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Director

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Jeffrey Kang, M.D.
Director, Office of Clinical Standards and Quality
Health Care Financing Administration
7500 Security Boulevard
Mailstop S3-25-25
Baltimore, Maryland 21244

Dear Dr. Kang;

We are pleased to submit for your consideration this Formal Request for a National Coverage Decision regarding Augmentative and Alternative Communication (AAC) devices. AAC devices are a class of medical devices that restore the ability to speak for individuals with severe communication disabilities. 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 for Disability, Aging, and Long-Term Care Policy, who has cerebral palsy, also uses an AAC device to speak.

Both Bob Williams and Stephen Hawking have severe dysarthria, which, along with apraxia, and aphasia, are the three communication disabilities recognized by the professional literature and by clinical practice as the impairments most closely associated with AAC device need and AAC device use. For Williams and Hawking, and for others with these severe communication disabilities, it is impossible, using natural speech techniques, to meet the communication needs arising in the course of their daily activities. Instead, they must rely on AAC interventions, including electronic voice-output AAC devices, to achieve functional communication.

In mid-June, HCFA staff contacted the Assistive Technology Law Center and suggested that a Formal Request for an AAC device National Coverage Decision be submitted. We then worked together to identify the types of information that will facilitate HCFA's review of this

matter. That process was completed in mid-August after a series of meetings with HCFA staff.

Since then, fourteen distinguished health care professionals, who are the recognized leaders in AAC research, education and clinical practice, worked to prepare this Formal Request. These AAC professionals are identified in **Section 2**; their professional qualifications and experience are described in **Appendix I, Tab A**. Their work product -- the attached Formal Request -- provides a solid foundation for Medicare coverage of AAC devices. It describes the professional literature and current clinical practice standards for severe dysarthria, apraxia and aphasia, and the detailed assessment and clinical decision making process that precedes an AAC device treatment recommendation (**Section 3**). It also explains how AAC interventions satisfy all the relevant statutory standards required for Medicare coverage (**Section 4**), and the characteristics of the 3 technologically and clinically distinct categories of AAC devices that currently exist (**Section 5**). Lastly, these AAC professionals have crafted proposed coverage criteria (**Section 6**), and have volunteered to respond to questions from the DMERC Medical Directors or other Medicare decision makers who will review AAC device claims. (**Appendix I, Tab C**).

In addition, this Formal Request is being submitted on behalf of 13 organizations which represent the interests of Medicare beneficiaries, assessment and treatment professionals, AAC device manufacturers and advocates. All these organizations and the individuals they serve have direct interests in the development of appropriate, professionally sound Medicare coverage policy for AAC devices. They include: American Speech-Language-Hearing Association, National Multiple Sclerosis Society, United Cerebral Palsy Associations, Sunrise Medical, RESNA, Amyotrophic Lateral Sclerosis Association, Brain Injury Association, Center on Disability and Health, Communication Aid Manufacturers Association, Communication Independence for the Neurologically Impaired, International Society for Augmentative & Alternative Communication, National Association of Protection & Advocacy Systems, and the United States Society for Augmentative & Alternative Communication.

The AAC professionals who prepared these materials remain ready to respond to questions, participate in discussions, and provide additional information or to otherwise facilitate your staff's understanding of these materials and hopefully, adoption of the proposed AAC Device National Coverage Decision. In addition, as we mentioned in a July meeting with Tom Hoyer, Shana Olshan and other HCFA staff, we are available to provide a presentation that describes AAC devices for your staff.

Again, on behalf of the above named organizations and all the individuals who will benefit from Medicare coverage of AAC devices, we appreciate your prompt consideration of this request. We understand that a final determination on this Formal Request will be made by March 31, 2000.

Thank you.

Sincerely,

Lewis Golinker
Director