

Via online submission to [www.regulations.gov](http://www.regulations.gov)

June 6, 2011

Donald Berwick, MD  
Administrator  
Centers for Medicare & Medicaid Services  
Department of Health and Human Services  
Mail Stop C4-26-05  
7500 Security Boulevard  
Baltimore, MD 21244-1850

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

Dear Dr. Berwick:

The American Occupational Therapy Association (AOTA) is the national professional association representing the interests of more than 140,000 occupational therapists, therapy assistants, and students. The practice of occupational therapy is science-driven, evidence-based, and enables people of all ages to live life to its fullest by promoting health and minimizing the functional effects of illness, injury, and disability. Many occupational therapy practitioners are reimbursed under the Medicare fee-for-service system and invested in the Medicare Shared Savings Program. AOTA appreciates the opportunity to comment on the Centers for Medicare & Medicaid Services (CMS) proposed rule for the Medicare Shared Savings Program and Accountable Care Organizations (ACOs), which was published in the *Federal Register* on April 7, 2011 at 76 Fed. Reg. 19528.

AOTA supports CMS' three-part objective of achieving better health, better care and reduced growth of health care expenditures, and our members look forward to working with CMS to accomplish these important goals. We also endorse the specific goals that CMS established for ACOs, including commitments to: (1) patient-centered care, (2) coordinated care, (3) careful care transitions, (4) resource management, (5) patient care management, (6) the use of data to improve care delivery and patient outcomes, (7) the promotion of improved care for individuals and populations with lower expenditures, and (8) continuous workforce investment. With our support for the principals behind the Medicare Shared Savings Program, we also have concerns, detailed below.

**I. CMS Must Ensure Beneficiary Access to High Quality Care, Including Occupational Therapy**

Concerns arise in an environment where health care providers are financially rewarded for keeping costs down. Anyone who is "expensive" i.e., has a disability or chronic condition or

requires specialized or complex care, is at risk of losing access to specialized medical care, devices, technology, and other services. This includes rehabilitation care at the appropriate level of intensity, frequency and duration to meet the needs of the individual patient. ACOs should simply not be permitted to share in savings achieved through the denial of high quality patient care. ACOs cannot be just a new payment mechanism but rather a new way of delivering quality health care across the continuum.

## **II. CMS Should Consider Expanding the Definition of “Primary Care Services”**

The proposed rule narrowly defines “primary care services,” and consequently AOTA is not clear how CMS envisions the organization of care such as occupational therapy within the proposed ACO framework. It appears that only physician Evaluation & Management (E&M) codes will be used to determine the plurality of care – but will the provision of other services not be considered? Or will they only be considered in terms of savings? The latter seems inadequate and inappropriate.

## **III. CMS Must Include More Longitudinal and Functional Quality Measures**

ACO quality measures should have at their foundation the achievement of patient-centered outcomes in terms of health and quality of life. Primary and acute care process and outcome measures are certainly necessary, but they are not sufficient for people with disabilities and chronic conditions, who make up a large portion of Medicare beneficiaries. Outcome measures for this population must include measures based on function, not simply health care provision and status. A study sponsored by the National Quality Forum and conducted by RAND Health supports this logic, stating: “Using a longitudinal measurement framework will naturally emphasize health outcomes. In particular, the measurement of changes in functional status, morbidity, and quality of life will be attractive to clinicians to the extent that these results can guide clinical care.”<sup>1</sup>

For example, a person who experiences a traumatic injury or surgical operation may achieve completely acceptable primary care outcomes (e.g., blood pressure, blood sugar, heart rate, and cholesterol) six months later, but the real indicator of a successful outcome is the level of independence and continued health (e.g., no falls, no depression) the person enjoys. Is the person not only “healthy” but living at home as independently as possible, having returned to work and normal activities, or is that person significantly compromised in terms of their function, living in a nursing home, unemployed and out of the mainstream of normal activities? Measures to assess functional status of this kind will need to be employed if ACOs are truly going to improve quality and outcomes while saving money. AOTA would argue that this broader focus saves money in the long term.

