**Electronic Data Interchange (EDI)**

2. GUEST1 [Y,N]?

If this is correct, press <Enter>. If not, type N, press <Enter> and re-enter your log on name correctly.

3. Password

Type "PGBA"

**NOTE:** You'll see several messages asking if you'd liked to read the next bulletin or if you'd like to check your mail. Just answer "NO" to these questions.

**DMERC Region C publications via BBS**

To locate DMERC Region C publications on the BBS:

1. Type "F" for File Area from the Main Menu.

2. Type "A" for Area Change from the File Menu.

3. Type the number of the area you wish to view. For example, *DMERC Medicare Advisories* are located in Area 43.

4. Once you switch to an area, you will see the File Menu again. Look in the upper left corner of the screen to verify the area number. If you are in the correct area, type "F" at the first prompt to view a list of files within the area. If you want to view a list of all files in the area, simply press the <Enter> key at the second prompt.

5. You will see a list of all files within the area. Make a note of which files you wish to download. Press <Enter> to return to the File Menu.

6. Type "D" to download a file. Type the name(s) of the files you wish to download. Press <Enter> to begin the download, "/q" to abort the download, or "/g" to log off automatically after you have finished downloading your files.

7. If you did not choose to log off automatically after download, you will need to log off manually. To log off, type "G" from the File Menu, then select "Y" to disconnect.
Effective September 1, 1997, Palmetto GBA will discontinue paper remittances for all submitters who have been receiving electronic remittances for at least 60 days. Electronic remittance notices (ERNs), which are downloaded from an electronic mailbox or from the Bulletin Board System (BBS), duplicate the information contained on paper remittances. New submitters who choose to receive electronic remittances after September 1, 1997, will receive both paper and electronic remittances for 60 days after the initial ERN enrollment date. After the 60-day period has expired, they will receive electronic remittances only.

Palmetto GBA offers two low-cost print programs to view and print ERNs for both PACES and non-PACES users. Both these programs print remittances which are acceptable to secondary insurers as proof of payment or denial. Suppliers who are interested in receiving their remittances electronically should contact the EDI Help Desk at 803-788-9751 to request a Software Order Form. Suppliers who wish to discontinue receiving ERNs should also contact the EDI Help Desk.

NOTE: Your software vendor may also offer software to view and print ERNs. Palmetto GBA offers a list of Certified Software Vendors which is available from the EDI Help Desk at 803-788-9751.
**Anti-Fraud Unit**

**Supplier sanctions**

**Louisiana**
Alfred Klein  
LaSalle General Dr. - 2  
Jena, La.  71342  
Specialty: N/A  
Period of Exclusion: Indefinite  
Effective Date: 2/25/97

**South Carolina**
Dongha H. Chung  
P.O. Box 263  
Anderson, S.C.  29622  
Specialty: N/A  
Period of Exclusion: 10 yrs.  
Effective Date: 5/5/97

John R. Guthrie  
216 Beechwood Dr.  
Spartanburg, S.C.  29307-2949  
Specialty: Osteopath  
Period of Exclusion: 3 yrs.  
Effective Date: N/A

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**New Ombudsman for Arkansas/Oklahoma**

**Brooke Dieterlen** is the new ombudsman for Arkansas and Oklahoma. A graduate of the University of Oklahoma, Brooke earned a bachelor of science degree in education, and worked in retail marketing before joining Palmetto GBA. Her education and marketing background will serve Brooke well in her efforts to clarify billing and policy issues for Arkansas and Oklahoma suppliers.

A native of Oklahoma, Brooke is based in Tulsa. She has already presented Back to Basic workshops both in Tulsa and Little Rock, and is now busy answering calls and visiting suppliers who have requested her help. You can reach Brooke at the following address: Suite 376, 6528 East 101st Street, Tulsa, Okla. 74133-6754, (918) 252-4481.
**Inherent Reasonableness Final Notice**

**Enteral nutrient coding and pricing changes**

In the December 1996 *DMERC Medicare Advisory*, a notice was published of Palmetto GBA's intent to apply Inherent Reasonableness (IR) to the allows for Category IV and V enteral nutrients and to replace temporary Level III product-specific local HCPCS codes with existing Level II permanent HCPCS codes, B4154 and B4155. Suppliers were asked to submit comments in response to this notice by January 31, 1997. Palmetto GBA received 19 responses. After careful consideration of each comment, Palmetto GBA is proceeding with this initiative.

This article will serve as final notice that, effective for dates of service (DOS) on or after January 1, 1998, local HCPCS codes XX030-XX058 and XX073-XX084 will be replaced by code B4154 and codes XX059-XX072 will be replaced by code B4155. The XX codes should continue to be used for dates of service prior to January 1, 1998, regardless of the date of claim receipt. The XX codes will be rejected as invalid if the DOS is on or after January 1, 1998.

