ATTORNEY OR PARTY WITHOUT ATTORNEY (NAME AND ADDRESS):	TELEPHONE:	FOR COURT USE ONLY
Diane "Dee" Hansch, Esq. 160 Hart Avenue Santa Monica, CA 90405	(310)399-4299	ORIGINAL FILED OCT 06 1995 SUPERIOR COURT
ATTORNEY FOR (NAME): Plaintiff in Pro Per		
Insert name of court, judicial district or branch court, if any, and post office and street address: Superior Court of California County of Los Angeles West District 1725 Main St. Santa Monica, CA 90401		
PLAINTIFF: Diane "Dee" Hansch, Esq.		
DEFENDANT CIGNA Private Practice Plan & CIGNA Healthplan of Northern California, its agents, employees, providers and assigns; Joan Feltman, M.D.; Santa Monica Bay Physicians, its agents, employees, providers and assigns; and ☒ DOES 1 TO ~~10~~, inclusive.		
First Amended ☒ COMPLAINT ☐ CROSS-COMPLAINT		CASE NUMBER: SC038049

1. This pleading, including attachments and exhibits, consists of the following number of pages: 63

2. a. Each plaintiff named above is a competent adult , (hereinafter, "HANSCH").
   ☐ **Except** plaintiff *(name)*:
   - ☐ a corporation qualified to do business in California
   - ☐ an unincorporated entity *(describe)*:
   - ☐ other *(specify)*:

   b. ☐ Plaintiff *(name)*:
   - ☐ has complied with the fictitious business name laws and is doing business under the fictitious name of *(specify)*:
   - ☐ has complied with all licensing requirements as a licensed *(specify)*:

   c. ☐ Information about additional plaintiffs who are not competent adults is shown in Complaint—Attachment 2c.

3. a. Each defendant named above is a natural person

☒ **Except** defendant *(name)*: CIGNA Private Practice Plan & CIGNA Healthplan ...	☒ **Except** defendant *(name)*: Santa Monica Bay Physicia
☐ a business organization, form unknown	☐ a business organization, form unknown
☒ a corporation	☒ a corporation
☐ an unincorporated entity *(describe)*:	☐ an unincorporated entity *(describe)*:
☐ a public entity *(describe)*:	☐ a public entity *(describe)*:
☐ other *(specify)*: (hereinafter, "CIGNA").	☐ other *(specify)*: (hereinafter, "PHYSICIANS").

   b. The true names and capacities of defendants sued as Does are unknown to plaintiff. (Hereinafter, "DOES".)

   c. ☐ Information about additional defendants who are not natural persons is contained in Complaint—Attachment 3c.

   d. ☐ Defendants who are joined pursuant to Code of Civil Procedure section 382 are *(names)*:

   e. Joan Feltman, M.D. shall hereinafter be designated "FELTMAN".

(Continued)

SHORT TITLE: HANSCH v. CIGN t al	CASE NUMBER: SC098049

FIRST AMENDED **COMPLAINT**

4. [X] Plaintiff is required to comply with a claims process and
   a. [X] plaintiff has complied with applicable claims process
   b. [X] plaintiff is excused from complying because *(specify)*:
   CIGNA, on its own behalf and on behalf of FELTMAN, PHYSICIANS and DOES released HANSCH from mandatory arbitration requirement and granted leave to sue.
5. [ ] This action is subject to [ ] Civil Code section 1812.10 [ ] Civil Code section 2984.4.
6. This action is filed in this [ ] county [X] judicial district because
   a. [ ] a defendant entered into the contract here
   b. [ ] a defendant lived here when the contract was entered into.
   c. [ ] a defendant lives here now
   d. [X] the contract was to be performed here. See number 8 below.
   e. [X] a defendant is a corporation or unincorporated association and its principal place of business is here.
   f. [ ] real property that is the subject of this action is located here.
   g. [X] other *(specify)*: injuries occurred here.
7. [X] The following paragraphs of this pleading are alleged on information and belief *(specify paragraph numbers)*:
8. [X] Other: The "Group Service Agreement," the employee benefit plan agreement at issue herein shall also be referred to herein as "the contract", "the agreement", "the Contract", or "the Agreement".
9. The following causes of action are attached and the statements above apply to each: *(Each complaint must have one or more causes of action attached.)*
   [XX] ERISA Action S502 (a)(1)(B)
   [XX] Other *(specify)*:
   ERISA Action S502 (a)(3)(B)
   [ ] Common Counts
   Fraud
   Medical Malpractice
   Intentional Tort
   Civil Rights
10. PLAINTIFF PRAYS
   For judgment for costs of suit; for such relief as is fair, just, and equitable; and for
   [X] damages of $ 250,000 plus such other damages according to proof
   [X] interest on the damages [X] according to proof [ ] at the rate of _____ percent per year from *(date)*:
   [X] attorney fees [ ] of $_____ [X] according to proof
   [X] other *(specify)*:
   Exemplary Damages
   Treble Damages
   Any other relief which is just, fair and equitable

Diane "Dee" Hansch, Esq.
(Type or print name)

_____
(Signature of plaintiff or attorney)

(If you wish to verify this pleading, affix a verification.)

SHORT TITLE: HANSCH v. CIGNA, et al	CASE NUMBER: SC038049

First (number) **CAUSE OF ACTION—** ERISA Action S502 (a)(1)(B)

ATTACHMENT TO [X] Complaint [ ] Cross-Complaint

(Use a separate cause of action form for each cause of action.)

E1 -1. Plaintiff *(name)*: HANSCH

alleges that on or about *(date)*: January 1, 1992
a [X] written [ ] oral [ ] other *(specify)*:
agreement was made between *(name parties to agreement)*:
Plaintiff's employer, Orrick, Herrington & Sutcliffe, and CIGNA

[X] A copy of the agreement is attached as Exhibit A, or

[ ] The essential terms of the agreement [ ] are stated in Attachment BC-1 [ ] are as follows *(specify)*:

[X] The agreement incorporates the Knox-Keene Healthcare Service Plan Act of 1975 (Chapter 2.2 of Division 2 of the California Health and Safety Code) and the regulations promulgated thereunder (Subchapter 5.5 of Chapter 3 of title 10 of the California Code of Regulations).

[X] As an employee of Orrick, Herrington & Sutcliffe, Plaintiff HANSCH was a participant in the employee benefit plan articulated in the agreement. Accordingly, the agreement falls within the scope of the Employee Retirement Income Security Act of 1974 ("ERISA") (29 U.S.C. S 1001, et seq.)

E1-2. On or about *(dates)*: January 1, 1992 to present
defendant breached the agreement by [X] the acts specified in Attachment BC-2 [ ] the following acts *(specify)*:

E1 -3. Plaintiff has performed all obligations to defendant except those obligations plaintiff was prevented or excused from performing.

E1 -4. Plaintiff suffered damages legally (proximately) caused by defendant's breach of the agreement
[XX] as stated in Attachment BC-4 [ ] as follows *(specify)*:

E1 -5. [X] Plaintiff is entitled to attorney fees by an agreement or a statute
[ ] of $
[X] according to proof.

E1.-6. [X] Other: Plaintiff HANSCH is informed and believes that Defendant CIGNA, Defendant FELTMAN, Defendant PHYSICIANS and Defendant DOES are parties to an agreement or agreements among and between them to provide services under the Agreement.

Attachment E1-2, part 1

Defendants CIGNA, FELTMAN, PHYSICIANS and DOES violated Plaintiff's rights under the Agreement by their:

a. Failure to provide health care to Plaintiff in a timely and appropriate manner, including the failure to listen to Plaintiff's concerns, the failure to spend sufficient time on Plaintiff's concerns, and the failure to give advice, information, diagnosis, referrals and treatment for Plaintiff's abdominal symptoms and related concerns.

b. Failure to obtain and make accurate medical information and records available to Plaintiff, including results of pap tests, in a timely and appropriate manner.

c. Allowing fiscal considerations to unduly influence medical decisions regarding Plaintiff, including decisions regarding the allocation of time spent on Plaintiff's concerns and the provision of advice, information, diagnoses, referrals and treatments for Plaintiff's abdominal symptoms and related concerns.

d. Allowing health care provided to Plaintiff to be reduced or limited due to Plaintiff's conditions attributable to exposure to diethylstilbestrol, including care provided in listening to Plaintiff's concerns, allocating time on Plaintiff's concerns, giving advice, information, diagnosis, referrals and treatment for Plaintiff's abdominal symptoms and related concerns.

e. Failure to provide reimbursement to Plaintiff for her health care expenses.

f. Failure to provide Plaintiff with required claim and grievance processes.

g. Failure to excercise proper care in the selection, training, supervision, management and actions of Defendant FELTMAN as a Primary Care Physician, as that term is defined in the Agreement.

(Required for verified pleading) The items on this page stated on information and belief are *(specify item numbers, not line numbers)*:

Attachment E1-2, part 2

Additionally, Defendants CIGNA and DOES should be estopped from invoking those provisions of the Agreement which limit the repayment for emergency services due to the following:

h. Defendant CIGNA's phone operator, after speaking with Plaintiff regarding Plaintiff's severe pain and need for services, instructed Plaintiff to seek emergency services, without limitation, for her pain and abdominal symptoms, which services would be reimbursed by CIGNA.

i. Plaintiff reasonably relied on the representation of CIGNA's phone operator in subsequently incurring emergency expenses for pain and abdominal sypmtoms, unaware of any ambiguity in the Agreement regarding the repayment of such expenses.

j. Defendant's provisions regarding the repayment for emergency expenses is ambiguous.

Further, Defendants CIGNA and DOES should be estopped from invoking those provisions of the Agreement which limit the repayment for emergency services for the alleviation of severe pain due to the following:

k. Defendant CIGNA's Grievance Committee failed to address in their determination letter the language in the Agreement regarding the repayment for emergency services for the alleviation of severe pain.

(Required for verified pleading) The items on this page stated on information and belief are *(specify item numbers, not line numbers)*:

Attachment E1-4

The violation of Plaintiff's rights under the Agreement by Defendants CIGNA, FELTMAN, PHYSICIANS and DOES caused Plaintiff the following damages:

Health care bills	$ 1,200.00
Prospective health care bills	$ 5,000.00
Loss of earnings	$200,000.00
Loss of professional education and experience	$ 43,000.00
Increased amounts for replacement health insurance	$ 1,100.00

Experience of deteriorated health, severe physical pain, fear of reproductive cancer and death, plus other damages according to proof.

Plaintiff prays for actual damages plus attorney's fees.

(Required for verified pleading) The items on this page stated on information and belief are *(specify item numbers, **not** line numbers)*:

This page may be used with any Judicial Council form or any other paper filed with the court.

