

# ASSISTANT SECRETARY OF DEFENSE WASHINGTON, D.C. 20301

JAN 28 1985

HEALTH AFFAIRS

BEFORE THE OFFICE, ASSISTANT

SECRETARY OF DEFENSE (HEALTH AFFAIRS)

UNITED STATES DEPARTMENT OF DEFENSE

Appeal of	•		 )		
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Sponsor:		<u>.</u> ,	 )	OASD(HA) File 84-4 FINAL DECISION	
SSN:			)	TIME DECISION	

This is the FINAL DECISION of the Assistant Secretary of Defense (Health Affairs) in the CHAMPUS Appeal OASD(HA) Case File 84-41 pursuant to 10 U.S.C. 1071-1092 and DoD 6010.8-R, chapter X. The appealing party is the CHAMPUS beneficiary who was represented by counsel. The beneficiary is the sponsor, a retired officer of the United States Navy. The appeal involves the denial of CHAMPUS cost-sharing for cardiac rehabilitation services provided from February 19 to April 12, 1982. The amount in dispute is \$360.00 representing the maximum payable amount on billed charges of \$480.00.

The hearing file of record, the tape of oral testimony and the argument 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 the cardiac rehabilitation services provided to the beneficiary in 1982 be denied CHAMPUS cost-sharing. The Hearing Officer found that the cardiac rehabilitation services have not been demonstrated to have been medically necessary and at an appropriate level of care contemporaneous with the dates of care.

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 the recommendation 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 the cardiac rehabilitation services provided to the beneficiary from February 19, 1982, to April 12, 1982. This determination is based on findings that: (1) the beneficiary was diagnosed in early 1982 as suffering from anginal syndrome with arterial hypertension; (2) the prescribed course of treatment included the prescription of medications for angina and hypertension, and participation in a cardiac

rehabilitation therapeutic exercise program; (3) the medical documentation, recognized professional opinion, and authoritative medical literature, contemporaneous with the dates of care in this case, do not document the general acceptance and efficacy of cardiac rehabilitation programs.

#### FACTUAL BACKGROUND

The beneficiary, a retired United States Navy Officer, received cardiac rehabilitation services which were prescribed by a physician, conducted in a hospital setting, and supervised by a physical therapist and a cardiac nurse. However, at the time the services were provided CHAMPUS did not authorize cost-sharing of cardiac rehabilitation services based on previously issued FINAL DECISIONS which found that the medical necessity and appropriateness of such cardiac rehabilitation programs had not been established.

The Hearing Officer's Recommended Decision describes in detail the beneficiary's medical condition, the prescribed cardiac rehabilitation program, medical testing and evidence, and the case precedents (FINAL DECISIONS) relied upon in reaching his Recommended Decision. Because the Hearing Officer adequately discussed the factual record, it would be unduly repetitive to summarize the record, and it is accepted in full in this FINAL DECISION.

The Hearing Officer has provided a detailed summary of the factual background, including the appeals that were made and the previous denials, and the medical opinion of the beneficiary's physician.

The hearing was held on February 7, 1984, at Jacksonville, Florida, before OCHAMPUS Hearing Officer William E. Anderson. Present at the hearing were the beneficiary, the treating physician, the treating cardiac nurse, and the beneficiary's counsel. The Hearing Officer has issued his Recommended Decision and issuance of a FINAL DECISION is proper.

#### ISSUES AND FINDINGS OF FACT

The primary issue in this appeal is the medical necessity of the cardiac rehabilitation program, provided to the beneficiary at Baptist Medical Center, Jacksonville, Florida from February 19 to April 12, 1982. The Hearing Officer also addressed issues involving whether the cardiac rehabilitation program could be considered a general exercise program, preventive care, or physical therapy under CHAMPUS. He correctly concluded, however, that these issues attain significance only if the cardiac rehabilitation program is determined to have been medically necessary and appropriate treatment for the beneficiary's condition.

