ASSISTANT SECRETARY OF DEFENSE
WASHINGTON, D. C. 20301

HEALTH AFFAIRS

6 JAN 1983

BEFORE THE OFFICE, ASSISTANT

SECRETARY OF DEFENSE (HEALTH AFFAIRS)

UNITED STATES DEPARTMENT OF DEFENSE

Appeal of)
)
Sponsor:) OASD(HA) File 82-07
)
) FINAL DECISION
ID No.)
)
)

This is the FINAL DECISION of the Acting Assistant Secretary of Defense (Health Affairs) in the CHAMPUS Appeal OASD(HA) Case File 82-07 pursuant to 10 U.S.C. 1071-1089 and DoD 6010.8-R, chapter X. The appealing party in this case is a beneficiary of the Civilian Health and Medical Program of the Veterans Administration (CHAMPVA), as the widow of a 100% disabled veteran. CHAMPVA is administered under the same or similar limitations as the medical care furnished certain beneficiaries of the Civilian Health and Medical Program of the Uniformed Services (CHAMPUS). By agreement between the Administrator, Veterans' Administration and the Secretary of Defense, pursuant to the provisions of Title 38, U.S.C. 613, CHAMPVA claims are processed and appealed under rules and procedures established by the CHAMPUS regulation.

This appeal involves the denial of CHAMPVA claims in the amount of $724.01 for prescription drugs and medical supplies obtained by the beneficiary in March, April and May 1980. The denial of these claims was based upon a failure to document the medical necessity of the kinds and amounts of medications and supplies claimed. Also at issue are claims in the amount of $7,812.45 for prescription drugs and medical supplies submitted between June 1977 and March 1980 which were previously paid by the CHAMPVA Fiscal Intermediary, Blue Cross of Rhode Island. The fiscal intermediary paid $5,859.39 as the CHAMPVA cost-share of these claims. In addition, there are a number of subsequent claims which have been suspended pending the resolution of this appeal.

The hearing file of record, the tape of oral testimony and argument presented at the hearing, the Hearing Officer's

Recommended Decision and the recommendation of the Director, OCHAMPUS have been reviewed. It is the Hearing Officer's recommendation that the denial of claims for medications and supplies from March 21, 1980 through May 9, 1980 and those still pending be upheld. The Director, OCHAMPUS concurs in the Recommended Decision, but recommends issuance of a FINAL DECISION which also denies CHAMPVA coverage of the claims submitted between June 10, 1977 and March 21, 1980, and all pending claims which are not supported by documented medical necessity.

The FINAL DECISION of the Acting Assistant Secretary of Defense (Health Affairs) therefore is to adopt the Recommended Decision of the Hearing Officer and deny CHAMPVA coverage of the claims, medications and supplies obtained by the beneficiary from March 21, 1980 through May 9, 1980, as well as all subsequent claims suspended during the appeal. It is also my decision that the record does not adequately document the medical necessity of the kinds and quantities of medications and supplies claimed by the beneficiary from June 10, 1977 through March 24, 1980. Consequently, the CHAMPVA payments issued on these claims were erroneous and should be recouped under the provisions of the Federal Claims Collection Act, 31 U.S.C. 951-953. This FINAL DECISION is based on the appeal record as stated above and applicable authorities.

FACTUAL BACKGROUND

In July 1977, the beneficiary began submitting CHAMPVA claims for prescription medications and medical supplies. These claims were filed as "shoe box" claims, that is, claims in which receipts for a relatively large number of medical services and supplies obtained over a period of time were submitted together utilizing one CHAMPVA claim form. The fiscal intermediary, Blue Cross of Rhode Island, routinely paid these claims until June 1980 when the fiscal intermediary began denying them. The fiscal intermediary's denial was based upon a finding that there was insufficient medical information to support the medical necessity for the large quantities and many kinds of medications being claimed.

