# ASSISTIVE TECHNOLOGY LAW CENTER

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**Director**

April 17, 2003

Ms. Ann N. Fazzini
Medical Benefits & Reimbursement Systems
Tricare Management Authority
16401 East Centretech Parkway
Aurora, Colorado 80011-9066

RE: Augmentative Communication Devices/
Speech Generating Devices

Dear Ann:

It was a pleasure to speak with you earlier this afternoon. I write to follow up our telephone conversation by providing the information you requested.

As we discussed, the proposed regulations published at 68 Federal Register 18575 (April 16, 2003) regarding AAC device coverage are almost identical to the request we submitted to Tricare in March 2001. For this reason, we intend to ask the SLP, AAC, disability, manufacturer and advocacy organizations interested in AAC device coverage to submit comments that support the adoption and implementation of the proposed regulations. These organizations also formed a coalition to support Medicare's AAC device coverage policy change in 2001.

We also discussed the few differences between the proposed rules and the Medicare coverage criteria:

1) one of the sub-categories of AAC devices/SGDs included in the Medicare National Coverage Decision for SGDs, # 60-23, was omitted. The proposed rule lists only type of "digitized speech output" SGD, instead of 2. The Medicare guidance, but not the proposed rules, includes:

May have digitized speech output, using pre-recorded messages, greater than 8 minutes of recording time.

Medicare National Coverage Decision 60-23.

As Tricare has organized the proposed rules, this category should be inserted between existing sub-paragraphs (1)(ii) and (1)(iii) in the speech generating device definition.

2) the Medicare NCD 60-23 states that computer and PDA based AAC devices are not covered. This category of AAC devices/SGDs is excluded because they are multi-functional devices, i.e., they can do more than serve as an individual's AAC device. This provision has been copied into the proposed Tricare rules.

Not stated in the NCD, however, is that Medicare has modified this exclusion. Shortly after the NCD went into effect, the manufacturers of these AAC devices identified a way to satisfy Medicare's concern that multi-functional devices are not able to meet the Medicare DME definition. The solution they designed, as I explained during our telephone call, was to create new models that are dedicated SGDs. These models are computer or PDA based, but they have locked out all functions other than their ability to serve as AAC devices. A user turns the device on to the AAC software, and cannot exit it except by turning the device off.

All the computer based and PDA based devices have been adapted in this way. In April and May 2001, these new models were demonstrated to Tom Hoyer, Director, Chronic Care Policy Group, CHPP, CMS, and to Dr. Robert Hoover, the Medicare Region D DMERC medical director. The outcome of these meetings was Medicare's acceptance that these devices are covered. I enclose the correspondence I exchanged with Tom Hoyer on this subject. I also enclose a catalog from two of the manufacturers of these devices that illustrate the characteristics of these models.

I ask that Tricare adopt the same solution to this group of devices as did Medicare, either by acknowledging these devices are covered in the regulation; or, as you suggested, that they be identified as covered in the Tricare policy manual.

Alternately, I encourage Tricare to consider whether this limitation is needed by your program at all. Medicare, which does not utilize a prior approval procedure, believed this coverage limitation is needed to protect against fraud. Medicaid programs and insurers, by contrast, use prior approval and have not adopted this dedicated-computer/PDA-based device limitation. Prior approval provides the opportunity to ensure every funding request is presented on behalf of someone with a severe communication disability who truly requires such a device. This eliminates the risk of fraud. Equally significant: the dedicated twins of the computer/PDA based devices are more expensive than the multi-functional models. As long as Tricare can assure through prior approval that the documentation supports provision of an SGD to the enrollee, the least costly equally effective alternative to a dedicated computer or PDA based SGD will be the multi functional model of that device.

Lastly, on this point, you mentioned this would be a matter discussed with Tricare medical directors. If they wish, I will be happy to come to their office with an SLP with long-term AAC

experience, to display, demonstrate and discuss these devices. As noted above, identical offers were accepted by both Dr. Hoover and Tom Hoyer in 2001. Please let me know if you or your colleagues would like a similar opportunity.

Thank you for speaking with me earlier today. Please contact me if I can provide any further information regarding AAC device/SGDs.