The Hearing Officer in his Recommended Decision correctly stated the issues and correctly referenced the applicable law,

regulations, and prior precedential FINAL DECISIONS in this area, particularly OASD(HA) Case File 01-81, which was issued by this office on May 21, 1982, and OASD(HA) Case File 83-41, issued by this office on December 27, 1983.

The Hearing Officer found that ". . . although the cardiac rehabilitation sessions provided to the beneficiary . . . were provided by conscientious professionals who strongly believe in their value, and they do in fact appear to have been of use in diagnosis and to the beneficiary's sense of well-being and return to a normal life-style, they must . . . be denied CHAMPUS cost-sharing because such services have not been demonstrated to have been medically necessary and . . . (appropriate) contemporaneous with the dates of care."

Having determined that the care in question was not medically necessary under CHAMPUS, the Hearing Officer appropriately did not discuss the other identified peripheral issues at length because the finding on the medical necessity question rendered them essentially moot and because they have been adequately addressed in previous FINAL DECISIONS issued by this office.

The Hearing Officer also discussed two secondary issues which developed during the course of the hearing process. These dealt with the applicability of state insurance laws to CHAMPUS appeals and the precedential value of previous ASD(HA) FINAL DECISIONS in resolving a current appeal. With respect to the first secondary issue the Hearing Officer found that state insurance laws do not apply to CHAMPUS appeals. In the second secondary issue the Hearing Officer found that previous OASD(HA) FINAL DECISIONS are to be given precedential value in resolving subsequent cases unless they are found to be legally or factually distinguishable.

I find the Hearing Officer's analysis and rationale to be correct with respect to both of the secondary issues. For the reasons stated, I concur in the Hearing Officer's findings and recommendations on all of the primary and secondary issues addressed. I hereby adopt the Hearing Officer's Recommended Decision, including the findings and recommendations, as the FINAL DECISION in this appeal, with a minor modification discussed below.

There is one matter pertaining to the Hearing Officer's Recommended Decision which I find requires some clarification and modification. In referencing the authorities applicable to this appeal, the Hearing Officer included definitions taken from chapter II, DoD 6010.8-R, of "medically necessary" and "appropriate medical care" (which is included by reference in the definition of "medically necessary." However, in his case summary which concludes the Recommended Decision, the Hearing Officer states that CHAMPUS cost-sharing of the claims in question must be denied, "because such services have not been demonstrated to have been medically necessary and at an

appropriate level of care contemporaneous with the dates of care." (Emphasis added.) Although the concept of "appropriate medical care" encompasses the concept of "appropriate level of care," under DoD 6010.8-R the two are not identical and cannot be used interchangeably in the context of this case. "Appropriate level of care" is a concept which applies to inpatient treatment and is not involved herein. It is the concept of "appropriate medical care," in the sense of care that is in keeping with the generally accepted norm of medical care in the United States, which is cited and discussed by the Hearing Officer and which was relied upon by him in reaching his Recommended Decision. Therefore, I conclude that the reference by the Hearing Officer to "appropriate level of care" in the Recommended Decision was erroneous and unintentional, and that the words "and appropriate care" should be substituted for the words "and at an appropriate level of care" in the SUMMARY paragraph of the Recommended Decision.

#### SUMMARY

In summary, the FINAL DECISION of the Assistant Secretary of Defense (Health Affairs) is to deny CHAMPUS cost-sharing of the cardiac rehabilitation services provided to the beneficiary at the Baptist Medical Center, Jacksonville, Florida, from February 19 to April 12, 1982, because they were not medically necessary in the treatment of the beneficiary's diagnosed condition based on the lack of medical documentation, authoritative medical literature, and recognized professional opinion, sufficient to establish the general acceptance and efficacy of the program at the time the care was received. The appeal of the beneficiary is, therefore, 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 McKenzje Acting Principal Deputy Assistant Secretary

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

Appeal of	)	~ · ·
	)	RECOMMENDED
Sponsor:	)	
	)	DECISION
	)	
SSN:	)	

This is the Recommended Decision of CHAMPUS Hearing Officer William E. Anderson in the CHAMPUS appeal case file of . Jr., authorized pursuant to DoD 6010.8-R, chapter X. The appealing party is beneficiary/sponsor . Jr., represented by legal counsel K. Alexandra Krueger. The appeal involves the denial of CHAMPUS cost-sharing for cardiac rehabilitation sessions between February 19 and April 12, 1982. The amount in dispute is \$480 in billed charges.

