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October 12, 2005

Mr. Sean Dalenberg
Centers for Medicare & Medicaid Services
Mailstop C5-08-27
7500 Security Boulevard
Baltimore, Maryland 21244

RE: DME Competitive Bidding
Exemption for Speech Generating Devices

Dear Mr. Dalenberg:

The Assistive Technology Law Center (ATLC) submits these comments in support of the exemption of Speech Generating Devices (SGDs) and related items from Medicare "competitive bidding."

These comments are submitted on behalf of all parties interested in Medicare coverage of SGDs: Medicare beneficiaries; the speech-language pathologists (SLPs) who determine patients' need for an SGD and who provide SGD treatment; the manufacturers of SGDs; and advocates. The organizations on whose behalf these comments are submitted include the:

American Speech-Language-Hearing Association (ASHA);
Assistive Technology Industry Association (ATIA);
Assistive Technology Law Center (ATLC);
Dynavox Technologies;
International Society for Augmentative & Alternative Communication (ISAAC);
Rehabilitation Engineering and Assistive Technology Society of North America (RESNA); and
United States Society for Augmentative & Alternative Communication (USSAAC).

Please take note that the individuals and organizations responsible for the comments that follow are the same as those on whom HCFA (now CMS) and the DMERC medical directors relied to develop the current Medicare SGD national coverage determination, and the current SGD Regional Medical Review Policy (RMRP).

Summary Statement of Position

The nine HCPCS codes that comprise the product family "speech generating devices and related items" E 2500-2599, should be exempted from the Medicare competitive bidding process and procedure. The basic assumptions underlying competitive bidding are false as applied to SGDs and related items.

First, SGD models, even within the same code, are not functionally and qualitatively equivalent, such that they are able to compete on the basis of price. To the contrary, SGD models are functionally and qualitatively distinct. SGD models do not merely copy each others' capabilities. Instead, different models seek their own niche: to address still-unmet needs among patients' enormous range of physical, cognitive, sensory and linguistic functioning. For this reason, SLPs make SGD recommendations on the basis of "feature-matching" between patients' abilities and needs and the distinct functional capabilities and limitations of various SGD models.

Second, the imposition of competitive bidding is not required to ensure that Medicare SGD and related items recommendations reflect the lowest cost, equally effective alternative. That standard represents the ***current*** basis for SLP decision making, imposed by the ***current*** Medicare SGD coverage criteria. It also represents the generally accepted current standard for SLP decision making for all third party SGD funding programs.

Third, the distribution of SGDs and related items is distinct from that of other DME items. Almost without exception, distribution is made directly by the SGD manufacturer. Unless all SGD manufacturers are allowed to compete in each geographic area subject to competitive bidding, some SGD models will cease to be available, and some patients will be unable to acquire an SGD appropriate to meet their needs.

Finally, imposition of competitive bidding for SGDs and related products cannot yield significant cost savings for Medicare. Overall utilization is exceedingly low: only approximately 1,220 SGDs per year are purchased by Medicare, divided among 6 HCPCS codes. SGDs and related items may well have the lowest utilization of any DME product category covered by Medicare.

Medicare Speech Generating Device Coverage

Medicare's coverage of Speech Generating Devices (SGDs) is based on a National Coverage Determination, NCD Manual, § 50.1, Coverage Issues Manual, CIM, § 60-23 (Jan. 1, 2001). This guidance is supplemented by a Regional Medical Review Policy (RMRP), jointly issued by all four DMERCs.

The National Coverage Determination defines SGDs as:

> Speech aids that provide an individual who has a severe speech

impairment with the ability to meet his functional speaking needs.

The NCD also describes the functional characteristics of SGDs, which are reflected in the nine HCPCS codes that currently define SGDs and related items, such as software, mounting systems, and accessories:

