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February 16, 2001

Robert Berenson, M.D.
Acting Administrator
Health Care Financing Administration
200 Independence Avenue, S.W.
Room 314-G
Washington, D.C. 20201

RE: Medicare Coverage of Augmentative & Alternative Communication (AAC) Devices, or "Speech Generating Devices" (SGD's)

Dear Dr. Berenson:

I write on behalf of the coalition of disability, SLP, manufacturer, and advocacy organizations listed at the conclusion of this letter. Specifically, we ask to meet with you at your earliest possible convenience. The purpose of this requested meeting is to discuss the current status of Medicare coverage of AAC devices, which Medicare calls "speech generating devices" or "SGDs."

We wish to bring to your attention an important flaw in the National Coverage Decision on SGDs that HCFA issued on November 30, 2000. That NCD will be published at Medicare Coverage Issues Manual, § 60-23.

We believe this flaw arose in significant part because the NCD was developed without any input from or discussion with any members of this coalition. In addition, the specific issue we wish to discuss regarding computer-based AAC device coverage contradicts an assurance we had been given at a meeting with Tom Hoyer and other CHPP staff in July 1999. The issuance of *any* AAC device National Coverage Decision also contradicts an assurance we had been given at a meeting with Sean Tunis M.D., and other CAG staff on November 6, 2000, just 3 weeks before the NCD was issued. We were told at that

meeting that no AAC device NCD would be developed. That an NCD on AAC devices exists also is directly contradictory to the information HCFA continues to offer the public: the HCFA web-site page related to AAC devices still states that no NCD for AAC devices will be developed.

The specific flaw in this NCD is in one of the examples of "non-dedicated" SGDs, which the NCD declares are "non-covered" devices. The flaw is found in the following text:

> Devices that would not meet the definition of speech generating devices and therefore, do not fall within the scope of § 1861(n) are characterized by:
>
> Devices that are not dedicated speech devices, but are devices that are capable of running software for purposes other than speech generation, e.g., devices that can also run a word processing package, an accounting program, or perform other non-medical functions.
>
> **Laptop computers, desktop computers, or PDAs, which may be programmed to perform the same function as a speech generating device, are non-covered since they are not primarily medical in nature and do not meet the definition of DME. For this reason, they cannot be considered speech-generating devices for Medicare coverage purposes.**
>
> A device that is useful to someone without severe speech impairment is not considered a speech generating device for Medicare coverage purposes.

(Emphasis added.) A full copy of CIM, § 60-23 is attached.

The three paragraphs quoted above provide examples of non-covered devices. The first and third of these paragraphs describe how to identify an excluded device: look at its *functional capabilities.* If the device is capable of running software for purposes other than speech generation, or, if it is useful to someone without speech impairment, it is not a dedicated device, and is non-covered.

The second example, by contrast, does not focus on the functional capabilities of the device, but on its *appearance or design.* Neither of these characteristics is a relevant factor related to Medicare coverage of an item of durable medical equipment. This example fails to acknowledge that both laptop computer- and PDA-based SGDs can be made to function as dedicated devices consistent with the first and third examples, and should, therefore, be covered as are other dedicated devices.

When modified to be a dedicated speech generating device, there is no basis to assert that a dedicated-laptop-based or dedicated-PDA-based device is "not medical in nature." Computers and PDAs generally are not medical in nature because of their wide general-

purpose functionality. But when modified to be dedicated devices, they will not be distinguishable, except by their appearance and design, from a Dynavox or Dynamyte, two dedicated devices which are generally recognized as covered.

Medicare should not be favoring one product design over another, particularly when they are functionally indistinguishable. This is particularly true for AAC devices, the different models of which are intended for use by individuals with different physical abilities and communication needs. For example:

>> laptop computer-based AAC devices include the Freedom 2000, the AAC device used by Professor Stephen Hawking, who has Amyotrophic Lateral Sclerosis (ALS or Lou Gehrig's Disease). The Freedom 2000 is often recommended for people with ALS because its AAC software includes powerful word prediction and abbreviation expansion features that are extremely well adapted to message assembly by scanning. It creates the potential for users to approximate normal conversational rate, content and accuracy.

The AAC software that runs on the Freedom 2000 does not run on dedicated devices such as the Dynavox or Dynamyte, or the dedicated devices manufactured by the Prentke Romich Company.
The Freedom 2000 can have its capabilities altered so that it functions solely as a dedicated speech generating device. However, because it is based on a laptop computer, no matter how it may be modified, it is excluded *per se* by this example in the NCD.