The Hearing file of record has been reviewed. It is the OCHAMPUS position that the First Level Appeal decision issued on December 21, 1982, denying CHAMPUS cost-sharing of the sessions be upheld on the grounds that cardiac rehabilitation sessions do not constitute "physical therapy" within the meaning of the CHAMPUS regulation and the further ground that the sessions were not "medically necessary" as that term is defined in the CHAMPUS regulation inasmuch as general acceptance and efficacy of cardiac rehabilitation exercise sessions in the treatment of heart conditions is not supported by medical documentation or recognized professional opinion and authoritative medical literature contemporaneous with the dates of care.

It is the appealing party's position that the sessions are appropriate for cost-sharing on the grounds that such programs have become accepted by the medical community. It is the OCHAMPUS position that they are not, and OCHAMPUS further suggests that a recent Final Decision in a case numbered OASD(HA) 83-41 is a controlling precedent in the case at hand.

Based on the evidence of record, the Recommended Decision of the Hearing Officer is that the case at hand is not factually or legally distinguishable from case number 83-41 and, therefore, the appeal must be denied on the grounds that the claimed benefits do not constitute physical therapy and that the medical necessity of such sessions has not been proved to have been documented as of the dates of care.

# FACTUAL BACKGROUND

The beneficiary was born June 23, 1922. The beneficiary received an EKG on January 18, 1982, and was diagnosed as having angina pectoris, hypertension, and a right bundle branch block. He subsequently underwent additional diagnostic procedures including a thallium stress test and heart catheterization. Larry H. Birch, M.D., the treating physician, diagnosed the beneficiary's condition as anginal syndrome with arterial hypertension. As a result of the diagnostic procedures the physician prescribed medications for angina and hypertension and ordered that the beneficiary participate in cardiac rehabilitation therapeutic exercise programs at Baptist Medical Center in Jacksonville, Florida.

The stated purposes of the cardiac rehabilitation sessions were to further diagnose and monitor the extent of the beneficiary's cardiac symptoms and signs in order to determine the effectiveness of and modify accordingly the medications prescribed and to set appropriate limitations on activity, to improve the beneficiary's confidence and sense of well-being and to return the beneficiary to normal activity and life-style. Twenty sessions at a rate of three sessions per week were conducted, each session lasting approximately one and one-half hours and involving supervision by a cardiac nurse specialist and a physicial therapist. The sessions included interval training sessions on treadmills, bicycles, arm ergometer and weights, with a warm up and cool down, continuous EKG monitoring and initial and cool down blood pressure and pulse recording. Other symptoms were reported to the nurse who recorded them. Testing results were reported to the physician. As a result of the sessions the physician changed the beneficiary's medications and the beneficiary ultimately returned to a normal life-style.

A claim was submitted on May 25, 1982, for the 20 sessions. It was denied by the fiscal intermediary on June 11, 1982. The beneficiary requested a reconsideration on August 12, 1982, which upheld the denial on September 15, 1982. A first level appeal was recuested on October 13, 1982, and a decision issued on December 21, 1982, affirming the initial denial. A hearing was requested by the claimant in due time and a hearing was scheduled.

The hearing was postponed and rescheduled at the request of the beneficiary and the matter was ultimately heard on February 7, 1984, by the undersigned Hearing Officer. Persons present at the hearing included the beneficiary, the treating physician, Larry H. Birch, M.D., the cardiac nurse, Diane Raines, and the beneficiary's counsel, K. Alexandra Krueger.

