

1 I just received a notice postmarked March 29, 2007 from EDS NHIC stating that
2 they had the individual beneficiaries appeals without any notice to me whatsoever.
3 [attachment 1]
4

5
6 In 2005, EDS NHIC hearing officer, Lilia Kleinman scheduled this in-person
7 individual beneficiaries appeals with Bruce Quinn, M.D., Don Adams, M.D. and Tom
8 Horowitz, D.O., as our witnesses. The EDS NHIC records will reveal that she put the
9 in-person individual beneficiaries appeals on hold. She stated two reasons:
10

- 11 1. EDS NHIC was waiting for the outcome of the LCD appeal
- 12
- 13
- 14 2. EDS NHIC demanded I must drop my Medicare FOIA request first
- 15

16 Charity Horton, the second EDS NHIC Hearing officer now writes:

17
18 "Transfer factor is a non-specific term that refers to
19 an extract derived from dialyzable human
20 leukocytes. There are no FDA approved
21 preparations of this substance. The use of
22 parenteral transfer factor to treat any illness is not
23 a recognized treatment modality accepted by the
24 scientific and medical community, and may be
25 dangerous. The use of parenteral transfer factor is
26 not a covered benefit under Medicare. CFR, Reg. 42,
27 Section 411.15(k), specifically excludes any
28 services that are not reasonable and necessary for
the following purposes: (1) for the diagnosis or

1 treatment of an illness or injury, or to improve the
2 functioning of a malformed body member. "

3
4 The NHIC hearing officer denies reimbursement retroactively for years on all
5 patients with the same clinical diathesis transfer factor immunomodulatory therapy
6 based on what the DHHS DAB determined to be a Local Coverage Determination.
7 The relevant provisions of the LCD were withdrawn by NHIC. EDS NHIC has no legal
8 authority to apply this LCD policy sub rosa.

9
10 EDS NHIC had no legal authority to conduct this joint individual beneficiaries
11 hearing:

- 12 • under the false pretenses that I requested it
- 13 • without any notification to me
- 14 • without my presence and
- 15 • without our witnesses: Drs. Quinn, Adams and Horowitz.

16
17 I respectfully request that EDS NHIC be ordered to reverse this hearing officer's
18 determination.

19
20 I declare that the information in this declaration and attachment 1, my letter to the
21 EDS NHIC Hearing Office is true and correct to the best of my knowledge under
22 penalty of perjury on this 2nd day of April 2007 in Laguna Hills, CA.

23
24
25 By: _____

26
27 Dorothy Calabrese, M.D.

DOROTHY CALABRESE, M.D.
ALLERGY & IMMUNOLOGY
24953 PASEO DE VALENCIA 4A
LAGUNA HILLS, CA 92653-4342
949-454-0509
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Pager: dvc9@columbia.edu

April 1, 2007

Charity Horton
Medicare Hearing Officer
National Heritage Insurance Company
Medicare Hearings Department
PO Box 515300
Los Angeles, CA 90051-6600

Dear Ms. Horton,

I just received your letter postmarked March 29, 2007 which contains the following information:

You write:

This is your MEDICARE PART B Hearing Officer HEARING DECISION.
Appellant's Party Status: Physician
RE: Beneficiaries: Multiple
Health Insurance Claim Numbers: Multiple
Claim Control Numbers: Multiple
Physician Name: Dorothy V. Calabrese, MD
Dates of Service: Multiple
Type of Services: Various
Accounts Receivable Number: 7104324131800
Hearing Case Number: 4506291491000

This decision is UNFAVORABLE.

This is my decision based on the evidence in the case file, including:

- Hearing request
- Patients' Medical Records
- Information from the Post Payment Medical Review Department
- Medicare correspondence
- Copies of the original claims

You asked that a Hearing Officer re-evaluate the Carrier's decision on your Medicare claims based on the information contained in the case file. I am an authorized Hearing Officer for the Medicare Part B Contractor, NHIC, Corp.

RESPONSE #1:

I was told by NHIC's Mary Lou Cartas that I could take no action until we received a final determination, which we received in December 2004. Then in accordance with timely statutory requirements for filing I did two things:

1. Requested a Joint Local Coverage Determination which was accepted by the DAB.
2. Requested individual beneficiary appeals starting with an in-person hearing with the NHIC Hearing office, with Bruce Quinn, M.D., Ph.D., Don Adams, M.D., and Tom Horowitz, D.O. as witnesses.

