ASSISTANT SECRETARY OF DEFENSE
WASHINGTON, D.C. 20301

HEALTH AFFAIRS

JAN 25 1985

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

UNITED STATES DEPARTMENT OF DEFENSE

Appeal of	)	
	)	
Sponsor:	)	OASD(HA) File 84-49
	)	FINAL DECISION
SSN:	)	

This is the FINAL DECISION of the Assistant Secretary of Defense (Health Affairs) in the CHAMPUS Appeal OASD(HA) Case File 84-49 pursuant to 10 U.S.C. 1071-1092, and DoD 6010.8-R, chapter X. The appealing party is the CHAMPUS sponsor, who is a retired Lieutenant of the United States Navy. The appeal involves denial of CHAMPUS cost-sharing for a cardiac rehabilitation program provided the sponsor from March 14, 1983, through June 7, 1983, at Providence Hospital, Medford, Oregon. The amount in dispute is approximately $1,030.10 in billed charges.

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 expenses for the cardiac rehabilitation program from March 14, 1983, through June 7, 1983, be denied. The Hearing Officer found that the cardiac rehabilitation program was not medically necessary in the treatment of post-bypass surgery heart disease because of a lack of medical documentation, authoritative medical literature, and recognized professional opinion sufficient to establish a general acceptance and efficacy of this cardiac rehabilitation program at the time it was received. The Hearing Officer also found that the cardiac rehabilitation program did not meet the definition of physical therapy as set forth in the CHAMPUS Regulation, and thus cost-sharing cannot be authorized for physical therapy. Further, the Hearing Officer found that certain aspects of the cardiac rehabilitation program were educational in nature which are specifically excluded from CHAMPUS cost-sharing under the CHAMPUS Regulation. Finally, the Hearing Officer found that all services and supplies related to the noncovered treatment are excluded from CHAMPUS cost-sharing.

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 beneficiary's claims for the cardiac rehabilitation program provided the beneficiary from March 14, 1983, through June 7, 1983, at Providence Hospital. This determination is based on findings that: (1) the cardiac rehabilitation program was not medically necessary in the treatment of post-bypass surgery heart disease because of a 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; (2) the cardiac rehabilitation program does not qualify as physical therapy and, therefore, cost-sharing cannot be authorized as physical therapy; (3) certain aspects of the cardiac rehabilitation program were educational in nature and are specifically excluded from CHAMPUS cost-sharing; and, (4) all services and supplies related to the noncovered treatment are also excluded from CHAMPUS cost-sharing.

FACTUAL BACKGROUND

The sponsor, a retired United States Navy Lieutenant, underwent coronary bypass graft surgery at Letterman Hospital on June 9, 1982. Subsequent to that operation, the sponsor participated in a cardiac rehabilitation program at Providence Hospital beginning on March 14, 1983, through June 7, 1983.

The Hearing Officer's Recommended Decision describes in detail the beneficiary's medical condition, the events leading to the coronary bypass graft surgery, and the circumstances leading up to the patient's participation in the cardiac rehabilitation program. 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 prior precedential decisions issued by the Office of the Assistant Secretary of Defense (Health Affairs)

The hearing was held on June 28, 1984, at Medford, Oregon, before OCHAMPUS Hearing Officer, Suzanne S. Wagner. Present at the hearing were the beneficiary, his wife, and Mark Gibbons, the Director of the Center for Health Promotion at the Providence Hospital. The Hearing Officer has issued her Recommended Decision and issuance of a FINAL DECISION is proper.

ISSUES AND FINDINGS OF FACT

The primary issues in this appeal are: (1) whether the cardiac rehabilitation program, including the related services, were medically necessary and generally accepted treatment for the beneficiary's heart condition; (2) whether the cardiac

rehabilitation program constituted physical therapy by a therapist; and (3) whether the cardiac rehabilitation program constituted education or training.

The Hearing Officer, in her Recommended Decision, correctly stated the issues and correctly referenced the applicable law, regulations, and prior precedential Final Decisions in this area.

The Hearing Officer found that:

> ". . . The Cardiac Rehabilitation Program was not medically necessary in the achievement of post bypass surgery heart disease based on the lack of medical documentation, authoritative medical literature and recognized opinion sufficient to establish the general acceptance and efficacy of the program at the time the care was received. [T]he program does not meet the definition of physical therapy set forth in DoD 6010.8-R, chapter II, B.134., and DoD 6010.8-R, chapter IV, C.3.j., and, therefore, cost-sharing cannot be authorized as physical therapy. [C]ertain aspects of the program are educational in nature and are specifically excluded from CHAMPUS coverage by DoD 6010.8-R, Chapter IV, G.46. All services and supplies related to the noncovered treatment are also excluded under DoD 6010.8-R, Chapter IV, G.1."

I concur in the Hearing Officer's findings and recommendations. I hereby adopt in full the Hearing Officer's Recommended Decision, including the findings and recommendations, as a FINAL DECISION in this appeal.

ADMINISTRATIVE CORRECTIONS

I note on page 22 of the Recommended Decision that the Hearing Officer has identified two previous Final Decisions as OASD(HA) File 83-45. The last reference is corrected to read OASD(HA) File 83-46 instead of OASD(HA) File 83-45.

SUMMARY

In summary, the FINAL DECISION of the Assistant Secretary of Defense (Health Affairs) is to deny CHAMPUS cost-sharing of the cardiac rehabilitation program provided the beneficiary during the period of March 14, 1983, through June 7, 1983, because the program was not medically necessary in the treatment of post-bypass surgery heart disease. Further, the program has not been shown to be medically necessary, based on 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.

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 : **Beneficiary**

Sponsor :

S.S.N.

Provider : Providence Hospital

This is the Recommended Decision of CHAMPUS Hearing Officer, **Suzanne S. Wagner,** in the CHAMPUS appeal file , and is authorized pursuant to 10 U.S.C. 1071-1089 and DoD 6010.8-R, Chapter X. The appealing party is the beneficiary, a retired United States Naval Lieutenant, and his is representing his own claim. The appeal involves the denial of CHAMPUS cost-sharing for cardiac rehabilitation from March 14, 1983, through June 7, 1983. The amount in dispute is approximately $1,030.10 in billed charges.

The Hearing File of record has been reviewed. It is the OCHAMPUS position that the Formal Review determination, dated March 16, 1984, denying CHAMPUS cost-sharing for the cardiac rehabilitation be upheld on the basis that CHAMPUS regulations exclude all services and supplies related to non-covered treatment; therefore, the services provided in connection with the cardiac rehabilitation program are not a CHAMPUS benefit.

The Hearing Officer, after due consideration of the appeal record concurs in the recommendation of OCHAMPUS to deny CHAMPUS cost-sharing.

