network administration.[7]

Beyond MTM services, community pharmacists also provide valuable preventive disease management services. A 2006 study by Lee and others demonstrated that a 6-month pharmacy intervention program for patients studied led to a 97% medication adherence rate, improved blood pressure values, and decreased LDL scores. Discontinuation of the pharmacy intervention led to a 16% drop in adherence after two months.[8] Similarly, a 2007 study by Murray and others revealed that during a 9 month pharmacy intervention period, adherence rates were greater in the intervention group compared to the usual care group, 78.8% to 67.9%, respectively. Medications taken on time were greater in the intervention group when compared to the usual care group, 53.1% to 47.2%, respectively. Both of these deltas dissipated over the 3 month post intervention period. There were also less emergency department visits in the intervention group by 19.4%. Moreover, the direct health care costs were lower for the intervention group by $2,960 per person. There were also less adverse drug events and medication errors in the intervention group.[9]

Unlike DSMT, MTM and disease management services are not part of the Part A/B FFS system and under the Proposed Rule it is not clear that pharmacists are eligible to serve as ACO providers Accordingly, NCPA seeks clarification from CMS that non-FFS services, such as MTM and disease management services, when provided by ACO participant community pharmacists, should be eligible for ACO participation and shared savings. Community pharmacists should be authorized to serve as part of an ACOs to provide MTM and disease management services, as well as DSMT services, to ACO beneficiaries and be eligible for shared savings from that ACO for those services.

Without CMS providing for express ACO reimbursement for MTM and disease management services, it is not clear whether or not pharmacists would otherwise be eligible to participate in an ACOs to provide services which are not traditional FFS services. NCPA fears that ACOs will fail to capitalize on the value offered by pharmacists and pharmacies unless CMS expressly provides that ACOs are authorized include pharmacists for all of the valuable preventive services that they provide.

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[7] Health Affairs Paper (March 2011): In Connecticut: Improving Patient Medication Management In Primary Care.
[8] Lee JK, Grace KA, Taylor AJ. Effect of a pharmacy care program on medication adherence and persistence, blood pressure, and low-density lipoprotein cholesterol: a randomized controlled trial. *JAMA* 2006;296(21):2563-2571.
[9] Murray M, Young J, Hoke S et al. Pharmacist intervention to improve medication adherence in heart failure. *Ann Intern Med.* 2007;146:714-25.

Services for ACO Beneficiaries Rendered Before a Patient is Deemed to Be an ACO Patient

The current proposed rule provides for retrospective patient assignment within an ACO, meaning that an ACO and its members will not know whether a patient is an ACO beneficiary until the end of the ACO contract year. This retrospective assignment poses a problem for ACO participant pharmacists that provide services to an ACO and its beneficiaries because the pharmacist will not know whether a given patient is an ACO beneficiary until long after the service is provided.

To better illustrate this problem, with the assumption that CMS clarifies the scope of pharmacist participation in an ACO as described above, suppose a patient goes to a pharmacy that is under contract with an ACO. The pharmacist and/or the ACO determines that that patient is eligible for and a good candidate for MTM services. The pharmacist needs to determine whether to provide targeted MTM services as defined by the ACO and potentially to be appropriately compensated since these services are not covered under traditional Part A and B Medicare today. Nevertheless, the ACO itself will not know until the end of the year whether or not that particular patient is actually an ACO patient. Accordingly, ACOs may be unwilling to contract with pharmacists for MTM services provide to beneficiaries under these circumstances. The retrospective attribution of ACO patients is the root of this problem.

In light of this problem, there appears to be only a few possible solutions. First, a mechanism would have to exist for ACO providers, including pharmacists, to offer and services such as MTM and to beneficiaries and have a mechanism to ensure that ACO resources can be used to target services to these beneficiaries. Since it is unlikely that an ACO will want to invest resources or reallocate current resources to patients who might not be ACO beneficiaries after the end of the year and for which any savings would not be attributed to that ACO, this would seem to be a challenge to accomplish. As the Proposed Rule is presently designed, there is no incentive for an ACO to reallocate resources to provide such services. Alternatively, the patient attribution system would have to be designed so that patients are assigned to an ACO on a prospective basis, so that both the pharmacist and the ACO know that a particular patient is an ACO patient at the time of service. In this way, the ACO has a way to know where to allocate resources to provide services like disease management and MTM which might not otherwise be covered services In short, NCPA requests that CMS either establish some type of mechanism to make it possible for ACOs to determine where to allocate resources in advance or adopt a prospective patient assignment system so that ACOs are assured that the resources they do invest are targeted appropriately.

Notification of ACO Status to Patients Opting Out of ACO Participation

The Proposed Rule requires all providers within an ACO to notify Medicare beneficiaries that that particular provider is an ACO provider and what the implications are for the patient, assuming that patient becomes an ACO beneficiary. Moreover, potential beneficiaries must be made aware that their participation in the ACO is voluntary and they may opt out of the ACO if they choose to do so.

The Proposed Rule bases patient attribution on patients meeting certain requirements with regard to utilization of an ACO's primary care services. In other words, a patient's ACO beneficiary status is solely determined by his or her use of an ACO primary care provider and

not by his or her utilization of services provided by an ACO hospital, ACO specialist or a pharmacy under contract with an ACO. A patient could use the services of the latter providers as much as he or she wants and not be assigned to an ACO, provided he or she uses a non-ACO primary care provider. The only way for a patient to assure that he or she opts out of the ACO is for him or her to go to a non-ACO primary care provider.