Lilia Kleinman, the NHIC hearing officer agreed to this. Subsequently, your hearing office records will show that Ms. Kleinman delayed the in-person hearing, as allowed by law stating:

1. She wanted to wait for the outcome of the LCD appeal.
2. NHIC required that I drop my FOIA request before a hearing would be allowed.

That was the last communication I had with respect to scheduling an individual beneficiary hearing for all the Medicare beneficiaries.

You write: "You (Dorothy Calabrese, M.D.) asked that a Hearing Officer re-evaluate."

RESPONSE #2

I never made such a request.

Furthermore, this after-the-fact letter is the first notice I've had since 2005 that you were now having a hearing.

I filed in Federal court in Santa Ana, CA on December 15, 2006 to have all aspects of this case properly adjudicated.

Moreover, if there is going to be a hearing now, I never waived the right to an in-person hearing and the right to my witnesses: Drs. Quinn, Adams and Horowitz. M.D

RESPONSE #3

You have made me retroactively liable for 98.6% of all monies paid me for all patients for years. This is in dispute. Firstly, my staff and my accountant Jenefer Luckey, C.P.A. can provide competent testimony that in all requests made for the actual numbers through Margie Navas, telephonically, and through written communication, the NHIC hearing office remained totally unresponsive.

Secondly, based on the facts in evidence and the law, there is absolutely no basis in this case for retroactive liability. In fact, Dr. Quinn has been documented to say that this was done to eliminate concern that NHC would have to defend a track record of paying for these services, as the previous carrier, Transamerica Occidental had paid. You have absolutely no legal authority to make me retroactively liable, which is unduly punitive and prejudicial.

You write:

The basis of reimbursement under the Medicare program is to provide payment for the level of service that is "medically necessary and reasonable" and will meet the patient's needs. Historically, the Centers for Medicare and Medicaid Services (CMS) has interpreted the statutory terms "necessary" and "reasonable" to mean that a device must be safe and effective, medically necessary and not experimental. For most Medicare coverage purposes, the term experimental has been used synonymously with the term investigational. Therefore, a device categorized by the Food and Drug Administration (FDA) as being investigational served as indication that it was not "necessary" and "reasonable" within the meaning of the Medicare Program.

RESPONSE #4

I've been a practicing allergist-immunologist for 27 years dealing with refractory patients. All the care was delivered with the standard of excellence I learned at Columbia College of Physicians and Surgeons. There was nothing experimental or investigational. In the material you "considered" you don't even mention the 788 pages of scientific and medical articles all currently available from the Yale University School of Medicine, the extremely positive patient outcomes or the extremely positive patient satisfaction.

You write:

Transfer factor is a non-specific term that refers to an extract derived from dialyzable human leukocytes. There are no FDA approved preparations of this substance. The use of parenteral transfer factor to treat any illness is not a recognized treatment modality accepted by the scientific and medical community, and may be dangerous. The use of parenteral transfer factor is not a covered benefit under Medicare. CFR, Reg. 42, Section 411.15(k), specifically excludes any services that are not reasonable and necessary for the following purposes: (1) for the diagnosis or treatment of an illness or injury, or to improve the functioning of a malformed body member.

RESPONSE #5:

You are denying all patients with the same clinical diathesis transfer factor immunomodulatory therapy based on what the DHHS DAB determined to be a Local Coverage Determination. The relevant provisions of the LCD were withdrawn by NHIC. You have no legal authority to apply this LCD policy sub rosa.

You write:

Section 1862(a), of the Social Security Act, states in pertinent part, "Notwithstanding any other provision of this title, no payment may be made under part A or part B for any expenses incurred for items or services; and (1)(A) which, except for items and services described in a succeeding subparagraph, are not reasonable and necessary for the diagnosis or treatment of illness or injury or to improve the functioning of a malformed body member."

Billing for transfer factor is not customary or medically reasonable and necessary.

RESPONSE #6:

You have no legal authority to apply the LCD policy sub rosa. The legislature wrote the LCD appeal as an alternative to the individual beneficiary appeals process.

1. The DHHS DAB wrote that there was an LCD. NHIC told both FOIA and the DHHS DAB there was no LCD docket. By law that means the LCD is withdrawn and reimbursement is reestablished.
2. The DHHS DAB determined that the relevant provisions of the LCD appeal were withdrawn by NHIC. The legislature's intent was for this to reinstate reimbursement, and certainly not to be demanding retroactive reimbursement for years with interest.