On May 7, 1980, OCHAMPUS was notified that through routine utilization review the fiscal intermediary had identified this case as one involving possible overutilization of medications. As a part of the utilization review process, both the prescribing physician and the dispensing pharmacy were contacted for additional information. Neither source was able to provide significant additional information; the pharmacist claimed that his records were incomplete, and the prescribing physician refused to release medical information without a signed release from the patient. Subsequently, the claims submitted for prescriptions filled in March, April and May 1980, were denied because insufficient information had been submitted to determine the medical necessity for the number and quantities of medications and supplies claimed.

There were two claims so denied. The first contained charges for medications and supplies provided between March 21, 1980, and April 14, 1980, totaling $441.67. These charges were denied by the fiscal intermediary on June 5, 1980 with a stated explanation that insufficient medical information had been provided. The second denied claim contained charges for prescription medications and supplies obtained from May 1, 1980 to May 9, 1980 in the amount of $282.34. This claim was also denied by the fiscal intermediary on June 5, 1980, because insufficient medical information had been submitted. Prior to the denial of these two claims, on May 21, 1980, the beneficiary was requested to sign a release of medical information. The beneficiary refused the release of any medical information on May 27, 1980 and again on June 9, 1980. She also requested that the denial of her claims be reviewed.

On June 16, 1980, a medical reviewer at the fiscal intermediary (a Registered Nurse) concluded it was "obvious it would be impossible to utilize the inordinate amount of supplies claimed. There also appears to be an abuse in the quantity of medications." Consequently, on June 17, 1980, the fiscal intermediary issued its Informal Review Decision which upheld the initial denial of the beneficiary's claims, again based "upon the lack of medical records to substantiate the medical necessity of certain medications."

Because of the amount in dispute involved, the fiscal intermediary automatically referred the case to the next higher level of appeal. On June 23, 1980, the beneficiary reconfirmed her refusal to consent to the release of the requested medical documentation. As a part of the reconsideration review the case was again sent to medical review. The reviewing physician stated that the quantity of medications seemed inappropriate for the diagnoses given raising a serious question of drug abuse. He also recognized that certain of the medications appeared medically necessary but recommended denial of payment unless the case was better documented.

The fiscal intermediary's Reconsideration Decision of July 7, 1980 upheld the denial of the claims in question, again on the basis that the diagnoses and medical documentation supplied did not establish the medical necessity of the quantities of medications and supplies claimed.

The beneficiary appealed the case to OCHAMPUS on July 14, 1980. OCHAMPUS also requested that the beneficiary authorize the release of medical records and information to support her claim. The requested information was not provided and the OCHAMPUS First Level Review of November 28, 1980, upheld the actions of the fiscal intermediary. The beneficiary requested a hearing on December 22, 1980. The beneficiary also submitted an additional claim for prescription medications obtained between April 7, 1980 and November 14, 1980. This claim has, to date, not been adjudicated, pending the resolution of this appeal.

Enclosed with the beneficiary's December 22, 1980 hearing request were statements from three of her attending physicians. These statements confirm that the beneficiary suffers from diabetes and hypertension complicated by secondary manifestations. The statements also confirm that the beneficiary requires multiple medications, but no medical records were supplied and there is no indication of the specific medications and quantities required to treat the beneficiary's conditions.

OCHAMPUS requested a peer review of the entire medical record available in this case on February 3, 1981. The peer review was conducted by the Colorado Foundation for Medical Care. Their report stated that based on the meager medical documentation available, it did not appear that the kinds and quantities of medications claimed were in keeping with the generally accepted norms for practice in the United States.

The hearing in this case was held on July 30, 1981, in Mineola, New York. The evidence adduced at the hearing consisted primarily of the documents and testimony presented by the beneficiary. The beneficiary presented fourteen documentary exhibits at the hearing, five of which were already contained in the hearing file of record. The remainder of these exhibits consisted primarily of correspondence dealing with the administrative development of the case. These exhibits are now shown as Exhibits 29 through 42 in the hearing file of record.