The list of quality measures in the proposed rule does not generally measure outcomes and there are vast areas of clinical practice which are not addressed at all. For instance, there are no measures for treatment of cancer, severe arthritis, stroke, osteoporosis, or chronic pain – common conditions for the Medicare population. CMS has stated its intention to move toward

---

<sup>1</sup> Schneider, E., Hussey, P., and Schnyer, C. (2011). Payment Reform: Analysis of Models and Performance Measurement Implications. Technical Report. *RAND Health, sponsored by the National Quality Forum.*

outcome measures as they become available. While it will be challenging to create outcome measures that capture all key attributes of successful treatment, those currently available through the Physician Quality Reporting System (PQRS) should be standards that ACOs must live up to (e.g., PQRS measure #155, Falls: Plan of Care).

AOTA calls for the specific inclusion of longitudinal measures such as hospital readmission, depression follow-up and management, quality of life and functional outcomes, and freedom from falls (e.g., post-hip replacement).<sup>2</sup> Evidence-based approaches are available to be implemented and should be required for ACOs. CMS should also prioritize participation in the community, independence in activities of daily living (ADLs), and integrated mental health care.

#### **IV. CMS Must Work to Ensure Cost Concerns Do Not Stifle Innovation**

A "cheapest is best" approach for ACOs could have the unintended negative effect of discouraging providers from adopting new forms of care and stifling innovation. Avoiding this would require provisions to support early adopters of new treatments and technology and emphasize outcomes over cost savings. For new treatments that meet CMS standards, ACO providers should not suffer financially for being first to adopt a treatment that promises to significantly improve patient care because it might raise costs in the short term. Many new treatments may not only improve patient care but may also reduce costs over the long term.

CMS must ensure that it achieves the essential goals of payment reform — improving quality care and reducing cost growth — while at the same time fulfilling Medicare's mission of guaranteeing each senior citizen the best care that American medicine can provide.

#### **V. CMS Should Ensure Data Links**

Valuable data is captured in the Minimum Data Set (MDS) Version 3.0, the OASIS-C tool, the Post Acute Care (PAC) tool, and the Group Practice Reporting Option (GPRO) collection tool that can inform ACO providers and help them plan care and measure outcomes. What is CMS doing to ensure that this information is linked and accessible to ACO participants?

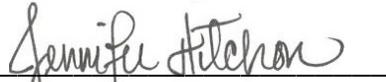
---

<sup>2</sup> McClellan, M. et al. (May 2010). A National Strategy to Put Accountable Care into Practice. *Health Affairs*, 29:5.

\* \* \* \* \*

AOTA respectfully requests that careful consideration be given to these comments. Should you have any questions, or if you would like additional information, please contact us at (301) 652-6611 ext. 2023 or [jhitchon@aota.org](mailto:jhitchon@aota.org). AOTA looks forward to a continuing dialogue with CMS on ACOs and other payment and delivery methods that affect the ability of occupational therapists to provide quality care to Medicare beneficiaries.

Sincerely,

A handwritten signature in cursive script that reads "Jennifer Hitchon". The signature is written in black ink and is positioned above a horizontal line.

Jennifer Hitchon  
*Regulatory Counsel*

**Attachment:** Studies related to Occupational Therapy and Cost Effectiveness, compiled June 2011.

## Studies Related to Occupational Therapy and Cost Effectiveness

*AOTA, June 2011*

<b>Study</b>	<b>Type of Study</b>	<b>Research Question/ Purpose of Study</b>	<b>Methods/ Participants</b>	<b>Outcomes/ Conclusions</b>
1. A study protocol of a randomized controlled trial incorporating health economic analysis to investigate if additional allied health services for rehabilitation reduce length of stay without compromising patient outcome	Randomized control trial	Examine if providing additional physiotherapy and occupational therapy on a Saturday reduces health care costs and improves the health of hospital inpatients receiving rehabilitation compared to the usual Monday to Friday service. Investigate the cost effectiveness and patient outcomes of such a service.	Patients aged 18 years or older that have been admitted for rehabilitation at either of the two rehabilitation facilities	Preliminary information suggests additional Saturday rehabilitation services could reduce the time a patient stays in hospital by three days.
2. Cost-effectiveness analysis of an occupational therapy-led lifestyle approach and routine general practitioner's care for panic disorder.	Unblinded randomized control trial	To assess the cost-effectiveness of an occupational therapy-led lifestyle approach to treating panic disorder in primary care compared with routine general practitioner's (GP) care.	An economic evaluation was conducted alongside an unblinded pragmatic randomised controlled trial with assessment at 5 and 10 months. Costs and consequences, as measured by the Beck anxiety inventory (BAI) and quality adjusted life years (QALYs), were compared using incremental cost-effectiveness ratios (ICERs).	The burden of mental health disorders is considerable. Cost-effective interventions are necessary to alleviate some of these burdens. Habitual lifestyle behaviors influence mood, although to date mainly single lifestyle factor trials have been conducted to examine the effects on anxiety. The occupational therapy-led lifestyle intervention was more costly than routine GP care at both 5 and 10

