ASSISTANT SECRETARY OF DEFENSE
WASHINGTON, D.C. 20301

HEALTH AFFAIRS

JAN 16 1985

BEFORE THE OFFICE, ASSISTANT

SECRETARY OF DEFENSE (HEALTH AFFAIRS)

UNITED STATES DEPARTMENT OF DEFENSE

Appeal of	)	
	)	
Sponsor:	)	OASD(HA) File 84-42
	)	FINAL DECISION
SSN:	)	

This is the FINAL DECISION of the Assistant Secretary of Defense (Health Affairs) in the CHAMPUS Appeal OASD(HA) Case File 84-42 pursuant to 10 U.S.C. 1071-1092 and DoD 6010.8-R, chapter X. The appealing party is the CHAMPUS beneficiary, who is also the sponsor, a retired officer in the United States Air Force. The appeal involves the denial of CHAMPUS cost-sharing on claims for chelation therapy provided to the beneficiary for the treatment of coronary artery disease from January 21 through March 10, 1982. The billed charges for this therapy and related services were $3,465.00. The amount in dispute is $2,598.75 (i.e., $3,465.00 less the 25 percent beneficiary cost-share).

The hearing file of record, the recorded hearing transcript, the Hearing Officer's Recommended Decision, and the Analysis and Recommendation of the Director, OCHAMPUS, have been reviewed. It is the Hearing Officer's recommendation that the OCHAMPUS First Level Review determination, which denied CHAMPUS coverage of chelation therapy and related services, be upheld. The Hearing Officer's recommendation is based upon a finding that chelation therapy and related services in the treatment of arteriosclerosis were not "rendered in accordance with generally accepted professional medical standards" as required by the CHAMPUS regulation, Department of Defense Regulation 6010.8-R. The Director, OCHAMPUS, concurs in this Recommended Decision and recommends that it be adopted as the FINAL DECISION.

The Assistant Secretary of Defense (Health Affairs), after due consideration of the appeal record accepts the recommendation of the Director, OCHAMPUS, and adopts the Hearing Officer's Recommended Decision. The FINAL DECISION of the Assistant Secretary of Defense (Health Affairs), therefore, is to deny CHAMPUS claims for chelation therapy services provided to the beneficiary in 1982. This FINAL DECISION is based upon the appeal record as stated above.

FACTUAL BACKGROUND

The beneficiary was hospitalized in March 1980, with diagnoses of atrial fibrillation, angina, hypertension, and diabetes. The record indicates that the beneficiary was initially recommended for a coronary angiogram but determined not to proceed immediately with it. In August and September 1980, his coronary status was reevaluated and a determination made that a coronary angiogram was not then necessary. He was placed on a nutrition, exercise, and drug therapy with an annual follow-up. He was considered a candidate for possible coronary by-pass surgery if his condition worsened. Although the beneficiary continued on this prescribed regimen, he felt no improvement but seemed to be getting weaker and noticed some numbness in his left foot.

In January 1982, the beneficiary, apparently on his own initiative, came under the care of Paul McGuff, M.D., an advocate of the use of chelation therapy in the treatment of coronary artery disease. The beneficiary was extensively evaluated by Dr. McGuff on January 21, 1982. This initial screening consisted of a comprehensive history and physical including an Ultrasonic Roppler Vascular Study, Thermography Vascular Study, EKG, Kevex Metal Profile, and Chem-Screen Profile testing. He began Edetate (EDTA) infusion treatment for arteriosclerosis on the next day, January 22, 1982. The beneficiary received twenty-nine Edetate and nutritional supplement intravenous infusions from January 22, 1982, to March 10, 1982, with a subsequent thermographic study being provided on April 27, 1982. The course of the beneficiary's ongoing treatment was followed by periodic blood and urine tests to monitor his reactions to it.

A CHAMPUS claim in the billed amount of $3,295.00 for all of Dr. McGuff's services through March 10, 1982, was filed with the appropriate fiscal intermediary. (A subsequent claim included the April 27, 1982, thermographic study in a billed amount of $170.00.)