The beneficiary's Exhibit 13 (now #41 in the hearing file of record) is a letter dated July 22, 1981, in which she challenged the credentials of the physicians who conducted the peer review in her case. In her testimony at the hearing, she persisted in her challenge of the opinion of the Program's medical reviewers, summarized by the Hearing Officer as follows:

> "(The beneficiary) testified that she is elderly and quite ill, but beyond that she did not testify at all as to her physical condition nor her use of the medications and supplies claimed. Her testimony was confined to her belief that OCHAMPUS 'defamed and slandered' her when ' ,' representing the FI, called her doctor and pharmacist and insinuated that she was overutilizing medications and supplies. She said that ' ,' who is said to work for the FI, is not a medical doctor, but that he is a 'Doctor of Literature.' She claimed that ' ' had no right to make insinuations of fraud against her to her doctor and to her pharmacist.
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> "(The beneficiary) then challenged the efficacy of the opinions of and . (She) adduced

evidence that the original Physician Qualifications Sheet stated that name though listed as ' ' was incorrect. She maintained that this was not a mistake, but an effort on the part of OCHAMPUS to deceive her. That since there was no ' ' who fit the credentials listed in his professional qualifications in the Who's Who of Medicine, 1979 Ed., that his opinion was of no value. (The OCHAMPUS representative) duly noted the correction of name into the record, and that a corrected statement of Professional Qualifications had been sent to (the beneficiary) prior to the hearing. As to (the beneficiary) presented evidence that he was admitted into practice in 1965 and not in 1962 as stated in his professional qualifications and that this was also an attempt to perpetrate a fraud against her. She therefore claimed that the Peer Review opinion holds no credence as the doctors' credentials were erroneously presented.

"(The beneficiary) also challenged the opinion of R.N. as being unimportant as she was an R.N. and not a qualified doctor.

"(The beneficiary) quoted from the Peer Review report 'Because of lack of an adequate history and other medical information it is impossible to decide what medications were indicated and at what frequence.' She maintained that this statement supported her theory that if there isn't sufficient evidence, then there isn't sufficient evidence to determine that too many medications were claimed.

"(The beneficiary) presented testimony that CHAMPVA has had adequate medical evidence to substantiate her claims. She used her Exhibit numbers 2, 4 and 5 (OCHAMPUS Exhibit #18), 6, 7, and 8 as evidence that CHAMPVA had been routinely checking on her claims and honoring them, and she used them to show that there was adequate medical documentation (OCHAMPUS Exhibit #18) to substantiate her claims. (She) stated that it was the responsibility of CHAMPVA to make sure that

> her claims were valid, and that by paying those claims, CHAMPVA had attested to the validity of the claims.
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> "(The beneficiary) stated, '... they have adequate medical records and they have had right along and they had access to my doctors at any time to call up for records and they have been doing that until the time when he ( ) called my drug store and said I had committed fraud, and made several charges against me. And at that point I instructed my doctors, after they talked to me, to give them no further information under any circumstances.'
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> "(The beneficiary) presented no further evidence of her medical condition or the need for the kinds and quantities of medications and supplies claimed. She offered no medical records nor any further statements from her doctors beyond that which was already included in the Hearing Record."

The Hearing Officer has submitted his Recommended Decision in this case. All prior administrative levels of appeal have been exhausted and issuance of a FINAL DECISION is proper.

ISSUES AND FINDINGS OF FACT

The primary issue in this appeal is whether or not the prescription medications and supplies purchased by the beneficiary during the period of June 10, 1977 to November 14, 1980, were medically necessary and at an appropriate level.

The evidence of record in this appeal establishes that the beneficiary purchased large quantities and numerous types of prescription medications and supplies during the period in question. Attached as an Appendix to this decision is a compilation of the kinds and quantities of medications involved in this case.