E2500	SPEECH GENERATING DEVICE, DIGITIZED SPEECH, USING PRE-RECORDED MESSAGES, LESS THAN OR EQUAL TO 8 MINUTES RECORDING TIME
E2502	SPEECH GENERATING DEVICE, DIGITIZED SPEECH, USING PRE-RECORDED MESSAGES, GREATER THAN 8 MINUTES BUT LESS THAN OR EQUAL TO 20 MINUTES RECORDING TIME
E2504	SPEECH GENERATING DEVICE, DIGITIZED SPEECH, USING PRE-RECORDED MESSAGES, GREATER THAN 20 MINUTES BUT LESS THAN OR EQUAL TO 40 MINUTES RECORDING TIME
E2506	SPEECH GENERATING DEVICE, DIGITIZED SPEECH, USING PRE-RECORDED MESSAGES, GREATER THAN 40 MINUTES RECORDING TIME
E2508	SPEECH GENERATING DEVICE, SYNTHESIZED SPEECH, REQUIRING MESSAGE FORMULATION BY SPELLING AND ACCESS BY PHYSICAL CONTACT WITH THE DEVICE
E2510	SPEECH GENERATING DEVICE, SYNTHESIZED SPEECH, PERMITTING MULTIPLE METHODS OF MESSAGE FORMULATION AND MULTIPLE METHODS OF DEVICE ACCESS
E2511	SPEECH GENERATING SOFTWARE PROGRAM, FOR PERSONAL COMPUTER OR PERSONAL DIGITAL ASSISTANT
E2512	ACCESSORY FOR SPEECH GENERATING DEVICE, MOUNTING SYSTEM
E2599	ACCESSORY FOR SPEECH GENERATING DEVICE, NOT OTHERWISE CLASSIFIED

The SGD NCD and RMRP represent the outcome of an 18 month policy review by HCFA staff. In June 1999, the HCFA administrator contacted the Assistive Technology Law Center to announce she was initiating a re-examination of Medicare coverage policy toward what were then called “augmentative and alternative communication” (AAC) devices. The Administrator asked the ATLC to coordinate the preparation of a “Formal Request” for Medicare coverage.

A work group of the nation’s leading AAC researchers, educators, and clinicians was formed to prepare the *Formal Request for National Coverage Determination for Augmentative & Alternative Communication Devices*. This document was submitted to HCFA on December 30, 1999. It contains a comprehensive review of the medical literature related to AAC interventions and of current standards of clinical practice. It describes the neurological conditions most closely associated with SGD need and use; it outlines the speech-language pathology (SLP) assessment process, and the key clinical indicators that lead to a determination that an SGD is the appropriate form of SLP treatment; and it describes the most important characteristics of SGDs. (The *Formal Request* is posted for review at www.augcominc.com/funding.html (scroll to bottom of page))

After submission of the *Formal Request*, HCFA staff and the DMERC Medical Directors continued to work with the SLP work group for the next 16 months, until May 2001. At that time the final components of updated Medicare coverage policy were completed. This long-duration, positive working relationship shaped Medicare policy toward SGDs. Of greatest significance, it led to acknowledgement in the RMRP that the SLP is the key professional to determine the need for an SGD and to recommend the specific model of SGD and any related items. Indeed, SGDs and related items are the only category of Medicare covered items or services for which a non-physician is given primary responsibility for determination of medical need.

The *Formal Request* explained that SGDs and related items are used by individuals *with the most severe or complex* speech and language disabilities. Persons whose speech and language disabilities are less severe or less complex are served by other speech-language pathology treatment interventions. Those interventions allow the person to utilize natural communication methods, such as speaking, writing, signing or a combination of those methods to meet daily communication needs. *SGDs and related items are recommended **only** when the severity or complexity of the person's expressive communication disability makes it impossible for the person to meet daily communication needs using those natural communication methods.* RMRP, Coverage & Payment Rules, at ¶¶1(b); 3; and 4. This constitutes the "reasonable and necessary" standard for SGDs incorporated into the RMRP.

The Formal Request described the 7 most common neurological conditions that are associated with SGD need and use. These include:

Amyotrophic Lateral Sclerosis (ALS) (also known as "Lou Gehrig's Disease")
Cerebral Palsy
Locked In Syndrome
Multiple Sclerosis
Parkinson's Disease
Brain Stem Stroke
Traumatic Brain Injury

These diagnoses, however, do not equate to SGD need. Each of these conditions has a wide range of severity. As the RMRP acknowledges, the need for an SGD can only be determined upon completion of a comprehensive SLP evaluation.

