SUNRISE MEDICAL

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Via E-Mail and UPS Overnight

Mr. Jonathan Young
Associate Director for Disability Outreach
Office of Public Liaison
The White House
1600 Pennsylvania Avenue, N.W.
Washington, D.C.

Dear Mr. Young:

I am writing to follow up your meeting in October with my colleague, Marilyn Hamilton. As Marilyn probably told you, Sunrise Medical designs, manufacturers and markets assistive technology devices for people with disabilities and patient care products used in nursing homes, hospitals and homecare settings. We are a U.S. based company with annual sales of over $650 million. Our products are distributed in more than 100 countries around the world. Sunrise Medical's mission is to improve people's lives by creating innovative, high quality products. Enclosed is a copy of our Annual Report.

One of the products we manufacture is a medical device known as an "augmentative communication device" (AAC device), which I describe in greater detail below. This product, the Dynavox, is the most popular brand of AAC device, although several other companies manufacture competing models. Information and a short video demonstrating the Dynavox are enclosed. For patients whose disability has robbed them of the ability to speak, an AAC device enables them to communicate. It is currently funded by the federal government (CHAMPUS, VA), state (Medicaid) and private insurance companies. It is not funded by the Medicare program. We have been seeking Medicare coverage of and reimbursement for these critically important devices with little success.

I would like to explain the value of AAC device for the patients that need them as well as describe our frustrating attempts with the Health Care Financing Administration to obtain coverage for these products. I believe that after reading this information you will also be in agreement that these valuable devices need to be covered by Medicare and will agree to help us in the future to obtain this coverage.

Augmentative Communication Devices

The Dynavox and other AAC devices are battery-operated, microprocessor driven, and portable. They operate when a user selects (by touching, for example) a display screen or keyboard with letters, pictures and/or symbols, which are "read" by built-in software, "translated" into words, phrases or sentences, and then "spoken" by a speech-synthesizer. An AAC device like the Dynavox is capable of producing whatever speech its user will want to. It is typically used by people whose disabilities prevent them from communicating by speech, sign language or writing, or otherwise. For people who rely on the Dynavox and other AAC devices for speech, there is no speech-language pathology technique and no other device that will be of any benefit.

The people who need an AAC device are extremely few in number and are among the most severely physically disabled of all Medicare recipients. The need for an AAC device is associated with the speech and language related disabilities known as anarthia, severe dysarthria, aphasia and apraxia of speech. Stephen Hawking, the world-renowned physicist who has anarthria due to ALS, is perhaps the best known person who uses an AAC device. Others include Bob Williams, a Deputy Assistant Secretary of HHS, who has severe dysarthria due to Cerebral Palsy, and Stephen Hall, M.D., a renowned psychiatrist, who has anarthria due to "locked-in syndrome," the most severe of physical consequences of a stroke.

For people with these conditions, the Dynavox and other AAC devices restore the ability to speak and use language, which is recognized by scientists as a uniquely human characteristic, and by the courts as a "vital" functional ability. Among people with acquired or progressive impairments, such as ALS, there is a general recognition that of all the abilities people lose, the loss of the ability to communicate is the most frightening. The ability to communicate is hardly a "convenience," but as you will see in the paragraphs below, this is how Medicare describes it.

Sunrise Medical's Efforts to Obtain Medicare Coverage of AAC Devices

As I indicated earlier, other insurance programs recognize the value of these devices as medically necessary. Most payors cover them as prosthetic devices (a device that replaces all or part of the function of a permanently inoperative or malfunctioning external body member or internal body organ) and reimburse for them. This includes every state Medicaid program, hundreds of commercial health insurance providers, CHAMPUS and the Department of Veteran's Affairs.

Unfortunately, more than a decade ago, Medicare issued a national coverage determination on AAC devices, classifying them as "communicators." The agency denied coverage for these items and wrongly described them as "convenience items, not primarily medical in nature." We believe HCFA made this determination many years ago, based on early devices very different from those available today.