SECOND CAUSE OF ACTION - ERISA ACTION S502(a)(3)

ATTACHMENT TO COMPLAINT

E2-1. Plaintiff alleges that Defendants CIGNA, FELTMAN, PHYSICIANS, and DOES, each acting as fiduciaries toward Plaintiff pursuant to their authority to allocate resources and services under the Agreement, caused damages to Plaintiff. On or about January 1, 1992 to the present, at Los Angeles County, Defendants breached their fiduciary duties to Plaintiff by the following wanton, willful or bad faith acts or omissions of acts:

a. Failure to provide health care to Plaintiff in a timely and appropriate manner, including the failure to listen to Plaintiff's concerns, the failure to spend sufficient time on Plaintiff's concerns, and the failure to give advice, information, diagnosis, referrals and treatment for Plaintiff's abdominal symptoms and related concerns.

b. Failure to obtain and make accurate medical information and records available to Plaintiff, including results of pap tests, in a timely and appropriate manner.

c. Allowing fiscal considerations to unduly influence medical decisions regarding Plaintiff, including decisions regarding the allocation of time spent on Plaintiff's concerns and the provision of advice, information, diagnoses, referrals and treatments for Plaintiff's abdominal symptoms and related concerns.

d. Allowing health care provided to Plaintiff to be reduced or limited due to Plaintiff's conditions attributable to exposure to diethylstilbestrol, including care provided in listening to Plaintiff's concerns, allocating time on Plaintiff's concerns, giving advice, information, diagnosis, referrals and treatment for Plaintiff's abdominal symptoms and related concerns.

e. Failure to provide reimbursement to Plaintiff for her health care expenses.

f. Failure to provide Plaintiff with required claim and grievance processes.

g. Failure to excercise proper care in the selection, training, supervision, management and actions of Defendant FELTMAN as a Primary Care Physician, as that term is defined in the Agreement.

SECOND CAUSE OF ACTION - ERISA ACTION S502(a)(3)

E2-2 Because of the breach of fiducary duties owed to Plaintiff by DEFENDANTS CIGNA, FELTMAN, PHYSICIANS, and DOES, Plaintiff suffered damages as follows:

Health care bills	$ 1,200.00
Prospective health care bills	$ 5,000.00
Loss of earnings	$200,000.00
Loss of professional education and experience	$ 43,000.00
Increased amounts for replacement health insurance	$ 1,100.00

Experience of deteriorated health, severe physical pain, fear of reproductive cancer and death, and other damages according to proof.

Plaintiff accordingly prays for actual damages, attorney's fees and such other relief that is just, fair and equitable.

(Required for verified pleading) The items on this page stated on information and belief are *(specify item numbers, **not** line numbers)*:

SHORT TITLE: HANSCH v. CIGNA, et al	CASE NUMBER: SC038049

Third (number) **CAUSE OF ACTION—Fraud** Page 9

ATTACHMENT TO [X] Complaint [ ] Cross-Complaint

(Use a separate cause of action form for each cause of action.)

FR-1. Plaintiff *(name)*: HANSCH

alleges that defendant *(name)*: FELTMAN, PHYSICIANS AND DOES

on or about *(date)*: March 1, 1992 to present defrauded plaintiff as follows:

FR-2. [X] **Intentional or Negligent Misrepresentation**

a. Defendant made representations of material fact [X] as stated in Attachment FR-2.a [ ] as follows:

b. These representations were in fact false. The truth was [X] as stated in Attachment FR-2.b [ ] as follows:

c. When defendant made the representations,
[X] defendant knew they were false, or
[ ] defendant had no reasonable ground for believing the representations were true.

d. Defendant made the representations with the intent to defraud and induce plaintiff to act as described in item FR-5. At the time plaintiff acted, plaintiff did not know the representations were false and believed they were true. Plaintiff acted in justifiable reliance upon the truth of the representations.

FR-3. [X] **Concealment**

a. Defendant concealed or suppressed material facts [X] as stated in Attachment FR-3.a [ ] as follows:

b. Defendant concealed or suppressed material facts
[X] defendant was bound to disclose.
[X] by telling plaintiff other facts to mislead plaintiff and prevent plaintiff from discovering the concealed or suppressed facts.

c. Defendant concealed or suppressed these facts with the intent to defraud and induce plaintiff to act as described in item FR-5. At the time plaintiff acted, plaintiff was unaware of the concealed or suppressed facts and would not have taken the action if plaintiff had known the facts.

(Continued)

SHORT TITLE: HANSCH v. CIGNA, et al	CASE NUMBER: SC038049

Third (number) **CAUSE OF ACTION—Fraud (Continued)** Page 10

FR-4. [X] **Promise Without Intent to Perform**

a. Defendant made a promise about a material matter without any intention of performing it [X] as stated in Attachment FR-4.a [ ] as follows:

b. Defendant's promise without any intention of performance was made with the intent to defraud and induce plaintiff to rely upon it and to act as described in item FR-5. At the time plaintiff acted, plaintiff was unaware of defendant's intention not to perform the promise. Plaintiff acted in justifiable reliance upon the promise.

FR-5. In justifiable reliance upon defendant's conduct, plaintiff was induced to act [X] as stated in Attachment FR-5 [ ] as follows:

FR-6. Because of plaintiff's reliance upon defendant's conduct, plaintiff has been damaged [X] as stated in Attachment FR-6 [ ] as follows:

FR-7. Other:

This cause of action is separate from ERISA causes.

Attachment FR-2.a

Defendant FELTMAN stated she was competent to give appropriate gynecological care, administer pap tests and monitor Plaintiff's conditions attributable to exposure to diethylstilbestrol.

Attachment FR-2.b

Defendant FELTMAN was not competent to give appropriate gynecological care, administer pap tests and monitor Plaintiff's conditions attributable to exposure to diethylstilbestrol.

Attachment FR-3.a

Defendant FELTMAN concealed or suppressed Plaintiff's medical information and records, including information regarding the inadequacy of pap tests administered by Defendant FELTMAN.

Attachment FR-4.a

Defendant FELTMAN promised she would give appropriate gynecological care, including properly administering pap tests and monitoring Plaintiff's conditions attributable to exposure to diethylstilbestrol.

Attachment FR-5

Plaintiff was induced to purchase and use inappropriate health products, fear reproductive cancer and death, and make severe lifestyle changes including the resignation from her high paying job.

Attachment FR-6

Health care bills	$ 1,200.00
Prospective health care bills	$ 5,000.00
Loss of earnings	$200,000.00
Loss of professional education and experience	$ 43,000.00
Increased amounts for replacement health insurance	$ 1,100.00

Experience of deteriorated health, severe physical pain, fear of reproductive cancer and death, plus other damages according to proof.

Plaintiff accordingly prays for actual damages and exemplary damages.

SHORT TITLE: HANSCH v. CIGNA, et al	CASE NUMBER: SC038049

Fourth (number) **CAUSE OF ACTION—** MEDICAL MALPRACTICE **Page** 12

ATTACHMENT TO [X] Complaint [ ] Cross-Complaint

(Use a separate cause of action form for each cause of action.)

MM-1. Plaintiff *(name)*: HANSCH

alleges that defendant *(name)*: CIGNA, FELTMAN, PHYSICIANS AND DOES

[ ] Does _____ to _____

was the legal (proximate) cause of damages to plaintiff. By the following acts or omissions to act, defendant negligently caused the damage to plaintiff
on *(date)*: on or about January 1, 1992 to present
at *(place)*: Santa Monica

(description of reasons for liability): as stated in attachment MM-1

SHORT TITLE:	NUMBER:
HANSCH v. CIGNA, et al	SC038049

Attachment MM-1

a. Plaintiff sought healthcare from Defendants CIGNA, FELTMAN, PHYSICIANS, and DOES, licensed health care providers.

b. Defendants CIGNA, FELTMAN, PHYSICIANS, and DOES agreed to provide health care to Plaintiff.

c. Defendants CIGNA, FELTMAN, PHYSICIANS, and DOES failed to possess and excercise that degree of knowledge and skill ordinarily possessed and excercised by other health care providers in the same professions as Defendants.

d. Defendants CIGNA, FELTMAN, PHYSICIANS, and DOES failed to provide health care in a timely and appropriate fashion, which failure included the failure to listen to Plaintiff's concerns, the failure to spend appropriate time on Plaintiff's concerns, and the failure to give advice, information, diagnosis, referrals and treatment for Plaintiff's abdominal symptoms and related concerns.

e. By so doing, Plaintiff suffered the following damages:

Health care bills	$ 1,200.00
Prospective health care bills	$ 5,000.00
Loss of earnings	$200,000.00
Loss of professional education and experience	$ 43,000.00
Increased amounts for replacement health insurance	$ 1,100.00

Experience of deteriorated health, severe physical pain, fear of reproductive cancer and death, and other damages according to proof. Plaintiff prays for actual damages and such other damages as determined by the court.

(Required for verified pleading) The items on this page stated on information and belief are *(specify item numbers, not line numbers)*:

SHORT TITLE: HANSCH v. CIGNA, et al	CASE NUMBER: SC038049

Fifth (number) **CAUSE OF ACTION—Intentional Tort** Page 14

ATTACHMENT TO [X] Complaint [ ] Cross-Complaint

(Use a separate cause of action form for each cause of action.)

IT-1. Plaintiff *(name)*: HANSCH

alleges that defendant *(name)*: FELTMAN, PHYSICIANS and DOES

on: July 9, 1993

at: Santa Monica

Defendants FELTMAN, PHYSICIANS and DOES scheduled or allowed to be scheduled gastro-intestinal tests for Plaintiff in the late afternoon knowing Plaintiff was in a weakened condition, causing increased strain and time without nutrition for Plaintiff.

SIXTH CAUSE OF ACTION - VIOLATION OF CIVIL RIGHTS

CR-1 Plaintiff alleges that Defendants CIGNA, FELTMAN, PHYSICIANS and DOES were engaged in business in California at all times mentioned in this complaint. On or about January 1, 1992 to the present, at Los Angeles County, Defendants CIGNA, FELTMAN, PHYSICIANS and DOES violated the Unruh Civil Rights Act, Civil Code of California § 51, et seq., by failing and refusing to provide health care services owing to Plaintiff, such failures and refusals included the:

a. Failure to provide health care to Plaintiff in a timely and appropriate manner, including the failure to listen to Plaintiff's concerns, the failure to spend sufficient time on Plaintiff's concerns, and the failure to give advice, information, diagnosis, referrals and treatment for Plaintiff's abdominal symptoms and related concerns.

b. Failure to obtain and make accurate medical information and records available to Plaintiff, including results of pap tests, in a timely and appropriate manner.

c. Failure to provide reimbursement to Plaintiff for her medical expenses.

d. Failure to provide Plaintiff with required claim and grievance processes.

The failure and refusal to provide health care in a timely and appropriate manner was due to Plaintiff's sex and Plaintiff's condition as diethylstilbestrol exposed daughter.

(Required for verified pleading) The items on this page stated on information and belief are *(specify item numbers, **not** line numbers)*:

CR-2

Due to Defendants wrongful acts, Plaintiff was damaged as follows:

Health care bills	$ 1,200.00
Prospective health care bills	$ 5,000.00
Loss of earnings	$200,000.00
Loss of professional education and experience	$ 43,000.00
Increased amounts for replacement health insurance	$ 1,100.00

Experience of deteriorated health, severe physical pain, fear of reproductive cancer and death, plus other damages according to proof.

Plaintiff accordingly prays for actual damages, treble damages, attorney's fees and other relief that is fair, just and equitable.

(Required for verified pleading) The items on this page stated on information and belief are *(specify item numbers, not line numbers)*:

FYI

DIANE "DEE" HANSCH, ESQ.
160 Hart Avenue
Santa Monica, CA 94050
(310) 399-4299

EDUCATION

Master's Candidate, Institute for Dispute Resolution
Pepperdine University School of Law, Malibu, CA 1995 - Present.

Juris Doctorate, Magna Cum Laude
Santa Clara University School of Law, Santa Clara, CA 1989
Law Review Articles Editor; 2nd Year Class Prize; Community Service Award; Research Assistant; Jesuit Honor Society; Judicial Extern; Emory Scholarship; Public Interest Law Certificate.

Bachelor of Arts in Anthropology, Honors in the Major
University of California at Santa Cruz, Santa Cruz, CA 1982
Thesis - Guadalupe: Politics & Religion; Graduation Speaker.