The RMRP acknowledges that the SLP will play the central role in the assessment and decision making process related to SGD need. The SLP assessment is the centerpiece of the RMRP. It requires the SLP to gather data about and assess the significance of more than a dozen factors that affect both the person who ultimately will use the SGD as well as that person's primary communication partners, such as his or her spouse or primary caregiver. This broad-based inquiry is necessary because of the extraordinarily wide range of physical, sensory, cognitive, and linguistic functioning among people with severe speech and language disabilities. People with SGD needs range from having no physical impairment beyond their loss of speech, to being "locked in" to the point where "eye gaze" or "eye blinks" are their only volitional movements. Cognitively, people with SGD need range from having mental retardation or having aphasia, to having the abilities of Stephen Hawking. In addition, not only must the SLP assessment focus on the

individuals involved in communication, it also must consider the primary environments in which communication with the SGD will occur. All of these factors can have SGD selection implications.

The assessment process required by the RMRP leads to a specific SLP recommendation. The SLP must determine SGD need, and recommend *a specific SGD model, plus all necessary related items, such as software, a mount, or accessories.* Moreover, it is a general element of SLP practice to recommend the least costly equally effective alternative. This applies to all Medicare SGD recommendations as well as the recommendations made to all third party funding programs.

Finally, the RMRP acknowledges the professional and financial independence of the SLP. SLPs who conduct SGD assessments have no connections to either the SGD manufacturers or suppliers. Their recommendations reflect solely their professional judgment about the most appropriate SGD and related items needed to meet the Medicare beneficiary's functional communication needs.

Viewed as a whole, the Medicare National Coverage Determination and RMRP for Speech Generating Devices supports Medicare SGD coverage without limitation.

As noted above, the *Formal Request* described *who* are the Medicare beneficiaries who will seek SGDs, and *how* their need for an SGD will be identified. In addition, the *Formal Request* described *how many* SGDs will be sought. Demographic research about persons with severe communication impairment support estimates that the need for SGDs will arise among 0.12 percent of the general population. Within a U.S. population as a whole of almost 300 million persons, the total "need" for SGDs is approximately 360,000. Within the approximately 38 million Medicare beneficiaries, approximately 46,000 have current SGD needs. The data presented in the *Formal Request* also made clear that SGD "need" and SGD "demand" are distinct. Annual SGD demand (and correspondingly, SGD costs to Medicare) will be an exceedingly small subset of SGD need.

Once again, the focus falls on the SLP. Every person seeking an SGD must first be assessed by an SLP, but SLPs who conduct SGD assessments are in exceedingly short supply. Many factors limit the number of SLPs working with this population. The patient population is exceedingly small, and represents individuals with the most severe and complex communication, physical, cognitive and sensory disabilities. SLPs require an extensive, ongoing commitment to continuing professional education. Moreover, other forms of SLP treatment receive higher levels of reimbursement. In addition, many SLPs with these skills are employed full time by schools and therefore are not available to serve the primarily adult Medicare beneficiary population. Another factor limiting SLP supply is that SLPs are not able to work independently as Medicare services providers. Taken together, these limitations will allow fewer than 3 percent of persons with SGD need to be able to seek Medicare reimbursement per year. Of 46,000 Medicare recipients with current needs, the *Formal Request* estimated that no more than 1,320 SGD claims will be submitted annually if Medicare adopted favorable SGD coverage policy.

These estimates are consistent with Medicare's actual claims experience. In the four years between 2001 and 2004, only approximately 1,211 Medicare recipients have acquired SGDs, per year, divided across 6 HCPCS codes. Total Medicare SGD expenditures, since coverage began four years ago, is less than $ 27 million. SGDs may well have the lowest utilization of any DME product family covered by Medicare.

Imposing Competitive Bidding On SGDs Will Have Significant Adverse Impacts On Medicare Beneficiaries

A competitive bidding process or procedure, if applied to SGDs and related items, will have significant adverse impacts on Medicare beneficiaries. The underlying assumption for competitive bidding is that Medicare beneficiaries now have access to multiple device choices that are sufficiently similar in function and quality, but which vary in price. Competitive bidding is intended to force these functionally and qualitatively equivalent items to compete on the basis of price. For SGDs, however, that fundamental assumption is not accurate: SGDs, even devices within the same HCPCS code, are not functionally or qualitatively equivalent.

Because SGD models are not functionally or qualitatively equivalent, imposing competitive bidding will substantively alter the scope of Medicare SGD coverage. As noted previously, the present scope of Medicare SGD coverage is *without limitation*, *i.e.*, any Medicare beneficiary will be able to acquire the SGD that will meet his or her functional communication needs. Imposing competitive bidding, however, will reduce the scope of SGD models available to Medicare beneficiaries. This will cause some Medicare beneficiaries to be able to access *no* SGD that will meet their needs. Other Medicare beneficiaries will not have access to the most effective SGD.