>> PDA based devices are a new platform on which AAC devices are built. These devices are unique based on their size and portability. They are far smaller and lighter than the Dynamyte, which is advertised for its portability. The PDA based devices weigh a few ounces and can fit in a pocket. The Dynamyte, by contrast, weighs more than 3 pounds and is carried with a shoulder strap and/or case. The PDA based devices also have newly developed software that accelerates the ability to create messages.

PDA based devices are intended for use by people with bulbar onset ALS, who lose their speech function before they lose limb function. They also will be of use to people who have had laryngectomies, but who cannot use an artificial larynx. PDA based devices also will be used by two groups of people who do not need devices with large screens: *i.e.*, people with vision impairments who use auditory scanning features, and people who construct messages by Morse Code.

As with the Freedom 2000, the PDA based devices can be made to function solely as dedicated devices. However, they will still be *per se* excluded by the NCD based solely on their appearance and design.

These are but two examples of the devices that can provide unique benefits to Medicare beneficiaries who need AAC devices, but are needlessly excluded because of the middle example in the NCD. It should also be noted that both the computer-based devices and the PDA based devices -- even after they are modified to be dedicated devices -- are less costly than the "purpose-built" dedicated devices currently covered in the K 0544 code.

We seek to meet with you and for HCFA to re-examine the NCD on SGDs because there is no legitimate Medicare interest in excluding devices on the basis of their appearance or design, as compared to their functional abilities. If the underlying policy concern for this limitation is fraud prevention: i.e., to prevent individuals without severe communication impairments from using Medicare funds to purchase a computer, that risk is completely addressed by insisting that all AAC devices/SGDs be "dedicated speech generating devices." But once that functional limitation has been satisfied, there is no further legitimate Medicare interest in the component parts from which a device is assembled or the way it appears.

Luckily, a simple solution exists that will satisfy Medicare policy concerns and also allow the full range of AAC devices to be available to Medicare beneficiaries who need them. We would like to review that proposed solution with you at the requested meeting.

Specifically, as noted above, the AAC devices that are based on laptop computers and PDAs can be made to function solely as dedicated speech generating devices, consistent with the first and third examples of the NCD. Prototypes of these devices have been built, and we would like to discuss the limitations on their functions and show them to you and to other HCFA staff. We also would like to discuss with you the solution that will make these devices, as dedicated devices, able to be covered by Medicare. Our proposal is for HCFA to delete the middle example of non-covered devices now stated in the NCD. To do so will leave intact Medicare's policy decision to require all SGDs to be dedicated devices. But, it will not exclude classes of devices that offer unique benefits.

We ask to meet with you to discuss these matters as soon as possible. The flaw in NCD 60-23 will cause many individuals to be unable to obtain the most appropriate SGDs that will meet their communication needs. Medicare will thus become the only health benefits program that interferes with the role of the patient's speech-language pathologist and physician to identify, recommend and prescribe an SGD.

Also, there is an urgent need to address this issue because among the people who are intended users of the now excluded devices are people with ALS. As you know, ALS is a progressive impairment and it is one of the neurological conditions most closely associated with AAC device need. The professional literature estimates that 75 % of all individuals with this condition will lose functional speech prior to death, and AAC device use is recognized as part of the standard of care for ALS treatment. In addition, people with ALS were just exempted by Congress from the standard 24 month waiting period for Medicare following disability onset. Thus, just as Congress has eased the requirements for Medicare eligibility, and coincidentally, as HCFA is initiating coverage for AAC

devices, people with this condition -- because of this flaw in NCD 60-23 -- will not be able to select the device most appropriate device to meet their needs.

We believe that the deletion of the middle example of NCD 60-23 is a discrete, corrective action that will eliminate the unnecessary limitation on the scope of AAC devices/SGDs, while not involving any compromise by HCFA on Medicare coverage principles. To be covered, AAC devices will continue to be dedicated speech generating devices, thus eliminating any risk that people without severe communication impairments will want them.

Please contact me by telephone or e-mail to schedule this requested meeting.

Thank you.

Sincerely,

Lewis Golinker

cc: Jeff Kang, M.D.
Sean Tunis, M.D.
Tom Hoyer
Henry Claypool
Robert Hoover, M.D.
Paul Hughes, M.D.
Adrian Oleck, M.D.
Paul Metzger, M.D.
Kenneth Nelson, M.D.

Organizations Participating in the Coalition:

American Speech-Language-Hearing Association
Amyotrophic Lateral Sclerosis Association
Brain Injury Association
Center on Disability & Health
Communication Aid Manufacturers Association
Communication Independence for the Neurologically Impaired
International Society for Augmentative & Alternative Communication
National Association of Protection & Advocacy Systems
National Multiple Sclerosis Society
RESNA
United Cerebral Palsy
United States Society for Augmentative & Alternative Communication