SUNRISE MEDICAL.

Richard H. Chandler
Chairman and President

Sunrise Medical Inc.
2382 Faraday Avenue
Suite 200
Carlsbad, CA 92008
Tel: (760) 930-1500
Fax:(760) 930-1575

April 30, 1999

The Honorable Donna Shalala
Secretary of Health & Human Services
Hubert H. Humphrey Building
200 Independence Avenue, S.W.
Washington, D.C. 20201

Dear Donna:

I enjoyed meeting you at dinner last week at Kathy Kemper's house and am following up our conversation regarding Medicare's current non-coverage of augmentative communication devices.

Augmentative and alternative communication devices ("AAC devices"), such as the Dynavox and DynaMyte units manufactured by Sunrise Medical, restore the ability to speak for people with severe speech disabilities. (See enclosed literature with photos, as well as a video showing the products in use, Attachment 1.) Stephen Hawking, the physicist, who is disabled by ALS, is perhaps the best known user of an AAC device. Much closer to home, Bob Williams, the Deputy Assistant Secretary of Disability, Aging and Long-Term Care Policy, who has cerebral palsy, also uses an AAC device to speak. The devices combine microprocessor and touchscreen technology with a voice synthesizer to enable users to communicate audibly both routine and emergency needs, while helping them to lead a normal life, attend school, or hold a job.

Both Bob Williams and Stephen Hawking have severe neurologic impairments to the brain and nerve pathways, respectively, that comprise two of the three body structures involved in speech production. The third structure includes the numerous internal organs that produce speech (e.g., the larynx, soft palate, tongue, lips and jaw). Intelligible speech will result when all three function properly and in precise coordination; when they do not, due to severe disability, intelligible speech is not possible. AAC devices have been developed for people who, as a result of severe disability, must have a functional substitute for these body structures to be able to produce intelligible speech.

As we discussed, Medicare does not cover these devices, even though prosthetic devices are a Medicare benefit category, and prosthetic devices are defined as devices that replace the function of body parts that are missing, or are mal- or non-functioning.

My staff has been researching the basis for the Medicare exclusion of AAC devices, and has discovered that AAC devices are currently considered "convenience items" under the Medicare durable medical equipment benefit category (See National Coverage Decision § 60-9, Attachment 2). This decision evidently dates back to some time in the 1980s, when AAC devices were quite crude and hard to use. Recent advances in microprocessor technology have allowed AAC devices to become much more user friendly and, indeed, an essential assistive device for their users. It is hard to understand why Medicare beneficiaries should not have

access to this life-changing technology. When we tried to learn why AAC devices were classified as DME or why they were considered "conveniences," we were told no records exist (See Attachment 3).

When we looked further, we discovered that Medicare does not consider either speech-related treatment, or other speech-related devices to be "conveniences"; to the contrary, Medicare covers speech-language pathology services (See 42 C.F.R. § 410.10(m)); and also covers the artificial larynx as a prosthetic device (National Coverage Decision § 65-5). This guidance describes an artificial larynx as a speech-related prosthetic device that provides a functional substitute when the larynx has been removed or is not functioning, but it is not useful to people like Stephen Hawking or Bob Williams, each of whom has impairments to other body structures involved in speech production.

In short, Medicare's AAC device coverage policy seems to be internally inconsistent: a) AAC devices were classified as DME, but the artificial larynx is covered as a prosthetic device; b) AAC devices were excluded as "convenience items," yet speech-related treatment and speech-related devices are both covered; and c) Medicare covers a device that is a functional substitute for one body organ involved with speech production, but excludes devices that serve as functional substitutes for any other body organs involved in speech production. The basis for these inconsistencies never has been discovered or explained. And of the four claim denials that have been appealed to Medicare administrative law judges, all have been decided favorably for the beneficiaries. The ALJs all decided that AAC devices should be covered based on an objective reading of Medicare regulations.

Medicare's classification of AAC devices as DME also stands in stark contrast to the FDA, which classifies them as "physical medicine prosthetic devices" (21 C.F.R. § 890.3710), as well as the prosthetic device classification of AAC devices by the Department of Veterans Affairs. Overall, 48 of 50 state Medicaid programs, the VA, CHAMPUS and most insurers (including Blue Cross, Blue Shield and Kaiser Permanente) all cover AAC devices. Government funding programs for the disabled and elderly in most other developed countries also cover AAC devices (e.g., U.K., Germany, Netherlands, Norway, Sweden).

Medicare's exclusion of AAC devices as convenience items is thus inconsistent with the conclusions by virtually every other major health benefits program and independent decision maker who has considered the issue. It is also inconsistent with a great volume of professional literature about AAC treatment, and the inclusion of AAC intervention research projects among the grant priorities set by the National Institutes of Health, Institute on Deafness and Other Communication Disorders.

As a final point, the conditions that are associated with AAC need—severe dysarthria and anarthria, dyspraxia and apraxia of speech, and aphasia—are relatively low incidence conditions. Moreover, AAC need will arise only following a comprehensive assessment by a specially skilled speech-language pathologist. Thus, while the numbers of users and cost impact to Medicare will be low, the need for these devices is critical to those for whom it is the only means of speaking.

In summary, we believe speech is a vital human function and that Medicare's historic coverage denial of AAC devices deserves to be re-evaluated in light of advances in technology and now accepted standards of medical practice. We ask that you direct Medicare to suspend its "convenience item" guidance, NCD § 60-9, and to convene a work-group of AAC professionals who can assist Medicare staff to develop coverage criteria based on accepted principles and policy of AAC intervention. Recently, major disability organizations throughout the country made the same request, (See Attachments 4 and 5), as have several members of Congress. Sunrise Medical associates are available to assist the HCFA staff in this effort in any way. While Sunrise is the leading manufacturer of AAC devices, I am writing on behalf of all AAC manufacturers, speech language pathologists, and speech disabled users who have been frustrated by HCFA's continuing refusal to recognize the medical necessity of this important technology.

I know, based on our dinner conversation and your past testimony to Congress, that you care deeply about the health and welfare of the elderly and disabled. I appreciate your willingness to look into this matter and satisfy yourself as to the proper Medicare policy toward AAC devices. I think you will end up agreeing with the logic and fairness of our position.

Sincerely,

Dick

Richard H. Chandler

RHC/crr

Attachments:

1. DynaVox brochures and video
2. National Coverage Decision 60-9
3. Letter dated July 8, 1998 to Elizabeth Carder from Philip Brown, Director, HCFA Division of Freedom of Information and Privacy
4. Letter dated February 26, 1999 to Nancy-Ann Min DeParle from 20 organizations comprising the Consortium for Citizens with Disabilities, Health Task Force
5. Letter dated March 1, 1999 to Nancy-Ann Min DeParle from Michael Havlicek, President, The Amyotrophic Lateral Sclerosis Association