ASSISTANT SECRETARY OF DEFENSE

WASHINGTON, D.C. 20301

HEALTH AFFAIRS

6 JUN 1980

FINAL DECISION: Appeal
OASD(HA) Case File 11-79

The Hearing File of Record, the tape of the oral testimony presented at the administrative hearing, the Hearing Officer's RECOMMENDED DECISION (along with the Memorandum of Concurrence from the Director, OCHAMPUS) on OASD(HA) Appeal Case No. 11-79 have been reviewed. The amount in dispute in this case is $2,242.50. It was the Hearing Officer's recommendation that the CHAMPUS Contractor's initial determination to deny CHAMPUS benefits for Adrenal Cortex Extract and B Vitamin preparations administered during the period 2 August 1976 through 20 March 1979 be upheld. It was his finding that the use of these preparations in the treatment of Hypoadrenocorticism and Hypoglycemia was not generally accepted as being rendered in accordance with accepted medical standards. He further found that there was no evidence of a Vitamin B deficiency for which replacement therapy was required. The Principal Deputy Assistant Secretary of Defense (Health Affairs), acting as the authorized designee for the Assistant Secretary, concurs with this recommendation and accepts it as the FINAL DECISION.

PRIMARY ISSUE(S)

The primary issue(s) in dispute in this case is whether the parenteral administration of Adrenal Cortex Extract and Vitamin B preparations prescribed as part of a treatment plan for Psychophysiological Endocrine Reaction, Functional Hypoglycemia and Hypoadrenocorticism constituted medically necessary and appropriate medical care--i.e., whether the treatment is generally accepted as being part of good medical practice and in accordance with accepted professional medical standards in the United States. The disputed care was rendered over a twenty month period and both Army Regulation AR 40-121 and CHAMPUS Regulation DoD 6010.8-R are applicable.

Army Regulation AR 40-121, applicable through 31 May 1977, authorized the payment of medical benefits for "... any procedures and types of care [not otherwise excluded] ... which are generally accepted as being part of good medical practice..." (Reference: Army Regulation AR 40-121, Chapter 5, Section 5-2) CHAMPUS Regulation DoD 6010.8-R, applicable on and after 1 June 1977, defines "Appropriate Medical Care" as that medical care"... performed in the treatment of disease or injury ... [which] are in keeping with

the generally acceptable norm for medical practice in the United States." (Reference: CHAMPUS Regulation DoD 6010.8-R, CHAPTER II, Subsection B.14.) This same regulation further addresses the issue in dispute in the description of the Program's exclusions and limitations, listing as an exclusion"...services and supplies not provided in accordance with accepted professional medical standards ..." (Reference: CHAMPUS Regulation DoD 6010.8-R, CHAPTER IV, Subsection G.16.)

Other issues involve the confirmation of the diagnoses presented in this case--i.e., whether the disputed care was medically necessary. Army Regulation AR 40-121 defines "necessary" services as "... those services ... ordered by a provider of care as essential for the [medical] care of the patient or treatment of the patient's medical or surgical condition." [emphasis added] (Reference: Army Regulation AR 40-121, Chapter 1, Section 1-3c.) CHAMPUS Regulation DoD 6010.8-R defines "Medically Necessary" as "...the level of service and supplies (i.e., frequency, extent and kinds) adequate for the diagnosis and treatment of illness or injury ... Medically necessary includes the concept of approprate medical care." Again, the issue is also addressed in the exclusion section, stating, "[Excluded are] Services and supplies which are not medically necessary for the diagnosis and/or treatment of a covered illness or injury." (Reference: CHAMPUS Regulation DoD 6010.8-R, CHAPTER II, Subsection B.103. and CHAPTER IV, Subsection G.1.)

The appealing party, the attending physician, a friend and a state Senator interested in this case, submitted statements detailing the factors, which in their view, supported the position that parenteral administration of Adrenal Cortex Extract and Vitamin B preparation was an appropriate, necessary and useful therapy for Psychophysiological Endocrine Reaction, Hypoadrenocorticism and Functional Hypoglycemia. Nonetheless, it is the finding of the Principal Deputy Assistant Secretary of Defense (Health Affairs) that the Hearing Officer's conclusion was a proper one based on the evidence presented and that his rationale and findings were correct.

In order to ensure that the appealing party fully understands the bases upon which the initial denial is being reaffirmed and upheld, each of the points presented by the appealing party, or on her behalf, is addressed in this FINAL DECISION.

1. Presence of Multiple Diagnoses. The attending physician claimed the appealing party suffered from Psychophysiological Endocrine Reaction, Hypoadrenocorticism, Functional Hypoycemia and Vitamin B Deficiency. He also indicated food allergies were suspected.