Indeed, this ruling is in direct conflict with the stance of the FDA, which recognizes AAC devices as medical devices. More specifically, the FDA classifies AAC devices as "powered communication systems," a type of "physical medicine prosthetic device." In addition, since 1981, the American Speech-Language-Hearing Association has recognized that use of an AAC device is a form of speech-language pathology treatment for very severe expressive

communication disabilities. Other medical literature, policy and practice, in the form of textbooks, treatises, peer-reviewed research journals, course-work in medical schools and graduate programs in speech-language pathology provide further recognition of the role of AAC Device as a treatment methodology for such conditions.

Moreover, this Medicare guidance stands in contrast to more than two decades of research, policy and practice by treatment professionals who specialize in expressive communication disabilities, as well as the practices of health benefits programs. The result has been to deter Medicare recipients from filing claims for Medicare AAC devices - based on this guidance, there is a belief that filing a Medicare AAC device funding request will be futile. In addition, this coverage determination causes the denials of any Medicare funding requests that are submitted.

Once we discovered that HCFA had issued this unfavorable national coverage decision, we took steps to discover how and why HCFA came to this decision. In the past year, HCFA was twice asked to provide information about the basis for this national coverage determination. (One of the requests came from Senator Paul Wellstone's office.) In response to both, HCFA stated that it had no relevant records, including none that would supply such basic information as when the guidance was first written, what device was evaluated, who was responsible for the "convenience item" conclusion it states, and what evidence the agency reviewed prior to issuing this guidance. The absence of any records also leads to the conclusion that Medicare has not re-evaluated this guidance since it was issued, despite changes in the technology. (The response to the most recent of these inquiries is attached.)

In short, the guidance continues to be applied, and to cause harm, yet Medicare cannot provide a foundation for *why* it exists. Just about the only information known about this coverage determination is that it was written prior to 1987, which was when Medicare made a general public release of its coverage documents.

In addition to asking HCFA on what basis it made its national coverage decision, we met recently with one of the Durable Medical Equipment Regional Carrier (DMERC) medical directors. The DMERC medical directors are HCFA's contractors who write regional medical coverage policies for durable medical equipment, orthotic and prosthetic devices, as well as in some cases making individual decisions on Medicare claims. Unfortunately, even though this DMERC medical director had no question as to the medical necessity and efficacy of the AAC Device, he stated that he would need to wait to obtain guidance from HCFA staff before making a decision in light of the national noncoverage decision. We are planning to meet with the other DMERC medical directors in the near future, and ultimately will seek a meeting with HCFA staff Tom Hoyer to address the HCFA coverage decision with him.

On the legislative side, we are working with several Members of Congress (e.g. Senator Paul Wellstone) to develop a strategy to obtain coverage of AAC devices.

Hopefully, you now have a better appreciation of the frustrations that we as a medical device manufacturer have undergone over the past few months in our attempts to get critically important AAC devices covered under the Medicare program. Again, as we stated earlier, our intent in this letter was to acquaint you with AAC devices, the patient population who benefit from them, and

the coverage (or lack thereof) and payment for them. We will call you in January to determine a convenient time for a meeting between you and our Washington representative for this issue, Phil Peter.

If you have any questions concerning the situation that I have described above or about the Dynavox itself, please do not hesitate in giving me a call. I wish you a very happy holiday season.

Sincerely,

Steven Jaye
SAJcrr

Enclosures by UPS Overnight:

(1) Sunrise 1998 Annual Report
(2) DynaVox Brochure and Video
(3) Business Week article, "Annual Design Awards … Touch and Talk", Medical & Scientific Products Silver Award for DynaMyte Augmentative Communicator
(4) Letter dated July 8, 1998 to Ms. Elizabeth Carder, from Philip Brown, Director, HCFA Division of Freedom of Information and Policy
(5) Letter dated November 13, 1997 to Ms. Nancy-Ann Min DeParle, Administrator, HCFA, from Paul D. Wellstone, U.S. Senator
(6) Letter from Ms. DeParle, HCFA, responding to Senator Wellstone's letter (#4 above)