



ASSISTANT SECRETARY OF DEFENSE

WASHINGTON, D.C. 20301

HEALTH AFFAIRS

BEFORE THE OFFICE, ASSISTANT
SECRETARY OF DEFENSE (HEALTH AFFAIRS)
UNITED STATES DEPARTMENT OF DEFENSE

JAN 20 1985

Appeal of)
Sponsor:) OASD(HA) File 84-54
SSN:) FINAL DECISION

This is the FINAL DECISION of the Assistant Secretary of Defense (Health Affairs) in the CHAMPUS Appeal OASD(HA) Case File 84-54 pursuant to 10 U.S.C. 1071-1092, and DoD 6010.8-R, chapter X. The appealing party is the CHAMPUS beneficiary, who is the spouse of a retired enlisted member of the United States Army. The appeal involves the denial of CHAMPUS cost-sharing for claims for prescription drugs (Valium, Doriden, Tylenol with Codeine, and Compazine) from June 28, 1982, through November 13, 1982. The amount in dispute is \$698.35.

The hearing file of record, the tape of oral testimony and the arguments presented at the hearing, 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 CHAMPUS cost-sharing of the prescriptive drugs be denied because the "prescription drugs provided between June 28, 1982, and January 3, 1983 [sic - November 13, 1982], have not been proven to be medically necessary, and have not been proven to be in keeping with the generally accepted norm for medical practice in the United States."

The Director, OCHAMPUS, concurs in the Recommended Decision and recommends adoption of the Recommended Decision as the FINAL DECISION. The Assistant Secretary of Defense (Health Affairs). after due consideration of the appeal record, concurs in the recommendation of the Hearing Officer and hereby adopts and incorporates by reference the Recommended Decision of the Hearing Officer as the FINAL DECISION.

The FINAL DECISION of the Assistant Secretary of Defense (Health Affairs) is, therefore, to deny CHAMPUS cost-sharing of the appealing party's claims for prescriptive drugs. This determination is based on findings that the beneficiary has neither documented the medical necessity of the prescription drugs, nor shown that the prescriptions were within the generally accepted norm for medical practice in the United States.

There are two points in the Hearing Officer's Recommended Decision that merit emphasis. The first is the lack of documentation by the treating physician. The need for the prescriptive drugs was totally undocumented by the treating physician, Russell P. Carter, M.D. Dr. Carter, in a letter dated August 6, 1982, simply made the statement that:

"It is understood that the specific drugs disallowed were APC with Codeine, Doriden, and Valium. The on-going diagnosis which prevailed during the aforesaid period were chronic anxiety, degenerative arthritis involving the thoracic and lumbosacral spine with associated muscle spasms and secondary insomnia.

"I believe that the use of these medications for the aforementioned conditions is appropriate and I do support the patient's claim for coverage in this case."

In a second letter dated May 22, 1984, Dr. Carter restated his position as follows:

"I believe that the use of these medications for the aforementioned conditions is medically necessary and in keeping with a generally acceptable norm for medical practice in the United States."

The Hearing Officer had suggested at the hearing that the sponsor may wish to obtain another letter from Dr. Carter regarding the medical necessity of the prescriptions. The Hearing Officer also suggested that Dr. Carter give medical reasons for his opinion. This was not done by Dr. Carter.

Though not cited in the Hearing Officer's Recommended Decision, this office in a previous FINAL DECISION, OASD(HA) Case File 82-07, held that failure to document the need for prescriptive drugs will necessitate the denial of CHAMPUS cost-sharing. The Hearing Officer correctly held the need for the prescriptive drugs was not documented.

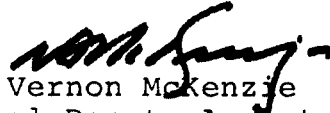
The second point I wish noted, is that the Hearing Officer remarked that the case, "Perhaps approached a drug dependency situation." The medical review, included in the record, contained an opinion that, "The patient indicates she has taken the medications for several years. If this is true, then it appears the case represents a drug dependency situation." The sponsor testified at the hearing that his wife had used the drugs for a number of years. However, there was no direct medical testimony or evidence detailing what drugs had been taken prior to the period in dispute and for how long. The record would not support a determination that there was a drug dependency situation and the Hearing Officer did not make such a finding.

