Via Electronic Submission

October 21, 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: Summary of Benefits and Coverage and the Uniform Glossary [CMS 9982-P] RIN 0938-AQ73 and [CMS-9982-NC] RIN 1210-AB52[1]

Dear Administrator Berwick:

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 rules, which address requirements for disclosure of a summary of benefits and coverage and a uniform glossary including the definition of "durable medical equipment" (DME) under group health plans and the individual and group health insurance markets.

AAHomecare is the national association representing the interests of DME providers. AAHomecare members include a cross-section of manufacturers and suppliers that make or furnish DMEPOS items and supplies that individuals use in their homes. Our members are proud to be part of the continuum of care that assures that patients receive cost effective, safe and reliable home care products and services. As we explain more fully below, the Association supports the inclusion of DME in the summary of benefits and coverage and a definition of DME in a uniform glossary.

I. THE SUMMARY OF BENEFITS AND COVERAGE SHOULD IDENTIFY DME AS A COVERED BENEFIT AND A DEFINITION OF DME SHOULD BE IN THE UNIFORM GLOSSARY

[1] 76 Fed. Reg. 52442 (August 22, 2011); 76 Fed. Reg. 52475 (August 22, 2011).

A. DME Products, Services, and Supplies Are Essential for Managing and Treating Chronic Health Conditions

It is impossible to overstate the importance of DME products, services, and supplies in controlling the costs associated with chronic health conditions. Numerous recent studies show that homecare technologies are effective for managing the health needs of the chronically ill while reducing the costs associated with inpatient care. 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."[2] He cites home oxygen therapy, parenteral nutrition, and home infusion therapy as examples of care that is less expensive than and equally as effective as institutional care.

Landers 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 inpatients 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." [3] 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 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.[4]

Another example of how homecare may be incorporated into a patient's treatment plan in order to effect 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. 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*

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

Infectious Diseases quantified cost savings of a home intravenous antibiotic program in a Medicare managed care plan. The average cost per day of home infusion therapy was $122, compared to $798 in the hospital and $541 in a skilled nursing facility.[5]

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.

B. DME Products, Services, and Supplies Constitute "Essential Health Benefits" That Belong in the Summary of Benefits and Coverage and Uniform Glossary

AAHomecare backs the inclusion of DME products, services, and supplies as a health benefit identified in the summary of benefits and coverage and defined in a uniform glossary. In support, we note that DME products, services, and supplies meet criteria identified by the Institute of Medicine (IOM) for inclusion in an essential health benefit (EHB) package. In a report issued in October 2011,[6] the IOM reinforced the need for effective, affordable health services to meet the needs of a larger population of covered persons.

Specifically, the IOM identified criteria that should be used to determine what benefits are the most important to include in an EHB package as well as ten broad categories of health care services that are similar to those currently available from employers today. Implicitly recognizing the importance of restoring functionality to the disabled and managing the costs of chronic disease, the IOM identified rehabilitative and habilitative services and devices and chronic disease management among the categories of health services that an EHB package should include. Although the report did not identify specific benefits in these categories, as the research we cited above indicates, DME products, services, and supplies are among the keys to achieving these goals.

Importantly, the IOM explicitly stated that its mission was to find a balance between coverage and cost, noting that, as coverage expands, its affordability becomes more important. AAHomecare believes that a balance of these priorities requires the use of DME products, services, and supplies to treat more patients at home across all health care market segments. There is no question that DME products, services, and supplies satisfy the criteria for selecting EHBs identified by the IOM. That is, DME products, services, and supplies have been proven to be safe, medically effective, and cost-effective in meeting the health needs and goals of the chronically sick and disabled as has

---

[5] Dalovision, J., et al., "Financial Impact of a Home Intravenous Antibiotic Program on a Medicare Managed Care Program," *Clinical Infectious Diseases*, 2000.

[6] See Essential Health Benefits Balancing Coverage and Costs, Institute of Medicine of the National Academies, available at: http://www.iom.edu/~/media/Files/Report%20Files/2011/Essential-Health-Benefits-Balancing-Coverage-and-Cost/essentialhealthbenefitsreportbrief.pdf.

been demonstrated in significant studies like the ones we cited above. Consequently, the Agencies should adopt the templates for the summary of benefits and coverage and uniform glossary as proposed.

C. The Definition of DME in the Uniform Glossary Is Consistent with Definitions Currently in Use by Government and Commercial Payers

Appendix "E" contains a proposed template for a uniform glossary that in includes the following definition of DME:

> **Durable Medical Equipment (DME)**
> Equipment or supplies ordered by a health care provider for everyday or extended use. Coverage for DME may include: oxygen equipment, wheelchairs, crutches or blood testing strips for diabetes.[7]

This definition captures the salient features of DME products, services, and supplies in language that is easy to understand. The definition highlights that: 1) DME items have a medical purpose and must be prescribed by a health care provider; 2) DME items are intended for everyday use over an extended period of time; and 3) DME items encompass a broad range of complex, sophisticated equipment and services such as oxygen equipment and wheelchairs, and more straightforward devices such as canes and crutches.

These features of DME – its medical purpose and durability such that it is appropriate for repeated or extended use – have been adopted by Medicare, nearly all state Medicaid programs, workers compensation laws and major private sector health insurers in their definitions of DME. AAHomecare supports the adoption of the definition proposed in the template uniform glossary inasmuch as it is consistent with the definition of DME currently used by most government and private sector payers. Maintaining consistency in the terminology used across all payers would permit a seamless implementation of the requirements of the Affordable Care Act of 2010 for individuals who require DME products, services, and supplies.

II. CONCLUSION

AAHomecare appreciates the opportunity to submit these comments. Please feel free to contact me if you have any questions or I can be of further assistance.

Sincerely,

Walter Gorski
Vice President of Government Affairs

[7] 76 Fed. Reg. at 52528.