BAR MEMBERSHIP

California State Bar 1989.
U.S. District Court: Northern CA 1989; Central CA 1992.

PUBLIC OFFICES/GOVERNMENTAL APPOINTMENTS

Member, California State, Los Angeles County and Santa Cruz County Democratic Central Committees, variously 1980-93.

Member, Santa Cruz City Planning Commission 1983-88. Chair, 1987.

Linda Brennan Assembly Intern, California State Assembly 1985.

PROFESSIONAL EXPERIENCE

Consultant, 1980 - Present
Services: Campaign management, compliance, confidential assistance, dispute resolution, design, executive development, finance, lobbying, management, media, organizational development, policy, research & writing, strategic planning, teaching. Representative engagements: Gov. Brown, IAM Communications, MGM, SC Legal Aid.

Associate Attorney, Orrick, Herrington & Sutcliffe, 1991-1993
Public finance practice representing public issuers & underwriters, negotiating & drafting multi-million dollar contracts, research & writing, governmental relations, due diligence, litigation, tax analysis. Established pro bono project. Summer associate in 1988.

→ Executive Director, California Democratic Party, 1990-1991
Managed $8.5 million annual budget, reorganized & supervised internal operations, directed litigation and compliance activities, convened meetings & conventions, published magazine, maintained press relations, advised campaigns, coordinated election efforts, assisted Chair. Joined CDP as fundraising associate in 1989.

F.Y.I.

Diane "Dee" Hansch
160 Hart Avenue
Santa Monica, CA 90405
(310) 399-4299

June 9, 1995

PERSONAL AND CONFIDENTIAL
Family Leaders & Other Personal Advisors

Dear Family Leaders & Other Personal Advisors:

As you know so well, I have really been through the mill the last couple of years. You have been there for me and I will never forget what you have done.

As you may also know, I have been pursuing a claim against my former healthcare provider (CIGNA) to compensate me for expenses I incurred for my healthcare during this crisis. I have been handling this matter myself for a variety of reasons. Among these reasons were my views and the views of certain of you and other advisors regarding the issues and amounts involved. However, as the enclosed document describes, my claim just snowballed into something much bigger. (I honestly never expected this.) And it may continue to snowball. It also may not - Godwilling.

I share this letter and the enclosure contained within to request your continuing assistance on this legal matter and to remind you to strictly guard my confidentiality. (For those of you who need a further reminder, that basically means that I do not want you to discuss me or my affairs with anyone other than myself or my clearly delegated representatives. Really. These matters are extremely personal and important. Even your well-intended and otherwise typical paternal/maternal/fraternal/sororal actions could have serious negative consequences. I trust you will decline the temptation to speak for me and always notify me of any attempts by any third parties to obtain information. We can then discuss what if anything to do in response.)

I do not forget for one minute how lucky I am to be surrounded by such an august group (no pun intended Uncle Gus) of business, legal, healthcare and human behavior experts.

Please also be aware that the reading of the enclosed document may make you feel sad and confused. Do not worry if you do not understand all of the language, concepts, history or positions. Each of you has a special area of expertise, none of you is expected to understand it all. Remember, I did survive this and the worst is basically all in the past. I am now trying to right wrongs and get on with a beautiful life.

L'chiam!

DEE HANSCH

Photo:

Enclosed to show you something about the impression I can make on decision makers, whether as sympathetic plaintiff or speaker.

THE WHITE HOUSE
WASHINGTON

December 10, 1995

John R. Lindhal, Sr.
The Lindhal Foundation
Box 123
Ashland, TN 37015

Dear Mr. Lindhal:

Thank you for your letter. It is so important that children in this country get high quality education and training. Foundations like yours do so much to help give our youth a better future.

I have forwarded your letter to the Office of Tax Policy in the Department of Treasury for their review.

Thank you again for writing.

Sincerely,

Jennifer Klein
Senior Policy Analyst

JOHN R. LINDAHL, SR.

October 9, 1995

Ms. Jennifer Klein
Senior Policy Analysts
Office of Policy Development
1600 Pennsylvania Ave., N.W.
Washington, D.C. 20500

Dear Jennifer:

America's competitive position in a world economy during the next century will depend upon our ability to provide education and training to American youth. Maximizing opportunities for post-secondary education must be a primary focus for American business in this decade. While government has attempted to meet the needs of America's youth for access to the educational process, fiscal policy and budgetary restraints continue to erode available funds for scholarship and loan programs sponsored by governmental agencies.

In 1991, I decided to do my part to provide educational opportunities and increased access to education and training to the children of the employees of State Industries, Inc. State Industries is a family-owned business which has grown and prospered due in large measure to the ingenuity and industriousness of the American worker, specifically the American workers who live in Middle Tennessee. State Industries is the world's largest manufacturer of residential water heaters. I have observed first-hand the dramatic changes which have occurred in this basic manufacturing industry as a result of the introduction of new technology and computerization. Concerned that the children of State's employees, many of whom would be first-generation college attendees, would not be able to obtain the necessary training, whether at college, university, or vocational schools, I founded the Lindahl Foundation.

The purpose of the Lindahl Foundation is to provide scholarships to average students seeking to further their education at colleges, universities and vocational training institutions. Since 1991, over 400 students from Middle Tennessee have received scholarships ranging from $1,000 to $4,000 per year. Enclosed is a brochure that explains our efforts and highlights some of the outstanding young people we have been able to assist. The Lindahl Foundation is funded entirely out of my personal resources and receives no contributions from State Industries or any other source. As I have attempted to expand the reach of the Lindahl Foundation to insure that every State Industries child has the opportunity to receive all of the education that their intellect and ambition will allow them to pursue, I have been shocked to discover limitations which the Internal Revenue Service has imposed upon the Foundation's ability to offer scholarship aid to students. At a time when government loan and grant programs are decreasing and when Congress is asking American business and businessmen to assume greater responsibility, the position of the Internal Revenue Service creates an unreasonable and unnecessary limitation in the area of scholarship grants by private foundations.

While the Internal Revenue Service has issued fair and effective guidelines to insure that the scholarships are awarded on an objective and non-discriminatory basis, the IRS has developed certain percentage tests which arbitrarily limit the number of scholarships that can be awarded to qualified applicants. I have enclosed a brief explanation of the restrictions currently in place with respect to employer-related scholarship programs.

Let me briefly summarize the problem. If a foundation is related to an employer (I am one of the owners of State Industries and the scholarship program is designed to benefit State Industries employees' children), the foundation **must refuse to grant scholarships** to up to 75% of qualified applicants **even if there are sufficient funds available with which to provide the scholarship aid.** If a foundation fails the percentage test, contributions to the foundation may not be tax deductible and benefits paid to students by the foundation may be taxable to the students' parents who are employees of the related employer. This makes no sense. So long as a scholarship program is designed for the purpose of providing benefits to the children of rank and file employees rather than highly-compensated employees, there should be no artificial percentage limitation on the number of scholarships which may be awarded. Abuse arises only if the scholarships are provided to highly-paid employees at the expense of rank and file employees. It is my goal that every State Industries child have an opportunity for a scholarship; however, the current percentage limitations severely limit my ability to achieve this goal.

I have enclosed proposed legislation that would allow the Lindahl Foundation and other similarly-situated foundations throughout the country to expand their scholarship and grant programs. The Internal Revenue Service guidelines for determining whether awards are made in an objective and nondiscriminatory manner should remain in place. The arbitrary percentage limitations should be abolished.

I would like to have your help in changing the Internal Revenue Service's interpretation of the laws so that American business may step up to the plate and provide assistance to worthy students. I hope I can count on your help. If you would like additional information, I would be happy to provide it. I look forward to talking with you soon.

Sincerely,

John R. Lindahl, Sr.

JL/wp

Executive Summary
EMPLOYER-RELATED GRANT PROGRAMS

BACKGROUND. Under certain circumstances, private foundations that provide scholarships or educational loans to employees (and their children) of a particular employer are subject to a determination that the scholarships or loans are "taxable expenditures," thereby subjecting the foundation to a 10% federal excise tax on those grants. The IRS's objective is to prevent employers from using these means to compensate employees on a tax-free basis. The primary test applied to educational loans and scholarships is whether they are awarded on an **objective and nondiscriminatory basis** pursuant to IRS-approved procedures.

PERCENTAGE TESTS. The IRS has established seven guidelines for meeting the test of being objective and nondiscriminatory. In addition to these guidelines, the IRS has developed a **percentage test** whereby the aggregate amount awarded to children of employees **cannot exceed 25%** of the number of employees' children who were eligible, applied and were considered for an award; **or, 10%** of the number of employees' children who were eligible for the awards, regardless of whether they applied. With respect to loans or grants to employees themselves, the aggregate amount of awards may not exceed 10% of those who were eligible. These percentage tests arbitrarily prevent employers from providing educational assistance to employees and their children. A foundation which follows procedures that are objective and nondiscriminatory under the guidelines can still be barred from providing assistance to a student who meets every requirement for an award simply because too many employees' children are qualified. In fact, a foundation is **required** to **turn down 75%** of the applicants **regardless** of financial need and academic qualification -- and despite the fact that money is available.

PROPOSED CHANGES. Rather than encouraging companies and foundations to provide scholarships and educational loans to all eligible applicants, the IRS percentage tests limit loan and scholarship programs. The rules arbitrarily deny educational opportunities to those who deserve them, or cause them to seek such assistance from other sources such as taxpayer-supported grant and loan programs. Maintaining the seven guidelines, but excluding the percentage tests, will prevent the use of scholarships and loans as disguised compensation while encouraging companies and foundations to provide educational opportunities.

CHANGES ARE REVENUE NEUTRAL. Abolishing the percentage tests will cause little, if any, loss of revenue, particularly if the seven guidelines are maintained. Under current regulations, an employer is entitled to a deduction regardless of whether the grant to an employee or employee's child is treated as compensation or as a scholarship. Thus, there is no revenue impact on the employer side. On the employee's side of the equation, treatment of the grants as scholarships only relieves the tax liability for that portion of the scholarship used for tuition, fees, books and supplies. Expenses associated with other educational expenses, such as room and board, are already fully taxable and would remain so even if the percentage tests are abolished. Further, any lost revenues that might be attributed to treating grants as scholarships rather than compensation will be minimal since the employees involved are generally at the lowest income tax brackets. In fact, because most of the recipients of the scholarships and educational loans would otherwise be eligible for student loans and grant programs sponsored by the federal government, a portion of that burden will be paid by companies and foundations that are currently prohibited from providing such financial assistance.

EMPLOYER-RELATED GRANT PROGRAMS

The proposed legislative change would remove percentage limitations currently imposed by the Internal Revenue Service which unduly restrict the number of scholarship grants and educational loans made by private foundations for the benefit of certain employees and their families under employer-related grant programs.

Present Law

Many foundations are formed primarily to provide scholarships and educational loans to employees, and the families of employees, of a particular employer. These foundations generally are organized as educational organizations under Section 501(c)(3) of the Internal Revenue Code (the "Code") and are classified as private foundations, as opposed to public charities, because their funding typically is derived exclusively from the employer or the employer's principal founder or shareholder. Because the contributions made to the foundation are generally deductible, and because the employee or employee's child may receive the scholarship tax-free under Section 117 of the Code, the Internal Revenue Service ("IRS") is concerned that the foundation may be used as an indirect means to provide compensation or a fringe benefit to employees of the employer.

