ASSISTANT SECRETARY OF DEFENSE
WASHINGTON, D. C. 20301

HEALTH AFFAIRS

OCT 25 1984

BEFORE THE OFFICE, ASSISTANT

SECRETARY OF DEFENSE (HEALTH AFFAIRS)

UNITED STATES DEPARTMENT OF DEFENSE

Appeal of	)	
	)	
Sponsor:	)	OASD(HA) Case File 84-21
	)	FINAL DECISION
SSN:	)	

This is the FINAL DECISION of the Assistant Secretary of Defense (Health Affairs) in the CHAMPUS Appeal OASD(HA) Case File 84-21 pursuant to 10 U.S.C. 1071-1092 and DoD 6010.8-R, chapter X. The appealing party is the CHAMPUS beneficiary, a retired officer of the United States Army. The appeal involves the denial of CHAMPUS cost-sharing of services provided in a Stress, Health, and Physical Evaluation (SHAPE) program at the University of Nebraska Medical Center on April 13, 1982. The amount in dispute is $810.00.

The hearing file of record, the Hearing Officer's Recommended Decision, and the Analysis and Recommendation of the Director, OCHAMPUS, have been reviewed. It is the Hearing Officer's recommendation that CHAMPUS cost-sharing of the services provided in the SHAPE program be denied. The Hearing Officer found the care was not medically necessary in the treatment of coronary artery disease, was provided above the appropriate level of care, was partially excluded preventive care, and was an educational, self-help program.

The Director, OCHAMPUS, concurs with the Hearing Officer's Recommended Decision and recommends its adoption by the Assistant Secretary of Defense (Health Affairs) as the FINAL DECISION provided the denial of cost-sharing on the basis of appropriate level of care be rejected as inconsistent with regulatory provisions.

The Assistant Secretary of Defense (Health Affairs), after due consideration of the appeal record, adopts and incorporates by reference the Hearing Officer's Recommended Decision, as modified in accordance with the recommendation of the Director, OCHAMPUS, to deny CHAMPUS cost-sharing of the services of the SHAPE program based on findings the care was not medically necessary in the treatment of coronary artery disease and, in part, constitutes excluded preventive care and an educational, self-help program.

ATTACHMENT B

In my review, I find the Recommended Decision adequately states and analyzes the issues, applicable authorities, and evidence in this appeal. The findings are fully supported by the Recommended Decision and the appeal record. Additional factual and regulation analysis is not required. The Recommended Decision is acceptable for adoption as the FINAL DECISION by this office with one modification.

The Hearing Officer found, as an additional basis for denial, that the care was provided above the appropriate level of care. The Hearing Officer cited the definition of appropriate medical care which includes a requirement that medical care be provided at an adequate level. In other provisions of DoD 6010.8-R, including Chapter IV, B.1.g., and Chapter IV, G.3., the regulation requirement that care be provided at the appropriate level of care is limited to inpatient institutional stays. In previous FINAL DECISIONS of this office, I have applied these provisions to inpatient stays. For regulatory consistency, I find the regulatory exclusion of care above the appropriate level of care applies only to inpatient stays. As the care in this appeal was at the outpatient level, the denial on the basis of care above the appropriate level was erroneous and is rejected. Rejection of the Hearing Officer's denial on this basis does not affect the denial under other regulatory provisions and, therefore, does not materially affect the Recommended Decision or this FINAL DECISION.

SUMMARY

In summary, the FINAL DECISION of the Assistant Secretary of Defense (Health Affairs) is to deny CHAMPUS cost-sharing of the services provided in the Stress, Health, and Physical Evaluation (SHAPE) program rendered April 13, 1982, as not medically necessary and, in part, excluded preventive care and an educational, self-help program. The appeal and claims of the beneficiary are, therefore, denied. Issuance of this FINAL DECISION completes the administrative appeal process under DoD 6010.8-R, chapter X, and no further appeal is available.

William Mayer, M.D.

84.21

RECOMMENDED HEARING DECISION

Claim for Benefits under the
Civilian Health & Medical
Program of the Uniformed Services
(CHAMPUS)

Beneficiary and Sponsor:

SSN:

This is the recommended decision of CHAMPUS Hearing Officer Hanna M. Warren in the CHAMPUS appeal of , and is authorized pursuant to 10 U.S.C. 1071-1089 and DoD 6010.8-R, Chapter X. The appeal involves the denial of CHAMPUS cost-sharing for services rendered to on April 13, 1982 in the Stress, Health and Physical Evaluation Program (SHAPE) at the University of Nebraska Medical Center. The amount in dispute is $810.00 less deductible, if any, and patient's cost share amount.

The hearing file of record and testimony at the hearing have been reviewed along with the material submitted subsequent to the hearing and admitted to the record. It is the OCHAMPUS position that the formal review determination dated June 20, 1983 denying CHAMPUS cost-sharing for the services provided to in the SHAPE program be upheld on the basis they were not medically necessary, were above the appropriate level of care and were specifically excluded as experimental, preventive and self-help care under the CHAMPUS Regulation.