Sincerely,

Lewis Golinker, Esq.
Director

Enclosure: Letter dated April 2, 2001; and April 25, 2001 to Thomas Hoyer from Lewis Golinker; Letter dated May 4, 2001 from Thomas Hoyer to Lewis Golinker

2003 Catalog, Words Plus, Inc.; Enkidu Research.

[Federal Register: April 16, 2003 (Volume 68, Number 73)]
[Proposed Rules]
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From the Federal Register Online via GPO Access [wais.access.gpo.gov]
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DEPARTMENT OF DEFENSE

Office of the Secretary

32 CFR Part 199

RIN 0720-AA77

**TRICARE**; Changes Included in the National Defense Authorization Act for Fiscal Year 2002, (NDAA-02), and a Technical Correction Included in the NDAA-03

AGENCY: Office of the Secretary, DoD.

ACTION: Proposed rule.

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SUMMARY: This rule proposes several changes to the **TRICARE** program that were enacted by Congress in the NDAA-02 (December 28, 2001). Specifically, revisions to the definition of durable medical equipment (DME); adoption of the same pricing methods for durable medical equipment, prosthetics, orthotics and supplies (DMEPOS) as are in effect for the Medicare program; clarification that rehabilitative therapy is a **TRICARE** benefit; addition of augmentative communication devices (ACD)/speech generating devices (SGD) as a **TRICARE** benefit; addition of hearing aids for family members of active duty members as a **TRICARE** benefit; revisions to the definition of prosthetics; permanent authority for transitional health care for certain members separated from active duty; and revisions to the time period of eligibility for transitional health care.

This proposed rule also addresses a technical correction found in section 706 of the NDAA-03 relating to transitional health care for dependents of certain members separated from active duty.

Public comments are invited and will be considered for possible revisions to the final rule.

DATES: Written comments will be accepted until June 16, 2003.

ADDRESSES: Forward comments to Medical Benefits and Reimbursement Systems, **TRICARE** Management Activity, 16401 East Centretech Parkway, Aurora, Colorado 80011-9066.

FOR FURTHER INFORMATION CONTACT: Ann N. Fazzini, Medical Benefits and Reimbursement Systems, **TRICARE** Management Activity, telephone, (303) 676-3803. Questions regarding payment of specific claims should be addressed to the appropriate **TRICARE** contractor.

SUPPLEMENTARY INFORMATION:

I. Durable Medical Equipment (DME)

Section 703 of the NDAA-02, Pub. L. 107-107, provides authority for any durable medical equipment that can improve, restore, or maintain the function of a malformed, diseased, or injured body part, or can otherwise minimize or prevent the deterioration of the patient's function or condition. It also provides authority for any durable medical equipment that can maximize the patient's function consistent with the patient's physiological or medical needs. Although the wording is not identical, **TRICARE**'s policies and definitions in place at this time currently provide coverage within these criteria. Nonetheless, we are revising the current DME definition by adding the phrases found in the NDAA-02 to the regulatory definition of DME in order to ensure consistency between the law and the regulation.

Section 703 also makes available coverage to customize or accessorize durable medical equipment if it is essential for achieving therapeutic benefit for the patient; making the equipment serviceable; or otherwise assuring the proper functioning of the equipment. Our policies in place at this time provide coverage within these criteria. Specifically, **TRICARE**'s current policy regarding Durable Medical Equipment includes a provision to allow customization, accessories, and

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supplies that are essential to provide therapeutic benefit, or to assure the proper functioning of the equipment or to make the equipment serviceable. Nonetheless, we are revising the current DME definition by adding the NDAA-02 language to the regulatory definition of DME in order to ensure consistency between the law and the regulation.