The determination to deny is based on the failure to document the need for the drugs, failure to establish medical necessity, and that the care was not in keeping with the generally accepted norm for practice in the United States.

There is the technical correction to the Hearing Officer's Recommended Decision. He refers to the dates the prescriptions were provided both as June 28, 1982, through November 13, 1982, and June 28, 1982, through January 3, 1983. The correct date is November 13, 1982; one of the claims was processed on January 3, 1983, but this is not when the prescription was issued.

SUMMARY

In summary, the FINAL DECISION of the Assistant Secretary of Defense (Health Affairs) is to affirm the CHAMPUS denial of cost-sharing of the beneficiary's claims for prescriptive drugs for the period from June 28, 1982, through November 13, 1982. The beneficiary has failed to document the medical necessity of the various prescriptive drugs - Valium, Doriden, Tylenol with Codeine, and Compazine and that the treatment was in keeping with the general accepted norm for practice in the United States. The claims are all denied. Issuance of this FINAL DECISION completes the administrative appeals process under DoD 6010.8-R, chapter X, and no further administrative appeal is available.



Vernon McKenzie
Acting Principal Deputy Assistant Secretary

RECOMMENDED DECISION
Claim for CHAMPUS Benefits
Civilian Health and Medical Program of the
Uniformed Services (CHAMPUS)

Appeal of) R E C O M M E N D E D
) D E C I S I O N
Sponsor:)
)
SSN:)
_____)

This is the Recommended Decision of CHAMPUS Hearing Officer Sherman R. Bendalin in the CHAMPUS appeal case file _____, and is authorized pursuant to 10 U.S.C. §1071-1089 and DoD Regulation 6010.8-R, Chapter X. The appealing party is the Beneficiary, _____, who filed an undated written Request for Hearing. (Hearing exhibit file, _____ Exhibit No. 24.) (Hereinafter "E. ____.") The appeal involved the denial of claims for CHAMPUS cost-sharing for drugs from June 28, 1982 through November 13, 1982, consisting of claims for Valium, Doriden, Tylenol with Codeine, and Compazine. The final OCHAMPUS decision was issued on December 16, 1983 denying coverage for the prescription drugs, upholding the previous decisions that the claims for the prescription drugs had not been documented to be medically necessary. (E. 23.)

Originally, according to the Notice of Hearing, at issue was a single issue. However, a secondary issue was raised at the hearing in the Hearing Officer's opinion. Consequently, the issues are now two in number. The first issue is whether or not the prescription drugs provided during the period June 28, 1982 through January 3, 1983 were medically necessary and in keeping with the generally acceptable norm for medical practice in the United States. The secondary issue raised by the Sponsor at the hearing, is as follows: If the Sponsor's private third party payer has paid for the drugs, why has CHAMPUS denied cost-sharing for the same claims.

A hearing was commenced by the undersigned Hearing Officer in Oakland, California at the George P. Miller Federal Building, Room 465, on May 16, 1984. The hearing commenced at 10:04 o'clock a.m. and concluded at 10:56 o'clock a.m. The Beneficiary did not appear. Appearing on behalf of the Beneficiary and the Sponsor was the Sponsor, _____ . No appearance was made on behalf of OCHAMPUS.

The amount in dispute is \$698.35.

The Hearing File has been expanded to include Exhibits 26 through 32. All Exhibits have been reviewed. The undersigned

has reviewed the tape recording of the hearing. After due consideration of the appeal record, the undersigned Hearing Officer concurs in the recommendation of OCHAMPUS to deny CHAMPUS cost-sharing for the claims for prescription drugs provided the Beneficiary during June 28, 1982 through January 3, 1983. It is the recommendation of the undersigned that the Beneficiary and the Sponsor have failed to meet the burden of proof to justify CHAMPUS cost-sharing. The medical necessity for the medication has not adequately been documented. The record suggests that the medications provided were not appropriate medical care. The record further suggests that a drug dependency situation existed during the time in question. As far as the secondary issue is concerned, the undersigned Hearing Officer resolves that issue against the Sponsor and the Beneficiary, based on the CHAMPUS Regulation, DoD 6010.8-R, specifically Chapter I, Section D. (Hereinafter "Regulation.")