The Recommended Decision of the Hearing Officer is, therefore, to deny cost-sharing for the beneficiary's cardiac rehabilitation program from March 14, 1983, through June 7, 1983, because it was not medically necessary nor appropriate medical care within the meaning of the Regulation

as it is not generally accepted medical practice and has not been demonstrated to be effective in the treatment of post by-pass heart disease; and the cardiac rehabilitation program does not meet the Regulation's criteria for coverage as physical therapy.

FACTUAL BACKGROUND

The beneficiary is a 62 year old retired U.S. Naval Lieutenant. His history revealed that he was non-diabetic and normotensive, and that his only symptom was an episode of amourosis fugax about one month prior to his hospital admission. He was determined to be suffering from ulcerative non-stenetic atherosclerotic carotid disease which was thought to be correctible surgically. His routine preoperative cardiac evaluation demonstrated positive stress test with followup cardiac catheterization supporting severe three vessel coronary arteriosclerosis with an as yet uncompromised left ventricle. It was noted that, "The patient denied any change in his exertional capabilities or symptoms compatible with angina, congestive heart failure or peripheral vascular insufficiency." (Exhibit 13, p.4)

On June 9, 1982, he underwent coronary bypass graft surgery times 4 at Letterman Hospital in San Francisco. He developed a low grade sternal infection about three weeks post operatively, and he responded to treatment for the infection. On June 23, 1982, the beneficiary was discharged and told to continue taking Aspirin and Persantine. His diagnosis was coronary arteriosclerosis, ulcerative atherosclerotic carotid plaque disease, and dental caries with abscess (for which he received a root canal on June 21, 1982, while still in the hospital). (Exhibit 13)

On December 16, 1982, a stress treadmill EKG was performed on the beneficiary at Providence Hospital by R.J. Naymick, M.D.. The test was done at the request of Vocational Rehabilitation. Dr. Naymick, in his report, noted that the beneficiary had had quadruple coronary bypass surgery and, post-operatively, his course was complicated by post-pericarditis and by a wound infection. He noted that the beneficiary was exercised for about 4.2 minutes at an MET level of about 5.0. He noted that

the beneficiary complained of shortness of breath and, "abruptly ended the test by stepping off the treadmill." In his assessment of the patient, Dr. Naymick stated:

> "1) A rather confusing picture of subjective shortness of breath limiting the stress test without evidence of objective clinical deterioration. As noted above, the patient's exercise pulse rate was not inordinately fast and his respiratory rate was not particularly labored when he decided to step off the treadmill. He did complain before and throughout the test of chest wall discomfort present in the area of sternotomy scar and this may have limited his exercisability with the subjective increase in pain due to this incisional infection." (Exhibit 13 pp 38-39)

On March 9, 1984, Roger C. Millar, M.D., the patient's cardiac surgeon, referred the beneficiary to the cardiac rehabilitation program at Providence Hospital. In his letter of introduction, Dr. Millar stated, in part:

> "...Basically, he is a 62 year old, white male that was referred to the hospital system because of a cholesterol emboli to his eye. In undergoing complete physical workup he was found to have a history compatible with angina precipitating a cardiac catherization, which demonstrated triple vessel coronary artery disease. On June 9, 1982, he underwent coronary artery bypass graft times 4 to the LAD diagonal, obtuse, marginal and posterior descending arteries. His wife called here on July 1, 1982 stating that he had a redness and lump in his incision. He was seen herein the office and over the ensuing months has been treated for a mediastinal incisional infection that goes down to the lower end of his sternum, right near the zyphoid . Because of this, he underwent open debridement

under general anesthesia on 1-21-83 in the short-stay unit at Rogue Valley Memorial Hospital. Since then, the wound has been granulating in and is nearly completely granulated at the present time. He has no systemic symptoms of infection. He does have some vague, chest-type pains that have felt to be related to his incision and/or this lowgrade infection. I feel that he can benefit from the Cardiac Rehabilitation Program to reassure him he can do physical things in his life." (Exhibit 5, p.3)

On September 28, 1983, Dr. Millar wrote the following to CHAMPUS in support of the Cardiac Rehabilitation Program for the beneficiary:

"The above named patient underwent coronary bypass surgery times four at Letterman General Hospital in June of 1982. Postoperatively he developed a sternal wound infection which required treatment and multiple debridement procedures, and took approximately 12 months to totally heal. During this period of time, this patient's mental status was very tenuous... he was bordering on becoming a neurotic cardiac cripple and I felt it was very wise and a medical necessity for him to participate in the Cardiac Rehabilitation Program offered at Providence Hospital in Medford, Oregon. He enrolled in that and did very well throughout that closely monitored rehabilitation program and it has helped him immensely adjust to his heart problem in an active and useful life." (Exhibit 3 p.2)

Based on the December 16, 1982, stress test (Exhibit 13 pp.38-39) and the letter of introduction from Dr. Millar, dated March 9, 1983 (Exhibit 5 p.3), an Exercise Prescription for the Cardiac Rehabilitation Program at Providence Hospital was devised by Mark H. Gibbons, M.S., the director of the Program. Significant in the Exercise Prescription were:

"Signs and Symptoms: shortness of breath, mild chest wall discomfort before and during test (perhaps due to incisional infection).

ECG Changes: isolated unifocal PVC's with some T-wave inversion (no ST-T depression noted)

Comments and Recommendations: [the patient] ended test himself stepping off treadmill. It may be difficult to differentiate between incisional pain and angina. It seemed that he could have walked further on the treadmill and that the shortness of breath was not excessive. Note chest feeling changes. Use very light load setting initially.

Reason for terminating test: patient stepped off treadmill complaining of S.O.B." (Exhibit 13 p.22)

The beneficiary participated in the Cardiac Rehabilitation Program from March 14, 1983, through June 8, 1983, when an exit stress test was performed so that an evaluation of his progress could be assessed. He attended the program on March 14, 16, 18, 21, 28, and 30; April 4, 6, 8, 13, 15, 18, 20, 22, 25, 27, and 29; May 2, 9, 11, 16, 18, 20, 23, 25, and 27; and June 1, 3, 6, and 8, 1983. In his letter to Dr. Millar assessing the beneficiary's progress in the Cardiac Rehabilitation Program, Mr. Gibbons stated, in part:

"EXERCISE TEST RESULTS

Parameter	Before	After	Comments
Work capacity	4.5METS	6.6METS	Average 6.6-8.6
Max. Heart Rate	102 bpm	106 bpm	METS

EKG - Significant ST-T changes observed over anterior and antereolateral ventricular wall. Occasional unifocal PVC's were observed during test.

[the patient] has improved his exercise capacity

significantly. Shortness of breath occured at higher levels of exertion. From a psychological perspective, he seems much more relaxed and lighthearted than when he entered the program.