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 services provided to the beneficiary on April 14, 1982 in the Stress, Health and Physical Evaluation Program (SHAPE) at the University of Nebraska Medical Center because the services were not medically necessary and excluded under the provisions of DoD Regulation 6010.8-R.

FACTUAL BACKGROUND

The beneficiary (who was 55 years old at the time) went to New Orleans, Louisiana to attend a convention in April, 1976, and while there he began experiencing chest pains which became more severe and caused him to become alarmed. He contacted his hometown physician and was told to go to the Oschner Clinic, which he did. He was admitted to the cardiology service there and on April 2, 1976, a catheterization and angiogram were performed (Exhibit 16). testified at the hearing he went into cardiac arrest during the catheterization. After these tests the physicians at the Oschner Clinic advised him that he would live approximately one year with proper medical management and recommended cardiac by-pass surgery. He accepted their recommendation and underwent a triple coronary artery by-pass on April 5, 1976. Post operatively he contracted a severe infection with high fever and

experienced a rather slow recovery with a gradual return to work over the next several years. He returned to the Oschner Clinic in New Orleans sometime from three to six months after the surgery for follow-up evaluation. He returned again in 1977, 1978 and 1979 for follow-up visits. In these visits he saw Dr. Benjamin F. Jacobs and he testified at the hearing they would take a chest X-ray, physical and treadmill tests each year except in 1977 they did not do a treadmill test. In 1980 the beneficiary started making periodic visits to Dr. Donald J. Wagner, who is an internist in the beneficiary's home town. He testified he was now seen at least annually (sometimes April and September) by Dr. Wagner for an annual physical at which time blood work and treadmill tests are done.

The beneficiary's wife saw an article in the newspaper regarding the SHAPE program at the University of Nebraska Medical School and the beneficiary called the program and asked that literature be sent to him. This was done and he sent the literature on to the two physicians who had been important in his treatment, Dr. Jacobs at the Oschner Clinic and Dr. Wagner locally. Both of them said they thought he should go. He sent the literature to the CHAMPUS fiscal intermediary, Mutual of Omaha, and also called them several times trying to get a definite answer as to whether CHAMPUS would pay for this program. He could not receive assurance it would be covered and finally, as he testified at the hearing, he "took a chance and came."

The material received by the beneficiary and referred to in the paragraph above is contained in Exhibit 14. In the foreword, Dr. Elliot says the Department of Preventive and Stress Medicine is the first of its kind in the world, which was also confirmed by Dr. Buell in his testimony at the hearing. Dr. Elliot's foreword starts out by saying, "The best cure is prevention." He discusses the need for new knowledge and new technology to promote health, as well as diagnosing and managing illness and rehabilitating patients. "With this new knowledge and technology we can teach the healthy and the ill to manage their own health through a personalized health portfolio." He continues, "The Department's interdisciplinary professional staff teaches scientifically based principles that allow professionals and other individuals to replace healthy for self-destructive behavior patterns before and after illness has occurred." He concludes; "We will measure our success by our ability to hold the personal and financial cost of medical care in line; by teaching individuals to take charge of their personal health through custom tailored portfolios based upon sound scientific, comprehensive and timely teaching--to be productive without being self-destructive." He discusses health patterns which can be modified to promote health and prevent illness and discusses the link between lifestyle behavior and stress and health and illness. "Realizing that lifestyle plays a powerful role, we have developed a Nebraska based program which goes beyond the annual health physical and encompasses a variety of new and significant advances. The purpose of the Stress, Health and Physical Evaluation (SHAPE) Program is to address these needs." It discusses components of the program and some corporate management options along with stress management group training, on-going research, and their educational goals and programs. "The most personal and effective form of education is individual counselling, which is a basic and essential component of the SHAPE Program outlined earlier."

The services which received in the SHAPE program were described as follows in the file (Exhibit 16, page 16):

(a) Diagnostic history and physical -- Gathering of background information on patient's family history and relevant lifestyle factors (i.e., smoking, alcohol consumption, etc.) necessary for proper diagnosis and/or referral. A complete physical examination including rectal exam and urinalysis is then performed. Patient contact time: One and one-half hours. $100.00

(b) CHEQS Summary -- Assessment of personality factors necessary for the proper diagnosis of patient's condition; report on these factors. $50.00

(c) Collection of blood specimen -- Withdrawal and analysis of blood; SMAC- 24 report, HDL, Catecholamine and Cortisol level report; thyroid screen. Performed to aid in diagnosis of disease. $60.00

(d) Cardiopulmonary Fitness Measurement -- Diagnostic tests for detection of respiratory or cardiovascular disease. Patient contact time one and one-half hours. $150.00

(e) Hemodynamic physiologic response testing -- Procedure for the detection of pathological changes in blood pressure, heart rate, cardiac output, arterial compliance and thoracic fluid volume. Necessary for the proper detection and classification of arterial disease including hypertension. Report is generated. Patient contact time; 2 hours. $245.00