Paragraph A.1., chapter IV, DoD 6010.8-R, defines the scope of benefits for the CHAMPVA as follows:

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

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

> "a. 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."

Basic Program benefits are available for prescription drugs and medicines under CHAMPVA. Prescription drugs and medicines are defined as "those ... which at the time of use were approved for general use by humans by the U.S. Food and Drug Administration as listed in the U.S. Pharmacopeia and the National Formulary, which were commercially available and which by law ... require a physician's or dentist's prescription, except that it includes insulin for known diabetics whether or not a prescription is required." (See Paragraphs B.138, chapter II, and D.3.f., chapter IV, DoD 6010.8-R.) Claims for prescription drugs and medicines (and insulin) must include, under paragraph B.2.K., Chapter VII, DoD 6010.8-R, receipted bills and the following additional information:

a. Name of the drug.

b. Strength of the drug.

c. Name and address of the pharmacy where the drug was purchased.

d. Prescription number of the drug being claimed.

Prior to the extension of benefits under the CHAMPVA, claims are subject to review for quality of care and appropriate utilization. (See paragraph A.10., chapter IV, DoD 6010.8-R.)

CHAMPVA prescription drug claims are also subject to post-payment utilization review. Claims that fail established post-payment utilization review screens or appear to involve abnormal patterns of prescribing are developed through associated claims history or the request of medical records. This review process is always retrospective because each claim is viewed after-the-fact of the purchase of the medical supply or service involved. Implicit in this utilization review process is the possibility that a particular medication supply or service at any time may be determined to be not medically necessary or beyond an appropriate level. This also means that

even though benefits are initially extended on a particular claim, post-payment review may result in the emergence of an aberrant pattern which calls into question the medical necessity or level of the services or supplies involved.

The responsibility of perfecting a CHAMPVA claim rests with the beneficiary or the provider acting on behalf of the beneficiary. (See paragraph A.3., chapter VII, DoD 6010.8-R.) Furthermore, as a condition precedent to the provision of benefits under CHAMPVA, the fiscal intermediary or OCHAMPUS may request and is entitled to receive information from a provider of services or supplies for which claims or requests for benefits are submitted. Such information and records may relate to the attendance, testing, monitoring, or examination or diagnosis of or treatment rendered or services and supplies furnished to a beneficiary and are necessary for the accurate and efficient administration of CHAMPUS benefits. Before a CHAMPVA claim will be adjudicated, the claimant must furnish to the fiscal intermediary or OCHAMPUS that information which may reasonably be expected to be in his or her possession and which is necessary to make the benefit determination. Failure to provide the requested information may result in the denial of the claim. (See paragraph B.4., chapter VII, DoD 6010.8-R.) The signature on the claim form specifically authorizes the release of medical records and information to the fiscal intermediary and OCHAMPUS. (See paragraph C.1.c., chapter VII, Dod 6010.8-R.)

The adjudication of this appeal has been particularly frustrating because, while it is apparent that this beneficiary is seriously ill and in need of many of the medications and supplies claimed, sufficient information has not been supplied upon which to determine the overall medical necessity of the kinds and amounts of medications and supplies claimed. This is true although there have been numerous attempts by both the fiscal intermediary and OCHAMPUS to obtain the necessary information. The initial efforts preceeded the actual denial of claims. The fiscal intermediary contacted the prescribing physician, the pharmacist and the beneficiary in an effort to obtain the required information before denying the claims for prescriptions filled in March, April and May 1980. The request for information was unsuccessful because the beneficiary refused the release of any medical information pertaining to her. The subsequent June 16, 1980 medical review confirmed the fiscal intermediary's initial denial of claims due to the lack of medical documentation. Throughout the appellate review process the beneficiary persisted in her request for review of her claims and her refusal to consent to the release of the requested medical information. The refusal of consent was reconfirmed in connection with the fiscal intermediary's reconsideration review, and again in connection with the OCHAMPUS First Level Review. Some additional medical information of a very general nature was submitted in connection with the beneficiary's hearing request but, at the hearing she again persisted in her refusal to provide the necessary specific information. The medical review conducted in connection with

the fiscal intermediary's Reconsideration and the peer review conducted in connection with the hearing both confirmed the need for additional documentation and the likely drug overutilization.