A private foundation is subject to a federal excise tax of 10% for each "taxable expenditure" it makes during a taxable year. I.R.C. § 4945(a). The purpose of this excise tax is to sanction a private foundation for making expenditures other than for charitable or educational purposes. One of the taxable expenditures subject to excise tax is any amount paid "as a grant to an individual for travel, study, or other similar purposes" (I.R.C. § 4945(d)(3)), unless the grant is "awarded on an objective and nondiscriminatory basis pursuant to a procedure approved in advance by the [IRS]," and it is demonstrated to the satisfaction of the IRS that the grant (1) constitutes a scholarship grant subject to the provisions of Section 117(a) of the Code and used for study at an educational institution, or (2) achieves a specific objective or improves a particular talent, skill, or capacity of the grantee. I.R.C. § 4945(g).

It is necessary for a private foundation to obtain advance approval of its grantmaking procedures from the IRS in order to make scholarships or educational loans to individuals without incurring an excise tax. Thus, the IRS is required to rule on the individual grant or loan procedures on a case-by-case basis. In order to provide guidance to private foundations that make scholarships or educational loans under an "employer-related grant program," the IRS has issued two revenue procedures setting forth guidelines which must be followed by these foundations in order to avoid the excise tax on taxable expenditures. Basically, an "employer-related grant program" is a program that gives employees, and the families of employees, of a particular employer a preference or a priority over others in the selection process for awarding scholarships or educational loans. If the guidelines set forth in these revenue procedures are not satisfied, the IRS will not approve the grant-making procedures. Rev. Proc. 76-47, 1976-2 C.B. 670 (guidelines for scholarships); Rev. Proc. 80-39, 1980-2 C.B. 772 (guidelines for educational loans).

The revenue procedures set forth seven requirements which must be satisfied in determining whether a scholarship or loan is made on an objective and nondiscriminatory basis and is thus not a form of disguised compensation to the employee. In addition to the seven requirements, the revenue procedures also provide two percentage tests that serve as "safe harbors," with one of the percentage tests applicable to the children of employees, and one applicable to the employees themselves. It is important to note that the number of scholarships and educational loans must be aggregated for purposes of satisfying the percentage tests. In addition, the IRS applies these tests regardless of the actual expenditures and the relationship of the founder of the foundation to the employer.

The percentage test for the children of employees provides that the aggregate grants and educational loans awarded to children of employees may not exceed (1) 25% of the number of employees' children who were eligible, applied to the foundation for a grant or loan, and were considered by the foundation's selection committee in selecting the recipients for that year; or (2) 10% of the number of employees' children who can be shown to be eligible for grants (whether or not they submitted an application) in that year. The 10% test is generally not a viable alternative, as few if any foundations are able to obtain information from employees relating to the age and educational status of their children who are eligible but do not apply. With respect to the percentage test for employees, the aggregate number of grants and educational loans awarded in any year to employees of a particular employer may not exceed 10% of the number of employees who were eligible, applied to the foundation for a grant or loan, and were considered by the foundation's selection committee in selecting the recipients.

In the event the "safe harbor" percentage test is not satisfied, the revenue procedures provide an alternate facts and circumstances test. However, the facts and circumstances test also restricts the number of scholarships and educational loans that may be granted. The stated purpose of the test is to determine the probability that a scholarship or loan will be made to any eligible individual who applies, impliedly nullifying the ability of a foundation to make scholarships or loans to all those who are eligible and apply, irrespective of their financial need. Furthermore, a foundation will be hesitant to rely on the facts and circumstances test if it does not satisfy the "safe harbor" percentage test because of the inherent uncertainty involved in a facts and circumstances test and the possibility that failing the test will result in the imposition of excise taxes. Thus, in practice, the percentage test is not merely a "safe harbor" but is in effect the rule.

The IRS did not comply with the notice and comment requirements of the Administrative Procedures Act in issuing these two revenue procedures. Thus, the procedures are not regulations and do not have the force of law. They merely set forth the methodology the IRS will employ in evaluating an application for advance approval of an employer-related grant program under Section 4945(g) of the Code. Nevertheless, because advance approval is required by statute, private foundations are required to comply with the guidelines, and particularly the percentage tests, if they desire to operate such programs without the imposition of excise taxes and the potential loss of their tax-exempt status.

Reasons for Change

Because of these guidelines, and in particular the rigid percentage tests, private foundations are unduly restricted in their ability to provide scholarships and educational loans under employer-related grant programs. The percentage tests and the alternate facts and circumstances test severely limit the use and effectiveness of foundation scholarship and loan programs. For example, the 25% limitation on scholarships or loans to employees' children forces a foundation to turn away three out of four applicants, irrespective of their financial need. This limitation is imposed despite the inherent uncertainty of a compensatory benefit to an employee, since such a benefit depends on whether the employee has a child of the appropriate age who desires to attend college at the time when a scholarship or loan is available. Importantly, there is absolutely no statutory authority either in the Code or in the regulations for the arbitrary percentage tests set by the IRS in these revenue procedures.

Rather than encouraging foundations to provide scholarships and educational loans to all eligible applicants, the IRS guidelines have forced foundations drastically to reduce their scholarship and educational loan programs. The reduction in programs designed to meet the financial needs of college bound students is occurring at the very time when educational costs are rising and the federal government is substantially reducing its funding of educational programs. At this juncture, the federal government is now encouraging the private sector to step up and replace the reduced federal spending. Given this current state of affairs, it is difficult to justify the arbitrary limitations that the IRS is imposing on employer-related grant programs.

The situation is particularly troublesome in view of the fact that most employer-related grant programs have been designed to favor the children of lower-paid employees, because these children will in all likelihood be unable to attend college without financial assistance. However, it is critical that the children of working Americans have access to higher education in order to obtain the knowledge and training needed to meet the demands of a new global economy and insure that the United States remains competitive into the 21st century. Unfortunately, the end result of the restrictive IRS guidelines is to place a college education beyond the reach of the average hardworking American family.

Explanation of Proposed Legislative Change

Two alternative changes are recommended, each of which would eliminate the percentage limitations imposed on employer-related scholarships and loans made by private foundations. The first proposal simply removes the percentage limitations, retaining the seven other guidelines set forth in the revenue procedures. The retention of the remaining guidelines will serve to insure that a scholarship or educational loan is not disguised compensation for services or otherwise results in a benefit designed primarily for the employer.

The second proposal would amend Section 4945 of the Code by adding a new Section 4945(i) which would address "qualified employer-related grant programs," as defined in the new section. The new provisions would statutorily impose the seven guidelines set forth

in the revenue procedures, but would exclude both the percentage tests and the facts and circumstances test. If the statutory guidelines are satisfied, scholarships and loans made by a private foundation under an employer-related grant program would be deemed to constitute scholarships or educational loans under Section 4945(g), rather than compensation, and would not subject the foundation to federal excise tax.

There would be no significant loss of revenue to the federal government as a result of either proposal. Under the current guidelines, a deduction will generally be available regardless of whether the grant is treated as compensation or as a scholarship. If treated as compensation, the employer receives a business deduction; if treated as a scholarship, the donor of the foundation receives a charitable deduction. With respect to the employee or the employee's child, the full amount of the grant will be taxable to the employee if treated as compensation. Alternatively, if the grant is treated as a scholarship, only that portion of the scholarship used for tuition, fees, books and supplies would not be subject to tax. Scholarship funds used for related college expenses, such as room and board, travel and the like, are fully taxable. Moreover, any tax savings attributable to a grant being deemed a scholarship rather than compensation would be de minimis, as the employees involved are by and large in the lower income tax brackets. Additionally, the principal of educational loans generally will not be deductible by the employer or includable by the employee as compensation because of the obligation of the recipient to repay the loan.

In conclusion, a private foundation should not be required to limit the number of scholarships and educational loans it grants to deserving applicants under an employer-related grant program. To do so at a time when the federal government is significantly reducing its funding of educational programs deprives the children of hardworking employees of the opportunity to obtain a college education. Since the proposed changes are practically revenue neutral, there is no justification for maintaining the status quo.

ALTERNATIVE PROPOSED AMENDMENTS TO SECTION 4945

1. Paragraph (1) of subsection (g) of section 4945 is amended to read as follows:

(1) the grant constitutes a scholarship or fellowship grant which would be subject to the provisions of section 117(a) (as in effect on the day before the enactment of the Tax Reform Act of 1986) or a loan and is to be used for study at an educational organization described in section 170(b)(1)(A)(ii),

2. Redesignate subsection (i) of section 4945 as subsection (j) and add a new subsection (i) to read as follows:

[Sec. 4945(i)]

(i) QUALIFIED EMPLOYER-RELATED GRANT PROGRAMS.--Any grant made pursuant to a qualified employer-related grant program shall be deemed to satisfy subsection (g)(1). The term "qualified employer-related grant program" means any employer-related grant program which--

(1) is not used to recruit employees of the employer, to induce employees to continue their employment with the employer, or otherwise follow a course of action sought by the employer,

(2) selects grantees by a committee consisting entirely of individuals who are not in a position to derive a private benefit, directly or indirectly, if certain potential grantees are selected, and who are not current or former directors, officers, or employees of the employer or disqualified persons with respect to the private foundation,

(3) limits potential grantees to those who meet the minimum standards for admission to an educational institution (within the meaning of section 170(b)(1)(A)(ii)),

(4) selects grantees based upon objective criteria related to enabling grantees to obtain an education solely for their personal benefit which are not related (aside from the initial qualification of the group of potential grantees) to the employment of the grantees or employees whose spouses or children are grantees, or to the employer's line of business,

(5) does not fail to make grants, or does not terminate or decline to renew grants previously made, solely because of the failure of employees who are grantees, or employees whose spouses or children are grantees, to remain employed by the employer for any length of time, or the failure of grantees to agree to become employed by the employer at any time,

(6) does not limit the courses of study for which the grants are available,

(7) is not established pursuant to an agreement which the Secretary of Labor finds to be a collective bargaining agreement between employee representatives and the employer, if there is evidence that the program was the subject of good faith bargaining between such employee representatives and such employer, and

(8) excludes from among the potential grantees--

(i) disqualified persons with respect to the private foundation, and

(ii) highly compensated employees, or spouses or children of highly compensated employees (within the meaning of section 414(q)(1)(A) or section 414(q)(1)(B)(as adjusted at the same time and in the same manner as under section 415(d)).

3. Subsections (3), (4) and (5) are added to redesignated subsection (j) of section 4945 to read as follows:

(3) EMPLOYER-RELATED GRANT PROGRAM.--The term "employer-related grant program" means any program of making grants conducted by a private foundation that (A) treats employees, or spouses or children of employees, of an employer as a group from which grantees of all or a portion of the grants will be selected, (B) limits the potential grantees of all or a portion of the grants to employees, or spouses or children of employees, of an employer, or (C) otherwise gives employees, or spouses or children of employees, of an employer a preference or priority over other individuals in being selected as grantees of such grants.

(4) EMPLOYER.--The term "employer" means the person for whom an individual performs or performed any service, of whatever nature, as the employee of such person, where such person is specified by the private foundation by name or by a class by reference to an employer specified by name.

(5) CHILDREN.--The term "children" means individuals who are sons, stepsons, daughters, and/or stepdaughters of employees of an employer.

PROPOSED AMENDMENT TO SECTION 4945

Section 4945(g) is amended by adding at the end thereof the following new sentence: "Nothing in paragraph (1) nor paragraph (3) shall be construed to authorize the Secretary or his delegate to provide (by regulations or otherwise) that the number of grants awarded by a private foundation may not exceed a fixed percentage of the number of applicants for such grants."