The fiscal intermediary's initial determination of May 29, 1982, cost-shared part of the claim for eight office visits and some of the diagnostic testing, but denied the infusion of Edetate and nutritional supplements as services or supplies not covered by CHAMPUS.

The Informal Review decision of June 22, 1982, made an adjustment and allowed the Thermography Vascular study as a medically necessary diagnostic test for coronary artery disease. However, the office visits for the infusion of Edetate remained denied because it was considered to be an investigational modality in the treatment of coronary artery disease.

The fiscal intermediary's Reconsideration decision of July 27, 1982, again denied the benefits for the Edetate therapy. The Reconsideration decision also denied benefits for the diagnostic services and office visits which had been previously

allowed. The fiscal intermediary stated that CHAMPUS considers the use of the drug EDTA for the treatment of coronary artery disease to be an investigational procedure. In addition, all services and supplies related to a non-covered condition or treatment are excluded from CHAMPUS benefits. The previously allowed diagnostic services and office visits were found to be related to the noncovered therapy.

A request for a First Level Appeal Review was received at OCHAMPUS on August 19, 1982. The OCHAMPUS First Level Review Decision of November 30, 1982, upheld the fiscal intermediary's Reconsideration Decision and found that, "the use of the drug Edetate Disodium (EDTA) for the treatment of arterioscleratic cardiovascular disease is not in keeping with the generally acceptable norm for medical practice in the United States." The Decision noted that, "even though the drug itself is not considered to be experimental (it has approved uses for other purposes), it remains under investigation as to its effectiveness in the treatment of generalized arteriosclerosis. Its use does not meet accepted professional standards for this condition." The First Level Review also determined that the diagnostic testing, lab work, and the office visits performed by Dr. McGuff, in administering EDTA therapy, also, cannot be approved for CHAMPUS cost-sharing because they are related to the non-covered treatment.

The beneficiary requested a hearing on January 7, 1983. The case was duly assigned to a Hearing Officer and the OCHAMPUS position statement was forwarded to the Hearing Officer and the beneficiary on March 23, 1983. The hearing was held in Austin, Texas, on May 3, 1983, before CHAMPUS Hearing Officer, Harold H. Leeper. The hearing was attended by the beneficiary and his attorney and by an attorney from the OCHAMPUS Office of Appeals and Hearings. The Hearing Officer issued a Recommended Decision on August 5, 1983. However, during the course of the review of the case by OCHAMPUS, a number of documents pertinent to the case were discovered which, inadvertently, had not been included in the exhibit file which was before the Hearing Officer. Consequently, OCHAMPUS requested that the Hearing Officer reopen the hearing record to allow consideration of these documents and any additional evidence from the beneficiary which he desired to submit in response to them. The Hearing Officer considered these additional exhibits and the beneficiary's comments on them. No additional hearing was requested by either party, and the Hearing Officer found that none was required. The Hearing Officer issued an amended Recommended Decision on April 12, 1984. Thus, all levels of administrative appeal have been completed and the issuance of a FINAL DECISION is proper.

ISSUES AND FINDINGS OF FACT

The primary issue in this appeal is whether the chelation therapy received by the beneficiary is qualified for cost-sharing under CHAMPUS during the period of January 21, 1982, through March 10, 1982. In addressing this issue, it is necessary to

consider the medical necessity and appropriateness of the care in question.

Medical Necessity

The Department of Defense Appropriation Act of 1976, Public Law 94-212, prohibits the use of CHAMPUS funds to pay, among other matters,

> ". . . any other service or supply which is not medically necessary to diagnose and treat a mental or physical illness, injury, or bodily malfunction. . . ."

All subsequent Department of Defense Appropriation Acts have contained similar restrictions.

This restriction is incorporated into the CHAMPUS regulation, DoD 6010.8-R, chapter IV, A.1., as follows:

> "Scope of Benefits. Subject to any and all applicable definitions, conditions, limitations, and/or exclusions specified or enumerated in this Regulation, the CHAMPUS Basic Program will pay for medically necessary services and supplies required in the diagnosis and treatment of illness or injury. . . ."