You write:

When you enrolled in Medicare and signed the Provider Enrollment Agreement you agreed to abide by Medicare laws, regulations, and program instructions. You agreed that you understood that payment of a claim by Medicare is conditioned upon the propriety of the claim and the underlying transaction. Payment of a Medicare claim is conditioned on the compliance of the claim with all laws, regulations and program instructions applicable to Medicare participation and coverage. You further agreed that you were responsible for the accuracy and completeness of all representations made in connection with each claim submitted for payment to Medicare with the Provider Identification Number (PIN) assigned to you.

I have determined that the Carrier acted in accordance with Medicare Laws, Regulations and the CMS Internet Only Manual (IOM) in re-opening the claim in question, determining that an overpayment existed, and attempting to recover the overpayment.

The citations are as follows: Medicare Program Regulations: the Code of Federal Regulations (CFR), Reg. 42, Part 405, Subpart C, Sections 405.350 through 405.359, dealing with review, overpayment recoupement, and adjudication.

A physician is liable for overpayment he/she received unless he/she is found to be without fault. A physician will be considered without fault if he/she exercised reasonable care in billing for and accepting payment; i.e., he/she complied with all pertinent regulations, he/she made full disclosure of all material facts and on the basis of the

information available to him/her, including but not limited to the Medicare regulations, he/she had a reasonable basis for assuming that the payment was correct.

In general, the Carrier will consider that the physician should have known a policy or rule, if the policy or rule is in the federal regulations or the Carrier had provided general notice to the medical community.

RESPONSE #7:

The first published notice that these services were no longer covered by this carrier was published on the NHIC website in 2004. All these services were billed in the preceding three years. Furthermore, you're accusing me of knowingly billing Medicare for medically unnecessary services which is a Federal crime. I have provided declarations to the DAB and the Federal Court in Santa Ana in our case originally filed December 15, 2006 stating that I absolutely never knew these services were not going to be covered. Moreover, reimbursement needs to be reinstated because the services are medically necessary and much suffering has been cause to the Medicare beneficiaries.

You write:

If you qualify for, and wish to request an ALJ hearing, you can request one by writing to:

National Heritage Insurance Company
PO Box 2811
Chico, CA 95927-2811

Response #7:

You had no legal authority to deny us an in person hearing. The Hearing Office docket is replete with this documentation. Why did you chose to ignore it? Who told you to conduct a hearing right now without any notice to me whatsoever?

It is our stated position that the relevant LCD provisions were withdrawn because that is what the DHHS DAB determined.

You must rely on the facts in evidence and the law.

Please correct my address in your records to include our suite number.

Sincerely,

Dorothy Calabrese, M.D.

1 **PROOF OF SERVICE**

2
3 I am a resident of the County of Orange, State of California. I am over the age of 18 and not a
4 party to the within action. I may be reached through the medical practice of Dorothy
Calabrese, M.D. at 24953 Paseo de Valencia, Suite 4A, Laguna Hills, California 92653-4342.

5 On March 28, 2007 I served the foregoing document described as:

6 Case No: SACV06-1217 CJC (RNBx) PLAINTIFFS' REQUEST FOR DETERMINATION REGARDING
7 NHIC DENIAL OF IN -PERSON HEARING WITH WITNESSES BRUCE QUINN, M.D., DON ADAMS
M.D. & TOM HOROWITZ D.O.

8
9 on all parties in this action by placing true copies thereof enclosed in sealed envelopes
addressed as follows:

10
11 John A. Conkle
12 Conkle, Kremer & Engel
3130 Wilshire Boulevard, Suite 500
Santa Monica, CA 90403-2351

13
14 U.S. Attorney Civil Process Clerk
300 North Los Angeles Street
15 Room 7516
Los Angeles, CA 90012

16
17 These mailings were deposited in a USPS mail deposit box with postage thereon fully prepaid at
San Juan Capistrano, CA in the ordinary course of business.

18 I am aware that on motion of the party served, service is presumed invalid if postal cancellation
19 date is more than one day after date of deposit for mailing in this proof.

20 I declare under penalty of perjury under the laws of the State of California and the United
21 States that the above is true and correct, and that this Proof of Service was executed this 2nd
day of April, 2007.

22
23
24
25 _____
Marguerite Kennedy