



Via Electronic Submission

December 12, 2011

Ms. Marilyn Tavenner
Acting Administrator and Chief Operating Officer
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: Proposed Changes to the Medicare Advantage and the Medicare Prescription Drug Benefit Programs for Contract Year 2013 and Other Proposed Changes; Considering Changes to the Conditions of Participation for Long Term Care Facilities¹

Dear Acting Administrator Tavenner:

The American Association for Homecare (AAHomecare) submits these comments in response to the Centers for Medicare and Medicaid Services' (CMS) request for comments on the above captioned proposed rule. CMS proposes to permit Medicare Advantage (MA) plans to limit enrollees to only certain, preferred, items of durable medical equipment (DME), services or supplies.

AAHomecare is the national association representing the interests of DME providers and manufacturers. Our members make quality products that meet all applicable regulatory requirements and function safely and effectively when used properly by patients in their homes. In light of our members' expertise and experience, AAHomecare is uniquely qualified to comment on the proposed rule.

It is impossible to overstate the importance of the work that AAHomecare members perform. Numerous recent studies show that homecare technologies are effective for managing the

¹ 76 Fed. Reg 63018 (October 11, 2011)

health needs of the chronically ill while reducing the costs associated with inpatient care.² The product innovations brought about by DME manufacturers allow Medicare to harness technology to ensure beneficiaries receive effective care quickly and safely without incurring expenses for hospitals or nursing homes.

Prompt access to appropriate medical devices and services is a prerequisite to achieving these important goals. Limiting access to DME technologies and services to reduce costs is ultimately self-defeating because Medicare will no doubt spend even more on higher intensity care for the frail elderly, disabled or chronically ill. Savings garnered from DME technologies and services will be modest compared to the costs of more frequent or prolonged hospital stays, skilled nursing facility admissions, home health episodes of care or physician visits that these beneficiaries will require.

As CMS acknowledges, establishing categories of “preferred” DME items and services is a complex undertaking and one that is fraught with the potential for unintended consequences. Importantly, CMS has not identified any principled basis to guide the selection of “preferred” items and services or considered the operational challenges of ensuring that beneficiaries receive appropriate equipment and services that meet their therapeutic goals. For the reasons we discuss in more detail below, AAHomecare recommends that CMS withdraw the proposed regulation.

I. COMMENTS

A. Costs Savings Should Not Be the Criterion for Selecting “Preferred” DME Technologies

As we noted above, access to DME technologies help Medicare save money by allowing the chronically ill and disabled to be cared for at home. The proposed rule would permit MA plans to limit beneficiaries’ DME benefit coverage to specific products or brands based on whether a plan has negotiated “bulk discounts” with the product manufacturer. Other than a few rudimentary procedural protections for beneficiaries, CMS does not limit a plans’ ability to restrict coverage in this fashion. AAHomecare is concerned that giving MA plans such broad permission to create DME formularies will limit access to brands or products that may be better suited to a beneficiary’s specific medical needs than those on the preferred list.

The proposed rule does not set forth any standards or criteria for selecting the products or product brands other than the plan’s ability to negotiate discounts with product manufacturers.

² See for example, Landers, S. “Why Health Care Is Going Home,” *New England Journal of Medicine*, October 20, 2010; Oba, Y. “Cost-Effectiveness of Long-Term Oxygen Therapy for Chronic Obstructive Pulmonary Disease,” *American Journal of Managed Care*, February 2009; Lau, J., et al., *Long-Term Oxygen Therapy for Severe COPD*, June 11, 2004, Tufts-New England Medical Center Evidence Based Practice Center.

Certain DME items such as power wheelchairs and wheelchair seating products must meet HCPCS code specifications for Medicare coverage. Under the proposed rule, an MA plan would not be required to include code-verified products as preferred DME and could choose, instead, less expensive products whose manufacturers might be willing to discount aggressively.

Importantly, MA plans should not be permitted to use preferred product lists to limit coverage for Medicare-covered items. In the case of power wheelchairs, for example, products are grouped together based on functionality and clinical coverage criteria. Group I power wheelchairs have only basic features and are the least expensive devices. Group I chairs would not be appropriate for individuals who have a clinical need for the higher level functionality found in Group II or III power wheelchairs. Medicare covers the full range of power wheelchairs, and MA plan Medicare enrollees should have access to the device that meets their functional and clinical needs.

Moreover, the basis for the proposed rule is an incorrect assumption that DME technologies are clinically and functionally interchangeable much like a generic drug might be to the brand name product. This assumption is wrong and allows the selection of "preferred" DME brands to occur arbitrarily, driven solely by cost. For example, the preamble highlights ostomy bags as examples of products that might be part of a plan's preferred product list. This example suggests that ostomy products are clinically equivalent to each other and may be substituted for each other without negative medical impact to the beneficiary.

The fact is ostomy products are not clinically interchangeable and differ greatly by brand. Specific features of an ostomy product may have significant medical impact for the patient, and selection of the appropriate ostomy products usually involves the recommendation of a clinician specially trained in ostomy. It is important to select an ostomy product that best meets a patient's unique needs and that will not cause medical complications which can result in additional and increased medical costs and suffering for the patient.

Further, many products such as power wheelchairs and seating systems or positive airway pressure (PAP) devices and supplies must be matched to a patient by a skilled professional who is aware of the differences between products and chooses what is most appropriate for a patient. It is impossible to make these decisions from a limited set of preferred products without reference to the patient's specific needs. For these types of products, the physician and the patient rely on the expertise of the DME provider to guide them based on the patient's clinical profile and therapeutic goals. Limiting the range of products to only preferred DME in order to save money is short-sighted and wrong, eventually resulting in higher costs.