THE WHITE HOUSE

WASHINGTON

November 30, 1995

Bill Thomas, CEO
Corporate Wellness Director
Wellness in the Sierras
2955 Lakeside Drive
Suite 219
Reno, Nevada 89509

Dear Mr. Thomas:

Carol Rasco asked me to thank you for your letter and the enclosed information on wellness. We very much appreciate your support of our work toward health care reform and your interest in continuing to work with us.

Sincerely,

Jennifer Klein
Senior Policy Analyst

THE WHITE HOUSE

WASHINGTON

November 1, 1995

Dr. Bernardo Benes
Executive Director
Chairman's Advisory Committee
Jefferson Bank of Florida
301-14th Street
Miami Beach, Florida 33140

Dear Dr. Benes:

Thank you for thoughtful advice on health care reform. I admire the work you have done in Florida.

As you know, the Clinton Administration is currently working to strengthen Medicaid and Medicare. The Administration has put forth a health care proposal which reduces the rate of spending in these programs, while protecting Medicare beneficiaries from new cost increases, preserving coverage under Medicaid, and ensuring that both programs continue to provide high quality health care.

I also thought you might be interested to know about our efforts to combat fraud and abuse in Florida. According to the General Accounting Office, fraud and abuse consume up to ten percent of the costs of Medicare. That is why the Clinton Administration launched a successful pilot program, "Operation Restore Trust", earlier this year to combat fraud and abuse in Florida, New York, California, Illinois, and Texas.

In its first six months,"Operation Restore Trust" has already saved the federal government $32 million. More than 3,000 citizens have called the newly established hotline, 20 people have been convicted for fraud, and 200 cases are currently under investigation.

Thank you again for your sharing your expertise and for your continuing support. Your activism has clearly made an enormous difference in Florida's health care services. Your support means a great deal to us and to what the Clinton Administration is trying to do for America.

Sincerely,

Jennifer Klein
Senior Policy Analyst

THE WHITE HOUSE

WASHINGTON

August 10, 1995

Ms. George Lewis
President
Metafusion, Inc.
3 Church Circle, Suite 103
Annapolis, MD 21401-1933

Dear Ms. Lewis:

Thank you for your letters about parenteral nutrition for Medicare dialysis patients. The First Lady asked me to respond.

I understand that a representative of the Health Care Financing Administration (HCFA) met recently with a member of your company and that, in a recent letter, HCFA Administrator Bruce Vladeck clarified the requirements for coverage of parenteral nutrition and explained prior inappropriate approvals.

Given the technical requirements for coverage I would encourage you to continue your discussions with Mr. Vladeck and his staff. The First Lady is very concerned about this issue however, so you should feel free to contact me with any further questions or concerns.

Sincerely,

Jennifer Klein

Jennifer Klein
Senior Policy Analyst

METAFUSION, INC.

3 CHURCH CIRCLE, SUITE 103
ANNAPOLIS, MD 21401-1933
1-800-334-8691 (410) 263-2060
FAX (410) 263-2355

May 8, 1995

First Lady Hillary Rodham Clinton
The White House
1600 Pennsylvania Avenue, N.W.
Washington, DC 20500

Dear Mrs. Clinton:

In order to keep you abreast of the latest developments concerning HCFA and reimbursement for IDPN, we are enclosing a copy of our second letter, dated May 5, 1995, to Bruce Vladeck, HCFA Administrator.

As you can see from the information provided, the DMERC's have clearly instituted their own criteria for reimbursement of IDPN and disregarded the guidelines as set forth by HCFA. The decisions of these DMERC Medical Directors are impacting greatly on the lives of our patients and their families, the majority of whom are low income, minorities. This can have a major effect on minority children, either directly (children who suffer from kidney disease and need Parenteral Nutrition/IDPN) or indirectly (due to the untimely demise of a parent or guardian who was denied IDPN coverage).

Unfortunately, the reason for much of the confusion concerning IDPN is information that was published in an inaccurate OIG report. We have outlined much of that misinformation in the letter to Mr. Vladeck.

We realize that you have a busy schedule and are constantly being inundated with many other serious problems, however, this issue is of utmost importance for our patients, their families and the health care professionals who strive to improve the quality of life for these patients. We look forward to hearing from you or your staff concerning this issue.

Very truly yours,

George Lewis
President

Enclosures

METAFUSION, INC.

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April 17, 1995

First Lady Hillary Rodham Clinton
The White House
1600 Pennsylvania Avenue, N.W.
Washington, DC 20500

Dear Mrs. Clinton:

As a female owner of a small Maryland health care company and knowing your concern for Health Care in this country, I am writing to you to share my concerns over a problem we are experiencing with Medicare/HCFA that impacts on the health of dialysis patients.

We have been supplying a therapy for over 8 years to patients who are on dialysis and can not absorb enough nutrients through their gastrointestinal tract to maintain their weight, strength and to sustain their lives. This therapy, called Intradialytic Parenteral Nutrition (IDPN) has been a covered therapy for more than 10 years under the Prosthetic Device Benefit (section 1861(s)(8) of the Social Security Act). To qualify as a prosthetic device, an item or service must replace the function of a body organ. For parenteral nutrition, the function replaced is the absorptive capacity of the gastrointestinal tract.

The problem has arisen since Medicare/HCFA instituted regionalization (DMERCS). Though HCFA maintains that the policy for payment of IDPN claims has not changed, the medical directors of the DMERCS have formulated their own interpretation and have denied payment across the board for any IDPN claims submitted after regionalization. As a Maryland corporation, we had to transfer to the DMERCS in January of 1994. Any of our patients that began therapy in or after January, 1994, have been denied coverage, even though these patients have the same medical conditions as patients that were paid before the DMERCS were instituted. If these qualified patients are denied this therapy, it has been documented that their risk of death increases by 50%, however, without reimbursement to cover our costs, our small company is on the verge of being put out of business and we will not be able to provide this life sustaining therapy to our patients, many of whom will lose their lives needlessly.

Since you have shown such concern for the rights of small business, for the health and welfare of the average citizen, and for reform in the health care industry, I desperately ask for your assistance. The insurance companies that administer payment for the DMERCS are paid by how many claims they process, so it is in their best interest financially to deny payment and force the claims into review, fair hearings and ALJ's, all of which they again get paid for processing. This is one of the reasons for the high cost of health care. You may also find it interesting that Travelers Insurance who administered claims for Region A DMERCS paid their CEO $52 million in 1994, yet denied payment on all of our new claims for a service that not only sustained but improved the quality of life for many patients. A few day's stay in the hospital can cost Medicare more than a month's IDPN treatment, yet without IDPN many of these patients will be in the hospital, if they remain alive. We are very careful in making sure that all the patients we supply meet the criteria stated in the HCFA manual and the

dietitians and the doctors prescribing IDPN for these patients have ruled out all other possible safe avenues for sustaining the patient's life.

This matter has become critical for our company and without some immediate relief for our claims that have been stalled in the review process we will be out of business in 30 days. We haven't even gotten to the fair hearing process on most of our patients and after that the ALJ's are backed up at least 18 months.

In order to keep this letter brief, I have only given you highlights of the situation. However, to illustrate the seriousness of this situation, I am enclosing copies of a few letters to and from Medicare and some other documentation that has been compiled by the Coalition for Renal Nutrition, a group of other small suppliers, Doctors and clinicians that we have joined in an effort to resolve this problem with Medicare, though presently to no avail. We are very concerned about what will happen to our patients if we can no longer provide this life sustaining therapy for them and I would appreciate the opportunity to meet with you or your staff concerning this issue.

Very truly yours,

George Lewis

George Lewis, President

Enc.

P.S. I really am a female - as a last daughter I was named after my father

METAFUSION, INC.

3 CHURCH CIRCLE, SUITE 103
ANNAPOLIS, MD 21401-1933
1-800-334-8691 (410) 263-2060
FAX (410) 263-2355

May 8, 1995

Mr. Bruce Vladeck
HCFA Administration
Hubert Humphrey Bldg., Room 314G
Washington, DC 20201

Dear Mr. Vladeck:

I am sending this letter as a follow-up to my letter to you dated May 1, 1995, which included EOMB's with a 416 denial code for IDPN as "**Noncovered** Parenteral Nutrition." We received another denial today from Region A DMERC with the same 416 code. To reiterate, your letter of August 9, 1994, to the Honorable Curt Weldon, Representative of the House, stated that "**Medicare covers parenteral nutrition** under Part B only as a prosthetic device used to replace the function of a permanently impaired internal body organ or system .... this means that the patient must have a loss of function of the alimentary tract of such severity that he or she cannot absorb sufficient nutrients through normal means...." Your statement was verified by Tom Ault in a meeting with Representative Robert Livingston on March 24, 1995, when Mr. Ault stated that IDPN is covered when there is a "dysfunction of the alimentary tract." The patient for whom we received the attached 416 denial has a documented dysfunction of the alimentary tract and is unable to "absorb sufficient nutrients through normal means to maintain weight and strength commensurate with the patient's general condition".

Through all our correspondence, telephone conversations and meetings, we are assured by HCFA that IDPN is a **covered** therapy, however, it appears as if the DMERC's have created their own criteria without regard to the established policy of HCFA. Since the DMERC's were established to administer claims for HCFA, it would seem reasonable that HCFA's guidelines would be honored, which you can clearly see, is not the case.

We are aware that much of the confusion concerning IDPN originated in an OIG report that was based on faulty premises, thereby making the conclusions concerning IDPN invalid. The report begins by assuming that the Prosthetic Device Benefit provides only for the "total" nutritional requirements of patients and since IDPN patients do not receive their total requirements from this therapy it must be "supplemental". The Prosthetic Device Benefit does <u>not</u> require "total" replacement of a body part or function. The Benefit requires "functional impairment", for example, a below the knee leg prosthesis is not a replacement for the entire leg. Secondly, the report bases much of its statistics on a random survey that relied on a 1% sample of 58 patients and 93 randomly selected outpatient dialysis facilities for its conclusions which does not represent a true picture of the IDPN situation. In fact, only approximately 4% (four percent) of the dialysis population may need IDPN therapy, which constitutes no more than 5 to 10% (five to ten percent) of the entire amount spent by Medicare on parenteral nutrition.

Also, the OIG surveyed various health care professionals, most of whom are not involved in the provision of IDPN, and therefore, do not have the background or experience to comment on this therapy. A physician who prescribes home TPN is not necessarily qualified or capable of commenting upon nutritional therapy in patients with ESRD and it is not appropriate to rely on the opinion of a single physician. A home health agency nurse has absolutely nothing to do with dialysis units and does not care for renal patients in the dialysis unit and a hospital pharmacist would usually have absolutely no interaction with dialysis patients, therefore they would not be qualified to comment on IDPN therapy. Furthermore, we are acquainted with many experts in the IDPN field, including physicians and dietitians who are specialists in renal nutrition, and they were not consulted for this survey.

There needs to be an immediate resolution to this problem. Many small companies, such as ours, will not be able to stay in business much longer. Patients, who clearly have a dysfunction of the alimentary tract, will no longer be provided with this life sustaining therapy because the DMERC's have blatantly disregarded HCFA policy. Unfortunately, the majority of these patients are low income, minority Medicare recipients who, because their coverage is being denied, help to create the two tiered medical system that President Clinton is trying so hard to avoid through health care reform. We look forward to hearing from you soon concerning this issue. If you have any questions, please do not hesitate to contact me at 410-263-2060.