Specifically excluded from CHAMPUS coverage are all "services and supplies which are not medically necessary for the diagnosis and/or treatment of a covered illness or injury." (DoD 6010.8-R, chapter IF, G.1.) The Regulation defines "medically necessary" as "the level of services and supplies (that is, frequency, extent and kinds) adequate for the diagnosis and treatment of illness or injury. . . . Medical necessity includes the concept of appropriate medical care." (DoD 6010.8-R, chapter II, B.104.) "Appropriate medical care" is defined in DoD 6010.8-R, chapter II, B.14., in part as:

> "a. That medical care where the medical services performed in the treatment of disease or injury, . . . are in keeping with the generally acceptable norm for medical practice in the United States."

The CHAMPUS Basic Program includes benefits for the treatment of arteriosclerotic vascular disease. However, under the provisions cited above, such benefits are not available when the treatment prescribed is beyond what is in keeping with the generally acceptable norm for medical practice in the United States. This general principle is also incorporated in the more specific regulation provisions relating to experimental treatments.

CHAMPUS excludes treatment modalities which are not provided in accordance with accepted professional medical standards, or related to essentially experimental, investigatory, or unproven treatment regimens. (Dod 6010.8-R, chapter IV, G.15.) The term "experimental: is defined, in part, in DoD 6010.8-R, chapter II, B.68., as:

> ". . .(M)edical care that is essentially investigatory or an unproven procedure or treatment regimen (usually performed under controlled medicolegal conditions) which does not meet the generally accepted standards of usual professional medical practice in the general medical community . . . . Use of drugs and medicine not approved by the Food and Drug Administration for general use by humans (even though approved for testing on human beings) is also considered to be experimental. However, if a drug or medicine is listed in the U.S. Pharmacopeia and/or the National Formulary and requires a prescription, it is not considered experimental even if it is under investigation by the U.S. Food and Drug Administration as to its effectiveness."

The evidence of record establishes that the chelation therapy provided to the beneficiary consisted of a series of injections of the drug ethylenediaminetetraaetic acid (EDTA). This drug is approved by the U.S. Food and Drug Administration in the treatment of heavy metal poisoning. The drug appears in the U.S. Pharmacopeia and the National Formulary as a drug acceptable for some human use.

The primary issue, stated in light of these controlling authorities and as correctly framed by the Hearing Officer, is "whether the services provided (the beneficiary) were appropriate medical care and in keeping with the generally accepted norm for medical practice in the United States."

The Hearing Officer succinctly summarized the evidence of record on this issue as follows:

> "OCHAMPUS' Evidence
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> "The Colorado Foundation for Medical Care expressed its expert opinion on December 1, 1981, that chelation therapy is not effective for other than acute toxicity due to heavy metal poisoning, and that chelation therapy was not considered effective for arteriosclerosis. It recommended against reimbursement for chelation therapy in this case.

The American Medical Association's Department of Drugs indicated its concern about the toxic potential of EDTA, and stated that it considered "investigational" the use of EDTA for the treatment of atherosclerotic coronary and peripheral vascular disease. Further, a report in the Journal of the AMA advised against this treatment.

Medicare and Medicaid do not pay for EDTA chelation therapy for the treatment or the prevention of atherosclerosis. The report stated, "It is not widely accepted and practiced by American physicians. EDTA chelation therapy for atherosclerosis is considered experimental." Medicare and Medicaid Guide, CCH, 1982.

The Office of Health Research, Statistics and Technology of the U.S. Public Health Services studied EDTA chelation therapy for the treatment and prevention of atherosclerosis. The report questioned the safety of the procedure, and found that its clinical effectiveness had not been established by well-designed, controlled clinical trials. It added, "It is not widely accepted and practiced by American physicians. EDTA chelation therapy for atherosclerosis is considered experimental." Assessment Report Series, Volume 1, Number 18, 1981.