(f) Stress evaluation -- Diagnostic psychological interview to detect psychological factors contributing to the disease process. Report is generated. Patient contact time; 1 hour. $60.00

(g) Nutritional Analysis -- Diagnostic nutritional interview to detect nutritional factors contributing to the disease process. Report is generated. Patient contact time, 1/2 hour. $20.00

(h) Medical Consultation and Summary -- Professional service by internist provided to interpret all test results and to make diagnosis and referral of patient, with patient's knowledge. Report is generated. Patient contact time, 1-1/4 hours. $125.00

The charge for each service billed to CHAMPUS is given at the end of the explanation above. The total charge was $810.00 (Exhibit 1).

The final evaluation summary by Dr. Elliot is included in the file as Exhibit 16, page 17. It starts out, "Primarily he would like to know about what the influence is of stress on health and illness, and second, his wife is very concerned about his state of health and his future prospects after having undergone coronary artery bypass surgery in 1976." It describes the history of his surgery and describes the patient as working full-time, active and able to "detach himself from his activities and that his behavior, lifestyle, and his ability to manage stress is remarkably changed as a result of the shock of the operation." It reports his family and medical history, describing his blood pressure as "slightly elevated", his appetite good, and with the exception of some fundoscopic alterations "probably of hypertensive origin", glasses and scars and high frequency finger tremor, "all findings within normal limits". The laboratory screen indicated "blood glucose and uric acid are slightly

elevated." He is within the normal range on percent of body fat, and "is able to perform to 10 METS which is quite good, achieving a heart rate of 160 beats per minute where his target maximum predicted rate was 167. The patient displayed a few ventricular ectopic beats but no evidence of ischemic ST or T wave change. All of the physiologic parameters were within normal limits thus is was a negative exercise tolerance test." The body stress stimulation laboratory test showed him to be a Group I hot reactor, the major response being to the competitive video game, with a modest response to other provocative stressers. Using the CHEQS showed low levels of "anxiety, hostility, depression and eroticism. He has slightly elevated levels of extroversion." The report discusses his psychological profile in more detail and concludes, "At the moment the major health problems that he faces are those of hypertension, hyperglycemia and hyperurecemia. He appears to be coping extremely well and in our view does not require further behavioral management." Dr. Elliot did recommend management for hypertension and it was testimony that he had been taking medication for that prior to being evaluated by Dr. Elliot. It was determined that he would be referred back to his local physician for management and for the diagnostic tests.

The fiscal intermediary denied payment of the claim and wrote Dr. Elliot that the services were excluded because "provided as a part of, or under a scientific medical study, grant or research program" (Exhibit 2). Dr. Elliot wrote back and expressed his concern over the fact that CHAMPUS consistently denied payment and stated that other carriers supported their program. He assured the fiscal intermediary that although the evaluation of each patient entered a data base which was periodically reviewed, the services were in no way a research program (Exhibit 3). The fiscal intermediary then wrote to Mr. Joseph Dodson in the Contract Management Division of OCHAMPUS and asked for a policy determination, stating they felt the services provided would be excluded under the exclusions for research programs, preventive care and not medically necessary. It was also stated to be a very expensive form of evaluation (Exhibit 5). A policy determination was made that the SHAPE program was a self-help program and thus not a benefit (Exhibit 7). Both Dr. Elliot and were notified of this determination (Exhibit 10) and in the reconsideration decision made by the fiscal intermediary the services were denied on the basis that the program was a self-help program and the letter also quoted the CHAMPUS exclusion for general exercise programs (Exhibit 11). The beneficiary then requested a formal review decision from OCHAMPUS and after the file was received a case review was held with Dr. Rodriguez, the OCHAMPUS Medical Director. Dr. Rodriguez concluded that for this beneficiary the SHAPE program was "a self-help, educational program which was not medically necessary" (Exhibit 18). The first level appeal decision issued June 20, 1983 denied coverage for the services provided to the beneficiary on the basis they were not medically necessary, were preventive care and a self-help program.

The OCHAMPUS position for the hearing was stated in their Position Statement (Exhibit 26) which was coverage should be denied for the services rendered to the beneficiary because "the SHAPE program is considered investigational, not appropriate medical care, preventive care and an educational self-help program, all of which are excluded from the CHAMPUS basic program pursuant to DoD Regulation 6010.8-R." The beneficiary's position is that the services rendered

were diagnostic and not preventive and also that he suffered from coronary artery disease so the services were medically necessary and not preventive or educational self-help.

The beneficiary requested a hearing which was held November 23, 1983 at the Swanson Conference Center on the campus of the University of Nebraska Medical Center, Omaha, Nebraska. Present, in addition to the beneficiary, were James C. Buell, M.D., Department of Stress and Preventive Medicine, University of Nebraska Medical School; and Dr. Alex Rodriguez, Medical Director, OCHAMPUS, who appeared as witnesses. Ms. Barbara Udelhofen, Attorney-Advisor, attended the hearing representing OCHAMPUS.