II. Durable Medical Equipment, Prosthetics, Orthotics, and Supplies (DMEPOS) Reimbursement

Section 707 of the NDAA-02, Pub. L. 107-107, changed the statutory authorization (in 10 U.S.C. 1079(j)(2)) that **TRICARE** payment methods ``may be'' determined to the extent practicable in accordance with Medicare payment rules to a mandate that **TRICARE** payment methods ``shall be'' so determined. As a result, **TRICARE** proposes to adopt Medicare's pricing of Durable Medical Equipment, Prosthetic, Orthotics, and Supplies (DMEPOS). Under Medicare, DMEPOS prices are established by using fee schedules, reasonable charge or average wholesale pricing (AWP). Most payments of DME are based on a fee schedule. A standard fee is established for each DMEPOS item by state. Payment is calculated using either the fee schedule amount or the actual charge submitted on the claim, whichever is lower. The fee schedule allowances include the

application of national floors and ceilings. Reasonable charge allowances by Medicare are stipulated by Medicare law and not left to the discretion of the Medicare carrier. Medicare law specifically states that the amount allowed by Medicare must be the lowest of: The actual charge, the suppliers customary charge or the 50th percentile of arrayed and weighted customary charges in the absence of a customary charge for the specific service rendered; the prevailing charge, the Inflation-Indexed Charge or the Lowest Charge Level.

III. Rehabilitative Therapy

Section 704 of the NDAA-02, Pub. L. 107-107, authorizes providing rehabilitative therapy to improve, restore, or maintain function, or to minimize or prevent deterioration of function, of a patient when prescribed by a physician. We interpret the term ``rehabilitative therapies'' to include physical therapy, speech therapy, and occupational therapy. We are adding a definition of rehabilitative therapy to our regulation and incorporating the NDAA-02 language found in section 704 into the definition. Physical, speech, and occupational therapies are currently covered by **TRICARE** to improve and/or restore function. Additionally, current policies provide no restrictions on medically necessary and appropriate therapies--in other words, there is no dollar limit on the care nor is care restricted to a specific number of visits.

Section 701 of the NDAA-02, Pub. L. 107-107, provides a definition of custodial care as treatment or services regardless of who recommends such treatment of services or where such services are provided that (a) can be rendered safely and reasonably by a person who is not medically skilled; or (b) is or are designed mainly to help the patient with activities of daily living. The definition was revised by the interim final rule published in the Federal Register, 67 FR 40602, June 13, 2002.

We read the language in section 704 of the NDAA-02 in conjunction with the language in Section 701(c) of the NDAA-02 and conclude when **TRICARE** will cover rehabilitative therapies. That is, rehabilitative therapies shall be covered to improve, restore, or maintain function, or to minimize or prevent deterioration of function, of a patient when prescribed by a physician. The rehabilitative therapy must be medically necessary and appropriate, necessary to the establishment of a safe and effective maintenance program in connection with a specific medical condition, and not custodial care.

IV. Augmentative Communication Devices (ACD)/Speech Generating Device (SGD)

Section 702 of the NDAA-02, Pub. L. 107-107, provides that an ``augmentative communication device may be provided as a voice prosthesis'' under **TRICARE**. We propose a policy that is in line with the policy developed by the Centers for Medicare and Medicaid Services (CMS). We further propose using the same terminology used by Medicare when referring to this type of device--CMS refers to ``augmentative communication devices'' as ``speech generating devices''. In order to facilitate consistent terminology in the industry, we propose adopting

the term ``speech generating device (SGD)''. In proposing this policy, we have also taken into consideration recommendations provided to us by the American Speech-Language-Hearing Association in defining this benefit.

V. Hearing Aids

Section 702 of the NDAA-02, Pub. L. 107-107, provides for coverage of a hearing aid if a family member of an active duty member has a ``profound'' hearing loss as determined under standards prescribed in regulations by the Secretary of Defense in consultation with the administering Secretaries. There is no industry standard or industry definition of ``profound'' hearing loss so we have developed one for **TRICARE** purposes and welcome comments regarding our proposed definition.

The policy proposed in this rule enhances current **TRICARE** coverage of hearing aids by: (1) Offering a hearing aid benefit via the **TRICARE** Basic Program to family members of an active duty member when the family member has a ``profound'' hearing loss; (2) differentiating hearing thresholds for adults and children; and, (3) revising the hearing threshold levels currently in **TRICARE** policy.

VI. Prosthetics

Section 702 of NDAA-02, Pub. L. 107-107, gives the Department the discretion to provide a prosthetic device that includes the following: (1) Any accessory or item of supply that is used in conjunction with the device for the purpose of achieving therapeutic benefit and proper functioning. (2) Services necessary to train the recipient of the device in the use of the device. (3) Repair of the device for normal wear and tear or damage. (4) Replacement of the device if the device is lost or irreparably damaged or the cost of repair would exceed 60 percent of the cost of replacement. (5) A prosthetic device customized for a patient may be provided under this section only by a prosthetic practitioner who is qualified to customize the device, as determined under regulations prescribed by the Secretary of Defense in consult with the other Secretaries.