- Psychophysiological Endocrine Reaction. The diagnosis of Psychophysiological Endocrine Reaction did not appear in the attending physician's clinical notes submitted for the Hearing File of Record but it was referred to in written statements and on the claim forms he submitted to CHAMPUS. It is a vague, non-specific diagnosis and from a professional point of view, generally unacceptable. It is assumed it was intended to indicate the presence of an endocrine imbalance (of an unknown nature) which was caused by mental/emotional factors rather than a pathological one. However, no clinical evidence was submitted which verified the presence of an endocrine imbalance. The records indicate the patient was receiving Premarin (her age at the time the disputed treatment commenced was 53), but it cannot be ascertained from the Hearing File of Record whether the attending physician in this case initiated this hormonal therapy or simply continued it. However, at no time does the physician or the appealing party relate a menopausal syndrome to the claimed endrocrine imbalance. In any event, since Psychophysiological Endocrine Reaction is not a definitive nor professionally acceptable diagnosis, it cannot be considered in establishing the medical necessity for the treatment in dispute. (Reference: Army Regulation AR 40-121, Chapter 1, Section 1-3c; and CHAMPUS Regulation DoD 6010.8-R, CHAPTER II, Subsection B.103, and CHAPTER IV, Subsection G.1.)

- Hypoadrenocortism. The attending physician also listed Hypoadrenocortism as a diagnosis and claimed that the Adrenal Cortex Extract was administered in treatment of this condition (and for Hypoglycemia). Again, this diagnosis did not appear in the physician's clinical notes submitted for the Hearing File of Record, but was referred to in written statements and on the claim form. This diagnosis indicates adrenal insufficiency which is the inability of the adrenal gland to respond to certain body needs, especially in times of stress. No documentation of diagnositic studies confirming the existance of this condition was presented. According to professional authorities, Hypoadrenocortism can be diagnosed by sophisticated measurements of adrenal hormones in blood and urine. Failure of the adrenal glands to respond to the administration of ACTH can also indicate a state of adrenal insufficiency. There is no evidence in the Hearing File of Record that these testing procedures were prescribed, ordered or performed on the appealing party either by the attending

physician in the case, or previously at the group practice plan facility (another health plan in which the appealing party was enrolled through her husband's employment). Since there is no clinical evidence establishing that Hypoadrenocorticism actually existed in this patient, any treatment for such a condition must therefore be concluded to be medically unecessary. (Reference: Army Regulation AR 40-121, Chapter 1, Section 1-3c.; CHAMPUS Regulation DoD 6010.8-R, CHAPTER II, Subsection B.103, and CHAPTER IV, Subsection G.1.)

o Functional Hypoglycemia. The attending physician also stated the appealing party suffered from Functional Hypoglycemia. (This is the primary diagnosis listed in the physician's clinical notes as well as in statements and on the claim forms.) Hypoglycemia indicates an abnormally diminished glucose content in the blood. It is a condition which is very difficult to accurately diagnose since the symptoms associated with it may be similar to other conditions, including menopause. Symptoms can be tremulousness, sweats, piloerection, hypothermia and headache, as well as confusion, hallucinations and bizarre behavior. Specifying that the Hypoglycemia is functional in nature indicates the attending physician found no underlying organic cause. The attending physician (and another physician who identified himself as the President of the American Academy of Medical Preventics) claimed the one Glucose Tolerance Test that was performed conclusively established the existance of Hypoglycemia in the appealing party. (This Glucose Tolerance Test was not ordered by the attending physician; it was done at the group practice plan facility prior to beginning the care under dispute.) These same test results were reviewed by the reviewing physicians associated with the Medical Care Foundation, which conducts peer review for OCHAMPUS. It was their opinion that the general medical community would not conclude that the results of the one Glucose Tolerance Test clinically confirmed the existance of the Hypoglycemia. Again, inasmuch as the weight of professional evidence does not support a finding that Hypoglycemia was definitively diagnosed, any treatment rendered in connection with such diagnosis must therefore be considered medically unnecessary. (Reference. Army Regulation AR 40-121, Chapter I, Section 1-3c.; CHAMPUS Regulation DoD 6010.8-R, CHAPTER II, Subsection B-103, and CHAPTER IV, Subsections G.1)

- Vitamin B Deficiency. It was also claimed that the appealing party had a deficiency of Vitamin B and a replacement program of injections of Vitamin B preparations was initiated. Again, this diagnosis appeared on at least one claim form submitted to CHAMPUS but is not discussed in the attending physician's clinical notes. The records indicate that a analysis of the Serum B12 was performed at the group practice plan facility during March 1976 (approximately three months prior to initiation of the replacement therapy) and that the results at that time were within normal limits. As a matter of fact, those test results indicated that the Serum B12 was in the upper range of the normal limit. No reports of subsequent testing were presented as evidence to the Hearing File of Record which indicated any finding to the contrary. Therefore, again, since a Vitamin B12 deficiency was not clinically established and no other condition for which B12 therapy is appropriate was reported, the use of B-12 and B complex injections would not constitute necessary medical care. (Reference: Army Regulation AR 40-121, Chapter 1, Section 1-3c; CHAMPUS Regulation DoD 6010.8-R, CHAPTER II, Subsection B.103. and CHAPTER IV, Subsection G.1.)