For 1998, the Medicare allows for codes B4154 and B4155 will be determined under the established reasonable charge methodology. This process involves the calculation of supplier-specific customaries, national prevailing charges, lowest charge levels (LCL) and inflation index charges (IIC). Payment is made at the lowest of these four values or the submitted charge. The submitted charges for the XX codes will be crosswalked to the appropriate B code prior to calculation of the 1998 customaries, prevailings and LCLs. However, the 1998 IICs for B4154 and B4155 will be based upon the previously published 1997 inherent reasonableness allowances ($1.18 for B4154 and $0.93 for B4155) updated by the annual consumer price index update (CPI-U) factor. The 1998 CPI-U factor has not been determined at this time.

*NOTE:* The 1997 allowances listed above will not be used to determine payment for 1997 dates of service.

**CMN instructions/other billing instructions**

For patients who have a certificate of medical necessity for an XX code which is valid as of December 31, 1997, another CMN does not need to be submitted for code B4154 or B4155 as long as the patient is receiving the same product. Palmetto GBA will use information from the most recent corresponding XX code certification record to set up the needed certification record for code B4154 or B4155. If the first claim submitted with code B4154 or B4155 is for a different Category IV or V product than the most recent XX code certification on file with Palmetto GBA, or if the patient is receiving two Category IV or two Category V nutrients at the same time, a revised CMN must be submitted to Palmetto GBA with the first claim for code B4154 or B4155. Also, if the Category IV or V enteral nutrient being provided is changed after January 1, 1998, a revised CMN must be submitted to Palmetto GBA. The initial date listed in Section A of a revised CMN for code B4154 or B4155 must match the initial date on the certification record created by Palmetto GBA from the CMN originally submitted with the XX code.
Each claim submitted with code B4154 or B4155 must include the product name of the nutrient which is provided. This should be entered in the HAØ record of an electronic claim or attached to a hard copy claim.

If two Category IV or two Category V nutrients are being provided at the same time, they should be billed on a single claim line with the units of service reflecting the total calories of both nutrients.

Only those products on the following list may be billed using code B4154 or B4155. If a manufacturer or supplier thinks another product meets the definition of this code, they should contact the Statistical Analysis DMERC for a coding determination. The SADMERC must issue a written determination approving use of code B4154 or B4155 before either may be used for a new product or a product not listed below.

**Product classification list**

For HCPCS code B4154 (enteral formulae, Category IV and a defined formula for special metabolic need):

| Accupep HPF | Peptamen Junior |
| Advera | Peptamen VHP |
| AlitraQ | Perative |
| Amin-Aid | Pregestimil |
| Choice DM | Pro-Peptide |
| Citroprotein | Pro-Peptide VHN |
| Crucial | Protain XL |
| Diabetisource | Provide |
| Entera OPD | Pulmocare |
| Fulfil | Reabilan HN |
| Glucerna | Renalcal |
| Hepatic Aid | Replete |
| Impact | Replete with Fiber |
| Impact 1.5 | SandoSource Peptide |
| Impact with Fiber | SLD |
| ImunnAid | Suplena (Replena) |
| Isosource VHN | Stresstein |
| L-Emental Hepatic | Traumacal |
| L-Emental Plus | Travasorb Hepatic |
| Liplsorb | Travasorb MCT |
| Nepro | Travasorb Renal |
| NutriHep | Vivonex Plus |
| Nutrivent | Vivonex T.E.N. |
| Peptamen | |

For HCPCS code B4155, enteral formulae, Category V, modular components (protein, carbohydrates, fat):

| Casec | Polycose |
| Elementra | Procare |
| Fibrad | ProMod |
| MCT Oil | Promix |
| Microlipid | Propac Plus |
| Moducal | Sumacal |
Summary comments and responses

Most comments received were similarly worded. They are represented by the following sample summary statements.

♦ Several commenters have alleged there is no legal authority for the application of the inherent reasonableness provisions of the law to the PEN benefit, citing a conference agreement report accompanying the Omnibus Budget Reconciliation Act of 1986. The referenced passage in the report is:

"The conferees expect that all available charge data submitted by suppliers of such services would be used in calculating the lowest charge levels. The Secretary and carriers would, therefore, be prohibited from using ‘inherent reasonableness’ in establishing the lowest charge level."

Whatever the expectations of the conferees at the time, there was no revision of the law then or subsequently that would prohibit the application of inherent reasonableness for PEN, and the conference agreement statement in itself is not binding. The “therefore” in the second sentence is based on an unfounded premise—that somehow reasonable charge limits other than those imposed by the LCL did not make use of all available charge data. In fact, all available charge data is routinely used in establishing all reasonable charge limits, and in no way precludes the subsequent adjustment of those charge limits under inherent reasonableness authority.

A discussion of inherent reasonableness vis-à-vis pricing at the lowest charge level in an April 1987 Federal Register clearly indicates the lowest charge level method of reimbursement does not preclude the application of inherent reasonableness:

"[The] use of inherent reasonableness is limited to special circumstances, while the use of LCLs is required whenever it can be determined that items do not vary significantly in quality. The use of LCLs does not guarantee an inherently reasonable result, so that this principle may be applied to those services for which LCLs have been established. Therefore, the use of LCLs and the use of inherent reasonableness screens must be viewed as concurrent limitations, not as substitutes for one another." [FR April 20, 1987, pg. 12975; underscoring added]

♦ Commenters also voiced concern HCFA and the DMERCs did not publish changes to the national policy and reasonable charge in the Federal Register as required by law.