A letter from Alex Rodriguez, M.D., Medical Director for OCHAMPUS addressed to [another CHAMPUS beneficiary] dated January 25, 1982, concerns a denial of chelation therapy for atherosclerosis, and establishes that OCHAMPUS has consistently refused to recognize this treatment as "generally accepted", and that it has consistently denied claims for chelation therapy for the treatment of atherosclerosis.

Appealing Party's Evidence

As evidence of his contention that FDA's lack of a position on EDTA chelation therapy does not establish whether such therapy is proper medical practice, [the appealing party's attorney] submitted an excerpt from FDA Drug Bulletin, Volume 12, Number 1, describing "Approved" and "Unapproved" and "Unlabeled" uses. The article concludes by saying, ". . . accepted medical practice

often includes drug use that is not reflected in approved drug labeling."

An article by Bruce W. Halstead, M.D., entitled, "The Scientific Basis of EDTA Chelation Therapy," contains an excellent description of the development of EDTA and its uses in treating a variety of illnesses, including atherosclerosis involving coronary artery disease, stroke, senility, early gangrine, essential hypertension, peripheral vascular occlusive disease, osteoarthritis, and related disorders. It states that "clinical studies have consistently shown a definite improvement in the circulation of the patient as evidenced by improvement in skin color, improvement of arterial pulsation in the feet, return of normal temperature to the feet, regaining ability to walk long distances comfortably, elimination of anginal pain, improved brain function and improvement of muscular coordination. Chelation therapy generally results in a significant improvement in coronary circulation in most cases to the extent that the patient no longer requires the use of nitroglycerine and similar drugs. It is believed that most coronary cases would not require bypass surgery if they were given adequate chelation therapy. In a large number of cases chelation therapy has been found to improve kidney function, decrease the amount of insulin required by diabetics and produce significant improvement in arthritis and some cases of Parkinson's disease." He pointed out that clinical double-blind studies were impossible to administer and thus controlled EDTA chelation research for atherosclerosis had not progressed to the point desired. He concluded, "Regardless of the obvious deficiencies in this field of therapy, any physician that has either taken the treatment himself or administered it to those suffering from atherosclerosis cannot help but be enormously impressed with the clinical results it achieved."

An editorial in the "American Journal of Cardiology", August, 1960, entitled, "Atherosclerosis, Occlusive Vascular Disease and EDTA", written by Norman E. Clark, Sr., M.D., Chairman of the Department of Research of Providence Hospital in Detroit, Michigan, states that EDTA is a safe mode of therapy for occlusive vascular disease, after several

> years of experience involving several hundred patients, and concludes that it is superior to other methods. He stated, "In summary, the treatment of atherosclerotic vascular complications with the chelation agent EDTA is supported by a large volume of information concerning the development of the atherosclerotic plaque, the role of calcium, the importance of the Ca:Mg ratio, and perhaps of other metals in maintaining mineral-enzyme systems for the restoration or repair of vascular injuries and the demonstration of unusual symptomatic and functional improvement in patients who had advanced states of various forms of occlusive vascular disease."
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> An article entitled, "The Chelation Answer - How to Prevent Hardening of the Arteries and Rejuvenate Your Cardiovascular System," was written by Morton Walker, D.P.M., in consultation with Garry F. Gordon, M.D. Appendix 1 contains the "current availability of chelation therapy for you," and lists physicians, both M.D. and O.D.s, in the various states and countries, from whom chelation therapy could be obtained."

Based upon the evidence of record and the specific provisions of the CHAMPUS regulation, it is clear that the drug used in the beneficiary's chelation therapy is not experimental; i.e., it is approved for some uses in humans. The evidence, however, is also clear that in this case the use of chelation therapy in the treatment of arteriosclerosis was not in keeping with the generally acceptable norm for medical practice in the United States. At the time these services were provided to the beneficiary, chelation therapy in the treatment of arteriosclerosis was an unproven treatment regimen whose efficacy and safety had not been established. Consequently, I find that chelation therapy in the treatment of arteriosclerosis does not qualify as a benefit under CHAMPUS during the period of time at issue in this appeal.