These results are not consistent with the Congressional purpose or intent for competitive bidding. Congress assumes competitive bidding will be applied under existing substantive DME coverage rules. For SGDs, this simply is not possible.

SGDs are organized into 6 HCPCS codes (with 3 others assigned to related items such as software, mounting systems and accessories). Upon review, the characteristics that define these codes are very broad. The four codes for digitized speech output devices consider only 2 factors: type of speech output (digitized) and amount of recording time. The 2 codes for synthesized speech output devices also consider only 2 factors: type of speech output (synthesized) and means of access (direct selection and spelling; or multiple methods).

By using only these pairs of characteristics to distinguish the SGD codes, the individual models that fit within each have very wide physical and functional variations. SGDs differ greatly in four ways. Within each code:

- **SGD models do not have the same features**; *E.g.*
    - SGDs have either dynamic or static displays (it is the SLP's responsibility to determine whether the client has the *physical* ability to use and the *cognitive* ability to understand the storage and organization techniques associated with a dynamic display; otherwise, only a static display SGD

will be appropriate. If a client lacks the *physical* ability to change the paper overlays of a static screen display independently, a dynamic screen SGD is the only way the client can communicate independently. A client with limited support from caregivers or spouse for programming the SGD may be more appropriate for a dynamic display SGD because they enable messages to be added or deleted easily or easily moved from one page or level to another.);

- Among the digitized speech output SGD models, only some support indirect access (scanning) while others require direct selection (activation by touch);
- Some SGDs produce synthesized speech only, while others offer a mix of digitized and synthesized speech (an SGD with both types of speech output is particularly important for patients who communicate with partners who speak English during part of the day (*e.g*., caregivers), and Spanish during another part of the day (*e.g*., family members));
- Only one model-family of SGDs offers visual output as well as speech output (this feature is especially important for communication partners who are hearing impaired, a relatively common factor considering the Medicare population and the effects of presbycusis, the normal age-related reduction in hearing ability);
- Some patients require feedback from the SGD to ensure they are properly constructing their intended message. Some SGD models will provide auditory feedback, visual feedback, tactile feedback, but the models vary in which type of feedback, if any, they offer;
- The most common access method for SGDs is direct selection by the client's finger. Other patients, however, require other means of access. This may include single switches, multiple switches, joysticks, optical pointers. SGD models vary in regard to the types of alternative access methods they will support. (It is the SLP's responsibility to determine which is the most effective and efficient access method, and to identify the SGD model(s) that will support that access method.);
- Only two models of SGDs offer access to persons who must rely on eye gaze to activate their device (patients who require eye-gaze are the most severely physically disabled of all persons who require SGDs; no other SGD models will be of any benefit);
- Only a few SGD models allow messages to be produced by use of Morse code, an important tool for patients with severe mobility limitations and who must rely on a head-activated switch to activate their SGD;
- Some SGDs offer rate enhancement techniques to speed up the rate of message formulation. Pre-storage of messages; abbreviation expansion; letter, word or phrase prediction are common means of rate enhancement. Not all SGDs have this capability and not all SGD models offer the same rate enhancement techniques;
- For AAC accessories, mounts and software, Medicare acknowledged the wide inherent differences in their functional characteristics by abstaining from developing a fee schedule for any of these items. Instead, they are priced individually;

- **Even if the same components or features are present, they do not function in the same way**; *E.g.,*

  - The cell or key sizes of many digitized speech output SGDs are distinct, ranging from ¾ inch to 1 1/8 inch square; some are fixed; others can be re-sized or shaped (an important consideration for a client who has limited fine motor control (the client must be able to hit (touch) a target with these dimensions, or s/he will not be able to produce messages accurately);
  - The display of most SGD models is arranged in the form of a "grid," with multiple rows and columns of cells or keys from which messages are selected or produced. These grids vary in size from model to model: they include grids of 1x3; 2x4; 2x5; 2x10; 4x6; and 8x16. Some of these grids are fixed, while other models allow them to be resized. (The SLP must ensure the client has the physical ability to reach and accurately select all the cells on the grid, as well as have access to an efficient amount of vocabulary to be able to communicate effectively.);
  - The layouts of new SGD models are arranged in other than grid format, based on the *cognitive* abilities and needs of patients (*e.g.* people with aphasia) to see their communication choices in specific contexts;
  - Among the keyboard based devices, E 2508, one model-family is useful only for one or two finger typing, while the other 2 models allow touch-typing;
  - Among the keyboard based devices, E 2508, one model-family has its speakers on the bottom of the device, which affects both loudness and speech clarity when the device is placed in the client's lap or on a solid surface; the other models have the speakers placed on the back of the device facing the communication partner. The size of the speakers also varies among these devices, which affects both speech output loudness and clarity. As a result, even though all of these SGDs produce synthesized speech and access the same synthesis software, they produce sound of different loudness and clarity;
  - Among the many SGD models that support indirect access (scanning), there are significant variations among SGD models in the degree to which the method of scanning can be controlled. Scanning methods and techniques include linear, row-column, block, automatic, inverted and step scanning, but not all SGD models support each, and not all models offer the same degree of control over scanning speed;