FACTUAL BACKGROUND

The Beneficiary is a female patient who has been diagnosed as having chronic anxiety, degenerative arthritis involving the thoracic and lumbosacral spine with associated muscle spasms and secondary insomnia. (E. 11, p. 3.) It appears, moreover, that the diagnosis remains uncontroverted by the evidence and the testimony. Based on the diagnosis, the treating doctor, Russell P. Carter, M.D., prescribed a series of medications including Valium, 10 mg., Doriden, .5 mg., Tylenol with Codeine, 1 gr., and Compazine. During the period in question, the Beneficiary received prescriptions and had filled prescriptions for approximately 800 Valium tablets, 470 Doriden tablets, 400 Tylenol with Codeine tablets and 24 Compazine tablets. (E. 1 and 6.)

Claims were submitted for cost-sharing the difference between what the Sponsor's third party payer, AETNA Insurance had paid, and the amount owed. (E. 1.) The Fiscal Intermediary immediately notified the Beneficiary that the claims for the medication during the period at issue could not be cost-shared as they were determined not to be medically necessary. (E. 2.)

A Request for Informal Review was received on February 7, 1983. (E. 14.) The Informal Review Decision, dated March 23, 1983 continued to uphold the decision of the Fiscal Intermediary, reaffirming that there was not sufficient available documentation to establish medical necessity. (E. 17.)

Automatic reconsideration resulted in a further decision upholding the previous decision against cost-sharing. (E. 18.)

A timely Request for Formal Review was received on May 20, 1983. (E. 19.) A Peer Review was obtained from the Colorado Foundation for Medical Care. The two physicians who reviewed

agreed that medical necessity had not been proven, that the drugs prescribed were not appropriate medical care, and that the case represented a drug dependency situation. (E. 21, p. 2.)

The Formal Review Decision, dated December 16, 1983, continued to uphold the denial of the claim. The reasons given were from the Peer Review, and in particular that the drugs prescribed were not medically necessary. (E. 23.)

A Request for Hearing, undated, was timely received by OCHAMPUS. (E. 24.) By letter dated March 7, 1984, OCHAMPUS accepted the Request for Hearing. (E. 25.)

By letter dated March 30, 1984, the Beneficiary was notified that the Request for Hearing had been forwarded to the undersigned Hearing Officer, and that a hearing had been scheduled for May 16, 1984 in Oakland, California. (E. 27.) The Notice of Hearing, issued by the undersigned Hearing Officer dated April 25, 1984, confirmed the hearing date of May 16, 1984.

The undersigned Hearing Officer has considered Exhibits 1 through 25 that were provided to both he and the Beneficiary in the Exhibit file. Additionally, considered and admitted, were Exhibits 26 through 32. Exhibit 26 is the Notice of Hearing dated April 25, 1984. Exhibit 27 is correspondence dated March 30, 1984 from Donald F. Wagner, Chief, Appeals and Hearings, OCHAMPUS, to the Beneficiary confirming the arrangements for the date, time and place of the hearing. Exhibit 28 is correspondence transmitting THE STATEMENT OF OCHAMPUS POSITION, from attorney/advisor William N. Voharas to the Hearing Officer dated April 10, 1984. Exhibit 29 is THE STATEMENT OF OCHAMPUS POSITION IN THE APPEAL OF . Exhibit 30 is the first of three post-hearing Exhibits. It is the letter of confirmation from the Hearing Officer to the Sponsor and Beneficiary concerning additional Exhibits, dated May 21, 1984. Exhibit 31 is a letter of clarification from the treating physician, Russell F. Carter, M.D., dated May 22, 1984. Finally, Exhibit 32 is the response of OCHAMPUS attorney/advisor William N. Voharas to Exhibit 31, dated May 29, 1984.