This finding is supported by the overwhelming weight of the evidence as applied to the specific regulatory provisions of CHAMPUS. The evidence of record establishes that as of April 1982, there were no controlled scientific studies demonstrating the efficacy of chelation therapy in treating arteriosclerosis. There was, however, evidence of significant nephrotoxicity, and there were reports of other adverse effects associated with the use of EDTA. Without the scientifically validated evidence which only such studies can produce, any positive perceived outcomes can only be considered as no different from those resulting from any other placebo effect. That is, without the independent scientifically validated evidence, there is no way to objectively

evaluate chelation therapy to determine if it is safe and effective and if it meets the generally accepted standards for practice in the general medical community. For this reason, I find that chelation therapy does not qualify for CHAMPUS benefits because it is essentially an unproven treatment regimen, the safety, efficacy, medical necessity, and appropriateness of which have not been demonstrated.

While the Department of Defense recognizes that individuals may perceive improvement as resulting from chelation therapy programs, I am constrained by law and regulation to authorize benefits only for services which are generally accepted in the medical community. Such acceptance must be documented by authoritative medical literature and recognized professional opinion. The evidence herein, and the professional reviews of the Colorado Foundation for Medical Care and the OCHAMPUS Medical Director, disclose no evidence of the documented effectiveness of chelation therapy in the treatment of arteriosclerosis at the time the care in question was rendered. Instead, the file clearly indicates its unproven nature.

The hearing file of record establishes that the Fiscal Intermediary made some payments on the claims for chelation therapy services provided to the beneficiary in 1981. Therefore, the Director, OCHAMPUS, is required to review this case based upon this FINAL DECISION and take appropriate action under the Federal Claims Collection Act in regards to these erroneous payments.

SECONDARY ISSUE

Discretionary Authority

At various times during the course of this appeal, the beneficiary has requested that consideration be given to paying his claims for the therapy at issue under the Discretionary Authority granted to the Director, OCHAMPUS, by DoD 6010.8-R. That provision states as follows:

> "When it is determined to be in the best interest of the CHAMPUS Program, the Director, OCHAMPUS (or a designee) is granted discretionary authority to waive a requirement(s) of this Regulation, except that any requirement specifically set forth in Chapter 55, Title 10, United States Code, or otherwise imposed by law, may not be waived. It is the intent that such discretionary authority be used only under very unusual and limited circumstances and not to deny any individual any right, benefit or privilege provided to him or her by statute or this Regulation. Any such exception granted by the Director, OCHAMPUS (or a designee), shall apply only to the

individual circumstance and/or case involved and will in no way be construed to be precedent setting."

In reviewing the facts, issues, and applicable authorities involved in this appeal, I concur with the Hearing Officer and have determined that this case is not one in which the exercise of the Director's Discretionary Authority is appropriate. The exercise of that authority has been carefully limited to avoid even the appearance of arbitrary results in the administration of CHAMPUS benefits. The guidelines which have been developed in this regard require that Discretionary Authority shall be exercised so that a waiver of a regulation provision would affect only an individual case rather than a class of cases; and the individual case should be so unique that application of the regulation provision would be contrary to the intent of the law or regulation, or, the individual care is so unique as not to have been adequately considered during the rule making process.

I find none of the foregoing elements present in this case. In fact, the result reached here is fully consistent with that reached in other similar cases involving the identical issue. For example, in ASD(HA) Case File 83-39 (December 29, 1983), we found that chelation (EDTA) therapy provided to a beneficiary from April to July 1981 was not a benefit of CHAMPUS for exactly the same reasons as stated herein. To now exercise Discretionary Authority and allow benefits in this case would be patently unfair to the beneficiary in other similar cases. Federal benefit programs must be administered in a manner which insures that similarly situated beneficiaries are treated equally. There is nothing in this case to indicate that this beneficiary occupies a unique position which would distinguish it from other similar cases. The exercise of Discretionary Authority is clearly not appropriate here.