Very truly yours,

George T. Lewis
President

cc: First Lady, Hillary Rodham Clinton
Senator Barbara Mikulski

Enclosures

METRAHEALTH INSURANCE CO.
P.O. BOX 6800
WLKS-BAR PA 18773-6800

YOUR EXPLANATION OF MEDICARE BENEFITS

Please Read This Notice Carefully
And Keep It For Your Records

THIS IS NOT A BILL

DATE: 05/01/95 000312

TELEPHONE NUMBER:
(717) 735-9445

METAFUSION INC
3 CHURCH CIRCLE
SUITE 103
ANNAPOLIS MD 21401-1933

PART B MEDICARE

THE MEDICARE DIVISION OF THE TRAVELERS HAS BECOME THE MEDICARE DIVISION OF METRAHEALTH INSURANCE COMPANY. YOU WILL SEE AND HEAR THIS NAME IN COMMUNICATIONS FROM US . THERE WILL BE NO CHANGE IN OUR LOCATION, TELEPHONE NUMBERS, OR THE PEOPLE IN OUR OFFICES.

DATE	PROVIDER NO	PROVIDER NAME	PAGE	SEE REVERSE SIDE FOR ADDITIONAL INFORMATION
05/01/95	0299080001	METAFUSION INC	1	

IMPORTANT NOTIFICATION OF THE PROCESSING OF THE CLAIM(S) INDICATED BELOW HAS BEEN SENT TO THE APPROPRIATE BENEFICIARY.

PHYSICIAN OR SUPPLIER NAME	DATES OF SERVICE FROM MMDD	DATES OF SERVICE TO MMDDYR	SEE BACK SERV TYPL	SUB CODE (ALWCODE)	BILLED AMOUNT	AMOUNT APPROVED	SEE ** ACT CDE	BENEFICIARY OBLIGATION DEDUCTIBLE	BENEFICIARY OBLIGATION CO-INS	MEDICARE PAYMENT TO BENEFICIARY	MEDICARE PAYMENT TO PROVIDER
BENEFICIARY: [redacted] HIC NUMBER: [redacted]											
CONTROL NO: 95094-72095-00 DE/MI: 5118B45 ACCT NO: 000000000081 TRC: 951211100755000											
METAFUSION INC	0301	033095	I 65	B4197	4225.00	0.00	416	0.00	4225.00	0.00	0.00
METAFUSION INC	0301	033095	I 65	B4186	750.00	0.00	416	0.00	750.00	0.00	0.00
METAFUSION INC	0301	033095	I 65	B4224	390.00	0.00	416	0.00	390.00	0.00	0.00
METAFUSION INC	0301	033095	I 65	B4220	195.00	0.00	416	0.00	195.00	0.00	0.00
METAFUSION INC	0331	033195	I 65	B4197	325.00	0.00	416	0.00	325.00	0.00	0.00
METAFUSION INC	0331	033195	I 65	B4186	150.00	0.00	416	0.00	150.00	0.00	0.00
METAFUSION INC	0331	033195	I 65	B4224	30.00	0.00	416	0.00	30.00	0.00	0.00
METAFUSION INC	0331	033195	I 65	B4220	15.00	0.00	416	0.00	15.00	0.00	0.00
CLAIM TOTALS:					6080.00	0.00		0.00	6080.00	0.00	0.00
* - REMARK CODES: S, **											
BENEFICIARY: FULRIO RANIERI HIC NUMBER: 018-14-1386A											
CONTROL NO: 95094-72095-10 DE/MI: 5118B45 ACCT NO: 000000000081 TRC: 951211100755000											
METAFUSION INC	0301	030195	I 65	B9004RRKI	475.00	0.00	416	0.00	475.00	0.00	0.00
CLAIM TOTALS:					475.00	0.00		0.00	475.00	0.00	0.00
* - REMARK CODES: S, **											
GRAND TOTALS					6555.00	0.00		0.00	6555.00	0.00	0.00

TOTAL AMOUNT APPROVED----------> 0.00

REMAINING AFTER PHYSICAL THERAPY OR OCCUPATIONAL THERAPY LIMITS ---------->

TOTAL AMOUNT APPLIED TO ANNUAL DEDUCTIBLE----------> 0.00

METRAHEALTH INSURANCE CO.
P.O. BOX 6800
WLKS-BAR PA 18773-6800

YOUR EXPLANATION OF MEDICARE BENEFITS

Please Read This Notice Carefully
And Keep It For Your Records

THIS IS NOT A BILL

DATE: 05/01/95 000314

TELEPHONE NUMBER:
(717) 735-9445

METAFUSION INC
3 CHURCH CIRCLE
SUITE 103
ANNAPOLIS MD 21401-1933

PART B MEDICARE

THE MEDICARE DIVISION OF THE TRAVELERS HAS BECOME THE MEDICARE DIVISION OF METRAHEALTH INSURANCE COMPANY. YOU WILL SEE AND HEAR THIS NAME IN COMMUNICATIONS FROM US . THERE WILL BE NO CHANGE IN OUR LOCATION, TELEPHONE NUMBERS, OR THE PEOPLE IN OUR OFFICES.

DATE	PROVIDER NO	PROVIDER NAME	PAGE	SEE REVERSE SIDE FOR ADDITIONAL INFORMATION
05/01/95	0299080001	METAFUSION INC	3	

IMPORTANT NOTIFICATION OF THE PROCESSING OF THE CLAIM(S) INDICATED BELOW HAS BEEN SENT TO THE APPROPRIATE BENEFICIARY.

PHYSICIAN OR SUPPLIER NAME	DATES OF SERVICE FROM MMDD	DATES OF SERVICE TO MMDDYR	SEE BACK SERV TYPL	SUB CODE (ALWCODE)	BILLED AMOUNT	AMOUNT APPROVED	SEE ** ACT CDE	BENEFICIARY OBLIGATION DEDUCTIBLE	BENEFICIARY OBLIGATION CO-INS	MEDICARE PAYMENT TO BENEFICIARY	MEDICARE PAYMENT TO PROVIDER

** - EXPLANATION OF ACTION CODES:
416-MEDICARE DOES NOT PAY FOR NONCOVERED PARENTERAL AND ENTERAL THERAPY.

METAFUSION, INC.

3 CHURCH CIRCLE, SUITE 103
ANNAPOLIS, MD 21401-1933
1-800-334-8691 (410) 263-2060
FAX (410) 263-2355

August 1, 1994

The Travelers Insurance Company
Region A Dmerc
P.O. Box P.O. Box 6800
Wilkes-Barre, PA 18773

Re: Written Appeals for [redacted]
HIC# [redacted]

Metafusion is appealing the decision not to pay for IDPN for [redacted] based on insufficient Medical justification. According to published regulations for payment for any parenteral nutritional therapy, (1) the patient must have a permanent impairment of the GI Tract, (2) the therapy must be needed to sustain life and (3) in the case of an intradialytic parenteral nutrition patient, must have medical justification for less than daily infusion.

Following these guidelines, the following information of medical necessity for Mr.. [redacted] is found on The Physician's Statement of Medical Necessity signed by Dr. James Strom, MD. The statement clearly documents the patient's multiple GI dysfunctions (1) including: **intractable nausea and vomiting secondary to severe GI bleeding unresponsive to Prolosec, extremely life threatening hypoalbumenemia of 2.8 and hypoproteinemia of 5.8 causing severe edema in the microvilli of the small bowel resulting in intestinal malabsorption and a 27% weight loss over the 6 months prior to beginning of therapy.** The Doctor has clearly indicated that the patient needs this therapy inorder to sustain his life (2) and without this therapy would probably expire. Finally, the Physician clearly indicates that under ideal circumstances, the optimal treatment regimen for patients with these medical conditions would be on a daily basis. Unfortunately (3), this is not an ideal situation. This severely fluid restricted ESRD patient must be given treatment only during dialysis to prevent potentially lethal fluid overload. To give treatment daily would necessitate either daily dialysis or would result in frequent hospitalizations due to extreme fluid overload.

If you have any questions. please feel free to call us at 410-263-2060.

Very truly yours,

George Lewis
President

MEDICARE

DME REGION A CARRIER

November 23, 1994

METRAFUSION INC
3 Church Circle
Ste 103
Annapolis MD 21401-1933

RE: [redacted]
HIC: [redacted]
CONTROL NO: 94095-78778

To Whom It May Concern:

As you asked, we reviewed this Part B Medicare Claim.

First Decision:
Date of Service: 01-25-94, 02-01-94, 03-01-94
Description of Service: B9004

A specially trained person made a new and separate review of this claim. This person did not take part in making the first decision. Based on this review we found that Medicare's initial decision is correct.

Under Medicare guidelines we have denied these claims as not meeting medical criteria per our Medical Director. No explanation was given as to what criteria was not met.
We regret that no further payment can be made without further documentation to support the medical necessity.

TheTravelers
P.O. Box 6800
Wilkes-Barre, PA 18773-6800
The Travelers Companies
Hartford, Connecticut 06183

You may want to know the Medicare statute, regulations or guidelines that apply. You can obtain copies by writing us.

You may ask for a hearing if you do not agree with this decision. You must request the hearing within 6 months of the date of this letter. The amount of benefits in question must be $100 or more in order to have a hearing. To meet the $100, you may combine the amounts for any claims on which we made a determination within the past 6 months based on (1) a request for review or (2) a reopening of an initial or review determination.

Write to us or contact any Social Security Office if you want a hearing. If you want help with your appeal, you can have a friend, lawyer or someone else help you. Some lawyers do not charge unless you win your appeal. There are groups, such as lawyer referral services, that can help you find a lawyer. There are also groups, such as legal aide services, who will give you free legal services if you qualify.

You may take or send someone to represent you. This person may be a lawyer or anyone you choose. Please note on your request who will attend the hearing. You do not have to appear in person. You may ask that a decision be made based on the facts in the file. A copy of the decision will be sent to you.

Sincerely yours,

Linda Marchakitus

Linda Marchakitus
Medicare Part B
Reconsiderations Department

METAFUSION, INC.

3 CHURCH CIRCLE, SUITE 103
ANNAPOLIS, MD 21401-1933
1-800-334-8691 (410) 263-2060
FAX (410) 263-2355

January 1, 1994

The Travelers Insurance Company
Region A Dmerc
P.O. Box P.O. Box 6800
Wilkes-Barre, PA 18773

Re: Request for formal hearing for [redacted]
HIC# [redacted]

We, at Metafusion, are requesting a formal hearing on a denial of an appeal to pay for IDPN for [redacted] based on your Medical Director's assessment that the patient does not meet Medicare guidelines. According to published regulations for payment for any parenteral nutritional therapy, (1) the patient must have a permanent impairment of the GI Tract, (2) the therapy must be needed to sustain life and (3) in the case of an intradialytic parenteral nutrition patient, must have medical justification for less than daily infusion and needs to receive at least 20 to 35 cal/kg.

Following these guidelines, the following information of medical necessity for Mr. [redacted] is found on The Physician's Statement of Medical Necessity signed by Dr. James Strom, MD. The statement clearly documents the patient's multiple GI dysfunctions (*1) including: **intractable nausea and vomiting secondary to severe GI bleeding unresponsive to Prolosec resulting in severe weight loss of 27% in 6 months and extremely life threatening hypoalbumenemia of 2.8 and hypoproteinemia of 5.8 causing severe edema in the microvilli of the small bowel resulting in intestinal malabsorption.** The Doctor has clearly indicated in the Statement of Medical Necessity that the patient needs this therapy inorder to sustain her life (*2) and without this therapy would probably expire. The Physician clearly indicates that under ideal circumstances, the optimal treatment regimen for patients with these medical conditions would be on a daily basis. Unfortunately (*3), this is not an ideal situation. This severely fluid restricted ESRD patient must be given treatment only during dialysis to prevent potentially lethal fluid overload. To give treatment daily would necessitate either daily dialysis or would result in frequent hospitalizations due to extreme fluid overload. Finally (*4), a total caloric intake of 20 to 35cal/kg is considered sufficient to achieve or maintain appropriate body weight. This patient receives 23cal/kg at every treatment.