*

*

*

As you know, we became concerned abouth [the patient] blood pressure when it began to average 150/90. He saw you at that point and Dyazide was prescribed. He has taken that as ordered and his only complaint from that has been mild dizziness..." (Exhibit 13, p 23)

On February 3, 1984, Mr. Gibbons wrote to an Appeals Specialist for CHAMPUS, and in support of the beneficiary's claim for cost-sharing, stated in part:

"The monitored exercise therapy sessions in our outpatient cardiac program has a strong medical focus. Activity prescriptions are first derived from a maximal exercise test which is physician supervised. At all times during the therapy sessions there is a coronary care nurse in attendance providing thorough medical supervision. The nurse consults the patient's private physician or our medical advisor should any contraindications to exercise arise. Electrocardiograms are taken at four different times during the therapy sessions and heart rates are carefully regulated. Most therapy involves progressive activity on a motorized treadmill or stationary bicycle... The Navy Guide for Retired Personnel and Their Families (2/1/79) states: 'New procedures and types of care become authorized benefits under CHAMPUS when they are accepted by the medical profession as being part of good medical practice'... (Exhibit 13 p. 25)

A mid-program progress report, dated 4/3/83, addressed to Dr. Millar states, in part:

> "Comments: During the exercise classes, I conduct educational sessions and we have discussed cardiac diet, stress management, sexuality, exercise and signs and symptoms of Angina." (Exhibit 13, p.27)

In his December 6, 1983, letter to the fiscal intermediary, Mr. Gibbons described the monitored exercise therapy sessions as consisting of the following procedures:

> "Screening - the nurse asks appropriate questions to insure the patient is medically capable of performing physical activity. Blood pressure is measured.
> Set-up - EKG telemetry equipment is connected to the patient and a resting EKG strip is maintained.
> Warm-up - the patient is led through a series of stretching exercises for a five minute period.
> Aerobic Activity - the patient spends five minutes at each of six exercise stations, exercising both the arms and legs aerobically. Stations include a bicycle, treadmill, armergometer, steps, and air dyne exercise (arm device)/
> Cool-down - at least five minutes is spent gradually decreasing the level of physical exertion."
> (Exhibit 5 p.1)

On April 16, 1984, the beneficiary, with his letter appealing the Formal Review Decision, included an article entitled "Rationale for Cardiac Rehabilitation" compiled by Mark GIbbons, M.S., the Director of the Center for Health Promotion. This article contains numerous studies supporting the efficacy of cardiac rehabilitation in the treatment

of heart disease. (Exhibit 10 pp.3-9 and Exhibit 15). Exhibit 10A pages 1 through 10 is an article enetitled " An Older Person's Guide to Cardiovascular Health" published by the American Health Association. Exhibit 10B pages 1 through 4 is an article entitled "Why Risk Heart Attack? Seven Ways to Guard Your Health," also published by the American Heart Association. Exhibit 10C pages 1 and 2 is an article published by the American Heart Association entitled "Eat Well But Eat Wisely". Exhibit 10D. pages 1 through 3 is the American Heart Association article entitled "How to Stop Smoking". Exhibit 10E pages 1 through 4 is an article entitled "'E' is for Exercise", also published by the American Heart Association. Exhibit 10F pages 1 through 3 is the American Heart Association publication enetitled "Heart Attack". And Exhibit 10G pages 1 through 27 is an American Heart Association publication entitled "Heart Facts". All of these artices encourage regular exercise in order to maintain good health and as a measure to prevent heart disease.

Procedurally, the initial claim for CHAMPUS cost-sharing for the Cardiac Rehabilitation Program was denied, and on October 15, 1983, the beneficiary requested a review of the denial from the fiscal intermediary, Blue Cross of Washington-Alaska. On November 22, 1983, the fiscal intermediary requested more information concerning the monitoring and exercise program. On December 6, 1983, the Provider sent information to the fiscal intermediary explaining the program (Exhibit 5). On December 19, 1983, a reconsideration determination letter was sent to the beneficiary upholding the denial of cost-sharing. On February 13, 1984, the beneficiary requested that OCHAMPUS review the denial of benefits. On February 28, 1984, OCHAMPUS acknowledged the beneficiary's request for an appeal. On March 16, 1984, a Formal Review Decision was issued upholding the denial of cost-sharing. On April 16, 1984, the beneficiary requested a Hearing. On April 28, 1984, OCHAMPUS acknowledged the beneficiary's request for a Hearing, and on May 10, 1984, OCHAMPUS requested additional medical information. On May 18, 1984, the beneficiary forwarded the medical documentation requested by OCHAMPUS. On June 11, 1984, the Hearing Officer notified the beneficiary by certified mail of the time, date and place of the Hearing. And on June 28, 1984, the Hearing was held at 3040 Biddle Road, the Bureau of Land Management, in Medford, Oregon. Present at the Hearing were: the beneficiary, his wife, and Mark Gibbons, the Director of the Center for Health Promotion at Providence Hospital.

The Hearing, which commenced at 8:45 A.M., began with the presentation of the Opening Statement by the undersigned Hearing Officer. When asked if there were any exhibits within the Hearing File the inclusion of which he objected, the beneficiary stated that he felt the determinations made by CHAMPUS in disallowing his claim were improper. He stated that the decision to disallow his claim and the precedential decisions (Exhibit 14) were, "improper and totally erroneous."

The beneficiary first questioned the ability of the Hearing Officer to make a decision in this case because she did not have medical training. He stated that one not trained in medicine would be ill equipped to make a d cision contrary to his doctor (Dr. Millar) who stated that the coronary rehabilitation program was "medically necessary" for the beneficiary (Exhibit 3 p. 2). The Hearing Officer explained to the beneficiary the fact that she was experienced, trained in the CHAMPUS regulation, and that the final Decision would be formulated by the Assistant Secretary of Defense for Health Affairs, who is a Medical Doctor. Also, the Hearing Officer explained the process of Peer Review to the beneficiary.

After the decision making process was explained to the beneficiary, he questioned the cost-effectiveness of holding a hearing on his claim which amounts to about $1,030.10. He contended that the government has spent "fifty to a hundred thousand dollars" in the appeal process rather than cost-share his claim. The Hearing Officer explained to him that he, and anyone else in his situation, has a right to a Hearing and that this was a fact finding Hearing. It was explained to the beneficiary that the hearing was to be informal and that the Hearing was to deal with the issue of the medical necessity of the cardiac rehabilitation program for which the claim was made. Both the beneficiary and his wife stated that the main issue in the appeal was money. To quote the wife of the beneficiary:

> "The CHAMPUS Regulations, as their contract per the government, and so forth, they say does not cover this type of thing. Therefore, they're not paying it. It's money. They

would rather spend $2,000.00 on fighting it than to pay the less than $800.00 it would be. It has nothing to do with whether it was medically [necessary]. It just doesn't fall into what their contract with the government says. So that is the issue. And that's what all these others are turned down on, too, and therefore, really I think the issue boils down to -- I think the contract should be -- somebody should be working on rewriting this. They're spending hundreds of thousands of dollars turning down $400.00, $600.00 and $1,100.00. It is rather a rediculous way of spending the taxpayers' money. It would certainly serve the purpose much better to be paying for veterans..." (Tape I side 1)

When the Hearing Officer explained to the beneficiary that the cost of the Hearing was not in issue, he stated that Congressman Bob Smith was monitoring his case and that he would keep the Congressman apprised of the happenings at this Hearing.