SUMMARY

In summary, it is the FINAL DECISION of the Assistant Secretary of Defense (Health Affairs) that chelation therapy provided to the beneficiary from January 21 through March 10, 1982, cannot be cost-shared under CHAMPUS. This determination is based upon findings that, at the time of the care in question, chelation therapy in the treatment of arteriosclerosis was not generally accepted as being part of good medical practice, the safety and efficacy of the procedure had not been established, and the treatment was unproven. The CHAMPUS claims for chelation therapy and the appeal of the beneficiary, therefore, are denied. The Director, OCHAMPUS, shall review the claims file and take appropriate action under the Federal Claims Collection Act in regard to payment of any CHAMPUS claims for chelation therapy and related services. Issuance of this FINAL DECISION completes the administrative appeal process as provided under DoD 6010.8-R, chapter X, and no further administrative appeal is available.

Vernon McKenzie
Acting Principal Deputy Assistant Secretary

REC DEC
84-42

RECOMMEMDED DECISION

Claim for CHAMPUS benefits
Civilian Health and Medical Program of the Uniformed Services

(Beneficiary)

(Sponsor)

SSN

This case is before the undersigned Hearing Officer pursuant to the Appealing Party's request for hearing dated January 13, 1983, concerning the denial by OCHAMPUS at its First Level Appeal of his claims totaling $2,265.00 covering twenty-one office visits and twenty-nine infusions of 500ml Lactated Ringers, w/20cc Edetate and nutritional supplements. The Fiscal Intermediary had found, and OCHAMPUS concurred, that the services and supplies furnished Colonel were not in accordance with acceptable medical practice and were not appropriate medical care for the treatment of arterial sclerotic heart disease and the other diagnoses of conditions.

The hearing was held pursuant to Regulation DOD 6010.8-R, Civilian Health and Medical Program of the Uniformed Services, Chapter X, Section F, Paragraph 4, in Austin, Texas on May 3, 1983. was present and was represented by David F. Bragg, Esq., of Austin, Texas. OCHAMPUS was represented by Assistant General Counsel Linda M. Bray, Esq. Post-hearing briefs were timely presented; the last was received by the Hearing Officer on June 30, 1983.

ISSUES

The general issue before the Hearing Officer is whether the services furnished to . by Paul McGuff, M.D., of Houston, Texas may be cost-shared by the CHAMPUS program.

The specific issues to be decided are whether the services provided by Dr. McGuff were appropriate medical care and in keeping with generally accepted norm for medical practice in the United States, and whether the claim should be paid under the discretionary authority of the Director, OCHAMPUS.

LAW AND REGULATIONS

Regulation DOD 6010.8-R is promulgated under the authority of, and in accordance with, Chapter 55, Title 10, United States Code.

The following citations from Regulation DOD 6010.8-R contain the relevant provisions of the Department of Defense Regulation which must be considered in resolving the issues in this appeal:

Chapter IV.A.1. - Scope of Benefits.

Chapter II.B.103 - "Medically necessary".

Chapter II.B.14 - "Appropriate Medical Care".

Chapter IV.G.1 - Exclusions - Not medically necessary.

Chapter IV.G.16 - Exclusion - Not in accordance with accepted standards; Experimental.

Chapter IV.G.63 - Exclusion - Food; Food Substitutes.

Chapter IV.G.69 - Exclusion - Non-covered condition.

EVIDENCE CONSIDERED

The Hearing Officer has considered all of the documents described in the List Of Exhibits attached to this Recommended Decision, the testimony at the hearing, and the post-hearing briefs presented by Mr. Bragg and Ms. Bray.

EVALUATION OF THE EVIDENCE

There is no dispute between the parties as to the nature of the services rendered, nor the amount of the charges that were presented. The only question is whether the treatments provided to by Dr. McGriff met all of the requirements of the Department of Defense Regulation 6010.8-R cited above.