- **Among synthesized speech output devices are those that function very differently because their operating software is different;** *E.g.,*

  - SGD speech synthesis software governs the operation of SGDs in the E 2508 and E 2510 codes. These software programs are unique to specific device models, and are not interchangeable.
  - SLPs must make a precise "fit" between a client's most effective method of assembling or producing messages and the software program that supports that method. For example, software in specific SGD models will allow production of messages from a wide variety of inputs: letters, whole words, phrases, or fully formed messages; as well as picture symbols and

actual photographs. But not all software will support all of these options. Also, only one software program will allow picture symbols to be assigned "multiple meanings," *i.e.*, they will produce different words and messages based on the combination of symbols used, and the order in which they are assembled in the message. All other software assigns picture symbols single meanings. The SLP must determine which of these input options is the most effective for the client, including whether combinations of methods is necessary;

- The SLP also must consider how the software operates, *i.e.*, how difficult or complex is the task of adding and storing new messages; and how other aspects of device operation controlled by the software, e.g., word pronunciation, and rate enhancement techniques operate. These functions will differ from program to program and correspondingly, among SGD models

- **The support offered by the SGD manufacturers is different**; *E.g.*,

  - A necessary, close, and lifelong tie must exist between SGD users and the SGD manufacturer. Patients and their caregivers or spouses remain in periodic contact with the SGD manufacturers to address a wide range of issues. SLPs must consider how the manufacturers conduct this ongoing customer support as part of their SGD selection determination. The manufacturers vary in terms of the amount and quality of support offered by phone; through the manufacturer's web-site; the clarity of its written materials; the ease of use of search tools for access to on-line information; whether upgrades to software are distributed for free for the life of the product; whether narrower solutions to specific issues or operational problems are circulated to existing owners of specific models; how repair is handled;
  - The SGD manufacturers vary in the size and geographic distribution of their support staffs; for patients and communication partner who will need a lot of support in order to learn how to operate the SGD effectively, it will be very valuable to select an SGD model that can be readily supported by staff that is close at hand and able to make a home visit;
  - The SGD manufacturers also vary in their reputations for repair, technical assistance and other aspects of device operation.

Because the SGD models are so different, and the examples provided above are mere illustrations rather than a list of the extent of their differences, the SLP's role in the assessment process is to rule out models – not on the basis of price – but instead, on the basis of "feature-matching" between the device model and the needs and abilities of the intended user. SLPs who conduct SGD assessments must know the characteristics of the various device models within each code, and apply them to the myriad of individual facts gathered during the assessment process. Ultimately, the SLP must recommend the SGD model with the features that best match the characteristics of the individual, primary communication partner and communication environment. In other words, the physical and functional differences among the SGD models, even within a code, have important selection or recommendation implications. Moreover, often the SLP, the Medicare beneficiary and his or her primary communication partner must choose between

competing functional characteristics of SGD models because the individual, partner or communication environment imposes needs that no one device most appropriately satisfies.

The leading treatise on AAC intervention, D. Beukelman & P. Mirenda, Augmentative & Alternative Communication (3d Ed.)(Baltimore: Brookes Publ. 2005), describes the feature matching process as one of the primary ways in which AAC assessment is conducted, and always has been conducted. Its roots date back to the mid-1980s. Beukelman & Mirenda describe it as follows:

> Several authors have suggested predictive profiling or *feature matching* as an extension of the criterion based approach (references omitted). In the predictive assessment approach, the team first assesses the capabilities of the individual using ***a number of carefully selected, criterion referenced tasks***. Based on the results of this assessment, the AAC team then predicts the efficiency with which the individual might utilize one or more devices or techniques. . . . Feature matching requires that the AAC team members be knowledgeable about the operational and learning requirements of a wide variety of AAC options. . . .