The beneficiary testified that the government takes a negative point of view with regard to interpreting the Regulation. He then presented the "Navy Guide for Retired Personnel and their Families" NAVPERS 15891E (March 1979). He referred to pages 52-53, paragraph 14-6 and 14-7:

"14-6: CHAMPUS Characteristics. The language used by Congress in authorizing the use of civilian medical facilities of CHAMPUS, leaves plenty of room for the program to grow. New procedures and types of care become authorized benefits under CHAMPUS when they are accepted by the medical profession as being part of good medical practice, provided they are not among those few items excluded by the Congress. These escluded items are covered in § 14-7.

"14-7: CHAMPUS Basic Program. Any procedure

or type of care which is generally accepted as being part of good medical practice other than ones excluded by law, is an authorized CHAMPUS benefit under the Basic Medical Program. Excluded by law are: domiciliary or custodial care; physical examinations not for diagnostic or treatment purposes; routine well baby care, except inpatient care of the newborn; spectacles or examination for ordinary refractive error; prosthetic devices other than limbs, eyes, and other dental prostheses; dental care, except as necessary in the treatment or management of a medical or surgical condition. If you can remember the basic rule and these exceptions, you will have a pretty good idea of what benefits are authorized. However, these additional facts concerning coverage may add to your understanding of those benefits which are authorized; benefits may be on inpatient basis or outpatient basis almost anywhere; treatment may be for medical or surgical conditions; for nervous, mental and emotional disorders; chronic conditions or contageous diseases. Medical services may be provided by a civilian physician, or by other medically related civilian specialists -- nurses, physical therapists, etc. when ordered by a physician... All necessary supplies ordered by a physician or other authorized professional person are authorized including among other items,..." (Tape I side 1)

The beneficiary testified that it was the "Navy Guide" which he used to determine whether the Cardiac Rehabilitation Program at Providence Hospital would be covered. He stated that CHAMPUS was taking erroneous definitions of words and phrases in order to deny benefits. He said that CHAMPUS was making negative interpretations in order to disallow

benefits. He said that CHAMPUS was not making interpretations to benefit veterans, but was, in fact, working in cross-purposes to the veterans.

The beneficiary referred to the letter of Dr. Millar to CHAMPUS dated September 28, 1983 (Exhibit 3) wherein Dr. Millar stated that the program was medically necessary for the beneficiary. He stated that if the issue in the hearing is whether the Cardiac Rehabilitation Program was medically necessary, that Dr. Millar had answered that question in the affirmative. He then referred to the CHAMPUS regulation defining medically necessary and to OASD (HA) 83-41, page 5 wherein a doctor is quoted as stating that cardiac rehabilitation programs were, in his opinion, appropriate medical care. He stated that important cardiologists have agreed that cardiac rehabilitation is appropriate medical care, and therefore should be recognized benefits in accordance with the above quoted "Navy Guide".

Both the beneficiary and his wife testified that they believed that it was already predetermined that benefits for the cardiac rehabilitation program in which he participated would be denied. They both stated that the previous decisions (Exhibit 14) indicate that, "No amount of testimony or documentation by medical doctors is going to change the opinion of those people at all. Because they have gone on record with a certain decision, and they will be damned if they will change." (Tape I Side 1) He stated that he believed that the previous decisions indicate that his appeal would be turned down summarily.

He stated that he has submitted writings by twenty doctors that the program is appropriate medical care (Exhibit 10 pages 3-7).

The wife of the beneficiary testified that her husband, after nine months of convalescence from his surgery, began to view himself as a cardiac cripple. She stated that he needed someone to convince him that he was capable of doing things again. She testified that the program is not one of general exercise -- that one needed a doctor's referral, an EKG, and monitoring. She reiterated that one must be reffered by a doctor to be admitted to the program.

The wife of the beneficiary also testified that she twice called the fiscal intermediary, and she was assured that if the program was one which required a doctor's referrral, that the program would be eligible for cost-sharing. She said that it was on the basis of the telephone assurance by the fiscal intermediary that the beneficiary enterred the program.

The beneficiary testified that Veteran and Military Hospitals have purchased the equipment used in cardiac rehabilitation. He maintained that if the government purchased such equipment, they must believe it is appropriate medical care. The Hearing Officer asked whether there were Cardiac Rehabilitation Programs available in Military Medical facilities, and the beneficiary answered that he was unaware of any such program.

The wife of the beneficiary then testified that the cost-effectiveness of the cardiac rehabilitation program should be considered. She stated that if these programs keep people out of the hospital and get people back to work sooner, then this should be considered.

The beneficiary testified that the Cardiac Rehabilitation Program made him a well man. He stated that he wanted to impress upon the Hearing Officer that the program was medically necessary for him (based on the letter from Dr.Millar), that the program made him well, and that this proved the medical necessity of the program for him. He testified that in relying on the "Navy Guide" as to whether or not the Cardiac Rehabilitation Program qualified for cost-sharing, he believed that Dr. Millar's terming the former as a "borderline neurotic cardiac cripple" for whom the program was medically necessary was sufficient to meet the requirements of the CHAMPUS Regulation.

The wife of the beneficiary testified that there is no exclusion for therapeutic exercise programs in 14-7 of the Navy Guide which would keep such a program out of CHAMPUS cost-sharing.

At this point, Mr. Mark Gibbons, the Director of the Center for Health Promotion at Providence Hospital, enterred the Hearing, and he described the Cardiac Rehabilitation Program as being:

> "Basically for high risk individuals who have known -- documented -- heart disease, whether it be mild cardial infarction or coronary bypass surgery. What we're doing in essence, is providing them a structured, supervised program to gain confidence in their ability to exercise, to teach them about exercise, and to get back into a normal life-style, hopefully, return back to work, if it's appropriate, and at least to a point where they're comfortable with their own bodies in terms of not being anxious about movement... anxiety is one of the biggest problems associated with heart disease after bypass surgery or infarct." (Tape I Side 2)

In answer to a question from the Hearing Officer as to whether the Cardiac Rehabilitation Program is physical therapy in accordance with the CHAMPUS Regulation, Mr. Gibbons said the program is physical therapy in that it is a program of therapeutic exercise. He stated that though he, himself, is not a physical therapist, that it is common for Cardiac Rehabilitation Programs to be directed by either physical therapists or exercise physiologists.