ISSUE AND FINDINGS OF FACT

There are now two issues in this appeal, the primary issue and the secondary issue. The primary issue is whether or not prescription drugs provided during the period June 28, 1982 through January 3, 1983 were medically necessary and in keeping with the generally acceptable norm for medical practice in the United States.

Chapter II of the Regulation consists of definitions used in the Regulation. Section B(14) defines Appropriate Medical Care, and reads as follows:

"14. Appropriate Medical Care. "Appropriate Medical Care" means:

- a. That medical care where the medical services performed in the treatment of a disease or injury, or in connection with an obstetrical case, are in keeping with the generally acceptable norm for medical practice in the United States;
- b. The authorized individual professional provider rendering the medical care is qualified to perform such medical services by reason of his or her training and education and is licensed and/or certified by the state where the service is rendered or appropriate national organization or otherwise meets CHAMPUS standards; and
- c. The medical environment in which the medical services are performed is at the level adequate to provide the required medical care."

Another definition is relevant to the primary issue. Section B(104) of Chapter II defines Medically Necessary, and reads as follows:

"104. Medically Necessary. "Medically Necessary" means the level of services and supplies (that is, frequency, extent, and kinds) adequate for the diagnosis and treatment of illness or injury (including maternity care). Medically necessary includes concept of appropriate medical care."

Chapter IV discusses Basic Program Benefits. Section A(1) deals with benefits in general, and reads as follows:

- "A. General. The CHAMPUS Basic Program is essentially a supplemental Program to the Uniformed Services direct medical care system. In many of its aspects, the Basic Program is similar to private medical insurance programs, and is designed to provide financial assistance to CHAMPUS beneficiaries for certain prescribed medical care obtained from civilian sources.
 1. Scope of Benefits. Subject to any and all applicable definitions, conditions, limita-

tions, 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, including maternity care. Benefits include specified medical services and supplies provided to eligible beneficiaries from authorized civilian sources such as hospitals, other authorized institutional providers, physicians and other authorized individual professional providers as well as professional ambulance service, prescription drugs, authorized medical supplies and rental of durable equipment."

Chapter IV, Basic Program Benefits, also defines other benefits. One subsection of Section D, Subsection D(3), defines other covered services and supplies, and at paragraph f prescription drugs and medicines is defined as follows:

- "f. Prescription Drugs and Medicines. Prescription drugs and medicines which by law of the United States require a physician's or dentist's prescription and which are ordered and prescribed for by a physician or dentist (except that insulin is covered for a known diabetic, even though a prescription may not be required for its purchase) in connection with an otherwise covered condition or treatment, including Rhogam.
1. Drugs administered by a physician or other authorized individual professional provider as an integral part of a procedure covered under Sections B or C of this CHAPTER IV (such as chemotherapy) are not covered under this Subparagraph inasmuch as the benefit for the institutional services or the professional services in connection with the procedure itself also includes the drug used.
 2. CHAMPUS benefits may not be extended for drugs not approved by the Food and Drug Administration for general use by humans (even though approved for testing with humans)."

The potential of drug abuse situations is recognized in the Regulation. Chapter IV(E)(11) defines a drug abuse situation as follows:

- "11. Drug Abuse. Under the CHAMPUS Basic Program, benefits may be extended for medically necessary

prescription drugs required in the treatment of an illness or injury or in connection with maternity care (refer to Section D of this CHAPTER IV). However, CHAMPUS benefits cannot be authorized to support and/or maintain an existing or potential drug abuse situation, whether or not the drugs (under other circumstances) are eligible for benefit consideration and whether or not obtained by legal means.