Id. at p. 161(emphasis supplied)

The SLP assessment mandated by the RMRP was based on extensive input from Dr. Beukelman and other leading AAC professionals, and consequently it incorporates this feature match process. It states "a number" – more than a dozen – "carefully selected, criterion referenced" sources of data must be collected during the assessment process. Included among these are:

- the Medicare beneficiary's impairment type and severity;
- the anticipated course of the person's physical and speech or language impairment;
- for the Medicare beneficiary and primary communication partner:
  - hearing status;
  - vision status;
  - physical status;
  - cognitive status;
  - language skills; and
- daily communication needs, including primary communication partners and communication environments.

Then, the assessment process requires the SLP to conduct a "feature match" to determine which SGD model, and if necessary, which related items of software, mounting system and accessories will be best able to accommodate all these abilities and needs. This task is spelled out in instructions for SLPs using the Medicare RMRP – whether for Medicare funding or SGD funding by other systems of health benefits – that were developed by the same SLP work group that prepared the *Formal Request* and advised HCFA and the DMERC medical directors. Those instructions state:

> V. Rationale for Device Selection

> This section [of the SLP report] will explain why certain device features are required based on the person's skills and abilities as described in Section II [complete functional assessment.] This section provides data that leads first to the selection of a specific device code and second to a specific device within that code, as well as specific accessories.

Medicare SLP Assessment Protocol, posted at http://www.aac-rerc.com/pages/medicare/MCAppProtocol.htm.

The instructions continue to state that matching of the individual's (and often the primary communication partner's) specific abilities or needs to the features of specific SGD models requires consideration of at least the following:

- **Selection technique**, *e.g.*, direct selection or scanning, including whether the display type should be dynamic or static, how many keys (cells) are on the display and how they are arranged; whether an electronic aid to direct selection will be used; whether eye gaze will be required; for scanning, how the scanning will be conducted – row column; linear; group-row; etc.; whether scanning will be directed by a joystick or trackball; for switches, how much pressure they require; must they provide feedback, such as tactile or auditory feedback; positioning of the switches and mounting for them;
- **Input features, and encoding**, *e.g.*, what will the user see and use to create or produce messages: will they be letters, words, phrases, picture symbols, actual photographs; will Morse code be used to produce messages; will semantic compaction be used; how must these items be arranged on the display
- **Message characteristics or features**, *e.g.* what is the message length needed; are many pre-formed messages needed; how are they to be stored and organized for retrieval;
- **Rate enhancement techniques**, *e.g.*, letter, word or phrase prediction; abbreviation expansion; screens or levels; other techniques;
- **Output features**, *e.g.*, type of voice output; loudness and clarity of speech output; visual output as well.
- **Characteristics of the visual display;** *e.g.*, size, contrast, color or black and white; and
- **Feedback needs**, *e.g.*, is visual or auditory or tactile feedback needed.

In short, the physical, sensory, cognitive and linguistic differences among people with SGD needs and their primary communication partners, the differences in the environments in which SGDs will be used, and the physical and functional differences among the device models themselves belie any suggestion that SGD models, even within a single code, are functionally or qualitatively equivalent, and therefore, can be subject to competitive bidding on the basis of price.

In addition to all of the foregoing, SGDs are distributed in a way that is distinct from almost all other Medicare DME product categories. SGDs are distributed almost exclusively by their manufacturers, and ***not*** by dealers or re-sellers. Some manufacturers, *e.g.*, Zygo, distribute nationally from their company headquarters and manufacturing

facility, located in Portland, Oregon. The three largest SGD manufacturers, Dynavox Technologies, the Prentke Romich Company, and Assistive Technology, Inc., use re-sellers in six or fewer states, and distribute their SGD models directly to all other locations from their company headquarters and manufacturing facilities in Pittsburgh, Pennsylvania, Wooster, Ohio, and Dedham, Massachusetts, respectively.

The effect of this distribution system is that in almost all locations throughout the country, and for almost all SGD models, particularly in the E 2508 and E 2510 codes, there will be a sole source of supply. Imposing competitive bidding on this distribution framework will result in the elimination of Medicare coverage for specific device models, which as noted above, may be the only models that are effective for individuals with specific combinations of physical, sensory, linguistic or cognitive abilities and needs.