In response to a request by the Hearing Officer to differentiate between a general exercise program and the therapeutic exercise offered in the Cardiac Rehabilitation Program, Mr. Gibbons stated that the primary difference is that the therapeutic program is highly supervised by trained personnel. He stated that monitoring for arrhythmias or ST changes (oxygen deprevation to the heart) is the key to the program. He also emphasized that the equipment used to monitor the program participant's heart separates the program from a general exercise program.

When asked by the Hearing Officer how the Cardiac Rehabilitation Program

constitutes specific treatment for coronary artery disease, Mr. Gibbons testified that this question is the subject of at least a hundred separate research studies in the country. He enterred into evidence a compilation of articles on the subject entitled, "Rationale for Cardiac Rehabilitation" which he had put together. (Exhibit 15 and also found in Exhibit 10 pages 3 through 7) He stated that by properly exercising the individual, one strengthens his peripheral muscles and thereby causes the heart muscle to become more efficient; these peripheral muscles work more efficiently, extracting oxygen better and therefore make a lower demand on the heart. He testified that because the heart patient is somewhat out of condition, his ability to do most chores is limited by the early onset of angina or shortness of breath. By exercising the patient properly, the peripheral muscles, acting more efficiently, allow the patient to accomplish more work before the onset of angina or shortness of breath due to the lowered demand on the heart.

As to whether the supervised exercise program effects changes in coronary circulation by stimulating collateral or expanded circulation, Mr. Gibbons stated that this is a controversial area. He stated that the Norwegian and Swedish studies are reputed to be the best studies in the area, and that these studies should not be excluded off-handedly in favor of purely American research. He testified that opinion appears to be somewhat evenly divided on this matter, and that a good study in microcirculation has not as yet been made available which would be conclusive. He also testified that he didn't feel qualified to testify as to the efficacy of one study over another in this area.

In answer as to the relation of coronary rehabilitation and the coronary artery disease process itself, Mr. Gibbons referred to page 3 of Exhibit 15 paragraph entitled "MORBIDITY AND MORTALITY, THE QUESTION OF RECURRENCE", wherein it states, in part:

> "In a study by Rechnitzer et al, cardiac patients who exercised consistently post-infaction experienced fewer recurrent infarctions and instances of sudder death. Shepherd demonstrated that exercise compliance in myocardial infarct patients was

> associated with a fivefold improvement in the odds ratio for both fatal and non-fatal recurrences of infarction. This treatment effect was independent of health habits (smoking) and disease severity (angina, cardiac enlargement, ST segment depression or ventricular aneurysm)."

The article continues, however, to state:

> "The role of exercise in the prevention of reinfaction is still controversial. Randomized studies by Kentala and Sanne have not demonstrated this positive treatment effect of exercise. Unfortunately there have been a few randomized studies examining the interaction between exercise and recurrence rate of infarction. Those which have been done other suffer for lack of numbers, problems with adherence to the exercise treatment program, and inadequate follow-up.
>
> "Finally, statistical correlation does not prove cause and effect..." (Exhibit 15 pages 3 and 4)

In the conclusion of Exhibit 15, Mr. Gibbons stated:

> "A comprehensive cardiac rehabilitation program can enrich the psychological, physiological, and vocational life of the cardiac patient. The community may benefit from a lightened disability load. whether or not exercise therapy lowers the recurrence rate of infarction remains as an unanswered question." (page 5)

Mr. Gibbons testified that although the beneficiary did not suffer from Angina, he did suffer from shortness of breath, which is considered

secondary to oxygen deprivation to the heart. He added that because of the close personal relationship which develops between the program participants and the staff, many times medicaitons are changed as a result of the monitor ing and observation by the supervising staff.

As to whether there were changes noted in the beneficiary by the supervising staff which precipitated alterations in medicaiton, the testimony and record supported that due to an elevation in blood pressure noted during exercise sessions, the beneficiary's physician placed him on Dyazide. He also reiterated that Angina is not the only form in which heart disease manifests itself, but that shortness of breath is also one of the manifestations of heart disease.

The beneficiary asked Mr. Gibbons whether the latter believed that the former derived substantial benefit from the program. Mr. Gibbons answered by referring to the exercise testing results. He noted that before the program, the beneficiary could do only about 4 METS of work before the onset of shortness of breath (METS being a term meaning energy expenditure). After the program, the beneficiary was capable of performing about 6.5 METS of work prior to the onset of shortness of breath (a 60% increase in work capacity). He stated that the goal of the beneficiary's program was to enable him to perform more work prior to the onset of shortness of breath, and that this goal was met.

Also, Mr. Gibbons stated that, on the human side, the beneficiary's "affect changed dramatically, he was much more positive, more carefree, and less hypochondraical." He testified that the beneficiary, through his participation in the program, broke through the "cardiac cripple" status.

Mr. Gibbons also testified as to the cost-savings involved in the cardiac rehabilitation program. He stated that in the Tappinger study it was noted that in people with coronary bypass surgery, patients who did not exercise remained on disability an average of 131 days while those who participated in an exercise program remained on disability an average of 75 days. He emphasized the importance, in the treatment of heart disease, of the feeling of well being and peace of mind.

Mr. Gibbons also testified that a Veteran's Administration study in 1979-1980 demonstrated that, excluding left main stem disease, there is no difference in longevity between those patients who had bypass surgery and those who had not had surgery but had participated in cardiac rehabilitation programs. The purpose of the bypass surgery was to ameliorate angina in those surgically treated. Mr. Gibbons suggested that the exercise program, post infarction, is not different from bypass surgery in that, by physical conditioning of peripheral muscles, the onset of Angina can be delayed or may not develop at all. He agreed that there is controversy as to whether exercise in post infarct patients enhances longevity, but that if bypass surgery is considered medical treatment, then so also should the exercise program -- as the results are the same -- the amelioration of Angina.

Specifically referring to the medical condition of the beneficiary prior to the cardiac rehabilitation program as contrasted with his medical condition after the program, Mr. Gibbons stated that the delayed onset of shortness of breath was very important. He stated he could not testify as to the actual condition of heart tissue, but that the beneficiary could do more work without symptoms. Mr. Gibbons' testimony compared the beneficiary's condition at the time of the December 16, 1982, stress test as compared to his condition at the exit stress test done at the completion of the cardiac rehabilitation program on June 8, 1983. (Documented in Exhibit 13, page 23.)

Significant in the changes which occured in the beneficiary between December 16, 1982 and June 8, 1983 are:

1. a 60% increase in ability to do work before the onset of shortness of breath.
2. Significant ST changes at rest and during exercise on June 8, 1983 (not present on the December 16, 1982 test) which may possibly indicate a decrease in the oxygen supply to the heart.
3. His blood pressure went up so that he was placed on Dyazide to lower his blood pressure.