Evidence received by the Hearing Officer at the hearing included the official file of documents duly transmitted to the Hearing Officer and the claimant prior to the hearing consisting of Exhibits 1 through 21 and an index of those exhibits, the testimony of Dr. Birch, nurse Raines, the beneficiary, and certain additional exhibits added to the case record at and after the hearing including Exhibit

22, Notice of Hearing; Exhibit 23, Supplemental Notice of Hearing; Exhibit 24, Second Supplemental Notice of Hearing; Exhibit 25, copies of final decisions in OASD(HA) case files 20-79, Ol-81, 83-41; Exhibit 26, witness list; Exhibit 27, photocopies of beneficiary's exercise report form; Exhibit 28, photocopy of Ehsani article; Exhibit 29, photocopy of Conn article; Exhibit 31, patient records including discharge summary; Exhibit 32, Memorandum of Facts and Law filed by counsel for appealing party; and Exhibit 33, responsive Memorandum by letter dated March 22, 1984, from OCHAMPUS attorney William N. Voharras.

# ISSUES AND FINDINGS OF FACT

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The issues in dispute are whether the cardiac rehabilitation therapeutic exercise sessions are (1) preventive care, (2) general exercise, (3) physical therapy, and (4) medically necessary within the CHAMPUS regulation.

If they are preventive care, they are excluded under Chapter IV, subsection G.38. as defined in Chapter II, subsection B.139. If they are general exercise programs they are excluded under Chapter IV, subsection G.45. If they are physical therapy, such sessions may be cost-shared if they are "medically necessary" and "appropriate medical care" as those terms are used in the regulation. If they are not physical therapy, they may still be cost-shared if they meet the "medically necessary/appropriate medical care" test.

Secondary issues that will be addressed are the non-applicability of insurance law principles of construing policies in coverage controversies and the use of ASD(HA) decisional precedents.

## Primary Issues:

## Preventive Care, General Exercise

Preventive care is defined in Chapter II, subsection B.139. as "diagnostic and other medical procedures not directly related to a specific illness, injury or definitive set of symptoms..., but rather performed as periodic health screening, health assessment, or health maintenance." It is excluded from cost-sharing under Chapter IV, subsection G.38.

The beneficiary in this case had a specific illness or definitive set of symptoms for which the cardiac rehabilitation sessions were prescribed as a diagnostic and treatment modality. They were not preventive care.

General exercise programs are excluded by Chapter IV, subsection G.45. "even if recommended by a physician." "General exercise program" is not defined in the regulation; in the absence of any definition or authority to the contrary, it appears to the undersigned Hearing Officer that cardiac rehabilitation sessions are specific types of exercise rather than a general exercise program.

# Physical Therapy, Medical Necessity

The CHAMPUS regulation, DoD 6010.8-R includes the following:

Chapter II, subsection 132., defines physical therapy services as one treatment of disease or injury by physical means such as massage, hydrotherapy, or heat.

Chapter II, subsection B.14., defines "appropriate medical care" as medical care which is in keeping with the generally acceptable norm for medical practice in the United States. Services which are not appropriate medical care are thus not medically necessary as defined in Chapter II, B.104 and are therefore excluded pursuant to Chapter IV, subsection G.1.

Chapter II, subsection B.104., defines "medically necessary", in part, as services and supplies (that is frequency, extent and kinds) adequate for the diagnosis and treatment of illness or injury and states that, "medically necessary" includes the concept of "appropriate medical care."

Chapter IV, subsection G.l., specifically excludes services and supplies which are not medically necessary for the diagnosis and/or treatment of a covered illness or injury.

Chapter IV, subsection G.15., provides for an exclusion as to "services and supplies not provided in accordance with accepted professional medical standards; or related to essentially experimental procedures or treatment regimens."

Chapter IV, subsection G.66., specifically excludes all services and supplies related to a noncovered condition or treatment.

The evidence in this case indicates that the cardiovascular rehabilitation program was conducted in the hospital setting, was prescribed by a cardiologist and was supervised by a physical therapist and a cardiac nurse. Significant monitoring of the beneficiary was performed and records were kept and made available to the cardiologist. He utilized the data as a diagnostic tool and modified the medication regimen, and as to certain medications, reduced those medications.