Assuming community pharmacists may participate in ACOs as ACO participants, NCPA is concerned that under the proposed language, Medicare beneficiaries who wish to opt out of an ACO program, may be confused by the patient notification information and signage provided by a given ACO provider, as required under the Proposed Rule. More specifically, NCPA is concerned that patients who want to opt-out of an ACO will review such written notification and/or signage and incorrectly interpret that information as requiring him or her to receive services only from non-ACO providers/suppliers, in order to ensure that he or she does not become assigned to an ACO. This should not be the case and patients should be educated that only their utilization of primary care provider services determines whether or not they are assigned to an ACO, not their utilization of non-primary care services, including pharmacy services.

Given the concerns above, all ACO providers/suppliers should be required to provide patients with very specific and clear notification information that only the patient's use of ACO primary care services determines whether or not the patient becomes an ACO beneficiary, not the patient's use of ACO non-primary care services. Without such clarification, NCPA is concerned that potential ACO patients, who are notified that a community pharmacy is a part of an ACO, but who wish to opt out, may determine that the only way to avoid becoming an ACO beneficiary is to go to a non-ACO pharmacy.

Privacy Liability Safe Harbors for Data Sharing for Non-ACO Patients

The Proposed Rule provides that CMS is authorized to share ACO beneficiary patient data with ACOs and ACO providers, without a risk of privacy violations, such as HIPAA violations. While NCPA welcomes this approach, NCPA is concerned that potential privacy or HIPAA violations may still occur where data sharing occurs with regard to a patient, who is a potential ACO beneficiary, but ends up not being assigned to the ACO.

For example, an ACO participant pharmacist may seek patient data on a potential ACO beneficiary in order to better identify whether or not that patient is a candidate for pharmacist-provided services, such as MTM or DSMT. If, at the end of the contract year, the patient is not assigned to that particular ACO, then some of the information shared with the ACO participant pharmacist may subject that pharmacist to breach of privacy liability. However, at the time that the ACO participant pharmacist received the information, it believed that the patient was a potential ACO beneficiary. ACO participant pharmacists should not face potential privacy liability, when they receive protected health information and had no way of knowing definitively whether or not that patient was an ACO beneficiary, until the end of the contract year.

In light of this quandary, CMS must develop some sort of privacy liability safe harbor mechanism whereby ACO participant pharmacists and other ACO participant providers can share and receive protected health information regarding potential ACO beneficiaries, who wind up not being assigned that ACO. If such a safe harbor is not implemented, then pharmacists and

other providers may refuse to share and receive protected health information, which will limit their ability to more effectively and efficiently treat patients and generate shared savings.

Reducing Costs and Eliminating Barriers to ACO Participation

The Proposed Rule provides ACOs with two choices of tracks for ACO participation. Under one track ACOs assume some financial risk for failure to generate savings, along with being subject to financial bonuses or incentives to generate such savings. Under a second track, initially, ACOs will not face any financial risk for a failure to generate savings, but will also receive smaller bonuses or financial incentives for generating such savings. However, with regard to the second track, in the third year of the ACO contract, the incentives and penalties would be the same as in the first track. NCPA is concerned that under either track, the size of the incentives and penalties, will combine to create a barrier, which will discourage ACOs from forming. NCPA is concerned that the start-up costs may be too high for many would-be ACOs.

Given these concerns, NCPA suggests that CMS consider a third option for would-be ACOs, which allows them to gain experience as an ACO without the immediate financial downside risk of the first track or delayed financial downside risk of the second track. ACOs choosing this third option would participate as an ACO, just like any other ACO, but, in the initial three year contract period, would be eligible for a smaller maximum share of savings than either of the first two tracks and would not be subject to any possible financial disincentives. The maximum shared savings percentage would need to achieve a balance of being large enough to potentially cover the ACO's start-up costs, while also being sufficiently smaller than the maximum shared savings in the first two tracks to acknowledge the start-up nature of the ACO. After the initial three year period, the third track ACO would have to adopt, for the next three year contract term, one of the first two tracks identified in the Proposed Rule. NCPA believes that such a third option would permit start up ACOs to form and obtain experience with the ACO program and later graduate to a model in which there is greater risk, but also greater amounts of potential shared savings.

Ensure that ACOs incorporate quality metrics related to medication management

While NCPA appreciates that CMS has strived to capture data on many different fronts via the proposed quality measures in five key domains that ACOs will be required to report on, we ask that a phased-in approach to data collection and measurement be considered, to gain the broadest uptake of the shared savings model possible. We also encourage CMS to recognize the importance of incorporating quality measures that will encourage ACOs to focus on the importance of appropriate management of prescription drug therapy and as part of a successful disease management protcol. . We were pleased to see measures included in the proposed regulations related to the medication use process and the pharmacist's role in providing patient care services such as immunizations and strongly recommend inclusion of these measures in the final set of measures for the ACO program.

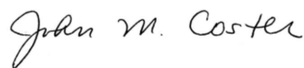
Conclusion

In conclusion, NCPA seeks the following changes and clarifications to the Proposed Rule:

- Clarify that ACO participant community pharmacists are eligible to be ACO participating providers and eligible for shared savings;
- Development of either a prospective patient assignment system or a mechanism for ACOs to use in determining where to direct and reallocate resource.
- Development of patient notification requirements, which make clear to patients that they can continue to receive services from non-primary care ACO participants, without the receipt of such services determining whether or not that patient is assigned to an ACO;
- Clarification that privacy liability safe harbors also apply to ACO participants who share patient data for a potential ACO beneficiary who ultimately is not assigned to an ACO;
- Ensure that ACOs retain and incorporate quality metrics related to the importance of medication management

NCPA appreciates the opportunity to comment on CMS-1345-P; Medicare Program; Medicare Shared Savings Program: Accountable Care Organizations. Please do not hesitate to contact Chris Smith, Director of Policy and Regulatory Affairs, by email at chris.smith@ncpanet.org, or by telephone at (703) 600-1185, if you have any questions.

Sincerely,



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