ISSUES AND FINDINGS OF FACT

The primary issue in dispute is **WHETHER THE CARDIAC REHABILITATION PROGRAM, INCLUDING THE RELATED SERVICES, WAS MEDICALLY NECESSARY AND GENERALLY ACCEPTED TREATMENT FOR A HEART CONDITION.**

Secondary issues that will be addressed are:

1. Did the cardiac rehabilitation program constitute physical therapy by a therapist?

2. Did the cardiac rehabilitation program come within the meaning of a general exercise program?

3. Did the cardiac rehabilitation program constitute education/training?

Also to be addressed is the issue as the whether CHAMPUS is estopped from denying cost-sharing because of verbal approval of coverage for the cardiac rehabilitation program and payment of the initial claim by the fiscal intermediary.

REGULATIONS

Regulation DoD 6010.8-R is promulgated under the authority of, and in accordance with, Chapter 55, Title 10, U.S.C., and it has the force and effect of the law.

Chapter II. DoD 6010.8-R contains specific definitions regarding benefits.

B.103. Medically Necessary. "Medically Necessary" means the level of services and supplies (i.e., 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.

B.134. Physical Therapist. "Physical Therapist" means a person who is specially trained in the skills and techniques of physical therapy (i.e., the treatment of disease by physical agents and methods such as heat, massage, manipulation, therapeutic exercise, hydrotherapy

and various forms of energy such as electrotherapy and ultrasound), who has been legally authorized (i.e., registered to administer treatments prescribed by a physician and who is legally entitled to use the designation physical therapist. A physical therapist may also be called a physiotherapist.

Chapter IV DoD 6010.8-R, defines basic CHAMPUS program benefits and exclusions.

A.1. Scope of Benefits. Subject to any and all applicable definitions, conditions, limitations, and/or exclusions specified or enumerated in this Regulation, the CHAMPUS Basic Program will pay for medically necessary services and supplies required in the diagnosis and treatment of illness or injury, 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.

C.3.j. Physical Therapy. To be covered, physical therapy must be related to a covered medical condition. If performed by other than a physician, the beneficiary patient must be referred by a physician and the physical therapy rendered under the supervision of a physician.

(1) Outpatient physical therapy is generally limited to a sixty (60)day period, two (2) physical therapy sessions per week, in connection with each medical condition. In order for CHAMPUS benefits to be extended for physical therapy rendered for a longer period of time than sixty (60) days; and/or for more than two (2) sessions per week, requires submission by the attending physician of documentation as to medical necessity and the reasonably anticipated results of such therapy.

(2) General exercise programs are not covered even if recommended by a physician. Passive exercise and/or range of motion exercises are not covered except when prescribed by a physician as an integral part of a comprehensive program of physical therapy.

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.

46. Educational/training. Educational services and supplies, training non-medical, self care/self help training and any related diagnostic testing or supplies. (This exclusion includes such items as special tutoring, remedial reading, natural childbirth classes, etc.)

48. Exercise. General exercise programs, even if recommended by a physician and regardless of whether or not rendered by an authorized provider. In addition, passive exercises and range of motion exercises are also so excluded except when prescribed by a physician and rendered by a physical therapist concurrent to, and as an integral part of, a comprehensive program of physical therapy.

Chapter VII DoD 6010.8-R deals with claims, submissions, review and payment.

A.3. Responsibility for Perfecting Claim. It is the responsibility of the CHAMPUS Beneficiary (or sponsor) and/or the authorized provider acting on behalf of the CHAMPUS beneficiary/patient to perfect a claim for submission to the appropriate CHAMPUS contractor. Neither a CHAMPUS contractor nor OCHAMPUS is authorized to prepare a claim on behalf of a CHAMPUS beneficiary.

B.4. Right to Additional Information. As a condition precedent to the provision of benefits under this Regulation, OCHAMPUS and/or CHAMPUS contractors may request and shall be entitled to receive information from a physician or hospital or other person, institution, and/or organization...providing services or supplies to the beneficiary for which claims or requests for approval for benefits are submitted. Such information and records may relate to attendance, testing, monitoring, or examination or diagnosis of, or treatment rendered, or services and supplies furnished to, a beneficiary and shall be necessary for the accurate and efficient administration of CHAMPUS benefits... Before an individual's claim of benefits will be adjudicated, the individual must furnish to CHAMPUS that information which may be reasonably expected to be in his or her possession and which is necessary to make the

benefits determination. Failure to provide the requested information may result in denial of the claim.

PRECEDENTS

OASD (HA) File 20-79
OASD (HA) File 01-81
OASD (HA) File 83-41
OASD (HA) File 83-43
OASD (HA) File 83-45
OASD (HA) File 83-45

Under the CHAMPUS appeal procedure, it is incumbent on the appealing party to provide whatever facts are necessary to support the opposition to a CHAMPUS determination. In light of the stated Regulations and above cited precedential decisions, the appealing party is obligated to establish the general acceptance and efficacy of the program in the treatment of post bypass patients as supported by medical documentation and recognized professional opinion and authoritative literature as of the dates which the service occured.

It is established through precedential decisions of the OASD (HA) and supported in both the testimony of Mr. Gibbons, the Director of the Center for Health Promotion, and his article entitled "Rationale for Cardiac Rehabilitation (Exhibit 15), that there is substantial controversy in the American medical community as to the efficacy of cardiac rehabilitation programs in the treatment of post bypass, post infarction, and coronary artery disease.

The program in which the beneficiary participated has not been shown to be different from the programs described in OASD (HA) 83-41, 83-43, 83-45, nor 83-46, all of which final decisions were issued December 27, 1983 (Exhibit 14). The program required referral by a physician; close monitoring by trained staff; electrocardiograms and blood pressure checks; educational sessions pertaining to stress management, diet, sexuality, exercise and signs and symptoms of angina; and exercising equipment consisting of bicycles, treadmills, arm ergometers, and air dyne machines.