**TRICARE** currently offers benefits for the above criteria 1, 2, 3, and 5. Regarding criterion (4), **TRICARE** currently allows for replacement when required due to growth or change in the patient's condition. Nonetheless, our policies will be revised to ensure consistency with the language found in section 702.

Regarding criterion 5, **TRICARE** has no specific provider requirements for a prosthetic practitioner to be qualified to customize the device. Rather, otherwise authorized providers currently provide prostheses and customization of prostheses. We are aware that CMS has established a Negotiated Rulemaking Committee on Special Payment Provisions and Requirements for Prosthetics and Certain Custom-Fabricated Orthotics. The purpose of this committee is to advise CMS on developing a proposed rule that would establish payment provisions and

requirements for providers of prostheses and custom-fabricated orthotics under the Medicare program. Once the Committee provides their findings, we will review them for consideration under the **TRICARE** program. In the meantime, we will continue to allow prostheses customization by otherwise authorized **TRICARE** providers.

This proposed rule also updates the definition of prosthetic device, and adds definitions for prosthetics and prosthetic supplies. This brings us in line with industry standards.

VII. Transitional Health Care

Section 736 of the NDAA-02, Pub. L. 107-107, makes permanent the authority for transitional health care benefits for certain members by deleting the expiration date that was in place for transitional health care benefits. Prior to Pub. L. 107-107, transitional health care benefits were to expire on December 31, 2001. Section 736 also extended coverage for either 60 or 120 days based on years of service to those eligible for transitional health care benefits. Further, it deleted coverage for dependents of those eligible for transitional coverage, but the Department of Defense created a demonstration project to include coverage for such dependents.

Section 706 of the National Defense Authorization Act for Fiscal Year 03 (NDAA-03) re-inserted transitional health care coverage benefits for dependents and deemed the provision to have been enacted as part of section 736 of the NDAA-02. Consequently, there is no need for this rule to include regulatory language addressing the removal of dependents from transitional health care coverage.

VIII. Regulatory Procedures

Section 801 of title 5, United States Code, and Executive Order 12866 requires certain regulatory assessments and procedures for any major rule or significant regulatory action, defined as one that would result in an annual effect of $100 million or more on the national economy or which would have other substantial impacts.

The Regulatory Flexibility Act (RFA) requires that each Federal agency prepare, and make available for public comment, a regulatory flexibility analysis when the agency issues a regulation which would have a significant impact on a substantial number of small entities.

This is not a major rule under 5 U.S.C. 801. It is a significant regulatory action but not economically significant, and has been reviewed by the Office of Management and Budget as required under the provisions of E. O. 12866. In addition, we certify that this proposed rule will not significantly affect a substantial number of small entities.

Paperwork Reduction Act

This rule, as written, imposes no burden as defined by the Paperwork Reduction Act of 1995 (44 U.S.C. 3501-3511). If, however, any program implemented under this rule causes such a burden to be imposed, approval thereof will be sought from the Office of Management and Budget in accordance with the Act, prior to implementation.

List of Subjects in 32 CFR Part 199

Claims, Dental health, Health care, Health insurance, Individuals with disabilities, Military personnel.

Accordingly, 32 CFR part 199 is amended as follows:

PART 199--[AMENDED]

1. The authority citation for part 199 continues to read as follows:

Authority: 5 U.S.C. 301; 10 U.S.C. chapter 55.

2. Section 199.2(b) is proposed to be amended by revising the definitions of ``Durable medical equipment", and ``Prosthetic device (prosthesis)", by adding definitions of ``Augmentative Communication Device", ``Profound hearing loss"; ``Prosthetic", ``Prosthetic supplies", ``Rehabilitative therapy", and ``Speech generating device" in alphabetical order to read as follows:

Sec. 199.2 Definitions.

* * * * *

(b) * * *

Augmentative communication device. See Speech generating device.