ISSUES AND FINDINGS OF FACT

The primary issue in dispute is whether the care provided the appealing party was medically necessary or excluded under the provisions of the CHAMPUS Law and DoD Regulation 6010.8-R. Secondary issues that will be addressed include the issues of coverage by other insurance companies, and precedent/estoppel.

Regulation DoD 6010.8-R is issued under the authority of and in accordance with Chapter 55, Title X, United States Code. It establishes uniform policy for the world-wide operation of the Civilian Health and Medical Program of the Uniformed Services (CHAMPUS). Chapter IV of the regulation defines basic program benefits and paragraph A-1 provides in pertinent part as follows:

"Scope of Benefits-Subject to any and all applicable definitions, conditions, limitations and/or exclusions specified or enumerated in this regulation, the CHAMPUS Basic Program will pay for medically necessary services and supplies required in the diagnosis and treatment of illness or injury, including maternity care. Benefits include specified medical services and supplies provided to eligible beneficiaries from authorized civilian sources such as hospitals or other authorized institutional providers, physicians and other authorized individual professional providers..."

Chapter IV provides other more detailed explanations of coverage and in paragraph C discusses professional service benefits. Section C(1) is a general statement that "Benefits may be extended for those covered services described in this Section C of Chapter IV, which are provided in accordance with good medical practice and established standards of quality by physicians or other authorized individual professional providers, as set forth in Chapter VI of this Regulation...Such benefits are subject to any and all applicable definitions, conditions, exceptions, limitations and/or exclusions as may be otherwise set forth in this or other chapters of this Regulation..." Paragraph IV,C,1(b) states as follows: "Services Must be Related. Covered professional services must be rendered in connection with and directly related to a covered diagnosis and/or definitive set of symptoms requiring medically necessary treatment."

Chapter IV(G) provides 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 (emphasis theirs).

"(1) Not medically necessary - services and supplies which are not medically necessary for the diagnosis and/or treatment of a covered illness or injury.

"(2) Unnecessary Diagnostic Tests - X-ray, laboratory and pathological services and machine diagnostic tests are not related to a specific illness or injury or a definitive set of symptoms.

"(16) Not in accordance with accepted standards: Eexperimental services and supplies not provided in accordance with accepted professional medical standards; or related to essentially experimental procedures or treatment regimens.

"(30) Preventive care - Preventive care, i.e. routine, annual or employment requested physical examination, routine screening procedures; immunizations...

"(40) Counselors: Counseling, Services of Counselors, except Marriage and Family Counseling as specifically provided in Chapter IV "Authorized Procedures."

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

At the end of the exclusions and limitations in IV,G is the following:

"NOTE: The fact that a physician may prescribe, order, recommend or approve a service or supply does not of itself make it medically necessary or make the charge an allowable expense even though it is not specifically listed as an exclusion."

Chapter II contains definitions which assist in understanding the language of the Regulation. Appropriate medical care is defined in paragraph 14 as follows: "a. That medical care where the medical services performed in the treatment of a disease or injury or in connection with an obstetrical case are in keeping with the general acceptable norm for medical practice in the United States. The authorized individual professional provider rendering the medical care is qualified to perform such medical services by reason of his or her training and education and is licensed and certified by the state where the service is rendered or appropriate national organization or otherwise meets CHAMPUS standards, and

c. The medical environment in which the medical services are performed is at the level adequate to provide the required medical care."

Paragraph 103 defines "medically necessary" to mean the "level of services and supplies (i.e. frequency, extent and kinds) adequate for the diagnosis and treatment of illness or injury. Medically necessary includes concept of appropriate medical care."

Paragraph 139 - "Preventive care means diagnostic and/or medically indicated essentially preventive procedures not directly related to an illness, an injury or a definitive set of symptoms. Preventive care includes (but is not limited to) well baby care (other than a new born exam), immunizations, annual physical examinations or screening procedures such as chest x-rays, pap smears performed on the basis of periodic preventive evaluation rather than on the basis of presenting symptoms. NOTE: Preventive care is not covered by CHAMPUS."

The beneficiary in this case is a very skillful advocate who clearly feels the diagnostic evaluation program known as SHAPE was beneficial to him given his past and present medical history. My decision is not that I find the services to be of no value to the beneficiary nor the program not a valid and beneficial one for those persons utilizing the services. I certainly agree with Dr. Rodriguez that wellness and preventive care are desirable goals that are becoming more acceptable and important to medical professionals and to lay people. In making my decision in this hearing though, I am bound by the Law and Regulation governing the CHAMPUS program. Every Department of Defense Appropriations Act funding the CHAMPUS program has contained a mandate that none of the funds authorized for CHAMPUS under the provision of Section 1079(a) of Title X, United States Code shall be available for "any service or supply which is not medically necessary to diagnose and treat a mental or physical illness, injury or bodily malfunction." Many provisions of the Regulation published under the APA show the intent to exclude medical services not related to a specific illness or symptoms and done for routine and/or health promoting purposes.

