ASSISTIVE TECHNOLOGY LAW CENTER

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TRICARE Management Authority
16401 East Centretech Parkway
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RE: Comments to Proposed Regulations
Related to Tricare Coverage of Augmentative
Communication Devices

Dear Sir or Madam:

The Assistive Technology Law Center provides nationwide technical assistance services to support and expand the coverage and funding of assistive devices needed by individuals with disabilities. Created in 1995, the ATLC has worked with state and federal government agencies, as well as individuals, services professionals and advocates to expand coverage of assistive devices by Medicare and Medicaid programs, and commercial insurance providers.

In June 1999, for example, the ATLC was requested by the Administrator of the Health Care Financing Administration, HCFA (now the Centers for Medicare & Medicaid Services, CMS), to work with Medicare program staff in a re-review of Medicare coverage of Augmentative & Alternative Communication (AAC) devices. The ATLC coordinated the effort to develop the *Formal Request for National Coverage Decision for Augmentative and Alternative Communication Devices*, (1999). The *Formal Request* was the primary resource Medicare staff relied on to rewrite its AAC device coverage policy.

Since the adoption of Medicare AAC device (speech generating device) coverage criteria in January 2001, the ATLC has continued to work with Medicare staff to resolve additional issues related to Medicare AAC device coverage. These include Medicare acceptance of coverage for dedicated-computer-based AAC devices, and most recently, the replacement of codes for digitized speech output devices. The ATLC also has trained Medicare DMERC staff regarding AAC device/SGD characteristics, and provided extensive training and support services to speech-language pathologists.

We write today to provide comments to [redacted] Tricare regarding its proposed regulations, published at 68 Federal Register 18575 (April 16, 2003), specifically, its references to Augmentative and Alternative Communication (AAC) Devices or speech generating devices.

Our initial comment is to applaud the decision by Tricare to adopt the Medicare AAC device/speech generating device (SGD) coverage criteria. The Medicare criteria were developed following a year and a half review procedure that included input from every element of the AAC community: speech language pathologists, disability organizations, physicians organizations, advocacy organizations and the manufacturers of AAC devices. Medicare's policy development for AAC devices was based on a review of the published professional literature, as well as extensive contact between Medicare staff and the nation's leading AAC researchers, educators and clinicians.

The coverage criteria that Medicare adopted, published in 2 guidelines: National Coverage Decision 60-23, and the Regional Medical Review Policy for Speech Generating Devices (attached), are recognized as consistent with current best practices in AAC assessment and documentation. Both Medicaid programs as well as insurers (such as Aetna, the nation's largest managed health care provider, and Care First Blue Cross-Blue Shield of Maryland), have formally adopted the RMRP's assessment and documentation requirements for their own use. Others rely on the RMRP informally.

The adoption of the RMRP on Speech Generating Devices and NCD 60-23, also has led to coordination of continuing professional education efforts for speech language pathologists. Beginning in the Spring, 2001, an extensive SLP education program related to these guidelines has been undertaken under the leadership of the U.S. Department of Education funded Rehabilitation Engineering Research Center (RERC) on AAC. In-person training sessions related to AAC assessment and documentation, and based on the RMRP have been provided at each of the major assistive technology and Speech-Language Pathology conferences each year (Assistive Technology Industry Association (ATIA); CSUN; RESNA; Closing the Gap; and ASHA). For those unable to attend such conferences, an audio conference training series was sponsored by ASHA, and an ongoing web-cast training series has been provided through a grant to the Kornreich Center, of the National Center for Disability Services. And, for all SLPs' use, detailed, written materials explaining the SLP's assessment and documentation requirements consistent with the Medicare RMRP have been prepared and are posted at the AAC-RERC's web page.

In short, Tricare's adoption of the Medicare AAC device/SGD coverage criteria is an excellent decision.