Clearly the information in the Medical Necessity signed and attested to by the attending physician more than meets the requirements in the Medicare guidelines for approval for payment of the claims for Mr. [redacted], therefore, we are confused as to why this patient has been denied for payment.

If there are any questions, please feel free to call us at 410-263-2060.

Very truly yours,

George Lewis

George Lewis
President

*SEE LETTER FROM W.P. CROCKETT (Next)

W. P. CROCKETT
Medicare Hearing Officer
313 Lakeshore Drive
Jackson, MS 39213

February 15, 1995

Mr. George Lewis
Metafusion, Inc.
3 Church Circle, Suite 103
Annapolis, MD 21401-1933

Regarding: [redacted]

Amount in Controversy: $23,816.00

Dear Mr. Lewis:

In response to your request of January 1, 1995 a hearing has been conducted. The decision that follows is a new and independent determination on your Medicare Part B claim. It is based on a full and thorough review of all available, relevant evidence in file, including any new evidence you have sent with or since the time of your hearing request. If you have questions about it or about your rights, you may contact me, the Medicare office or any Social Security Office.

While I am not an officer of the Federal Government I am nevertheless acting on its behalf. This decision is in compliance with provisions of Medicare statutes, regulations and instructions. It is also completely independent of previous determinations of the Medicare carrier.

SERVICES AND ISSUES:

At issue is the denial of Medicare reimbursement for certain items and supplies provided Mr. [redacted] during the period January 26, 1994 through June 30, 1994.

FACTS:

Medicare claims for reimbursement were submitted in the amount of $29,770.00 for parenteral nutrition solutions, administration kits and the rental of a portable parenteral nutrition infusion pump provided Mr. [redacted] during the period mentioned above. The Medicare carrier denied payment for these items and supplies.

A request for a review of this denial was dated August 1, 1994. In the review determination of the Medicare carrier, payment was again denied for these items and supplies.

A hearing request on this issue was dated January 1, 1995.

This file includes a certification of medical necessity and a physician's statement of medical necessity signed by Dr. James Strom.

In reaching the decision in this matter, consideration was given to all the evidence in the Part B claim file, including any presented with the hearing request. Based on this evidence, the following new and independent decision is rendered.

DECISION:

This case was decided under the Supplemental Medical Insurance benefit provisions of Title XVIII of the Social Security Act. This decision applies only to the services and circumstances considered on the claim or claims in question. If you have questions about it, or the procedures followed in reaching the decision, you may contact me, the Medicare office or any Social Security Office.

The prior determination of the Medicare carrier on this issue is affirmed.

RATIONALE:

The Medicare carrier is charged with the responsibility of determining those items and services covered under the Medicare program as well as the Medicare allowable amounts for those items and services. Regulations set out the procedures to be followed in doing so. These procedures are reviewed periodically by the Health Care Financing Administration, an agency of the Federal Government, to ensure that the proper processes have been followed, and that they are consistent with the law, regulations and guidelines.

Section 65-10.1 addresses parenteral nutritional therapy. Daily parenteral nutrition is considered reasonable and necessary for a patient with severe pathology of the alimentary tract which does not allow absorption of sufficient nutrients to maintain weight and strength commensurate with the patient's general condition.

For parenteral nutrition therapy to be covered under Part B, the claim must contain a physician's written order or prescription, and sufficient medical documentation to permit an independent conclusion that the requirements of the prosthetic device benefit are met and that parenteral nutrition therapy is medically necessary. An example of a condition that would typically qualify for coverage is a massive small bowel resection resulting in severe nutritional deficiency in spite of adequate oral intake. However, coverage of parenteral nutrition therapy for this and any other condition must be approved on an individual, case-by-case basis initially and at periodic intervals of no more than 3 months by the carrier's medical consultant or specially trained staff, relying on such medical and other documentation as the carrier may require. If the claim involves and infusion pump,

sufficient evidence must be provided to support a determination of medical necessity for the pump.

Some patients require supplementation of their daily protein and caloric intake. Nutritional supplements are often given as a medicine between meals to boost protein-caloric intake or the mainstay of a daily nutritional plan. Nutritional supplementation is not covered under Medicare Part B.

Region A medical policy regarding intradialytic parenteral nutrition (IDPN) is outlined, in part, below.

*SEE ITEM 2 IN PRECEDING LETTER

The patient must require intravenous nutrition to sustain life. Adequate nutrition must not be possible by dietary adjustment, oral supplements or tube enteral nutrition.

Intradialytic parenteral nutrition provided for patients without a significant gastrointestinal disease, but with impaired nutrition due to a poor appetite, will be denied as non-covered. Parenteral nutrition is covered in dialysis patients with a clearly documented, clinically *SEE ITEM 1 significant gastrointestinal condition which has resulted in malnutrition that cannot be corrected by dietary means and can be corrected with the prescribed parenteral nutrition regimen. In these circumstances, the prescribed parenteral nutrition is usually administered daily. Parenteral nutrition administered only during dialysis in these patients would rarely be medically necessary. *Detailed documentation would be required to justify IDPN. SEE ITEM 3

*SEE ITEM 4

A total calorie intake of 20 to 35 cal/kg/day is considered sufficient to achieve or maintain appropriate body weight. The ordering physician must document the medical necessity for a caloric intake outside this range in an individual patient.

The medical information in file has been considered by the Medical Director at the office of the Medicare carrier. The resulting opinion is that a properly placed jejunostomy tube, with a cautious, pump-controlled rate of administration of enteral formula would be a far more practical, nutritious and fluid-restricted method for replenishing this patient. This isn't feasible in a patient with GI bleeding.

In consideration of the above, and the fact that tube enteral feeding was not tried, it is determined denial of reimbursement is correct.

According to the guidelines Tube Feedings are not a requirement

APPEAL RIGHTS:

The beneficiary has transferred to you his right to benefits based on covered services. This gives you the same right to appeal as the beneficiary.

On the basis of this decision, it is determined that $23,816.00 remains in controversy. Since the amount remaining at issue exceeds $500.00 you are entitled to a hearing before an administrative law judge of the Office of

Hearings and Appeals of the Social Security Administration. If you are dissatisfied with this decision and wish the hearing you must file your request, in writing, within 60 days of the receipt of this notice. You may file your request with the Medicare Office or any Social Security Office.

If you want help with your appeal you can have a friend, lawyer or someone else help you. Some lawyers do not charge unless you win your appeal. There are groups, such as lawyer referral services, that can help you find a lawyer. There are also groups, such as legal aide services, who will give you free legal services if you qualify.

Copies of applicable laws, regulations and policies upon which this decision is based are available on request. If you would like a copy of this material, your request must be received within 30 days of this notice.

Sincerely,

W. P. Crockett
Medicare Hearing Officer

Coalition for Renal Nutrition, Inc.
• P.O. Box 484 • Lima, PA 19037 • 610-494-8700

April 7, 1995

HAND DELIVERY

Helen L. Smits, M.D.
Deputy Administrator
Health Care Financing Administration
700 East High Rise Building
6325 Security Boulevard
Baltimore, MD 21207

Re: Coalition for Renal Nutrition, Inc. -- Medicare Coverage and Payment for Intradialytic Parenteral Nutrition Therapy

Dear Dr. Smits:

The Coalition for Renal Nutrition, Inc. (the "Coalition") is an association of health care providers and others engaged in the provision of intravenous therapy, including intradialytic parenteral nutrition ("IDPN") therapy. We are writing to bring to your attention serious concerns relating to Medicare Part B payment denials for virtually all IDPN claims submitted on behalf of nongrandfathered patients (i.e., patients not receiving IDPN therapy prior to the transition to regional carriers) by each of the four Durable Medical Equipment Regional Carriers ("DMERCs").

This situation is particularly troubling because the Health Care Financing Administration ("HCFA") is on record as confirming that the Medicare program covers IDPN therapy for beneficiaries meeting applicable medical necessity criteria, and that the DMERCs are addressing our concerns.*/

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*/ See, e.g., letter to J. Darrell Boyd, President, National Infusion, from Carol Walton, Director, Bureau of Program Operations, HCFA (Mar. 12, 1995) (Tab A); letter to The Honorable Curt Weldon, House of Representatives, from Bruce C. Vladeck, Administrator, HCFA (Aug. 9, 1993) (Tab B); letter to Michael Reiner, Haemotronic Ltd., from Robert E. Wren, Director, Office of Coverage and Eligibility Policy, Bureau of Policy Development, HCFA (Sept. 7, 1993) (Tab C); letter to J. Darrell Boyd, National Infusion, from Carol J. Walton, Director, Bureau of Program Operations, HCFA (Jan. 19, 1994) (Tab D).

Although each of the DMERC Supplier Manuals provide that IDPN is a covered benefit, the DMERCs' medical review staffs have adopted unduly restrictive and clinically unsupportable medical review criteria that have resulted in denial of virtually all IDPN claims. These denials have subjected many dialysis patients to serious medical risk by forcing some providers to cease accepting Medicare beneficiaries needing IDPN. In addition to harming dialysis patients who need IDPN, this situation has been extremely detrimental to legitimate providers of this therapy as they have been providing unreimbursed services for all IDPN cases for which they have been providing services. This situation, which has now persisted for well over a year -- despite the consistent efforts of providers to resolve this matter through the DMERC medical directors, HCFA's Office of Coverage Policy and Bureau of Program Operations, and members of Congress -- requires a swift and global response to resolve the arbitrary and erroneous claims denials, and to develop clinically sound, workable medical review criteria that can be implemented by each of the DMERCs in processing IDPN claims. We would note that Dr. Metzger, Medical Director for the Region C DMERC, has told providers that he would approve payment of IDPN claims if given proper direction from HCFA.

As a result, we seek your immediate assistance in directing the DMERCs to process and pay IDPN claims in accordance with the well-established policy which provides coverage for IDPN therapy for Medicare beneficiaries meeting applicable medical necessity criteria.

Accompanying this letter is a clinical overview of IDPN therapy in which we clarify some of the common misconceptions about malnutrition in renal patients (Section I). This clinical framework is consistent with the Coalition's goal of providing medically necessary nutrition therapy to renal patients. Among other things, we explain that daily tube feedings are often contraindicated in the dialysis population. Following this discussion are copies of selected journal articles referenced in the paper addressing IDPN therapy results.

Second, we have included in Section II a brief summary of the Medicare statutory and HCFA and carrier manual provisions governing IDPN therapy, which establish unequivocally that parenteral nutrition provided to end-stage renal disease ("ESRD") patients is a covered benefit, and that there has been no legal change in the scope of coverage as a result of the transition to DMERCs.

Third, we will document improper and inconsistent claims processing determinations and highlight our procedural and substantive concerns with the review and fair hearing process (Section III). Fourth, we provide proposed Medicare coverage criteria to facilitate IDPN claim reviews (Section IV), and an IDPN Patient Information Form (Section V) which we believe the DMERCs should utilize to provide a consistent and clinically appropriate review of all IDPN claims, including those which have been reviewed and denied since the transition to DMERCs. Lastly, we include standards of practice for IDPN (Section VI) which reflect current clinical practice guidelines for IDPN therapy.