The repeated mention that people with SGD needs present an extraordinary range and great complexity of communication, physical, cognitive and sensory disabilities are not merely hypothetical statements. To the contrary, these are a reflection of the individuals who already have sought Medicare funding for SGDs. Upon request by the Assistive Technology Law Center, Dynavox Technologies, the largest SGD manufacturer, surveyed 47 files of Medicare beneficiaries who acquired Dynavox SGDs. The characteristics of these individuals reinforce the conclusion stated here that competitive bidding poses a great threat to the ability of people with SGD needs to acquire the SGD models that will fit their individual needs.

Among the 47 cases reviewed, all the most common neurological conditions associated with SGD need and use were represented, as were all the most common communication diagnoses (dysarthria, apraxia, aphasia; and aphonia). These patients also included people whose communication disabilities were stable, and those that will become progressively worse.

Thirty-four of the patients used direct selection to access their device. Of that total, 10 are recognized as having progressive impairments that will necessitate a change in access method to scanning at a later time. Two patients currently used a combination of direct selection and scanning. Six patients relied on switch-based scanning, utilizing at least 8 different types of switches. Five patients used other access methods, including a joystick, and Head Mouse.

The patients' receptive language skills, cognitive skills, vision and hearing ability were all reviewed as well. These functional areas ranged from normal to moderately to severely impaired.

In sum, the matters discussed in this document reflect the accumulated knowledge and experience of the speech-language pathologists who conduct AAC and SGD clinical assessment; and are an actual reflection of the Medicare beneficiaries who have sought SGD funding.

<u>Imposing Competitive Bidding on SGDs Will Not Generate Significant Savings to the Medicare Program</u>

Fewer than 5,000 SGDs have been purchased by Medicare since 2001: on average, only 1,211 per year. The four-year total number of digitized speech output devices purchased by Medicare is only 576, or only 144 per year; only 822 keyboard-based synthesized speech output SGDs have been purchased, or 206 per year; and only 3,449 multiple-access, synthesized speech output SGDs have been purchased, or 862 per year.

Among software, mounts and accessories, the total purchases are similarly small. In 2004, for example, Medicare spent only $ 4,562 on SGD software (E 2511); less than $ 220,000 was spent on mounting systems (E 2512), and less than $ 280,000 was spent on all SGD accessories.

The foregoing data make clear that competitive bidding for the nine codes representing SGDs and related items will not generate significant savings to the Medicare program. That is not possible: this product category is not a source of significant Medicare outlays.

In addition, the current process by which SLPs determine whether an SGD is needed, and if so, which one, and what if any related items are required, assures that only the least costly equally effective items are being recommended. The previously discussed SLP assessment process leads to that result.

Moreover, the RMRP for SGDs requires that all SLPs involved in SGD recommendations have ***no*** financial relationship with an SGD supplier or manufacturer. RMRP for SGDs, Coverage and Payment Rules, ¶ 7.

Conclusion

For the reasons stated above, representatives of all parties interested in Medicare SGD coverage: patients and their families; speech-language pathologists; SGD manufacturers; and advocates, request that CMS exempt the nine speech generating device and related items codes from the competitive bidding process. The wide range of functional differences among the Medicare beneficiaries who rely on these devices; the differences in the device models; the distribution system for these devices and related items; the fiscally sensitive assessment and recommendation process; and the exceedingly low utilization of these items all justify this exemption.

Please contact the undersigned if you have any questions or require any additional information.

Thank you.

Sincerely,

Lewis Golinker
Director

On behalf of:

American Speech-Language-Hearing Association (ASHA);
Assistive Technology Industry Association (ATIA);
Assistive Technology Law Center (ATLC);
Dynavox Technologies;
International Society for Augmentative & Alternative Communication (ISAAC);
Rehabilitation Engineering and Assistive Technology Society of North America (RESNA);
United States Society for Augmentative & Alternative Communication (USSAAC).

And the members of the Medicare Implementation Team, *i.e.* AAC professionals who worked with HCFA staff and the DMERC Medical Directors to develop the Medicare SGD coverage criteria, and who subsequently developed the Medicare funding resources posted at www.aac-rerc.com. The individual members of the Medicare Implementation Team are identified at http://www.aac-rerc.com/pages/medicare/MCgeneral.htm#mit.