Similarly, for diabetic testing supplies, selecting the right blood glucose monitor (BGM) and corresponding test strips is a critical and personal decision that a patient and doctor must make together based on the patient's individual needs. For example, some blood glucose monitors have features that allow beneficiaries with arthritis to handle the monitor more easily, while

others have larger screens that can be more easily be read by visually impaired beneficiaries. In order to ensure beneficiary access to quality diabetic testing supplies, we urge CMS to require that MA plans comply with the following formulary standards, which: (1) include the most commonly prescribed diabetes products for Medicare beneficiaries, as outlined in the December 2, 2010, Office of Inspector General *Memorandum Report: Medicare Market Shares of Mail Order Diabetic Testing Strips, OEI-04-10-00130*; (2) meet FDA BGM Accuracy Standards; (3) include anti-switching protections as required in Medicare's Competitive Bidding Program; and (4) use a non-interfering test strip platform.

B. The Proposed Rule Does Not Account for Necessary DME Provider Services

DME technologies are transforming how care is delivered to the elderly and those with chronic disease or disabilities. But this transformation also depends on an array of services which are necessary to ensure the DME items are used safely and effectively. Equipment or technology is ineffective without the services DME providers perform. The proposed rule does not address how MA plans will ensure these services are also provided when DME items they purchased in "bulk" are furnished to Medicare beneficiaries.

Although furnishing DME might appear to be straightforward, in actuality it is a complex endeavor and its success depends on the expertise and service delivered by the DME provider. Typically, equipment costs are a fraction of the costs of services beneficiaries receive. DME providers employ an array of professionals including clinicians such as respiratory therapists (RTs), physical therapists (PTs) or dieticians as well as skilled equipment technicians. DME providers are accredited and meet CMS supplier standards and quality standards that ensure beneficiaries are properly trained in using their equipment and that the patient and equipment are monitored on an ongoing basis.

It is very difficult, if not impossible, to divorce the DME device from the service provider who furnishes the item. The provider purchases and maintains equipment inventory, assures the equipment is in working order and employs technicians who are trained by manufacturers on the use and repair of the products. There is no mention of this crucial component anywhere in the proposed rule or the preamble. How do MA plans propose to deliver and set-up equipment, train beneficiaries and perform in-home assessments for DME items they purchased in bulk? Will these items be shipped using a common carrier? Who will repair them or be accessible for troubleshooting sophisticated equipment after business hours? CMS should not finalize the proposed rule until these issues have been carefully thought through and any new proposals addressing them are vetted through public comments.

C. Beneficiary Protections Are Inadequate

AAHomecare agrees that strong beneficiary protections are necessary if MA plans are allowed to limit access to DME technologies and services. The proposed rule outlines a number of

procedural rights that beneficiaries would have with respect to plans' preferred DME benefits. These include disclosure of how the plan limits coverage of the DME benefit and a 90-day transition period during which new enrollees can get refills and repairs of their existing supplies or equipment. MA plans would also be precluded from making negative changes on preferred equipment benefits in the middle of a plan year.

While these protections are necessary and important, they are insufficient to protect beneficiaries who may have a special need for a device with a specific feature not available through the preferred DME benefit. The need for a DME item presents suddenly, often as the result of a traumatic event or the deterioration of a chronic condition. It is not like elective surgery where the enrollee can "wait out" the MA plan's approval process. A beneficiary who needs DME to go home from the hospital has an immediate need for the item. Otherwise, the discharge is delayed pending the MA plan's approval of the "non-preferred" DME.

Consequently, the proposed rule should include a requirement that a physician's order for a non-preferred DME item results in a presumption that the item is medically necessary such that the beneficiary will have immediate access to the item pending the completion of the MA plan's approval process. This is similar to current policies that require MA plans to cover emergency care furnished by out-of-network providers when the enrollee had a reasonable belief that emergency care was necessary. This policy would acknowledge a beneficiary's urgent need for a specific product, permitting immediate access to medically necessary brands or models of DME pending the plan's approval of the item. It would be inadequate to insist that a beneficiary rely on a lengthy appeals process to gain access to medically necessary DME technology. Likewise, it is imperative that CMS ensure beneficiaries have access to new DME technologies and services when they become available. Again, beneficiaries should not be subjected to a lengthy appeals process to receive a DME item their doctors have determined to be medically necessary.

II. CONCLUSION

As we stated above, AAHomecare recommends that CMS withdraw the proposed rule. DME technologies, services and supplies are not interchangeable. Beneficiaries and physicians rely on the skill and knowledge of DME providers to ensure that beneficiaries are matched to equipment and supplies that are best suited to their clinical profile and therapeutic goals. DME providers also furnish a broad array of support services that enable patients to be treated safely and effectively in their homes. Furnishing DME and supply items purchased "in bulk" from manufacturers without providing support services places beneficiaries at risk.

Finally, in the event CMS finalizes the proposed rule, we recommend the following: (1) CMS must ensure that beneficiaries have immediate access to "non-preferred" medically necessary DME technologies, services and supplies pending an MA plan's approval of the item; and (2) CMS must require that MA plans follow formulary standards, like those described above for

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diabetes testing supplies, in order to help ensure that beneficiaries continue to have access to quality products.

AAHomecare appreciates the opportunity to submit these comments. We are available to discuss them at your convenience. Please feel free to contact AAHomecare's Walt Gorski at (703) 535-1894 should you have any questions or if the Association can be of further assistance.

Sincerely,

A handwritten signature in black ink, appearing to read "Walt J. Gorski". The signature is fluid and cursive, with the first name "Walt" being the most prominent.

Walter J. Gorski
Vice President of Government Affairs