Prior decisions in cases utilizing like programs for post bypass and post infarction patients have stated:

> "Further, it is acknowledged that the program may very well have produced beneficial results for the appealing party -- as would be anticipated for any individual, with or without a heart condition, who undertook a program of structured exercise and weight reduction. We do not concur, however, that the exercise/weight reduction regimen constituted specific treatment. Further, the fact that a physician orders, prescribes or recommends that a patient pursue a certain course does not, in itself, make it medically necessary treatment. A physician in caring for his or her patient [sic] may, and properly so, advise and recommend in many areas beyond specific treatment. This is particularly true relative to encouraging changes in lifestyles -- i.e., increased exercise, elimination of smoking, weight reduction, etc." (OASD(HA) 20-79)

> "[There is an] increasing acceptance of the programs by the general medical community. However, the opinions clearly state 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 program." (OASD(HA) 01-81)

> "CHAMPUS coverage of care is limited to medically necessary supplies and services: i.e., services and supplies adequate for the diagnosis and treatment of illness or injury. While the record in this appeal reflects an expansion

cardiac rehabilitation programs across the country, the general acceptance and efficacy of the program in the treatment of postmyocardial infarction or arteriosclerotic heart disease following bypass surgery is not supported by authoritative medical literature and recognized professional opinion contemporaneous with the dates of care in this case. Under the appeal procedure, the appealing party has the responsibility of providing whatever facts are necessary to support the opposition to the CHAMPUS determination." (OASD(HA) 83-41)

"While the Department of Defense recognizes that individual improvement in quality of life may occur through cardiac rehabilitation programs, I find that potential improvement in the quality of life does not constitute medically necessary care under CHAMPUS. While some physicians may endorse programs they believe may assist individual patients, I am constrained by regulatory authorities to authorize benefits only for services which are generally accepted in the treatment of disease or illness and are documented by authoritative medical literature and recognized professional opinion." (OASD(HA) 83-43)

"The Program is popular, the many medical professionals involved in cardiac rehabilitation programs believe in it, and the participants believe the program is effective; yet, there is no scientific evidence to confirm these opinions." (OASD(HA) 83-45)

"The evidence in the record supports the conclusion that cardiac rehabilitation programs are exercise programs that are considered beneficial, are

widely used throughout the United States, but are not used in all medical communities or in all major hospitals. The evidence does not support the conclusion that cardiac rehabilitation programs have been scientifically demonstrated to be appropriate medical care for those suffering from heart disease." (OASD(HA) 83-46)

In support of the medical necessity for the Cardiac Rehabilitation Program as specific treatment for heart disease, Mr. Gibbons, at the Hearing, referred to his article entitled "Rationale for Cardiac Rehabilitation (Exhibit 10 pages 3-7 and Exhibit 15); specifically he referred to the section entitled "MORBIDITY AND MORTALITY, THE QUESTION OF RECURRENCE". Herein it is stated:

"In a study by Rechnitzer et al, cardiac patients who exercised consistently post-infarction experienced fewer recurrent infarctions and instances of sudden death. Shepherd demonstrated that exercise compliance in myocardial infarct patients was associated with a fivefold improvement in the odds ratio for both fatal and non-fatal recurrences of infarction. This treatment effect was independent of health habits...

"The role of exercise in the prevention of reinfarction is still controversial...

"Finally, statistical correlation does not prove cause and effect. Within the next three years, data should be published from the National Exercise and Heart Disease Project (N.E.H.D.P.), a randomized trial assessing the value of exercise post-infarction in over 800 subjects.

"Conclusion.
A comprehensive cardiac rehabilitation program can enrich the psychological, physiological,

and vocational life of the cardiac patient. The community may benefit from a lightened disability load. Whether or not exercise therapy lowers the recurrence rate of infarction remain as an unanswered question." (pages 3-5)

Therefore, neither the testimony nor the medical evidence supported the contention of the beneficiary that the cardiac rehabilitation program has been scientifically demonstrated to be appropriate medical care in the treatment of post bypass heart disease.

The evidence presented by the beneficiary in his testimony at the Hearing, focused on the medical necessity of his participation in the cardiac rehabilitation program based on the March 9, 1983 and September 28, 1983 letters from Dr. Millar. (Exhibits 5 and 3 respectively) The first letter, an introduction of the beneficiary to the Cardiac Rehabilitation Program at Providence Hospital states, in part:

> "He does have some vague, chest-type pains that have felt to be related to his incision and/or this low grade infection. I feel that he can benefit from the Cardiac Rehabilitation Program to reassure him he can do physical things in his life."

The second letter, addressed to CHAMPUS, states, in part:

> "During this period of time, this patient's mental status was very tenuous -- he was bordering on becoming a neurotic cardiac cripple and I felt it very wise and a medical necessity for him to participate in the Cardiac Rehabilitation Program offered at Providence Hospital in Medford, Oregon. He enrolled in that and did very well throughout that closely monitored rehabilitation program and it has helped him immensely adjust to his heart problem in an active and useful life."

Certainly these letters suggest that the doctor believed that the beneficiary could benefit from participation in the program, but the mere use of the words "Medical Necessity" do not indicate that participation in the program was a medical necessity within the meaning of the Regulation. Neither letter indicates the exact nature of the heart disease from which the beneficiary suffered postoperatively, but the letters do indicate that the beneficiary's mental status was the precipitating cause of his recommendation into the rehabilitation program.

The testimony of the beneficiary focused on the fact that the program worked for him -- that today he is not a coronary cripple and he credits his participation in the program for his improved physical condition.

The testimony of Mr. Gibbons established that due to his participation in the program, the beneficiary was capable of performing about 60% more work prior to the onset of shortness of breath. He also testified that the beneficiary's "affect changed dramatically, he was much more positive, more carefree, and less hypochondraical." He established, through his testimony, that the beneficiary began the program as a "borderline cardiac cripple" and completed the program by breaking through that status and being able to accomplish about 60% more work prior to the onset of shortness of breath.

It is undisputed that the beneficiary garnered many benefits from his participation in the program. All of the Hearing File and testimony support the fact that he gained self-confidence in his ability to do physical things, and he became more positive and carefree. There is also the testimony of Mr. Gibbons which supports that the beneficiary's physical condition changed so as to allow him to perform more work (about 6.5METS) prior to the onset of shortness of breath. Prior to the program, when the beneficiary was tested on December 16, 1982, he was able to do only 4.2 METS before shortness of breath caused him to stop. However, in his report on this particular test (Exhibit 13 p. 22), Mr. Gibbons stated, in part:

"[the patient] ended test himself by abruptly

> stepping off treadmill. It may be difficult to differentiate between incisional pain and Angina. It seemed that he could have walked further on the treadmill and that the shortness of breath was not excessive..."

Dr. Naymick, in his report on the initial stress test (Exhibit 13 pp. 38-39) stated:

> "A rather confusing picture of subjective shortness of breath limiting the stress test without evidence of objective clinical deterioration. As noted above, the patient's exercise pulse rate was not inordinately fast and his respiratory rate was not particularly labored when he decided to step off the treadmill. He did complain before and throughout the test of chest wall discomfort present in the area of sternotomy scar and this may have limited his exercisability with the subjective increase in pain due to this incisional infection."

Thus, it is not clearly established that the benefit derived from the program caused actual medical changes in the nature of the beneficiary's heart disease, as it is possible that anxiety and fear and/or incisional pain prevented him from continuing the test enough to determine the actual amount of exercise he may have accomplished until the onset of shortness of breath. There is no evidence in the record which actually documents the medical changes in the beneficiary's disease resulting from the course of the exercise program.