				<p>months. Significant outcome improvements were evident at 5 months when using the BAI, although these were not maintained at 10 months. Small differences in mean QALYs were found. The estimated ICER was 36 pounds per BAI improvement for 5 months and 39 pounds for 10 months, and 18,905 pounds per QALY gained for 5 months and 8,283 pounds for 10 months.</p>
<p>3. Cost effectiveness of a telerehabilitation program to support chronically ill and disabled elders in their homes</p>	<p>Matched Control</p>	<p>Examine effects of a VA telerehabilitation program (Low Activities of Daily Living (ADL) Monitoring Program-LAMP on healthcare costs</p>	<p>LAMP patients received adaptive equipment and environmental modifications, which focused on self-care and safety within the home. LAMP Care Coordinators remotely monitored their patient's vital signs and provided education and self-management strategies for decreasing the effects of chronic illnesses and functional decline. The matched comparison group (MCG) received standard</p>	<p>For LAMP patients, the provision of adaptive equipment and environmental modifications, plus intensive in-home monitoring of patients, led to increases in clinic visits post-intervention with decreases in hospital and nursing home stays.</p>

			<p>VA care. Healthcare costs 12 months pre-enrollment and 12 months post-enrollment were examined through a difference-in-differences multivariable model. Using actual costs totaled for these analyses, no significant differences were detected in post-enrollment costs between LAMP and the MCG</p>	
<p>4. Community occupational therapy for older patients with dementia and their care givers: cost effectiveness study</p>	<p>Cost effectiveness study alongside a single blind randomized controlled trial</p>	<p>To assess the cost effectiveness of community based occupational therapy compared with usual care in older patients with dementia and their care givers from a societal viewpoint.</p>	<p>Memory clinic, day clinic of a geriatrics department and participant's home. Patients were 135 patients aged <math>\geq 65</math> with mild to moderate dementia living in the community and their primary caregivers. Intervention: 10 sessions of occupational therapy over five weeks, including cognitive and behavioral interventions, to train patients in the use of aids to compensate for cognitive decline and care givers in coping behaviors and supervision.</p>	<p>Incremental cost effectiveness ratio expressed as the difference in mean total care costs per successful treatment (that is, a combined patient and care giver outcome measure of clinically relevant improvement on process, performance, and competence scales) at three months after randomization. Community occupational therapy intervention for patients with dementia and their care givers is successful and cost effective,</p>

				especially in terms of informal care giving.
5. Cost-effectiveness of a day hospital falls prevention programme for screened community-dwelling older people at high risk of falls.	Economic evaluation alongside pragmatic randomized controlled trial	Cost-effectiveness in fall prevention	Intervention: randomized trial of 364 people aged $\geq 70$ , living in the community, recruited via GP and identified as high risk of falling. Both arms received a falls prevention information leaflet. The intervention arm were also offered a (day hospital) multidisciplinary falls prevention programme, including physiotherapy, occupational therapy, nurse, medical review and referral to other specialists. self-reported falls, as collected in 12 monthly diaries. Levels of health resource use associated with the falls prevention programme, screening (both attributed to intervention arm only) and other health-care contacts were monitored. Mean NHS costs and falls per person per year were estimated for both arms, along with the incremental cost-effectiveness ratio (ICER) and cost effectiveness acceptability	In the base-case analysis, the mean falls programme cost was 349 per person. This, coupled with higher screening and other health-care costs, resulted in a mean incremental cost of 578 for the intervention arm. The mean falls rate was lower in the intervention arm (2.07 per person/year), compared with the control arm (2.24). The estimated ICER was 3,320 per fall averted.