In cases such as this the burden necessarily rests on the appealing party to perfect his or her claim by producing the evidence upon which a determination can be based. In this case, in spite of diligent efforts on the part of the fiscal intermediary and OCHAMPUS, the beneficiary has not provided information necessary to adjudicate her claims and has thus not met the burden to perfect those claims.

The failure on the part of the appealing party to perfect her claims by submitting necessary medical documentation unfortunately compels me to sustain the previous denials of the CHAMPUS fiscal intermediary and OCHAMPUS and to adopt the Recommended Decision of the Hearing Officer. I further find that the utilization pattern of medication and supplies for prescriptions filled prior to March 1980 and for which CHAMPUS claims were paid does not differ significantly from that established in the denied CHAMPUS claims. Sufficient medical information was not submitted in connection with those claims and I find that they were paid erroneously. Any claims for prescription drugs or medical supplies submitted subsequent to those considered herein must be denied unless supported by adequate medical documentation as determined by the fiscal intermediary.

COLLATERAL ISSUES

Allegation of Fraud

The beneficiary has based her refusal to supply requested information upon an assertion that the fiscal intermediary accused her of submitting fraudulent claims in its dealings with her pharmacist and physician. The record does not document exactly what may have passed by telephone between representatives of the fiscal intermediary and the pharmacist or physician; however, it does document that only routine inquiry correspondence passed between the fiscal intermediary and these providers. There was no written allegation of fraud or program abuse communicated to them. It is not uncommon for a fiscal intermediary to communicate concerns with respect to possible overutilization or abuse of drugs that many come to its attention. In fact, a third party payor such as a fiscal intermediary can be an important resource to the medical establishment in bringing to light abuse situations involving multiple prescribing physicians and pharmacies. It is true that when this case was initially referred to OCHAMPUS on May 9, 1980 it was as a "possible overutilization and/or fraud" situation. This referral was done in the normal course of the fiscal intermediary's responsibility and function and was appropriate, especially in light of the fact that attempts to obtain supporting medical information had been unsuccessful.

It is not uncommon for OCHAMPUS to initiate investigations of suspected Program abuse or fraud. CHAMPVA cases in which there is a strong suspicion of possible criminal fraud are referred to the Veteran's Administration for investigation and possible coordination with the U.S. Department of Justice. There is no such suspicion in this case and it has not been referred to any investigative agency. The record establishes that the beneficiary is seriously ill and requires large quantities of medication. The sole interest of OCHAMPUS in denying these claims has been the obtaining of sufficient medical documentation upon which to determine the medical necessity of the kinds and quantities of medications and supplies for which CHAMPVA claims were submitted. The interests and purpose of OCHAMPUS in this regard were communicated to the beneficiary at the hearing by the OCHAMPUS representative and the hearing officer.

Privilege Against Self Incrimination

The beneficiary also based her refusal to supply testimony and medical documentation at the hearing upon her privilege against self incrimination as guaranteed by the 5th Amendment to the United States Constitution. This assertion is, of course, related to her feeling that CHAMPUS had accused her of fraud. As explained above, there has been no OCHAMPUS investigation or referral of this case for possible fraud. However, the protection that the Fifth Amendment grants against self incrimination is applicable to administrative proceedings whether they be of an investigatory or adjudicatory nature. The beneficiary was certainly within her rights in asserting this privilege.