To be medically necessary, the medical services must be at a frequency and extent adequate for the diagnosis and treatment of illness or injury and IV,C,1(b), bears repeating: "Covered professional services must be rendered in connection with and directly related to a covered diagnosis and/or definitive set of symptoms requiring medically necessary treatment." The medically necessary/appropriate level of care standard has many exclusions and limitations which have been raised in the context of this hearing: Experimental investigational, preventive care, counselors, self-help, educational and training services and diagnostic tests not related to a specific illness or definitive symptoms.. While many of these excluded services are of value, if not to the entire general population, to people exhibiting certain physical conditions, they all fall within the range of what I generally would call preventive care. The services provided the beneficiary in the SHAPE program contained some features of all the above limitations.

The beneficiary has made the argument that because an acronym has been given to these services they are being denied and if each individual test which was performed had been submitted separately, or done at a separate time, it would have been allowed. I don't know whether I agree with this assessment, but it is immaterial to my decision because these programs <u>were</u> performed together in a one-day evaluation and in making my decision I must consider them together and the purpose they were intended to serve in view of this particular

beneficiary's medical condition, and not how it might have been or could have been. Dr. Buell testified this program was originally put together as a package for annual physicals for corporate executives. It was then called Stress and Health Appraisal Program for Executives and included elements of prevention but was more than the usual physical. I think even the beneficiary would admit that if he had undergone this evaluation as part of a corporate benefit, it would not have been paid under the CHAMPUS program. Because it was performed at the University of Nebraska Medical School and because the beneficiary suffered from coronary artery disease it is his argument that changes the program to one medically necessary in his particular case. Based upon the record I cannot agree with him. The material submitted explaining the program has been quoted in some detail above and it is not necessary to repeat, but I believe it is clear that the goal of setting up this diagnostic and/or evaluation program in the Department of Preventive and Stress Medicine was to assist people to control certain factors over which they had control to promote wellness. Although the testimony at the hearing showed both Dr. Elliot and Dr. Buell had a private practice through the Faculty Practice Plan, SHAPE is a package deal according to Dr. Buell's testimony. He testified that the only unique feature of SHAPE is the life stress laboratory, in which they use behavioral techniques to manage physiology. There is absolutely no reference in the record to show that every person who participated in this evaluation series did not receive exactly the same services, and there is nothing to indicate the tests performed on the beneficiary in this hearing were tailored to his coronary artery disease or his hypertension or any specific physical condition. In fact, the testimony and the evidence is all to the contrary. It shows every person received exactly the same services. In view of this, it is difficult for me to find the services were directly related to a diagnosis or definitive set of symptoms.

It is clear the beneficiary suffered a serious illness in 1976 which required a lifestyle adjustment on his part. He does have coronary artery disease and in Dr. Buell's opinion this would be classified as a chronic illness. He has altered many of his lifestyle patterns including giving up smoking, avoiding strenuous exercise, and overeating. Although he has suffered no chest pain since his bypass surgery, he continues to carry nitroglycerin, takes two asperin a day, exercises, wears a mask in cold weather, and follows a low cholesterol diet. He testified at the hearing that when he left the Oschner Clinic they told him to avoid stress and this general prohibition has always concerned him since his surgery because he was not sure exactly what stress was to begin with and consequently wasn't certain he was following this important element of his health management. He testified he had read many books about stress and health and how they are interrelated. I believe it is fair to state that this stress management was the important feature of the program that attracted the beneficiary and in response to my question at the hearing he stated what he found out was how stress affects him, as it is different for each individual and what is stressful for one is not for another. He said the word distress was really more of a key word than stress. Being a trial lawyer would be very stressful for some, if not most people, but being in a routine, dull job might be more stressful for the beneficiary. The physicals he had received at the Oschner Clinic and the ones he received on a routine basis from his internist in Sioux City included all of the things that were done in Omaha

except for the nutritional counseling and stress aspects. As the beneficiary testified, these were "old hat". Dr. Buell confirmed that the unique feature of the SHAPE program is its life stress management.

