



***Via Electronic Submission***

June 6, 2011

Donald Berwick, MD  
Administrator, Centers for Medicare and Medicaid Services  
U.S. Department of Health and Human Services  
Room 445-G, Hubert H. Humphrey Building  
200 Independence Avenue, SW  
Washington, DC 20201

**Re: Centers for Medicare & Medicaid Services (CMS); Medicare Program; Medicare Shared Savings Program: Accountable Care Organizations [CMS-1345-P] RIN 0938-AQ22, 76 Fed. Reg. 19528 (Thursday, April 7, 2011)**

Dear Administrator Berwick:

The American Association for Homecare (AAHomecare) submits these comments in response to the proposed rule cited above. The proposed rule would implement section 3022 of the Patient Protection and Affordable Care Act (ACA), which establishes a Medicare shared savings program pertaining to the formation of accountable care organizations (ACOs). AAHomecare is the national association representing the interests of durable medical equipment, prosthetics, orthotics, and supplies (DMEPOS). AAHomecare members include local, regional and national manufacturers and suppliers that make or furnish DMEPOS items Medicare beneficiaries use in their homes. Our members are proud to be part of the continuum of care that assures that Medicare beneficiaries receive cost effective, safe and reliable home care technologies and services. By virtue of our standing as the primary association representing the broad spectrum of DMEPOS suppliers in the country, we are uniquely qualified to comment on the proposed rule.

Section 3022 of the ACA amended the Social Security Act (the Act) by adding a new section 1899. Section 1899, in turn, establishes a shared savings program to promote accountability for a patient population, coordination of delivery of care under Parts A and B, and investment in infrastructure and care processes to achieve high quality and efficient delivery of service. Section 1899 states that “groups of providers of services and suppliers meeting criteria specified by the Secretary may work together to manage and coordinate care for Medicare fee-for-service beneficiaries through an [ACO]”. Section 1899(a)(1)(B) of the Act also provides that ACOs that meet quality performance standards established by the Secretary are eligible to receive payments for “shared savings.”

Section 1899(a)(1)(B), identifies only four types of providers eligible to form ACOs. Generally, these include physician group practices and networks, hospitals that employ physicians, or joint ventures or

partnerships between physicians and hospitals. The Secretary, however, has authority to determine whether other providers and suppliers should be eligible to participate in ACOs. The preamble to the proposed rule states CMS' intent to exercise this authority. In addition to requesting comments generally on the proposed rule, CMS requests comments specifically on the following issues, among others:

- The kinds of providers and suppliers that should or should not be included as potential ACO participants;
- The potential benefits or concerns regarding including or not including certain provider or supplier types.

After considering the public comments, CMS will determine whether to expand the list of entities eligible to participate in the shared savings program either in the final rule or in future rulemaking. AAHomecare supports CMS' proposal to broaden the types of providers and suppliers that may participate in ACOs. We strongly believe that ACOs cannot meet the goals of providing high quality care while achieving program savings without the participation of DMEPOS providers and the in-the-home technologies and services that they provide. In fact, even the proposed rule, on page 19533, notes that one of the government's expectations for ACOs is that they "be able to continually reduce [their] dependency on inpatient care. Instead, [their] patients will more likely be able to be home, where they often want to be, and, during a hospital admission, they receive assurance that their discharges will be well coordinated, and that they will not return due to avoidable complications."

## **I. Comments**

In establishing the shared savings program and authorizing the Secretary to allow providers to form ACOs, Congress intended to encourage the formation of ACOs that seek to achieve three important goals: better care for individuals, better health for populations, and lower growth in expenditures. Section 1899(b)(1) of the Act establishes the types of providers and suppliers, with established mechanisms for shared governance that are eligible to participate as ACOs. Only the following groups of providers and suppliers are eligible to participate as ACOs:

- ACO professionals in group practice arrangements;
- Networks of individual practices of ACO professionals;
- Partnerships or joint venture arrangements between hospitals and ACO professionals;
- Hospitals employing ACO professionals; and
- Such other groups of providers of services and suppliers as the Secretary determines appropriate.