* * * * *

Durable medical equipment. Equipment for which the allowable charge is over $100 and which:

(1) Is medically necessary for the treatment of a covered illness or injury;

(2) Improves, restores, or maintains the function of a malformed, diseased, or injured body part, or can otherwise minimize or prevent the deterioration of the patient's function or condition;

(3) Can maximize the patient's function consistent with the patient's physiological or medical needs.

(4) Is primarily and customarily designed and intended to serve a medical purpose rather than primarily for transportation, comfort, or convenience.

(5) Can withstand repeated use;

(6) Provides the medically appropriate level of performance and quality for the medical condition present (that is, nonluxury or nondeluxe);

(7) Is other than spectacles, eyeglasses, contact lenses, or other optical devices, hearing aids (unless otherwise provided as a covered **TRICARE** benefit), or other communication devices (unless otherwise provided as a covered **TRICARE** benefit); and

(8) Is other than exercise equipment, spas, whirlpools, hot tubs, swimming pools or other such items.

* * * * *

Profound hearing loss (adults). An ``adult" (a spouse as defined

in section 199.3(b) of this part of a member of the Uniformed Services on active duty for 30 days) with a hearing threshold of:

(1) 40 dB HL or greater in one or both ears when tested at 500, 1,000, 1,500, 2,000, 3,000 or 4,000Hz; or

(2) 26 dB HL or greater in one or both ears at any three or more of those frequencies; or

(3) A speech recognition score less than 94 percent.

Profound hearing loss (children). A ``child'' (an unmarried child of an active duty member who otherwise meets the criteria (including age requirements) in section 199.3 of this part) with a 26dB or greater hearing threshold level in one or both ears when tested in the frequency range at 500, 1,000, 2,000, 3,000, or 4,000 Hz.

* * * * *

Prosthetic. Artificial legs, arms, and eyes.

Prosthetic device (prosthesis). Devices (other than a dental device) which replace all or part of an internal body organ (including contiguous tissue), or replace all or part of the function of a permanently inoperative or malfunctioning internal body organ are covered when furnished on a physician's order. Examples of prosthetic devices include cardiac pacemakers, breast prostheses (including a surgical brassiere) for post mastectomy patients, maxillofacial devices and devices which replace all or part of the ear or nose.

Prosthetic supplies. Supplies that are necessary for the effective use of a prosthetic device.

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Rehabilitative therapy. Speech therapy, occupational therapy, and physical therapy to improve, restore, or maintain function, or to minimize or prevent deterioration of function, of a patient and prescribed by a physician.

* * * * *

Speech generating device. (1) Speech aids that provide an individual who has severe speech impairment with the ability to meet his functional speaking needs. Such devices are considered

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prosthetic devices and are characterized by:

(i) Being a dedicated speech device, used solely by the individual who has severe speech impairment:

(ii) May have digitized speech output, using pre-recorded messages, less than or equal to 8 minutes recording time;

(iii) May have synthesized speech output, which requires message formulation by spelling and device access by physical contact with the device-direct selection techniques;

(iv) May have synthesized speech output, which permits multiple methods of message formulation and multiple methods of device access; or

(v) May be software that allows a laptop computer, desktop computer or personal digital assistant (PDA) to function as a speech generating device.

(2) Examples of devices that do not meet the above definition and are excluded from coverages as SGDs include, but are not limited to:

(i) Devices that are not dedicated speech devices, but are devices that are capable of running software for purposes other than for speech

generation, e.g., devices that can also run a word processing package, an accounting program, or perform other non-medical functions.

(ii) 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 prosthetic, prosthetic device, prosthetic supply, or durable medical equipment.

(iii) A device that is useful to someone without severe speech impairment is not considered an SGD.

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3. Section 199.3 is proposed to be amended by revising paragraph (e) to read as follows:

Sec. 199.3 Eligibility.

* * * * *

(e) Eligibility Under the Transitional Assistance Management Program (TAMP). (1) Transitional health care benefits under **TRICARE** are authorized for the following eligibles:

(i) A member who is involuntarily separated from active duty and the dependents of the member.

(ii) A member of a reserve component who is separated from active duty to which called or ordered in support of a contingency operation if the active duty is active duty for a period of more than 30 days and the dependents of the member.

(iii) A member who is separated from active duty for which the member is involuntarily retained under 10 U.S.C. 12305, in support of a contingency operation and the dependents of the member.