It is my decision after reviewing the record that the services provided were not medically necessary within the CHAMPUS Law and Regulation and were above the appropriate level of care. The record shows the beneficiary was working full-time, albeit in a very stressful occupation, but it appeared from the testimony that was given and the exhibits he had made a very satisfactory adjustment to this stressful occupation. He testified he had transient dizzy spells and felt that sometimes his heart skipped a beat. He also described a sleep disturbance which he had for some time, but which was also being managed. There is nothing in the record to indicate any worsening or change in his condition brought him to this particular evaluation. It was initiated by an article that his wife read in the paper and although there are several places in the record where the beneficiary states that Dr. Jacobs and Dr. Wagner recommended he go, it was his testimony at the hearing that he was the one who initiated the inquiry about this program by sending them literature and asking if they thought it would be beneficial for him. In response to a question to Dr. Buell of whether the SHAPE program was medically necessary, he responded that a periodic evaluation of patients with coronary artery disease is usually appropriate medical care. While a general statement of this type was in part disputed by Dr. Rodiguez' testimony, the beneficiary stated that he did routinely go at least once a year, sometimes in April and September, for a routine evaluation which was always paid for by CHAMPUS. It is not necessary that I decide in this hearing whether a periodic evaluation is necessary because these services are not the subject of this hearing. What I am deciding here is an additional evaluation which I find to be above an appropriate level of care to be medically necessary within the regulatory provisions. It was Dr. Buell's testimony that almost all of the services provided to the beneficiary are rather routinely part of an evaluation for patients with coronary artery disease except for the feature of their program which was unique is the life stress laboratory which deals with lifestyle behavior and stress and attempts to develop behavioral techniques to manage physiology. Dr. Buell testified that this unusual program is the only one in the country in a medical school. The record reveals no medical necessity to send the beneficiary to this particular program other than the general avoiding stress dictum given at the time of his surgery and the beneficiary's wanting to learn more about how this could be done. There is nothing to show that Dr. Wagner, his local internist, was concerned about this and how it was affecting the beneficiary's health and it is my conclusion that given the exclusions of the Regulation the services were not at an appropriate level to be medically necessary.

Dr. Rodriguez testified at the hearing that in his opinion the services provided were not medically necessary, and the medical records showed the beneficiary was asymptomatic and had no active symptoms. Because of this it was Dr. Rodriguez' opinion there was no medical necessity for such an extensive workup for the mild hypertension, hyperglycemia and hyperurecemia. His blood glucose and uric acid were only slightly elevated and the hypertension had been treated over several years and he was taking medication for that. The beneficiary himself agreed in his testimony that these diseases are probably sufficiently understood so that management could have been undertaken by his local doctor. He insisted that his coronary heart disease was the reason he

went. As to that condition, while I certainly am not disputing Dr. Buell's testimony that it is a chronic condition, I agree with Dr. Rodriguez' testimony that he had no active symptoms and was relatively asymptomatic. Dr. Wagner was seeing him on a regular routine basis and certainly had done a complete history and physical and routine blood and laboratory work. The beneficiary testified that he had previously received a treadmill or cardiopulmonary fitness measurement and because of his relationship with the patient Dr. Wagner was pretty familiar with his personality factors, even if he had not done a specific test. There is nothing in the record to show any psychological testing or counselling regarding stress and behavior modification had been suggested by Dr. Wagner or requested of him by . I would assume some services of this type were available in Sioux City. Dr. Rodriguez testified that even if an annual physical were to be found medically necessary for CHAMPUS cost-share, the program that is the subject of this hearing is an extremely expensive and inappropriate way to receive those services. The manager of the Utilization Review Department of the Fiscal Intermediary stated in Exhibit 5, "It is the opinion of our staff, that given the diagnosis in this case, this would be a quite expensive form of evaluation." I think the record supports this conclusion, especially on a routine basis. In Exhibit 24, the policy case analysis reflects my conclusions on page 2: "Under usual CHAMPUS procedures, and assuming that the billed services actually do represent the initial evaluation of the beneficiary's condition, the service would be considered a comprehensive new patient visit or, if the beneficiary were referred by his attending physician, a comprehensive consultation. Separate charges would be allowable only for the cardiovascular stress test and the laboratory work. A separate charge for the psychological evaluation could be covered if documentation were provided of the necessity for this service. The itemized charges for all the remaining services would be combined and allowed if the prevailing charge for a comprehensive visit or consultation." This was not an initial evaluation of this beneficiary's medical condition and could be considered a comprehensive new patient visit only because this was a new doctor to the beneficiary. I find nothing in the record to show the medical necessity for the psychological evaluation and again would reiterate the record indicates all of these services could have been provided at a more appropriate level and cost by the beneficiary's hometown internist.

Another feature of this appeal that is determinative for me in deciding there is no medical necessity as defined in the CHAMPUS Regulation is that the same series of tests were given to all participants in the program. Although the beneficiary makes an eloquent claim that because of his coronary artery disease the program was medically necessary, the fact is that he received the same tests that someone, to quote the language of the brochure in Exhibit 14, who is "aiming at detecting potentially self-destructive behavior in the unwary well in advance of overt disease problems." Because this is true I cannot find these services were "rendered in connection with and directly related to a covered diagnosis and/or definite set of symptoms."