At the outset, it should be recognized that the CHAMPUS program is an extension of the medical benefits program for members of the Uniformed Services; it is not an insurance program involving a contract guaranteeing the payment of specified claims in return for premiums paid. Further, the CHAMPUS program is not subject to regulation by administrative bodies or courts which control the private insurance sector in the States. Accordingly, it must be found that Mr. Bragg's excellent

brief concerning the holdings of Texas Courts has no relevance to the laws, regulations or issues in this appeal. Instead, the appeal must be adjudicated solely on the basis of the policies contained in the Department of Defense Regulation, which itself is not subject to review in this appeal. Such a challenge may be raised only in proceeding in a United States District Court.

The fundamental concept here is that CHAMPUS may cost-share only those medically necessary services and supplies which are covered by and not excluded by the applicable DOD Regulations. Chapter IV.A.1.

"Medically necessary" treatment is that level of services and supplies which is adequate for the diagnosis and treatment of illness or injury. This includes the concept of appropriate medical care. Chapter II.B.103.

"Appropriate medical care" is defined as "that medical care where the medical services performed in the treatment of a disease or injury..... are, in keeping with the generally acceptable norm for medical practice in the United States." Chapter II.B.14. As Mr. Bragg correctly points out, Sub-paragraphs B and C of Subparagraph 14 are not at issue in this appeal, as both of those requirements have been met.

Thus, the principal issue herein is whether the treatment received by [redacted] from Dr. McGuff constituted "appropriate medical care in keeping with the generally acceptable norm for medical practice in the United States."

As Ms. Bray points out in her post-hearing brief, "The question of what constitutes the generally accepted standard for medical practice in the United States is a question of fact; it is for this reason that a CHAMPUS hearing was held." She argued that under the Regulations, the Appealing Party has the burden of documenting his claim for benefits by substantial evidence.

The Hearing Officer concludes that Paragraphs H and I of Paragraph 16, CHAPTER X, place on the burden of producing evidence to prove that the treatments he received during the relevant period were in keeping with the generally acceptable norm for medical practice in the United States, for treatment of the diagnosed conditions which he had at the time the treatments were provided. The Hearing Officer does not agree with Mr. Bragg that OCHAMPUS has the burden of proving what the generally acceptable norm is, that chelation therapy violates that norm, and that failure to do so requires a conclusion that CHAMPUS was arbitrary and its decision had no basis in contract or other law.

Thus, the instant appeal must be decided solely on the basis of the evidence in the record concerning the nature of the treatment, plus the arguments of the parties as to whether that treatment was "appropriate medical care" for diagnosed medical conditions.

OCHAMPUS' Evidence

The Colorado Foundation for Medical Care expressed its expert opinion on December 1, 1981, that chelation therapy is not effective for other than acute toxicity due to heavy metal poisoning, and that chelation

therapy was not considered effective for arterioscelerosis. It recommended against reimbursement for chelation therapy in this case.

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A letter from Alex Rodriquez, M.D., Medical Director for OCHAMPUS addressed to Lt. Colonel Kent B. White dated January 25, 1982, concerns a denial of chelation therapy for atherosclerosis, and establishes that OCHAMPUS has consistently refused to recognize this treatment as

"generally accepted", and that it has consistently denied claims for chelation therapy for the treatment of atherosclerosis.

Appealing Party's Evidence

As evidence of his contention that FDA's lack of a position on EDTA chelation therapy does not establish whether such therapy is proper medical practice, Mr. Bragg submitted an excerpt from FDA Drug Bulletin, Volume 12, Number 1, describing "Approved" and "Unapproved" and "Unlabeled" uses. The article concludes by saying, ". . . accepted medical practice often includes drug use that is not reflected in approved drug labeling."

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would not require bypass surgery if they were given adequate chelation therapy. In a large number of cases chelation therapy has been found to improve kidney function, decrease the amount of insulin required by diabetics and produce significant improvement in arthritis and some cases of Parkinson's disease." He pointed out that clinical double-blind studies were impossible to administer and thus controlled EDTA chelation research for atherosclerosis had not progressed to the point desired. He concluded, "Regardless of the obvious deficiencies in this field of therapy, any physician that has either taken the treatment himself or administered it to those suffering from atherosclerosis cannot help but be enormously impressed with the clinical results it achieved."