This is not a national policy decision initiated by the HCFA. Rather, this initiative is a collective effort among the four DMERCs and the SADMERC. Therefore, publication of proposed changes in the Federal Register is not required; use of the DMERCs' advisories/bulletins is the appropriate mode of communication. It is also important to note that there are two separate, although related, issues involved: coding and pricing. The IR process, e.g. offi-
INHERENT REASONABLENESS
FINAL NOTICE
(continued)

cial notice and comment period, applies to the pricing issues only which are addressed in the second paragraph below.

The HCFA has, for some time, been concerned with the number of local codes in existence at its contractors, and as it moves toward the standardization of Part B claims processing, HCFA has notified carriers of the need to eliminate local variations in the HCPCS coding structure. Thus, the local XX HCPCS codes must be converted to permanent Level II HCPCS codes. The process by which this is accomplished, as well as the method of transferring pricing from deleted codes to existing codes, is governed by long-standing Medicare policy, distinctly different from the IR process. This coding change is distinctly different from the IR pricing issues described below.

The IR adjustment proposed is very narrow in scope, and relates only to the imposition of the 1996 inflation index limit. Due to technical requirements for determining reasonable charges, the three percent inflation limitation was not applied to the 1996 XX code allowances. The SADMERC determined the resulting unrestricted payment allowances, which were substantially in excess of what would have been allowed if the inflation index limitation had been applied, are inherently unreasonable. There is no reasonable rationale for exempting certain Category IV and V enteral nutrients from the inflation update limits while applying it to other products. Therefore, the 1995 allowances, which reflect inflation index limitations, will be used in the calculation of the 1998 payment allowances. The resultant 1998 allowances for B4154 and B4155 will be derived in the manner described above.

Many commenters alleged that Category IV enteral products are superior to Category I products, meeting the specific metabolic needs of patients with different diseases. They believe Category IV products are dissimilar from one another.

While it is true that these Category IV enteral nutrient products are dissimilar to those in the Category I class of products and to one another, they are categorized as being formulated to address the metabolic needs of specific disease states, having been developed based upon theoretical concepts of nutritional and metabolic requirements found in these disease states. Varying amounts of carbohydrates, amino acids, different forms of fatty acids, etc., constitute the various products, which theoretically may improve treatment outcomes in patients afflicted with diseased organs when used in conjunction with other medical therapeutic modalities. Studies done by their manufacturers are based on component aspects of disease states, often at the cellular level and represent in-vitro findings. However, no well-controlled published studies have been done to prove the increased in-vivo efficacy of treatment employing these Category IV nutrients, compared with regimens that use basic (B4150) enteral nutrients to support the nutritional needs of diseased or stressed patients.

For instance, in the case of diabetes mellitus, the proven value of Category IV products designed for this disease has not been demonstrated using actual patient populations controlled for other variables such as age, obesity, concurrent disease states, careful serum glucose monitoring with frequent and adept insulin
Adjustments, etc. These products have been classified as "foods" and not drugs by the Food and Drug Administration, thus allowing manufacturers to imply therapeutic effects while avoiding the need to prove their therapeutic efficacy and added value in the treatment of various disease states. If manufacturers wish to make claims of efficacy for these products similar to those of other medically proven treatment regimens (such as is required with medications), they should subject their products to the same rigors of testing in well controlled studies within clinical patient populations.

Use of Category IV nutrients by the general practicing community has developed as an unproven practice tradition, often based upon the marketing success of these products' manufacturers, and anecdotal impressions, rather than upon their proven therapeutic efficacy in patient outcomes, as established in published studies.

♦ Commenters suggested that Category IV Products should at least be collapsed into disease-specific coding categories to allow more differentiated levels of pricing, reflecting the different ingredients being supplied.

Based upon the fact none of the current Category IV products have had their therapeutic value proven, as established in the above comment, there is little rationale to subdivide these products by disease category, allowing for the differential (and higher) reimbursement of some disease-class products over others, when none have established their proven need.

Such reasoning begs the question, why retain any Category IV products in a coding classification distinct from Category I products, with its generically higher reimbursement amount? While such a more radical position might be justified based on lack of these products' proven efficacy, at this time the DMERCs have taken the current more moderate position of having at least one generic Category IV code in deference to the already established practice patterns of clinicians who order these products, either out of habit or tradition, or based upon personal subjective beliefs in their efficacy.

♦ Another concern commenters expressed was for the quality of healthcare for beneficiaries. Suppliers feel they will not be able to continue to supply the more expensive Category IV products based on one new generically established Medicare reimbursement rate. Medicare beneficiaries will be negatively impacted with less appropriate care, more hospitalizations, and overall poorer patient outcomes if certain Category IV products are rendered less available for use in their therapeutic regimens, due to decreased reimbursement levels.

Based upon the above comments, Medicare should not pay for any therapeutic modality that is not "reasonable and necessary" for the treatment of its beneficiaries. If what is reasonable and medically necessary is not established in well constructed, peer-reviewed published studies, then establishing the concept is reduced to subjective claims and marketing pressure.