In the correspondence the beneficiary had with the fiscal intermediary and later with OCHAMPUS, many of the specific exclusions of the Regulation were cited as the basis for their denial of the services. I can understand the beneficiary's confusion over this as several of them were first cited and then withdrawn. My decision rests primarily on the fact that the services provided to the beneficiary were not medically necessary and were above the appropriate

level of care because they were not related to any definite set of symptoms or medical condition and also were routinely performed (except for the stress management) by his local internist. I will briefly discuss each of the exclusions as I do not believe an extensive discussion is necessary. I will start with the nutritional counseling because it is clear under the Regulation (Chapter IV,4,G,40) that this counseling is specifically excluded as a benefit of the CHAMPUS program. realized that and in his final argument withdrew his claim for payment of the services for nutritional counselling. At one time the services were denied on the basis that SHAPE was a general exercise program and were provided as part of a medical grant or research program. I find these are not applicable to this claim, and the services would not fall under these exclusions. In the beneficiary's written final brief (Exhibit 41) he takes great exception to applying the experimental-investigational exclusion to the services which were provided to him. I agree with the beneficiary that this is a difficult issue for a layman to address. The statement of OCHAMPUS position relies on this exclusion and Dr. Rodriguez clearly believes the SHAPE program at the time of this hearing was not endorsed by major medical groups and could not be considered to be a "generally accepted standard of usual professional medical practice in the general medical community." Clearly the beneficiary's point is well taken; the treadmill test blood work, histories, physicals and psychological evaluations cannot be called experimental/investigational. What probably is still investigational is the idea that stress evaluation and management has been proven to be medically effective in the treatment of a specific disease or illness. Although Dr. Buell described this program as unique in the United States, he would certainly take the position that stress management in preventing illness and preventing deterioration of existing illness is no longer investigational. I do not feel that I can make this decision based on the material in the record, nor do I feel it is necessary to decide in the context of this hearing.

I do find that the services provided to the beneficiary fall within the preventive care exclusion of the Regulation. The beneficiary argues because he has coronary artery disease or artheriosclorosis which Dr. Buell testified was a chronic disease, that the services provided cannot be characterized preventive. I do not agree. I have discussed at some length above my finding that the services were not related to any specific set of symptoms or illness and were the same services provided to all people who came to participate in the program. In this sense they are a routine screening procedure. There is no evidence in the record to show they were specifically related to the beneficiary's illness even if he does have a chronic illness. The definition of preventive care describes it as medically indicated, but "essentially preventive procedures not directly related to an illness or definite set of symptoms." Dr. Buell's responding to the question as to whether the services provided were routine physical procedures hesitated and said, "No, I don't think so, because you have coronary artery disease." There is no question that the beneficiary has coronary artery disease, but the problem is that the services provided were not directly related to that disease, but were services provided to all participants.

I also find that the services provided to the beneficiary consisted in large part of education, training and self care/self help. Dr. Buell testified that all professionals strive for education and information to the people they are

serving and I agree with that. It is difficult to apply any one of these to this program because not any specific exclusion applies to all of the services, except the one of medical necessity and appropriate level of care. The self help exclusion is a good example of this because one could certainly argue it does not apply to the treadmill, history, physical, or blood work part of the program. Again, I would reiterate what I said above, and that is if this had been an initial evaluation or a consultation because of concern about symptoms, I probably would have found those to be covered services. I still would have a problem with the stress management and evaluation aspects of the SHAPE program unless there was some documentation that it was medically necessary. In the absence of that showing, the stress management counselling is in my opinion self help or educational aimed at assisting the beneficiary in what is commonly referred to as wellness "leading toward a better quality and perhaps quantity of life as well." (Exhibit 14).

PRECEDENT/ESTOPPEL

A great deal of evidence in this case and argument concerned another patient who had been seen by Dr. Elliot and as Dr. Buell testified, "had managed to acquire the same components over a period of time that the beneficiary had in one day and a half". A similar claim was submitted for this patient which was originally denied and after an exchange of letters, and case review and phone calls, the claim was paid. This patient will be referred to in this hearing as patient DOE. At the hearing I allowed evidence to come in regarding this case and reserved ruling on the relevancy of this patient's claim to the present hearing. Although at the hearing the beneficiary said he was not arguing misconduct on the part of CHAMPUS agents, his closing arguments appeared to me to do just that. He has emphasized the contact between high-up officers and the OCHAMPUS and the unfairness of the "pressure." My experience as a Hearing Officer shows this is not unusual. Most beneficiaries whose claims are denied feel unfairly treated and frequently write their Senator or have a high ranking officer attempt to intercede in their behalf. Many hearing files contain similar correspondence and I can certainly understand Dr. Elliot attempting to enlist a General's aid in order to change the CHAMPUS denial of reimbursement. If the beneficiary is raising the argument of estoppel or precedent against the government, I find there is no basis for that claim. There is nothing in the record to show there was detrimental reliance on the DOE claim; in fact, the record indicates it was only after his claim was denied that the beneficiary became aware of the DOE claim. In addition, his attempts to find out from the fiscal intermediary prior to receiving these services made it clear to him that it could not be determined ahead of time whether this claim would be paid or not and he received the services knowing that was the case.