We appreciate your consideration of this important issue. We understand that HCFA and the DMERCs are in the process of clarifying the Medicare coverage policy for parenteral and enteral nutrition, including IDPN therapy. We believe our efforts to resolve the serious problems being experienced with IDPN claims should be addressed as part of this ongoing effort as soon as possible. Robert Tallon, M.D., M.P.W., of Strategic Healthcare Management, will be contacting your office to schedule a meeting with you and your staff to discuss our concerns. In the meantime, if you have any

questions concerning this matter or require further information, please contact Jerry Francesco on behalf of the Coalition at (610) 494-8700.

Sincerely,

COALITION FOR RENAL NUTRITION, INC.

HAEMOTRONIC, INC.
HOME HEALTHCARE RESOURCES INC.
INTRX HEALTHCARE
IV SERVICES LTD.
I.V. SPECIALISTS, INC.
METAFUSION, INC.
NATIONAL INFUSION SERVICES
NUTRACARE
PENTECH INFUSIONS, INC.
PROFESSIONAL INFUSION SERVICES, INC.
TOTAL RENAL CARE, INC.
VIVRA/ASSOCIATED HEALTH SERVICES
Y MEDICAL ASSOCIATION, INC.

Attachments

cc (w/ attachments): Mr. Thomas Hoyer, HCFA (VIA HAND DELIVERY)
Ms. Carol J. Walton, HCFA (VIA HAND DELIVERY)

II. Medicare Coverage Of IDPN Therapy

A. Statutory Authority And HCFA Manuals

For over ten years, the Medicare program has covered IDPN therapy for ESRD patients with significant gastrointestinal malfunction and accompanying malnutrition. By way of background, section 1832(a)(2)(B) of the Social Security Act (the "Act") provides that Part B of the Medicare program covers "medical and other health services." 42 U.S.C. § 1395k(a)(2)(B). The term "medical and other health services" includes "prosthetic devices (other than dental) which replace all or part of an internal body organ. . . ." Section 1861(s)(8) of the Act, 42 U.S.C. § 1395x(s)(8). The prosthetic device benefit, in turn, includes enteral and parenteral nutritional therapy provided to a patient who has a permanently inoperative internal body organ or function (i.e., malfunction of the alimentary tract). Section 65-10 of the Medicare Coverage Issues Manual (HCFA-Pub. 6) (effective for items and services furnished on or after July 11, 1984) (Tab A).

Section 65-10 of the Coverage Issues Manual explains that, while enteral and parenteral nutrition therapy is not covered under Part B in situations involving temporary impairments, coverage of such therapy does not require a medical judgment that the impairment giving rise to the therapy will persist throughout the patient's remaining years. If the medical record, including the judgment of the attending physician, indicates that the impairment will be of long and indefinite duration, the test of permanence will be considered met. HCFA-Pub. 6, § 65-10; see also Medicare Carriers Manual (HCFA-Pub. 14-3), § 2130.A (Tab B).

Parenteral nutrition is considered reasonable and necessary for a patient with severe pathology of the alimentary tract which does not allow absorption of sufficient nutrients to maintain weight and strength commensurate with the patient's general condition. HCFA-Pub. 6, § 65-10.1. Section 3329 of the Medicare Carriers Manual sets forth the evidence required to establish medical necessity for parenteral and enteral nutrition therapy (Tab C). Parenteral nutrition administered during

dialysis is also covered under the Medicare program as long as the coverage requirements set forth in Section 65-10 of the Coverage Issues Manual are met. Id., § 3329.5. The Medicare Carriers Manual provides that renal dialysis patients qualify for coverage if they meet all the requirements for PEN coverage, including documentation from the attending physician "that the patient, despite the need for renal dialysis, suffers from a permanently impaired functional impairment that precludes swallowing or absorption of nutrients." Id. (emphasis added). See also Provider Reimbursement Manual (HCFA-Pub. 15-1), § 2711.6.A (Tab D).

B. PEN Specialty Carriers Manual And DMERC Supplier Manuals

Because the problems in Medicare coverage and payment for IDPN therapy began upon the transition from the parenteral and enteral nutrition ("PEN") specialty carriers to regional carriers, it is useful to review briefly the coverage criteria applied by the Medicare carriers prior to the transition to regional claims processing.

1. The PEN Supplier's Guide To Medicare

As you know, prior to the establishment of the DMERCs, PEN claims were processed by two specialty carriers, Blue Cross and Blue Shield of South Carolina and Transamerica Occidental Life Insurance Company. Blue Cross and Blue Shield of South Carolina issued a manual entitled "PEN Supplier's Guide to Medicare" ("PEN Manual") to set forth the coverage and claims processing rules applicable to PEN claims.[1] Under the section entitled "Parenteral and Enteral Coverage Rules and Guidelines," the PEN Manual provides that IDPN therapy to replace fluids and nutrients lost during dialysis "is often supplemental" and, therefore, not covered as a PEN benefit.[2] The PEN Manual goes

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1 Excerpts attached at Tab E. Although the PEN carrier for suppliers west of the Mississippi River, Transamerica Occidental Life Insurance, did not issue such a manual, the carrier issued updates setting forth the coverage criteria.

2 PEN Manual at p. 6.

on to state, however, that IDPN therapy is covered where documentation demonstrates that the patient has a permanently impaired gastrointestinal tract and that there is insufficient absorption of nutrients to maintain adequate strength and weight. The PEN Manual provides (page 6):

> In order to cover intradialytic parenteral therapy, documentation must be clear and precise to verify that the patient suffers from a permanently impaired gastrointestinal tract and that there is insufficient absorption of nutrients to maintain adequate strength and weight. Records should document that the patient cannot be maintained on oral or enteral feedings and that due to malabsorption, the patient must be infused for survival. Infusions must be vital to the nutritional stability of the patient and not supplemental to a deficient diet or deficiencies caused by dialysis. Physical symptoms of malabsorption must be clearly evident in any documentation submitted.

The PEN Manual sets forth specific documentation that could be used in making the coverage determination, including:

- Lab reports, especially albumin and protein levels;
- Reports from studies of the GI tract, i.e., endoscopic exams, x-rays, scans, gastric emptying studies, etc.;
- Medications prescribed and their effects;
- Reports of history and physical examinations documenting GI tract problems and/or diseases that produce malabsorption;
- Nutritional assessment records indicating the amount of oral intake, problem areas such as diarrhea, vomiting, weight loss as well as medication and treatment to alleviate these problems;
- Operative reports if applicable;
- Height and weight, both pre and post-dialysis.[3]

Consistent with established clinical practice, as described in Section I, and these documentation requirements, renal dietitians routinely explored various treatment options for ESRD patients with malnutrition such as diet management and enteral nutrition. Where these efforts were

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3 Id., p. 6.

inadequate to maintain the patient's weight and strength, and, as a result, the patient's physician ordered IDPN, suppliers compiled the necessary documentation and submitted the specific information regarding a patient's compromised nutritional state to demonstrate the patient's medical need for IDPN therapy.

2. The DMERC Supplier Manuals

As part of the transition to regional carriers, the DMERCs prepared draft and, following an informal comment period, final medical policies to be utilized in claims processing. The purpose for these new medical policies was to ensure consistency in claims processing. Significantly, according to HCFA, the transition to regional carriers was not to change well-established coverage rules for PEN therapy. In comments on the final rule implementing the changes in carrier jurisdiction for claims for durable medical equipment, prosthetics, orthotics and supplies ("DMEPOS") in June of 1992,[4] a number of commenters pointed out that coverage and utilization were standardized nationally for PEN products, and that there was supplier satisfaction with that standardization. Suppliers were concerned that the transition could result in significant changes in the established coverage and utilization guidelines for PEN therapy. In response, HCFA stated that "there are only a few items covered under the PEN program. It was relatively easy to establish national policy for those few items."[5] In fact, in the same rule, HCFA notes that the transition of the PEN claims should be relatively easy because of the "well-established coverage policy and utilization parameters":

> As mentioned above, we do not currently plan on moving the PEN claims after the transition of other types of claims. We view these claims, with their one national pricing locality and well-established coverage policy and utilization parameters, as the claims which will be easiest for the new regional carriers to absorb.[6]

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4 57 Fed. Reg. 27,290 (1992).

5 57 Fed. Reg. at 27,299.

6 Id. at 27,293 (emphasis added).

As described below, while the DMERCs have continued written coverage standards which are generally consistent with prior standards, they have implemented them in way that drastically curtails coverage.

Under each of the four regional DMERC Supplier Manuals,[7] issued in October 1993, IDPN is covered for patients with "a clearly documented, clinically significant gastrointestinal condition which has resulted in malnutrition that cannot be corrected by dietary means and can be corrected with the prescribed parenteral nutrition regime." The Supplier Manual goes on to explain that the prescribed parenteral nutrition is usually administered daily, but there is no specific requirement for daily administration. The Supplier Manual further states that "parenteral nutrition administered only during dialysis in these patients would rarely be medically necessary." This language caused significant concern among suppliers of IDPN when it was issued in draft form and was noted in their comments to the DMERCs. As a result, in issuing the final medical policies, the DMERCs included a clarification which appears in the "Comments & Responses to Draft Medical Policies" issued by each of the DMERCs.[8] The response states:

> Except in those policies which use the phrases "never medically necessary" or "only medically necessary" when. . . ," individual consideration of additional submitted documentation will always be employed by the DMERC in establishing the existence or absence of medical necessity of a given item (emphasis in original).

This clarification reemphasized the fact that IDPN therapy has always been -- and would continue to be -- subject to individual consideration by carrier claims processors.

Further, in specific comments addressing the impact of the draft enteral and parenteral nutrition policy, many suppliers objected to a proposed criteria that such therapy was required for

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7 Although there are some relatively minor differences among the four DMERC Supplier Manuals' policies on parenteral nutrition, references to "the Supplier Manual" include all four DMERC Supplier Manuals. Copies of the relevant provisions are attached at Tab F.

8 Tab G.

"sustaining life."[9] In response, the DMERCs deleted the phrase "sustaining life" as a requirement for coverage, and replaced it with the language from Section 65-10 of the Coverage Issues Manual that IDPN therapy is covered for patients unable to maintain weight and strength commensurate with the patient's overall health status.

The DMERC Supplier Manual sets forth specific documentation that is required to establish medical necessity. This includes:

(1) a certificate of medical necessity signed and dated by the ordering physician;

(2) the diagnosis relating to the need for parenteral nutrition;

(3) a copy of the test or operative report substantiating the diagnosis;

(4) a nutritional assessment by a dietitian;

(5) documentation of any weight loss;

(6) laboratory test results (with dates) documenting impaired nutritional status;

(7) a measure of the adequacy of dialysis (i.e., Kt/V) determined during the prior month on the patient's current dialysis regimen; and

(8) a description of the efforts made to increase oral caloric intake or use enteral nutrition.

These requirements are substantially similar to the documentation requirements utilized by the prior PEN carriers except that the DMERCs required submission of actual copies of the dietitian assessments, Kt/V's and lab reports rather than reporting the results of these studies on the certificate of medical necessity. Nonetheless, IDPN therapy providers have *always* been required to provide a certificate of medical necessity containing sufficient documentation to demonstrate the impaired nutritional status of the patient. The recent problems in coverage of and payment for IDPN therapy have resulted from the

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9 Comments and response from Region A is attached at Tab H. Identical language appears in the comments and response issued by the other DMERCs.

misinterpretation of the purpose of IDPN therapy and/or the misapplication of the medical necessity and documentation requirements.