In the opinion of the treating cardiologist, the cardiac rehabilitation sessions were the only treatment appropriate for this beneficiary and it would have been professionally negligent to allow the beneficiary to participate in a general exercise program in place of this supervised monitored program. The treatment was considered to be successful and at the time of the hearing the beneficiary was in good health and had returned to a normal life-style, symptom free.

It is noted at the outset that having a physical therapist present or even participating is not determinative of the ultimate issue of whether the sessions constituted physical therapy. Physical therapy has been defined by reference to the traditional examples, although the definition is not exhaustive, since it does not include range of motion exercises which are also a traditional area in which physical therapists assist patients. Whether the cardiac rehabilitation sessions are classified as physical therapy or not, however, to be cost-shared under the CHAMPUS regulation they must be "medically necessary."

Medical necessity as defined in the above regulation includes the concept of "appropriate medical care" which is defined as "medical care which is in keeping with the generally acceptable norm for medical practice in the United States."

The issue is, thus, whether cardiac rehabilitation sessions were in keeping with the generally acceptable norm for medical practice in the United States as of the dates of treatment. The attorney and cardiologist for the beneficiary presented a substantial amount of evidence describing the status of the medical literature as of the dates of care. In this case the dates of care were between February 19, 1982 and April 12, 1982.

Dr. Larry Birch, in presenting this documentary evidence, repeatedly commented that there is a lag time between the completion of studies, the informal dissemination of study results, and the actual publication date of articles. The studies and ensuing articles and reports which were discussed in the evidence in this case cover a period of several years prior to the dates of care. An overall view of these articles and reports indicates that the opinion of the medical community is in a state of flux, that more and more studies are being done to attempt to document the relationship between cardiac rehabilitation sessions and whether these sessions can be statistically proved to have an influence on mortality, morbidity, or improvement of myocardial function.

In various previous Final Decisions, the Office of the Assistant Secretary of Defense (Health Affairs), abbreviated hereinafter as ASD(HA), has considered the issue of "medical necessity/appropriate medical care" of cardiac rehabilitation exercise programs. Those Final Decisions have found that such sessions have not been found to be medically necessary and appropriate. Certain of these cases have been proffered as authorities upon which OCHAMPUS relies for the disposition of the case at hand. The substance of these prior decisions has been to the effect that (1) the acceptance and efficacy of cardiac rehabilitation programs must be documented, and (2) the medical documentation, recognized professional opinion and authoritative medical liberature have not documented the general acceptance and efficacy of the programs contemporaneous with the dates of care considered in those prior cases.

Case File 20-79 involves a cardiac rehabilitation exercise program. The dates during which the beneficiary participated is not specified, but reference is made to the pre-1977 regulation and also the post-1977 regulation, so it appears that the services were rendered in approximately 1977. The medical evidence indicates that the claimant experienced chest pain and an erratic heartbeat in 1976, but these were personal statements without clinical documentation. A claim of two heart attacks since 1963 was not documented.

In that case, the claim was denied on grounds of medical necessity and the specific exclusion, chapter II.B.132 "general exercise programs are not covered even if recommended by a physician." The claimant's position stated that the exercise and weight reduction regimen was complimentary to the drug therapy. He did not contend that the exercise was an alternative to bypass surgery. The Decision states that it would not matter if it was an alternative. The Decision concluded with the following: "The fact remains that exercise programs and weight loss regimens do not qualify for CHAMPUS benefits regardless of their merits, regardless of the environment in which they are administered, and whether or not they result in improving the general health of an individual."

Case File 01-81 involves a cardiac rehabilitation exercise program between July 10, 1978 and August-13, 1979. The beneficiary suffered an acute myocardial infarction in March, 1978. The program was for 39 weeks. The Final Decision held that the exercise program in this case is similar to Case No. 20-79, e.g. monitored exercise under the supervision of nurses. The Final Decision held: "The general acceptance and efficacy of the program in the treatment of post-myocardial infarction is not supported by medical documentation nor recognized medical opinion and authoritative medical literature contemporaneous with the dates of care."