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An article entitled, "The Chelation Answer - How to Prevent Hardening of the Arteries and Rejuvenate Your Cardiovascular System", was written by Morton Walker, D.P.M., in consultation with Garry F. Gordon, M.D.. Appendix 1 contains the "current availability of chelation therapy for you", and lists physicians, both M.D. and O.D.s, in the various states and countries, from whom chelation therapy could be obtained. The introductory remarks on page 225 of Appendix 1 are considered by the Hearing Officer as being very strong evidence as to whether chelation therapy is in keeping with the generally acceptable norm for medical practice in the United States in treating atherosclerosis and the other ailments suffered by Colonel

RATIONALE

The Hearing Officer is impressed with the breadth of the information furnished by OCHAMPUS which led it to conclude that EDTA chelation therapy for the treatment of atherosclerotic is not generally practiced in the United States and did not meet the Regulation's requirements for cost-sharing. On the other hand, the evidence produced by Colonel

does not meet his purden of producing substantial evidence to support his opposition to the CHAMPUS determination, as required by CHAPTER X.F.16.h. and i. On the contrary, the Hearing Officer concludes that the statements by proponents of chelation therapy clearly establish that such therapy is openly administered by only two hundred health professionals, not all of whom wanted their names to be listed in a directory, and that an estimated eight hundred doctors provide the

treatment clandestinely. While those physicians' reluctance to announce their use of this treatment may be entirely justified, such a high percentage of clandestine operations provides strong support for OCHAMPUS' position that the chelation therapy is not generally practiced by physicians in the United States, and thus, the treatments do not amount to "appropriate medical care in keeping with the generally acceptable norm for medical practice in the United States", a condition precedent to cost-sharing for the services by CHAMPUS.

No evidence or convincing argument was presented by to support his contention that the Director of OCHAMPUS should pay the claim on the basis of his discretionary authority. Medical Director Rodriquez' letter clearly discusses OCHAMPUS' reasons for consistently refusing to cost-share chelation therapy for the conditions Colonel had, for medical reasons which are within the authority of OCHAMPUS, and are regarded by the Hearing Officer as sound and reasonable.

FINDINGS

The undersigned Hearing Officer makes the following findings of fact: (1) filed a request for hearing, challenging the determination of OCHAMPUS that the services provided him by Dr. McGuff were not covered by the CHAMPUS program. (2) Documents and testimony in the record establish the accuracy of the OCHAMPUS conclusion that "EDTA treatment for atherosclerosis is not in accordance with medical

standards in the United States and thus, is not medically necessary treatment." (3) Because [redacted] various diagnoses are related to cardiovascular atherosclerosis, the EDTA treatments and related services and supplies such as office visits are excluded from the CHAMPUS basic program as not in accordance with medical standards in the United States and as not medically necessary treatment. (4) The Edta treatments for coronary artery disease, diabetes meelitus, vertigo, prostatism, tinnitus, arthritis and atrial fibrillation and related services and supplies are not authorized for cost-sharing because they are not documented as appropriate medical care or medically necessary treatment.

RECOMMENDED DECISION

It is recommended by the undersigned Hearing Officer that the First Level Appeal Decision of OCHAMPUS dated November 30, 1982, be upheld on the basis that it correctly denied [redacted] claims, since the EDTA infusions were not rendered in accordance with accepted medical standards, nor were they appropriate medical care for the treatment of generalized arteriosclerosis, and thus, were not authorized for payment by OCHAMPUS under DOD Regulation 6010.8-R; and further, that the diagnostic testing, office visits and lab work could not be considered for CHAMPUS cost-sharing since they were related to the non-covered treatments.

Harold H. Leeper

August 5, 1983
Dallas, Texas

Harold H. Leeper
Hearing Officer