(iv) A member who is separated from active duty pursuant to a voluntary agreement of the member to remain on active duty for a period of less than one year in support of a contingency operation and the dependents of the member.

(2) Time period of eligibility. Transitional health care shall be available for a specified period of time for members and dependents beginning on the date which the member is separated as follows:

(i) For members separated with less than 6 years of service, 60 days.

(ii) For members separated with 6 or more years of active service, 120 days.

* * * * *

4. Section 199.4 is proposed to be amended by revising paragraph (d)(3)(ii)(A), paragraph (d)(3)(vii), the text of paragraph (g)(41) preceding the note, paragraph (g)(47), paragraph (g)(51) and by adding new paragraph (e)(23), new paragraph (e)(24), and new paragraph (e)(25) to read as follows:

Sec. 199.4 Basic program benefits.

* * * * *

(d) * * *

(3) * * *

(ii) * * *

(A) Scope of benefit. Subject to the exceptions in paragraphs (B) and (C) below, only durable medical equipment (DME) which is ordered by a physician for the specific use of the beneficiary, and which complies with the definition of ``Durable Medical Equipment'' in Sec. 199.2 of this part, and which is not otherwise excluded by this Regulation qualifies as a Basic Program Benefit. In addition, any customization of durable medical equipment owned by the patient is authorized to be provided to the patient and any accessory or item of supply for any such authorized durable medical equipment, may be provided to the patient if the customization, accessory, or item of supply is essential for--

(1) Achieving therapeutic benefit for the patient

(2) Making the equipment serviceable; or

(3) Otherwise assuring the proper functioning of the equipment.

* * * * *

(vii) Prosthetics, prosthetic devices, and prosthetic supplies, as determined by the Secretary of Defense to be necessary because of significant conditions resulting from trauma, congenital anomalies, or disease. Additionally, the following are covered:

(A) Any accessory or item of supply that is used in conjunction with the device for the purpose of achieving therapeutic benefit and proper functioning;

(B) Services necessary to train the recipient of the device in the use of the device;

(C) Repair of the device for normal wear and tear or damage;

(D) Replacement of the device if the device is lost or irreparably damaged or the cost of repair would exceed 60 percent of the cost of replacement.

* * * * *

(e) * * *

(23) A speech generating device (SGD) as defined in Sec. 199.2 of this part is covered as a voice prosthesis. The prosthesis provisions found in paragraph (d)(3)(vii) of this section apply.

(24) A hearing aid, but only for a dependent of a member of the uniformed services on active duty and only if the dependent has a profound hearing loss as defined in Sec. 199.2 of this part. Medically necessary and appropriate services and supplies, including hearing examinations, required in connection with this hearing aid benefit are covered.

(25) Rehabilitation therapy as defined in Sec. 199.2 of this part to improve, restore, or maintain function, or to minimize or prevent deterioration of function, of a patient when prescribed by a physician. The rehabilitation therapy must be medically necessary and appropriate, must be necessary to the establishment of a safe and effective maintenance program in connection with a specific medical condition, and must not be custodial care.

* * * * *

(g) * * *

(41) Hair transplants, wigs, hair pieces, or cranial prosthesis.

Note: * * *

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(47) Eye and hearing examinations. Eye and hearing examinations except as specifically provided in paragraphs (c)(2)(xvi), (c)(3)(xi), and (e)(24) of this section, or except when rendered in connection with medical or surgical treatment of a covered illness or injury.

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(51) Hearing aids. Hearing aids or other auditory sensory enhancing devices, except those allowed in paragraph (e)(24) of this section.

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4. Section 199.14 is proposed to be amended by redesignating paragraphs (k) through (n) as paragraphs (l) through (o) and adding a new paragraphs (k) to read as follows:

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Sec. 199.14 Provider reimbursement methods.

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(k) Reimbursement of Durable Medical Equipment, Prosthetics, Orthotics and Supplies (DMEPOS). Reimbursement of DMEPOS is based on the same amounts established under the Medicare DMEPOS fee schedule under 42 CFR part 414, subpart D.

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Dated: April 9, 2003.

L.M. Bynum,

Alternate OSD Federal Register Liaison Officer, Department of Defense.

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