In that case, the peer review opinions had varied on the medical necessity/appropriate care issue. The peer review physicians in a review in December, 1979 approved the treatments but stated that "the evidence is not conclusive regarding reduction of mortality, morbidity or improvement of myocardian function." Additional peer review opinions indicated (1) a leaning toward the likelihood of such a program to cause a "reduction in death in the first six months following an acute myocardial infarction and the increasing acceptance of the programs by the general medical community" but (2) "that the cardiac rehabilitation programs remain an unproven modality, are not a standard of care in every community, and evidence does not support a reduction in heart disease as a result of the programs" although (3) there is an improved function capacity to perform activities of daily living with less fear.

The Final Decision in Case No. 01-81 concluded that a distinction must be made between potential improvement and quality of life on the one hand and on the other hand "services which are generally accepted in the treatment of diseases or illnesses and are documented by authoritative medical literature and recognised professional opinion."

The evidence in the case at hand includes articles or synopses of the following medical literature:

The study by Benjamin F. Jacobs, M.D. published April, 1981, concluded as follows:

"Closely monitored physical activities are tailored to a patient's physical and medical condition thereby providing a prudent mode of recovery for individuals with uncomplicated myocardial infarctions, coronary bypass surgery or disabling angina pectoris. Based on observed symptomathology and electrocardiography, simple exercises with gradual progression should begin soon after the cardiac incident."

"Historically, cardiac patients were prescribed several days or a week of minimal movement after myocardial infarction but many studies have documented the safety of early ambulation when complications such as congestive heart failure, cardiogenic shock, unstable arrhythmias. or recurrent chest pain are absent."

"The ultimate objective of exercise in cardiac rehabilitation is to allow the patient to return to a normal life-style within safely defined physical limits."

"Cardiac rehabilitative therapy should combine the art and science of individualized exercise prescription within the framework of exercise psychology. Proof that exercise decreases the risk of myocardial infarction or prolongs life, is lacking at the present time. But, even without such proved dramatic effects, we know that exercise therapy improves one's 'physical, emotional, vocational and recreational status' and overall quality of life. Disability after infarction or surgery is often largely psychological and the true benefits of cardiac exercise actually surpass the psychological parameters."

The study by Ali A. Ehsani, M.D., F.A.C.C., published in The American Journal of Cardiology in August, 1982 states the following:

"The circulatory adaptations to endurance training in patients with coronary artery disease include improvement in exercise tolerance and lessening of effort angina and ischemic S-T segment changes. These changes are considered primarily to be due to peripheral adaptation resulting in a lower product of systolic blood pressure and heart rate (Rate-Pressure Product). Data from previous studies suggest that exercise training does not improve left ventricular function in patients with coronary artery disease.... In a mical studies in which exercise training does not alter left ventricular performance, the training was relatively brist in duration and low in intensity....

In the present study, we report that prolonged endurance training of progressively increasing intensity can also result in favorable cardiac effects in selected patients with coronary artery disease. The data indicate that prolonged and vigorous exercise training results not only in peripheral adaptations but also in cardiac changes characterized by left ventricular enlargement and probable improvement in left ventricular performance in selected patients with ischemic heart disease. Additional studies are needed to corroborate these observations."

This study was published in the <u>American Journal of Cardiology</u>, Volume 50, August, 1982, the manuscript having been received in October, 1981, revised and resubmitted in February, 1982, and accepted for publication in March, 1982.

The study by Thad F. Waites, M.D. and others published in the American Journal of Cardiology in April, 1983, dealt with coronary artery bypass surgery as follows:

"It has not been demonstrated that surgical intervention coupled with a rehabilitation program was of greater benefit than surgery alone; nor has the value of a structured versus non-structured rehabilitation program been examined."

The questions posed were the following:

"For the postbypass patient, does a structured, supervised cardiac rehabilitation program improve cardiopulmonary function more than an individualized supervised program? Are there other benefits of compliance in a rehabilitation program such as improved return to work status and major coronary risk modification?"

The Waites study concluded as follows:

"Coronary bypass patients in a medically supervised program have greater oxygen consumption and exercise test duration, are more often at full working status, have fewer hospital readmissions, and are less likely to smoke. These data support benefits of patient compliance in an organized cardiac rehabilitation exercise program: however, some of these beneficial effects are likely due to strong selection factors associated with entrance into and adherence to the highly structured program."