- a. Limitations on Who Can Prescribe Drugs. CHAMPUS benefits are not available for any drugs prescribed by a member of the beneficiary/patient's family or by a non-family member residing in the same household with the beneficiary/patient (or sponsor). CHAMPUS Contractors are not authorized to make any exception to this restriction.
- b. Drug Maintenance Programs Excluded. Drug maintenance programs where one addictive drug is substituted for another on a maintenance basis (such as methadone substituted for heroin) are not covered. Further, this exclusion applies even in areas outside the United States where addictive drugs are legally dispensed by physicians on a maintenance dosage level.
- c. Kind of Prescriptions Which Are Carefully Monitored by CHAMPUS for Possible Abuse Situations.
 1. Narcotics. Examples are Morphine and Demerol.
 2. Non-Narcotic Analgesics. Examples are Talwin and Darvon.
 3. Tranquilizers. Examples are Valium, Librium and Meproamate.
 4. Barbituates. Examples are Seconal and Nembutal.
 5. Non-Barbiturate Hypnotics. Examples are Doriden and Chloral Hydrate.
 6. Stimulants. Examples are Amphetamines and Methedrine."

Section G of Chapter IV discusses Exclusions and Limitations. Subsection G(1) defines Exclusions and Limitations, and reads as follows:

"G. Exclusions and Limitations. In addition to any definitions, requirements, conditions and/or limitations enumerated and described in other CHAPTERS of this Regulation, the following are specifically excluded from the CHAMPUS Basic Program:

1. Not Medically Necessary. Services and supplies which are not medically necessary for the diagnosis and/or treatment of a covered illness or injury."

A second limitation involves "Not in Accordance With Accepted Standards." That definition, found at Chapter IV(G)(15) is as follows:

"15. Not in Accordance With Accepted Standards: Experimental. Services and supplies not provided in accordance with accepted professional medical standards; or related to essentially experimental procedures or treatment regimens."

Chapter X of the Regulations specifies the hearing procedures. At Section A(3), Burden of Proof is defined as follows:

"3. Burden of Proof. The burden of proof is on the appealing party, affirmatively to establish by substantial evidence, the appealing party's entitlement under law and this Regulation to the authorization of CHAMPUS benefits or approval as an authorized provider. Any cost or fee associated with the production or submission of information in support of an appeal shall not be paid by CHAMPUS."

As stated earlier, it is the Recommended Decision of the undersigned Hearing Officer that the prior decisions of OCHAMPUS be reaffirmed regarding the claim for cost-sharing for the various medications from June 28, 1982 through January 3, 1983. The record is replete with substantial evidence to support the decision of OCHAMPUS. In particular, the Peer Review mentioned above, contained as Exhibit 21, supports the OCHAMPUS decision. The two Peer Review doctors opined that the prescriptions at issue were not medically necessary. It is further their opinion that the drugs were not appropriate medical care. Finally, the doctors suggest in the Peer Review that the case as presented "represents a drug dependency situation." (E. 21.)

It is a basic tenet of the CHAMPUS claim procedure that claims must fall within the Regulation. If they do not, then they cannot be cost-shared. Although it is true that the treating doctor expresses his opinion in a letter dated August 6, 1982 regarding the necessity for the medication, (E. 11, p.3.), the evidence from the Peer Review physicians clearly outweighed the opinion evidenced from the treating doctor, since the opinion of the treating doctor was not supported by any medical records, results of clinical tests, or other supporting documentation.

It is also instructive to examine the testimony of the Sponsor at the hearing. His testimony indicated that the Beneficiary did not get better while taking the medications at issue. He testified that the medications only made life more bearable for the Beneficiary. He testified that the drugs were for maintenance only. He further testified, in his opinion, that the Beneficiary had been addicted to the drugs Valium, Doriden, Tylenol with Codeine and Compazine for several years, perhaps as long as 8 or 9 years. This testimony by the Sponsor clearly supports the decisions of OCHAMPUS not to cost-share the claim at issue.

The Sponsor further testified that he had attempted to obtain additional supporting documentation from the treating physician, Russell Carter, M.D. The Sponsor testified that Dr. Carter refused to write anything additional, indicating to the Sponsor that Dr. Carter suggested that any additional information would be ignored, so the Sponsor should just "forget" any additional documentation. The Sponsor also testified that the Beneficiary had undergone a psychiatric consultation at the request of the treating physician, but upon questioning did not know if a psychiatric consultation report had been written or if so, where it was kept.