AAC Device/SGD Assessment & Documentation Criteria

Substantively, it is noteworthy that the proposed regulations incorporate only the National Coverage Decision on Speech Generating Devices, NCD-60-23. It is equally important, if not of greater importance, that Tricare also adopt the Medicare Regional Medical Review Policy on Speech Generating Devices. The NCD is focused on a definition of AAC devices, or more generally, on the types of AAC devices that are covered. The RMRP, by contrast, focuses on the assessment and documentation requirements related to identification of AAC device need, and the decision making leading to AAC device recommendation.

It is strongly recommended that Tricare adopt the RMRP either as part of its regulations for AAC devices/SGDs, or include them as operating instructions in the Tricare Policy Manual.

AAC Device/SGD Definition

A second comment is directed to the incorporation of the definitions of the "codes" established by Medicare for AAC devices. The proposed regulations include 4 definitions for different types of AAC devices, and a fifth definition for AAC software. We question whether including these highly specific definitions in the Tricare *regulation,* is appropriate. Medicare's National Coverage Decisions and Regional Medical Review Policies are *sub-regulatory* guidance, and thus, can be changed, as necessarily, with a minimum of administrative effort or time delay. Regulations, by contrast, are not subject to easy change. The concern presented here is that Tricare may find it difficult to be responsive in a timely manner to subsequent changes in Medicare's coverage criteria.

For example, Medicare announced in early May, 2003 that it was replacing one of the codes for digitized speech output devices: those with greater than 8 minutes of recording time, with 3 codes. The K 0542 code will be replaced with K 0615 for digitized speech output devices with between greater than 8 and 20 minutes of recording time; K 0616 for digitized speech output devices with between greater than 20 and 40 minutes of recording time; and K 0617, for digitized speech output devices with greater than 40 minutes of recording time. These codes go into effect on July 1, 2003. Although these changes do not change the substantive scope of coverage of AAC devices/SGDs (these code changes merely re-group these devices for Medicare payment purposes), this example illustrates the relative freedom Medicare has to change its coverage rules: from announcement to operation within 60-75 days, which would not be possible for a formal regulatory change.

We propose that Tricare adopt a more general definition of AAC devices in its regulations, leaving the specific distinctions among the types of AAC devices for either the policy or payment manual. For example, a definition of AAC devices proposed for adoption by Texas Medicaid (and which is a synthesis of AAC device definitions in other similar policies) describes these devices as follows:

> An augmentative communication device (ACD) or speech generating device (SGD) allows the client to overcome the disabling effects of an expressive speech-

language disorder so that the client is able to meet his/her daily communication needs.

This is a functional definition of AAC devices, focused on how they provide benefits to their users. An additional sentence focused on the coverage limiting factor of "dedication" will address in full all of the elements of the 8 sub-divisions of the AAC device definition now stated in the Medicare NCD, and the proposed Tricare regulations.

> An augmentative communication device (ACD) or speech generating device (SGD) allows the client to overcome the disabling effects of an expressive speech-language disorder so that the client is able to meet his/her daily communication needs. To be covered by Tricare, an ACD or SGD must be a dedicated speech output device, that is useful only to an individual with a severe speech or expressive communication impairment.

This definition will not result in any devices being covered by Tricare that are not covered by Medicare. Its advantage as a substitute for the definition proposed by Tricare is that it will give Tricare the flexibility to respond to changes in Medicare's sub-regulatory coverage criteria.

Alternately, as a minimum, Tricare should amend the proposed regulations definition of digitized speech output AAC devices to reflect the new codes/definitions that Medicare has adopted for these devices.

Dedicated Devices / Computer and PDA-based SGDs

Another substantive comment is directed to Tricare's inclusion of the Medicare NCD's exclusion of computer and PDA based devices. Medicare's exclusion of these devices is limited in a way not mentioned in the formal language of the NCD. Specifically, Medicare's exclusion led the manufacturers of these devices to develop "dedicated computer" and "dedicated PDA" based devices. These devices run only AAC software; they do not allow a user access to any of the other programs or operations available to the user of a computer or PDA.