Generally, ACO professionals are physicians or practitioners including physician assistants, nurse practitioners, and clinical nurse practitioners. The statute defines hospitals to include only acute care hospitals. However, Congress gave the Secretary authority to identify other kinds of providers and suppliers that may be eligible to participate as ACOs. CMS proposes to expand the four groups of providers and suppliers identified under §1899 to allow ACOs to form broader collaborations with Medicare enrolled providers and suppliers.

AAHomecare agrees with CMS that in order to increase access to quality health care while achieving Medicare program savings and meeting ACOs' stated goals for patient-centeredness and care coordination across a variety of care settings, ACOs must include access to providers and suppliers that represent the entire continuum of care. Eligible ACO participants under the proposed rule would include: "[p]roviders or suppliers otherwise recognized under the Act that are not ACO professionals or hospitals, as defined in § 425.4."<sup>1</sup> AAHomecare supports this broad definition of eligible ACO participants and encourages CMS to explicitly identify DMEPOS providers and access to high quality DMEPOS technologies and services as essential components of ACOs.

CMS acknowledges that programs savings will derive mostly from a decrease in hospitalizations, especially for beneficiaries with chronic conditions. To achieve this goal, it is imperative that beneficiaries with chronic conditions have access to and receive quality, cost-effective care in their homes. ACOs must be able to ensure smooth patient transitions from inpatient settings to home care. Moreover, DMEPOS providers--working in close collaboration with primary care practitioners and specialists--can reduce or delay repeat hospitalizations or more costly skilled nursing care. The importance of DMEPOS professionals, technologies and services in managing chronic conditions at home has been recognized recently in a number of studies published in well-regarded peer reviewed journals.

In particular, studies have confirmed that treating chronic conditions such as chronic obstructive pulmonary disease (COPD) with technologies designed for home use is an effective alternative to more costly care. For example, Steven H. Landers, M.D. of the Cleveland Clinic describes demographic, clinical, economic, and technological forces that make home-based care "imperative."<sup>2</sup> He cites home oxygen therapy as an example of advances in portable medical technology, and cites parenteral nutrition and home infusion therapy as examples of care that is less expensive than and equally as effective as institutional care. He notes that there may be more than 70 million Americans over age 65 by 2030. "Many of these older adults will have limitations on their activities, including difficulty walking and transferring from bed to chair, that make leaving their homes difficult. Older adults are particularly prone to complications of confinement in hospitals, such as delirium, skin conditions, and falls. Treating people at home may be one way to avoid such complications." The government's own data suggests that patients in acute care settings are also more prone to hospital-acquired infections which result in protracted hospital stays, additional pharmaceutical and care costs or even stays in skilled nursing facilities (SNFs) if infusion therapy is required.

Other studies have confirmed the importance of access to in-the-home technologies like home oxygen and home infusion in managing chronic disease at lower costs than would be possible in other care settings. An article published in the February 2009 *American Journal of Managed Care* examining long-term oxygen therapy concluded that "continuous oxygen therapy for chronic obstructive pulmonary disease is highly cost-effective."<sup>3</sup> Similarly, a 2004 assessment of clinical literature on long-term oxygen therapy by the U.S. Agency for Healthcare Research and Quality found that oxygen therapy reduces mortality, hospital frequency and length of stay for patients with severe COPD. Specifically, the average

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<sup>1</sup> Proposed rule, 42 CFR §425.5.

<sup>2</sup> Landers, S. "Why Health Care Is Going Home," *New England Journal of Medicine*, October 20, 2010.

<sup>3</sup> Oba, Y. "Cost-Effectiveness of Long-Term Oxygen Therapy for Chronic Obstructive Pulmonary Disease," *American Journal of Managed Care*, February 2009.

number of hospital admissions per patient per year decreased from 2.1 to 1.6 and the average number of days hospitalized decreased from 23.7 to 13.4 for patients on long-term oxygen therapy.<sup>4</sup>