A study done at the University of Cape Town Department of Psychology published September, 1983, for used on the psychological benefits of an exercise training program. Compared with the control group, after six months of the exercise program, it concluded as follows:

"The exercising group showed significantly large reductions in depression (10%) and tension (14%) levels, and marked increase in emotional stability (14%) and imaginativeness (12%). We conclude that attendance at the program played an important role in normalizing their psychological constitutions."

In a study published in November, 1983, from the Davis School of Medicine it was concluded that patients "with coronary disease who take propranolol have the same potential to benefit from physical trained as patients who do not take beta-blockers and exercise does not need to be modified because of the drug."

A study performed at the University of Toyoko published in June, 1983, studied a ten-year sample of patients with acute myocardial infarction who participated in the cardiac rehabilitation research conference over a period of ten years ending in 1978. The rate of cardiac death was 8.4% in the rehabilitative group (exercise group) and 27% in the non-rehabilitative (control) group, and the rates of returning to work were 50.2% and 25% respectively, and there were significant differences in both the mortality rate and the working rate between these two groups.

A study conducted at the University of Amsterdam published in Hay, 1983, dealt with prognosis during five years of follow up after first myocardial infarction in a group of men aged 40 to 55 years as follows:

"A randomly applied o-week rehabilitation program shortly after MI (myocardial infraction) was associated with a 50% decrease in progressive CAD (coronary artery disease) when compared to the control group. The study noted that cholesterol and smoking were not significantly different between the two groups and concluded that the "direct effect on the rehabilitation program could thus not be excluded . . . ."

Comprehensive cardiac rehabilitation was the subject of the Second World Congress on Cardiac Rehabilitation held in December, 1981.

A study at the University of Wisconsin Medical School published in November, 1982, concluded that: "Participation in outpatient rehabilitation program was significantly related to postoperative work status for men employed before surgery."

A study published in December, 1981, showed that "substantial training effects may be achieved in CAD patients despite therapeutic doses of beta-blockers and a reduced training HR. Thus, there appears to be no indication to reduce beta-blockers in CAD patients engaged in cardiac rehabilitation."

A study by K. A. Harrington, M.D. and others published in April. 1981, tested 14 out of 29 partients having recent myocardial infarction

had complications including left ventricular impairment, continuing ischemia or rhythm disturbances. Individualized activity levels were determined in accordance with cardiac responses. Seven of the 14 with complications progressed in the same manner as those without complications.

A study by D. Jensen, M.D. and others in the American Journal of Cardiology in November, 1980, studied 19 patients with coronary artery disease with radionuclide ventriculography before and after six months of exercise, concluded the following: "These preliminary results suggest that exercise training may improve cardiac function during exercise in selected patients with coronary disease. A randomized study using similar techniques has been initiated."

A study published in the American Heart Journal in July, 1980, concluded that "selection of patients with a high risk for arrhythemias during rehabilitation is not feasible by either exercise testing or ambulatory tape recording.

A study published in the <u>Journal of Family Practice</u> in March, 1980, a 1978 cardiac rehabilition program was reviewed. "After training for six months, patients have shown an increase in exercise tolerance and a decrease in incidents of readmission for cardiac disease."

A study published in September, 1979, concluded that: "Progress in cardiac rehabilitation demands rehabilitation efforts for the patient after myocardial infarction or aorta coronary bypass surgery be intergrated into a comprehensive program of acute and ambulatory cardiac care."

A study performed by E. H. Conn. M.D. and others at the Duke University Medical Center Division of Cardiology was published February, 1982, in which the ability of patients "with severely impaired left ventrical function to perform short term exercise and to participate in a cardiac rehabilitation program and attain physical training effects was evaluated." It concluded "that selected patients with severely impaired left ventricular function can safely participate in a conditioning program and achieve cardiovascular training effects."

The oxygen pulse was used to assess a training effect and increased significantly.