Because the DOE claim was paid the beneficiary relies on Chapter I, P of the CHAMPUS Regulation requiring that benefits "should be adjudicated in a consistent, fair and equitable manner without regard to the rank or rate of the sponsor." It appears this program has been administered in a consistent manner from the record. Dr. Elliot wrote, "Over the past few weeks, we have received consistent denial of payment of services and diagnostic tests provided." (Exhibit 3, page 1). The record thus indicates that patient DOE was the only claim that has been paid and whether that was paid in error or whether the circumstances of that patient were medically different is not the subject of this hearing and cannot be decided by me in connection with my decision in

this hearing. Although the beneficiary devotes considerable time to linking the circumstances of patient DOE with his, the record shows considerable diffferences; age, diagnosis, prognosis, etc. Dr. Buell testified that Dr. Elliot was patient DOE's personal physician and followed his treatment even though patient DOE acquired the same components as were contained in the description of SHAPE, but over a period of time (November 24 through December 9, 1981 according to Exhibit 23). After a telephone conference with Drs. Buell and Elliot and the OCHAMPUS Medical Director, it was decided that the services provided to patient DOE were medically necessary for treatment of his essential systolic hypertension and would be allowed. The record indicates this was based on some of the concerns I have discussed in detail above and an evaluation of patient DOE in line with the policy case analysis in Exhibit 23. I cannot base my decision on the fact that it was possible this claim was paid in error and do as the beneficiary wishes: base payment for future claims on this one payment.

In a letter to me from the beneficiary (Exhibit 52), he stated: "I draw upon it (patient DOE case) as precedent and again point to Chapter I,P of the CHAMPUS Regulation and I charge that OCHAMPUS has the duty to follow it." I cannot agree with the position taken by the beneficiary. Because this hearing concerns the beneficiary and not patient DOE, I have no authority or jurisdiction, nor do I have enough information in spite of the considerable time that has been devoted to the patient DOE case to decide whether this claim was erroneously paid. Clearly, based on my findings above, I would certainly find the nutritional counselling to be in error, but be that as it may, this hearing does not involve whether or not the DOE claim was paid in error. The beneficiary's argument is that because there was some correspondence with high-ranking officers and the claim was paid, his claim should be paid. That does not seem to me to come within the language of the Regulation and I cannot base payment in this case on what may have been an erroneous payment in the previous case. To do so would perpetuate an error. I must examine the services provided to the beneficiary in connection with his particular medical condition and the circumstances under which he participated in this evaluation. That I have done, and I find that for this patient the services provided were not medically necessary within the CHAMPUS regulatory provisions and in addition were above the appropriate level of care. It must be clear from my discussion in this case that I am not finding that all services provided by the Department of Preventive and Stress Medicine at the University of Nebraska Medical Center are not a benefit of the CHAMPUS program, nor can I find that because services provided to one patient were paid, all services should be paid.

PAYMENT BY OTHER INSURANCE COMPANIES

Dr. Elliot wrote to the CHAMPUS fiscal intermediary that other companies were supporting his program and Mr. presented an argument that other companies were paying, although Dr. Buell maintained at the hearing he had no knowledge as to whether this program was being reimbursed by any other insurance companies. Whether or not other insurance insurance companies are paying for an evaluation through the SHAPE program is immaterial to my decision. CHAMPUS is not an insurance program, but is a benefits program and as such, is an "at risk" program. Beneficiaries receive services, submit a claim and a determination is made at that time as to whether a payment can be made under the Appropriations Act and the Regulation. This Law and Regulation

is the standard which must be used in deciding whether a claim will be paid and whether other third-party payors are covering the services is not relevant to whether a claim will be paid by CHAMPUS.

BURDEN OF EVIDENCE

A decision on a CHAMPUS claim on appeal must be based on evidence in the hearing file of record and under the CHAMPUS Regulation, the burden is on the appealing party to present whatever evidence he can to overcome the initial adverse decision (Chapter X, 16, i). Much reliance has been placed by the beneficiary in meeting this burden on the fact that the patient DOE claim was paid and that he had a chronic illness which made the services provided medically necessary. The beneficiary has objected to the reliance placed by OCHAMPUS on the statements made by Dr. Elliot in his final summary and evaluation. I think it is appropriate to rely on the notes written by the Director of this program contemporaneously with the services provided because it is probable that they reflect the current evaluation of the beneficiary at that time. I feel the same is true of the literature which was sent to the beneficiary and which is included in the hearing file because he used this information to make a self-referral essentially for this evaluation. It was also the material read and considered by the two doctors involved in his treatment when they said it sounded like a good program and he should go. I think that if Dr. Elliot had considered the beneficiary as his personal patient the record would have been clear on that point. There is not sufficient evidence in this case on which to base a reversal of the Formal Review Decision.

SUMMARY

In summary, it is the recommended decision of the Hearing Officer that the medical services provided the beneficiary on April 13, 1984 in the SHAPE program be denied CHAMPUS cost-sharing because the care was not medically necessary and was above the appropriate level of care. In addition, certain aspects of the care were excluded from cost-sharing under the provisions of DoD 6010.8-R, Chapter IV, G.

Hanna M Warren

HANNA M. WARREN
Hearing Officer