Another example of how home care may be incorporated into a patient's treatment plan in order to effect program savings is the use of home infusion therapy. Home infusion therapy has been safely and effectively prescribed by primary care and specialty physicians for almost three decades. Medicare Part B only covers a limited number of home infusion therapies today, and Medicare Part D's current dispensing fee structure is inadequate to cover providers' costs of providing it at home. Therefore, patients are being hospitalized needlessly in acute care hospitals or SNFs. Private insurers and existing ACOs definitely rely on home infusion providers to help them lower the total cost of care (including Medicare Advantage/senior populations). For example, intravenous antibiotic treatment in the home is highly cost effective compared to providing the same therapy in a hospital or skilled nursing facility. A study described in *Clinical Infectious Diseases* quantified cost savings of a home intravenous antibiotic program in a Medicare managed care plan. The average cost per day of home therapy was \$122, compared to \$798 in the hospital and \$541 in a skilled nursing facility.<sup>5</sup>

Similarly, for patients with chronic diabetes, patient self-monitoring of blood glucose levels has been shown to be highly cost effective in managing expensive complications from insulin dependent diabetes. An analysis in the *American Journal of Managed Care* documents the extremely large and growing economic burden of diabetes mellitus. However, patient self-monitoring of blood glucose levels has been repeatedly shown to improve glycemic control for insulin-using patients. Clinical guidelines recommend testing at least three times daily for patients with diabetes who use insulin. The report demonstrates cost-effectiveness from self-monitoring for patients who test both 1 and 3 times daily.<sup>6</sup>

## **II. Antitrust Concerns**

AAHomecare is encouraged to see that CMS intends to permit a broad range of Medicare enrolled providers and suppliers to participate in ACOs. We are also encouraged to see that CMS recognizes the potential for antitrust or conflict of interest violations if an ACO were to self-refer only to its hospital- or ACO participant-owned DMEPOS or home infusion provider entities. We believe that it is imperative for ACOs to include DMEPOS providers as ACO participants eligible to share in the savings they generate for the program and to not exclude non-ACO-owned DMEPOS/home infusion providers from being given the opportunity to participate in the ACO.

## **III. Timeliness of Shared Savings Payments from ACOs to Participants**

We are concerned that the proposed rule is silent on the issue of the timeliness in which an ACO would be expected to pay its participants their respective portion of any shared savings generated by the model. While the rule is clear about the three-year term of an ACO agreement with CMS, and the criteria on which the shared savings threshold would be determined (both in advance of any go-live date

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<sup>4</sup> Lau, J., et al., Long-Term Oxygen Therapy for Severe COPD, June 11, 2004, Tufts-New England Medical Center Evidence Based Practice Center.

<sup>5</sup> Dalovisio, J., et al., "Financial Impact of a Home Intravenous Antibiotic Program on a Medicare Managed Care Program," *Clinical Infectious Diseases*, 2000.

<sup>6</sup> Tunis, S., Minshall, M., "Self-Monitoring of Blood Glucose in Type 2 Diabetes," *American Journal of Managed Care*, March 2008.)

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and also at the end of the three-year period), the rule does not require the ACO to pay the shared savings it receives to its participants. In our industry's experience, third-party intermediaries between the DMEPOS/home infusion provider and a given payor often withhold payments for a protracted period of time, merely to earn interest on the sum or apply unwritten policies and rules to the contractual relationship retrospectively. For example, they may allege that the provider did not have a formal authorization to proceed with in-home care when in fact the provider did obtain necessary authorization. Meanwhile, weeks – if not months – can go by without the supplier/provider being paid for service it rendered in good faith. In the case of the ACO model, a supplier/provider participating in an ACO could theoretically wait an indefinite period of time beyond the end of the ACO three-year term, or beyond the date on which the ACO would be paid by the government.

AAHomecare's recommendation is that CMS determine that any shared savings paid to ACOs must in turn be paid to its formal participants within 90 days of the payment made from the government to the ACO.

#### IV. Summary

We also understand the need to address a number of administrative and operational requirements before the benefits from participation can be fully realized. AAHomecare members stand ready to assist CMS in identifying and addressing these issues with the goal of ensuring that beneficiaries continue to have access to high quality DMEPOS delivered through ACO entities and that providers, CMS, and taxpayers have an opportunity to share in the savings they generate.

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Thank you for the opportunity to submit these comments. Please feel free to contact me at (703) 535-1894 if you have any questions or comments.

Sincerely,



Walter Gorski

Vice President for Government Relations