Counsel for OCHAMPUS contends that the articles cited do not document that cardiac rehabilitation is "a proven modality for heart disease." The Hearing Officer finds that analysis persuasive, and adopts it as follows: Exhibit 28 and the American Journal of Cardiology, April, 1983 article deal with the state of medical knowledge after the period in question. Exhibit 30 is of limited use as it notes that "(p)roof that exercise decreases the risk of myocardial infarction or prolongs life. In lacking at the present time;" it merely concludes that "people in exercise programs generally feel netter, work better and live better" (p. 54). This is not the same

as saying that cardiac rehabilitation is a proven treatment modality. The Conn <u>et al</u> article can only be given minimal weight; the authors themselves noted that there may have been selection bias and that, because of the small number of patients, the results must be regarded as preliminary warranting further research (pp. 299-300).

Further, in the continuing evolution of the evaluation of the medical necessity/appropriate care aspect of such programs, there has been a recent ASD(HA) Final Decision which has reaffirmed case No. G1-81. That Final Decision issued as recently as December 27, 1983. It dealt with a claim for cardiac rehabilitation sessions provided after a diagnosis of angina pectoris and arteriosclerolic disease. The sessions were provided between February and April, 1982, which are the dates in the case at hand. That Final Decision considered specifically the sessions rendered at the same hospital as in the case at hand. That case does not appear to be distinguishable factually or legally and is therefore entitled to due weight as a precedent, as is discussed hereinafter under a section dealing with the Secondary Issue of the use of decisional precedents.

## Secondary Issues:

## Non-Applicability of Insurance Laws

Counsel for the appealing party contends that a generally accepted principle of insurance law that an unclear insurance policy should be construed against the insuror and in favor of the beneficiary specifically requires that an insurance provision limiting coverage to necessary medical services must be strictly construed against the insuror. OCHAMPUS contends that, first, "... CHAMPUS is not an insurance program..." as stated in Chapter I, Section D and, second, that the burden of proof which is imposed on the appealing party by Chapter X, Section A.3. negates the asserted rule of construction. The Hearing Officer finds that the CCHAMPUS position is correct on this issue.

#### Decisional Precedents

OCHAMPUS contends that the referenced decisions at the ASD(HA) level are precedents for the decision in this case. The appealing party questions whether they are of precedential value and if so whether they are distinguishable.

The CHAMPUS Hearing Officer's Handbook adopted pursuant to the CHAMPUS regulation and governing the procedures and other aspects of appeal hearing decisions provides in Chapter X, paragraph 24 the following:

"Authority of the learing Officer. The hearing officer in exercising the authority to conduct a hearing under this Regulation is to comply with Chapter 55 of Title 10, United States (de. Chapter 5 of Title 5, United States Code and this Regulation, as well as with policy statements, manuals, instructions, procedures, and other

guidelines issued by the Assistant Secretary of Defense (Health Affairs) and/or by the Director, OCHAMPUS (or a designee) in effect at the time the service and/or supply in dispute was rendered. A hearing officer may not establish or amend policy, procedures or instructions."

The foregoing section establishes the regulatory basis for a conclusion that a CHAMPUS Hearing Officer is indeed bound by Final Decisions issued at the ASD(HA) level unless such decisions are found to be inapplicable because they are distinguishable factually or legally in accordance with sound principles of judicial analysis. The particular asserted precedent dealt with a comparable diagnosis, comparable level of care, comparable results, and comparable time period; no sufficient basis exists upon which to find that it is distinguishable. Accordingly, it is followed in this case.

## SUMMARY

In summary, it is the Recommended Decision of the Hearing Officer that although the cardiac rehabilitation sessions provided to the beneficiary in this case between February 19, 1982 and April 12, 1982 were provided by competent and conscientious professionals who strongly believe in their value, and they do in fact appear to have been of use in diagnosis and to the beneficiary's general sense of well-being and return to a normal life-style, they must, for the reasons stated, be denied CHAMPUS cost-sharing because such services have not been demonstrated to have been medically necessary and at an appropriate level of care contemporaneous with the dates of care.

William E. Anderson CHAMPUS Hearing Officer