Also, neither the beneficiary, his wife, Mr. Gibbons, nor the authorities cited by them were able to establish that participation in a cardiac rehabilitation program, at the time the service was rendered, constitutes services which are generally accepted in the treatemnt of disease or illness and are documendted by authoritative medical literature and recognized professional opinion.

The testimony of the beneficiary and Mr. Gibbons, and the various exhibits in the Hearing file, establish that the beneficiary's Cardiac Rehabilitation Program was similar to those addressed in prior OASD(HA) decisions referred to hereinabove. The beneficiary has not established that at the time the program was undergone, that it was medically necessary underthe Regulation, nor has he established the efficacy of the cardiac rehabilitation program in the treatment of heart disease. The fact that a medical doctor has stated that the program was medically necessary and prescribed the program is not conclusive as to the determination of "medical Necessity" under the Regulation. The "Medically Necessary" treatment must be demonstrated by the appealing party to be a generally accepted treatment of disease or illness and documented by authoritative medical literature and recognized professional opinion. The beneficiary has not met his burden.

The program followed by the beneficiary in this appeal was from March 14, 1983, through June 7, 1983. The evidence submitted in the record supports the prior decisions of the OASD(HA) and the conclusion that at the time the program was undergone, it was not medically necessary as defined in the CHAMPUS Regulation. The Hearing Officer finds that the beneficiary's Cardiac Rehabilitation Program was not medically necessary and is excluded from CHAMPUS cost-sharing.

PHYSICAL THERAPY

Though the Hearing Officer has found that the Cardiac Rehabilitation Program was not medically and therefore ineligible for cost-sharing, the beneficiary and Mr. Gibbons have suggested that the program is physical therapy.

Mr. Gibbons stated that the cardiac rehabilitation program, as one of therapeutic exercise, qualified as a physical therapy program with the definition in the CHAMPUS Regulation. He testified that although heat, massage and biofeedback are not utilized in the program, the fact that therapeitic exercise is utilized, places the program within the CHAMPUS definition of Physical Therapy. He testified that although he is an exercise physiologist and not a physical therapist, Cardiac

Rehabilitation Programs can be directed by either physical therapists or exercise physiologists. His testimony was that it is not material whether such a program is directed by an exercise physiologist or a physical therapist. He stated that the important factor is that highly trained personnel supervise every aspect of the program.

Mr. Gibbons testified that the difference between a general exercise program and a therapeutic exercise program is that the therapeutic exercise program is supervised by trained personnel. He stated that the equipment used to monitor the participants in the program during exercise also distinguishes it from a general exercise program.

The Hearing Officer finds that the record and testimony do not establish that the treatment received was of the type that is considered physical therapy under the CHAMPUS regulation; i.e., the treatment of desease by physical agents and methods. The CHAMPUS Regulation dealing with physical therapy specifically excludes general exercise programs.

GENERAL EXERCISE PROGRAM

OASD(HA) decisions 01-81 and 10-79 discuss thoroughly the issue of cardiac rehabilitation programs as being general exercise programs. The program in which the beneficiary in the present appeal participated has not been demonstrated to be different from the programs described inOASD(HA) 01-81 and 20-79. The exercises (warm-up, bicycle, treadmill, arm ergometer and air dyne, and cool down) were primarily those which could have been done at home, in a gym, or in a spa. The monitoring and testing were adjunctive to the general exercise itself and not done for the diagnosis and/or treatment of the disease and are therefore excluded under Chapter IV Dod 6010.8-R, G.1. and G.48.

EDUCATION/TRAINING

Mr. Gibbons, in his testimony and in the documentary evidence provided in his Progress Note of 4/83 (Exhibit 13 p. 27) stated that a major aspect of the Cardiac Rehabilitation Program was educational. In the

Progress Note dated 4/3, he stated, in part:

> "During the exercise classes, I conduct educational sessions and we have discussed cardiac diet, stress management, sexuality, exercise and signs and symptoms of angina."

The Regulation of Chapter IV DoD 6010.8-R G.46 specifically excludes:

> "Educational services and supplies, training non-medical, self care/self help training and any related diagnostic testing or supplies."

a major goal of the cardiac rehabilitation program was life-style modification as expressed by the director of the program in his 4/3 Progress Report (above cited). Though the goal is beneficial and desirable for the participants, these goals would benefit any individual with or without heart disease. Even though the Hearing Officer has already found the program not to meet the Regulation requirement of Medical Necessity, the specific aspects of the Cardiac Rehabilitation Program which were educational in nature are specifically excluded from cost-sharing.

ESTOPPEL

The wife of the beneficiary testified that she twice was verbally assured by the fiscal intermediary that if the program was prescribed by a physician, it would be eligible for cost-sharing, and that it was on the basis of this verbal assurance that the beneficiary enterred the program. She also testified that the first claim submitted to the fiscal intermediary for the beneficiary's participation in the Cardiac Rehabilitation Program was paid.

CHAMPUS is an "at risk" program. Claims are filed, appropriate information is obtained and the claim is adjudicated. Verbal approval is without authority and cannot bind the government. Available information is not sufficient to justify reliance on the verbal assurances of the fiscal intermediary and the fiscal intermediary was acting beyond the

scope of his authority in giving such approval. The erroneous payments also do not result in estoppel as the United Stated is not estopped to deny erroneous payments in contravention of law or regulation. Therefore, this argument lacks legal and factual merit in this appeal. The fact that an erroneous payment was made (whether or not subsequently identified and recouped) is not in any way binding on the program in connection with future benefit payments. An error cannot be used as the basis for making further erroneous payments; to do otherwise would result in perpetrating a mistake instead of correcting it.

SUMMARY

In summary, it is the Recommended Decision of the Hearing Officer that the Cardiac Rehabilitation Program was not medically necessary in the treatment of post bypass surgery heart disease 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 Hearing Officer also finds that the program does not meet the definition of physical therapy set forth in DoD6010.8-R, Chapter II B. 134 and DoD 6010.8-R Chapter IV C.3.j., and therefore cost-sharing cannot be authorized as physical therapy. The Hearing Officer finds that certain aspects of the program were educational in nature and are specifically excluded from CHAMPUS coverage by DoD 6010.8-R, Chapter IV G.46. All services and supplies related to the non covered treatment are also excluded under DoD 6010.8-R Chapter IV G.1. The claims for participation in Cardiac Rehabilitation Program at Providence Hospital by the beneficiary from March 14, 1983 through June 7, 1983, should not be cost-shared and the Formal Review Decision issued March 16, 1984, denying cost-sharing for this period should be upheld.

Suzanne S. Wagner

SUZANNE S. WAGNER

July 5, 1984

Date