			curve.	
6. Adjuvant occupational therapy for work-related major depression works: Randomized trial including economic evaluation	Randomized trial	Major depression has far-reaching consequences for work functioning and absenteeism. In most cases depression is treated by medication and clinical management. The addition of occupational therapy (OT) might improve outcome. We determined the cost-effectiveness of the addition of OT to treatment as usual (TAU).	Sixty-two adults with major depression and a mean absenteeism of 242 days were randomized to TAU (out-patient psychiatric treatment) or TAU+OT [6 months, including (i) diagnostic phase with occupational history and work reintegration plan, and (ii) therapeutic phase with individual sessions and group sessions]. Main outcome domains were depression, work resumption, work stress and costs. Assessments were at baseline and at 3, 6, 12 and 42 months.	The addition of OT to TAU: (i) did not improve depression outcome, (ii) resulted in a reduction in work-loss days during the first 18 months, (iii) did not increase work stress, and (iv) had a 75.5% probability of being more cost-effective than TAU alone. Addition of OT to good clinical practice does not improve depression outcome, improves productivity without increasing work stress and is superior to TAU in terms of cost-effectiveness.
7. The Effectiveness and Cost of Home Care: An Informational Synthesis	Systematic analysis	(1) briefly review the history of home care program evaluations and the approaches and problems of earlier reviews of this literature, (2) present our method of study selection, (3) describe the studies reviewed, (4) list our criteria for assessing the methodologic soundness	This information synthesis summarizes results from studies of home care using experimental or quasi-experimental designs, explicitly including judgments of methodologic soundness in weighing the results.	In 12 studies of programs targeted at chronically ill populations, home care services appear to have no impact on mortality, patient functioning, or nursing home placements. Across studies, these services either have no effect on

		<p>of the studies reviewed, (5) present the results of our information synthesis for each dependent variable assessed, and (6) discuss the results together with their implications for system managers, program managers, clinicians, and researchers.</p>		<p>hospitalization or tend to increase the number of hospital days; ambulatory care utilization may be increased by 40 percent. The cost of care either is not affected or is actually increased by 15 percent. The critical need at present is for better-designed studies to test the effects of different types of home care, targeted at various types of patients, on the outcomes assessed in the existing studies, as well as on other important outcomes such as family finances, quality of life, and quality of care.</p>
<p>8. Environmental assessment and modification to prevent falls in older people</p>	<p>Three-armed randomized controlled trial</p>	<p>To assess the effectiveness of an environmental falls prevention intervention delivered by qualified occupational therapists or unqualified trained assessors.</p>	<p>238 community dwelling adults aged 70 and older with a history of falls in the previous years Assessment and modification of the home environment of people at greater risk of falls. Fear of falling was the primary</p>	<p>The intervention had no effect on fear of falling (P5.63). The occupational therapy group had significantly fewer falls than controls 12 months after the assessment (incidence rate ratio</p>

			<p>outcome measure, and an analysis of covariance was conducted on the area under the curve at 12 months. As a secondary outcome, falls were analysed using negative binomial regression. Quality of life and independence in activities of daily living (ADLs) were also measured.</p>	<p>(IRR)50.54, 95% confidence interval (CI)50.36–0.83, P5.005). There was no significant effect on falls in the trained assessor group (IRR50.78, 95% CI50.51–1.21, P5.34). Environmental assessment had no effect on fear of falling. Environmental assessment prescribed by an occupational therapist significantly reduced the number of falls in high-risk individuals whereas that prescribed by a trained assessor did not. Further research in other settings is needed to confirm this, to explore the mechanisms, and to estimate cost-effectiveness.</p>
<p>9. Early physical and occupational therapy in mechanically ventilated, critically ill patients: a randomised controlled trial</p>	<p>Randomized control trial</p>	<p>Assessed the efficacy of combining daily interruption of sedation with physical and occupational therapy on functional outcomes in patients receiving mechanical ventilation</p>	<p>Sedated adults (<math>\geq 18</math> years of age) in the ICU who had been on mechanical ventilation for less than 72 h, were expected to continue for at</p>	<p>All 104 patients were included in the analysis. Return to independent functional status at hospital discharge</p>