By telephone call and letter dated April 17, 2003, I explained to Ann Fazzini that Medicare staff was given an in-person orientation in which they examined these new devices, and as a result, Medicare accepted them as covered. We request that a copy of the May 4, 2001 letter from Thomas Hoyer, the Medicare staff member responsible for DME coverage, be incorporated with these comments. Mr. Hoyer's letter states that these devices will be covered by Medicare, and in fact, they have been and continue to be covered.

Mr. Hoyer's letter noted that we had agreed that no vocabulary changes were necessary to the NCD. As long as Medicare was willing to cover these devices when claims were submitted, i.e., that in practice it accepted that "dedicated-computer" and "dedicated-PDA" based devices were "dedicated" as required by the NCD, that was sufficient.

We request that Tricare also adopt this Medicare conclusion and apply it to claims that will be presented for Tricare payment for dedicated-computer and dedicated-PDA based AAC devices.

No change in the proposed regulatory text will be necessary if Tricare includes this discussion in its response to these comments when the final AAC device coverage rules are adopted.

Alternately, we propose an additional sentence be added to the Tricare definition of AAC devices:

> (ii) laptop computers, desktop computers, or PDAs, which have been manufactured as dedicated speech devices will be covered. Laptop computers, desktop computers or PDAs , which may be programmed to perform the same functions as a speech generating device, are not covered since they are not ....

Or, if Tricare adopts the proposed AAC device definition stated above, the following can be added to address this point of clarification:

> An augmentative communication device (ACD) or speech generating device (SGD) allows the client to overcome the disabling effects of an expressive speech-language disorder so that the client is able to meet his/her daily communication needs. To be covered by Tricare, an ACD or SGD must be a dedicated speech output device, that is useful only to an individual with a severe speech or expressive communication impairment. Laptop computers, desktop computers, or PDAs, which have been manufactured as dedicated speech devices will be covered.

Conclusion

We recommend Tricare adopt these recommended changes to the proposed regulations. They are intended only to clarify the scope of coverage Tricare has proposed, *i.e.*, to parallel the scope of AAC device/SGD coverage adopted by Medicare. These changes will not expand or otherwise change this proposed scope of coverage. Instead, they will (a) ensure that Tricare beneficiaries will benefit from application of best current assessment and reporting protocol; (b) give Tricare more flexibility to mirror future changes that Medicare may adopt for AAC device coverage; and (c) they will clarify that one type of device: dedicated computer and PDA based devices, are covered by Tricare as they are by Medicare.

We also wish to extend an offer to conduct training regarding AAC devices, AAC assessment and documentation to Tricare staff and the speech-language pathology and medical professionals who will be evaluating and treating Tricare beneficiaries. As noted above, this training has been given to Medicare staff, including staff at all four DME regional carriers, and Medicare's central office staff.

Finally, already we have been contacted by a small number of Tricare beneficiaries who have been recognized as having current AAC device needs, but who cannot yet receive them because Tricare refuses to approve AAC devices without final regulations. That there only a small number of such individuals exist is consistent with anticipated demand for these devices: although they are of great importance and value, AAC devices are a very low incidence need among individuals with disabilities.
These individuals have no treatment alternative and they will experience severe harm because of their inability to meet daily communication needs. For this reason, we urge Tricare to adopt these

rules, with the suggestions made herein, as soon as possible. If possible, Tricare should adopt these regulations independently: separate from the others that were incorporated as part of the notice of proposed rulemaking.

Please contact the undersigned if we can provide any further information, or if you wish to pursue the offer of training for Tricare staff and professionals.

Thank you.

Respectfully submitted,

Lewis Golinker, Esq.
Director

Attachment: Medicare NCD 60-23
RMRP on SGDs
April 17 letter to Ann Fazzini