CHAMPVA is a Federal health benefits program through which beneficiaries may receive payment of claims for medical care. A necessary condition precedent to the extension of benefits under such a program is that the claimant provide sufficient information upon which an informed adjudication of a claim may be based. When the invocation of any privilege effectively frustrates the adjudicatory process, while the right to assert the privilege may stand, the right to payment of the claim must fall. To hold otherwise would effectively frustrate an agency's responsibility to fairly and efficiently administer benefit programs as a fiduciary of the public funds entrusted to it.

Invasion of Personal Privacy

The beneficiary has alleged that the actions of the fiscal intermediary in contacting her physician and pharmacist for additional information regarding her claims for medications and supplies constituted an invasion of her personal privacy and a violation of the Privacy Act.

When a beneficiary files a CHAMPVA claim he or she is required to sign the claim form upon which the claim is submitted. In so doing the beneficiary certifies the accuracy of the eligibility

and other information contained on the claim form. In addition, the signature on the claim form authorizes the release of medical records connected with the claim to both the CHAMPVA Fiscal Intermediary and the government.

Each CHAMPVA claim form is accompanied by a Privacy Act statement which advises the beneficiary of the routine uses to which the information may be put. Those routine uses include disclosure to third party contacts, without consent of the individual to whom the claim information pertains, in situations where the party to be contacted has, or is expected to have, information necessary to establish the validity of evidence or to verify the accuracy of information presented concerning eligibility for benefits, the amount of benefit payments, any review of suspected abuse or fraud, or any concern for program integrity or quality appraisal.

I conclude, therefore, that the actions of the fiscal intermediary and OCHAMPUS in this case were proper and in compliance with program requirements and that there was no unwarranted invasion of the beneficiary's personal privacy or violation of the Privacy Act.

Qualifications of Peer Reviewers

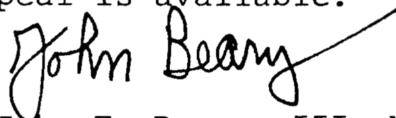
Both prior to and during the hearing the beneficiary challenged the qualifications of the peer reviewers who reviewed this case on behalf of OCHAMPUS. This challenge was directed at the accuracy of the information in the qualifications statements which are contained in the record. Evidence adduced at the hearing indicates that there were inaccuracies in the qualification statements originally provided to the beneficiary. In one case the physician's name was inaccurately reported. This error was corrected prior to the hearing. In the other case there was an apparent three year discrepancy in the date of admission to practice medicine. We do not find this discrepancy to be of sufficient magnitude to warrant the sustaining of a challenge to the physician's qualifications.

SUMMARY

In summary, it is the FINAL DECISION of the Acting Assistant Secretary of Defense (Health Affairs) that the claims for prescription medications and supplies purchased by the beneficiary during the period March 21, 1980 through May 9, 1980 were properly denied because insufficient information has been presented to establish the medical necessity of the kinds and quantities of medications and supplies involved. Further, insufficient medical information was provided to determine the medical necessity of the kinds and quantities of medications and supplies purchased by the beneficiary from June 10, 1977 through March 20, 1980. I am, therefore, referring this case back to the General Counsel, OCHAMPUS, for the initiation of appropriate recoupment action pursuant to the provisions of the Federal Claims Collection Act. I am also directing the Director,

OCHAMPUS, to instruct the fiscal intermediary in this case that any claims which have been suspended during the pendancy of this appeal and any future claims for prescription medications or medical supplies are to be denied unless documentation is submitted within prescribed time limits which establishes the medical necessity for the kinds and quantities of medications and supplies claimed. There are to be no additional appeal rights extended to this beneficiary for any such denials unless and until substantial medical documentation as required herein is submitted.

This FINAL DECISION in no way implies that the beneficiary does not have need of some portion of the medications and medical supplies around which this dispute has arisen. It only confirms that the beneficiary has failed to produce sufficient evidence to establish the medical necessity of the claimed medications and supplies. The issuance of this FINAL DECISION completes the administrative appeals process under DoD 6010.8-R, chapter X, and no further administrative appeal is available.



John F. Beary, III, M.D.
Acting Assistant Secretary