		<p>in intensive care.</p>	<p>least 24 h, and who met criteria for baseline functional independence were eligible for enrolment in this randomised controlled trial at two university hospitals. We randomly assigned 104 patients by computer-generated, permuted block randomisation to early exercise and mobilisation (physical and occupational therapy) during periods of daily interruption of sedation (intervention; n=49) or to daily interruption of sedation with therapy as ordered by the primary care team (control; n=55). The primary endpoint—the number of patients returning to independent functional status at hospital discharge—was defined as the ability to perform six activities of daily living and the ability to walk independently. Therapists who undertook patient assessments were blinded to treatment assignment. Secondary</p>	<p>occurred in 29 (59%) patients in the intervention group compared with 19 (35%) patients in the control group (p=0.02; odds ratio 2.7 [95% CI 1.2–6.1]). Patients in the intervention group had shorter duration of delirium (median 2.0 days, IQR 0.0–6.0 vs 4.0 days, 2.0–8.0; p=0.02), and more ventilator-free days (23.5 days, 7.4–25.6 vs 21.1 days, 0.0–23.8; p=0.05) during the 28-day follow-up period than did controls. There was one serious adverse event in 498 therapy sessions (desaturation less than 80%). Discontinuation of therapy as a result of patient instability occurred in 19 (4%) of all sessions, most</p>
--	--	---------------------------	---	--

			<p>endpoints included duration of delirium and ventilator-free days during the first 28 days of hospital stay. Analysis was by intention to treat.</p>	<p>commonly for perceived patient-ventilator asynchrony. <b>Interpretation</b> A strategy for whole-body rehabilitation—consisting of interruption of sedation and physical and occupational therapy in the earliest days of critical illness—was safe and well tolerated, and resulted in better functional outcomes at hospital discharge, a shorter duration of delirium, and more ventilator-free days compared with standard care.</p>
--	--	--	--	---

References:

1. Taylor, NF, Brusco, NK, Watts, JJ, Shileds, N, Peiris, C, Sullivan, N; Kennedy, G, Teo, CK, Farley, A, Lockwood, K, and Radia-George, C (2010). A study protocol of a randomized controlled trial incorporating health economic analysis to investigate if additional allied health services for rehabilitation reduce length of stay without compromising patient outcome. *BMC Health Services Research*, 10: 308d09: 10.1186.
2. Lambert, RA, Lorgelly, P, Harvey, I, and Poland, F (2010). Cost-effectiveness analysis of an occupational therapy-led lifestyle approach and routine general practitioner's care for panic disorder. *Social Psychiatry & Psychiatric Epidemiology*, 45(7):741-50
3. Bendixen, RM, Levy, CE, . Olive, ES, Kobb, RF, Mann, WC (2009). Cost effectiveness of a telerehabilitation program to support chronically ill and disabled elders in their homes. *Telemedicine Journal & E-Health*. 15(1):31-8.

4. Graff, MJL, Adang, EMM, Vemooij-Dasse, MJM, Dekker, J, Jonsson, L, Thijssen, M, Hoefnagels, WHL, and Rikkert, MGMO (2007). Community occupational therapy for older patients with dementia and their care givers: Cost effectiveness study. *British Medical Journal*, bmj.com.
5. Irvine, L, Conroy, SP, Sach, T, Gladman, JRF, Harwood, RH, Kendrick, D, Coupland, C, Drummond, A, Barton, G, and Masud, T (2010). Cost-effectiveness of a day hospital falls prevention programme for screened community-dwelling older people at high risk of falls. *Age & Ageing*, 39(6): 710-6.
6. Schene, AH, Koeter, MWJ, Kikkert, MJ, Swinkels, JA, and McCrone, P (2007). Adjuvant occupational therapy for work-related major depression works: Randomized trial including economic evaluation. *Psychological Medicine*, 37, 351-362.
7. Hedrick, SC and Inui, TS (1986). The effectiveness and cost of home care: An informational synthesis. *Health Services Research*, 20: 6.
8. Pighills, AC, Torgerson, DJ, Sheldon TR, Drummond, AE, and Bland, JM (2011). Environmental assessment and modification to prevent falls in older people. *The American Geriatrics Society*, 59: 26-33.
9. Schweickert, WD, Pohlman, MC, Pohlman, AS, Nigos, C, Pawlik, AJ, Esbrook, CL, Spears, L, Miller, M, Franczyk, M, Depirizio, D, Schmidt, GA, Bowman, A, Barr, R, McCallister, KE, Hall, JB, and Kress JP (2009). Early physical and occupational therapy in mechanically ventilated, critically ill patients: a randomized controlled trial. [www.thelancet.com](http://www.thelancet.com), Published online May 14, 2009; DOI:10.1016/S0140-6746(09)60658-9.