It is unfortunate, in the Hearing Officer's eyes, that the Sponsor's attempts in obtaining additional documentation were frustrated by the treating doctor. Nevertheless, due to the lack of such supporting documentation, both Sponsor and Beneficiary have clearly failed to meet their burden of proof.

At the end of the hearing, additional time was afforded the Sponsor to obtain additional medical support from the treating doctor. Exhibit 30 is the letter of clarification from the undersigned to the Sponsor regarding the additional documentation. What was received is another terse letter from Russell Carter, M.D., that does not add any support to the Beneficiary's claim. In addition to giving his opinion, if the treating physician would have attached supporting documentation, the results of any diagnostic tests, or perhaps if available, the results of the psychiatric consultation, perhaps it would have been more persuasive. Nevertheless, Exhibit 31 as admitted does not help the Beneficiary nor the Sponsor meet their burden of proof.

The weight of the evidence, both the written Exhibits and the oral testimony clearly supports the decision of OCHAMPUS to deny cost-sharing for the medications during the period at question.

SECONDARY ISSUE

As stated earlier, as a result of the hearing, the undersigned Hearing Officer has decided that a secondary issue was raised by the Sponsor at the hearing. The secondary issue is as follows: If the Sponsor's private third party payer has paid for the drugs, why has CHAMPUS denied cost-sharing for the same claims.

The secondary issue must also be resolved against the Sponsor. As stated earlier, CHAMPUS is a program governed by the Regulation. The Regulation treats the secondary issue raised by the Sponsor, where at Chapter I, Section D, the following is found:

- "D. Medical Benefits Program. The CHAMPUS is a program of medical benefits provided by the Federal Government under public law to specified categories of individuals who are qualified for these benefits by virtue of their relationship to one of the seven Uniformed Services. Although similar in structure in many of its aspects, CHAMPUS is not an insurance program in that it does not involve a contract guaranteeing the indemnification of an insured party against a specified loss in return for a premium paid. Further, CHAMPUS is not subject to those state regulatory bodies or agencies which control the insurance business generally."

Consequently, the Regulation specifies that actions of third party payers or any other source of payment of medical claims has no bearing on what CHAMPUS should or should not do. The Regulation itself governs. As set forth earlier in this Recommended Decision, it is the undersigned Hearing Officer's opinion that the Regulation requires and indeed supports denial of the Beneficiary's claim.

SUMMARY

For the reasons set forth above, it is the recommended decision of the undersigned Hearing Officer that the previous decisions of CHAMPUS be affirmed. Prescription drugs provided between June 28, 1982 and January 3, 1983 have not been proven to be medically necessary, and have not been proven to be in keeping with the generally acceptable norm for medical practice in the United States. Although the treating doctor opined to the

contrary, his opinion without supporting documentation including the results of diagnostic tests, office examinations or any indication of his care and treatment of the Beneficiary are simply unsupported opinions of the treating physician. On the other hand, the record contains voluminous documentation, including the written opinion of two Peer Review physicians, that indeed the prescriptions at issue were not medically necessary, were not appropriate medical care, and perhaps approached a drug dependency situation. The Sponsor's own testimony supports the decision of OCHAMPUS since, in the words of the husband of the Beneficiary, the Beneficiary was not getting better by using the medication, was addicted to the drugs for as long as 8 to 9 years, and used the drugs for maintenance only.

The secondary issue raised by the Sponsor, that of why has CHAMPUS denied coverage when private third party payers have paid, is also resolved against the Sponsor and the Beneficiary. The Regulation is specific that the actions of third party payers are not to be considered, and is not binding on OCHAMPUS. There being no evidence, written or oral, to support the position advocated by the Sponsor with regard to the secondary issue, it must be resolved against the Sponsor and Beneficiary.

DATED: June 13, 1984.


Sherman R. Bendalin
CHAMPUS Hearing Officer