- Possible Allergies. The attending physician also indicated a diagnosis of "possible allergies." However, no details were presented concerning associated symptoms or their severity. In June 1977, approximately ten months after the appealing party commenced the treatment in question, a type of test known as Serum Allergy Testing was performed for food allergies. (Serum Allergy Testing is also not generally accepted in the medical community--it is considered "investigational.") The results of those tests indicated positive reactions to several foods--i.e., pork, coffee, oats, tea, lettuce, potato, string beans and sugar beets. The clinical information indicates the appealing party was advised to avoid certain foods to which she apparently had some reaction. However, no specific therapy was introduced to control allergies other than diet. Therefore, while there is some evidence that allergies might have been present, because the disputed treatment was not directly related to the allergies, this finding has no impact on the Program's decision that the disputed care was medically unnecessary.

- Mental Disorder. Throughout the Hearing File of Record there are anecdotal references which indicate the presence of a mental disorder. In addition to the treatment in dispute, the appealing party received

psychotherapy from the attending physician in this case, for which CHAMPUS benefits were extended. The records also indicate the appealing party had been in group therapy for some time. She described depression as one of her symptoms and the attending physician's notes indicated difficulty in handling stress. It is not an unreasonable conclusion that the appealing party's described symptoms could have been caused and/or exacerbated by depression. However, no specific diagnosis or clinical information concerning her mental condition was submitted to the Hearing File of Record. Therefore, in the absence of adequate documentation relative to the psychiatric aspect of this case, the fact that the appealing party may have been experiencing mental problems cannot be considered in reaching a decision as to the medical necessity of the treatment in question.

o Extent of Diagnostic Testing. It was the position of the attending physician that the diagnoses in this case were properly established. However, we find he ordered almost no diagnostic testing procedures. Except for two minor exceptions, the diagnostic testing that was done, was done at the group practice facility where the appealing party had sought care prior to commencing the treatment in dispute. While the attending physician may have had access to the results of these tests, there is little evidence they were given any substantial consideration. And relying on a single 5-hour Glucose Tolerance Test to diagnose Hypoglycemia and render related treatment for almost two years must be considered professionally inadequate, even if the initial test findings had been significant--which in this case they were not. The results of the Serum B-12 analysis which showed no deficiency were apparently ignored. The attending physician did order Serum Allergy Testing for food which confirmed the presence of some food reactions but there was no indication that these tests had any relationship to the treatment in dispute. The attending physician also ordered several chemical analyses of hair samples, but this test is not useful in establishing the existence of Hypoglycemia or Hypoadrenocorticism. These tests indicated the appealing party's mineral balance was within normal limits except for calcuim which was reported higher than usual. The hair analysis procedure is not generally performed unless there is significant indication of mineral imbalance due to heavy metal ingestion--and there was no such indication in this case. A review of the record indicates there was no clinical documentation presented to support the diagnoses presented. It must be concluded therefore that since

the presence of the diagnoses is not supported, any related treatment cannot be considered medically unnecessary regardless of the type. (Reference: Army Regulation AR 40-121, CHAPTER 1, Section 13c; CHAMPUS Regulation DoD 6010.8-R CHAPTER II, Subsection, B.103.)

- o Medical Necessity. Despite claims to the contrary, the evidence in the Hearing File of Record and the oral testimony presented at the hearing, do not support a finding that the diagnoses (except possibly for allergies) were clinically established. And further, with the exception of advice concerning diet, the various treatments rendered did not appear to relate to the stated symptomatology. Therefore, it is the position of the Principal Deputy Assistant Secretary of Defense (Health Affairs) that in the absence of clinically supported diagnoses and no apparent relationship to symptoms, the disputed treatment could not be considered essential--i.e., it was not medically necessary. (Reference: Army Regulation AR 40-121, Chapter 1, Section 1-3c; CHAMPUS Regulation DoD 6010.8-R, CHAPTER II, Subsection and B.103. and CHAPTER IV, Subsection G.1.)

2. Treatment Modalities. It was maintained by the appealing party, and supported by her attending physician, that she required the parenteral administration of Adrenal Cortex Extract and Vitamin B preparations to control the symptoms associated with Hypadrenocorticism, Funtional Hypoglycemia and Psychophysiological Endocrine Reaction plus Vitamin B deficiency. These symptoms were said to include sweating, weakness, faintness, blurred vision and a general loss of energy to the point where the patient spent a great deal of time at bed rest. Food allergies were also suspected. The physician's plan of treatment was initiated in August 1976 and continued through March 1979 and included intravenous and intramuscular injections of Adrenal Cortex Extract, intramuscular injections of Vitamin B complex and Vitamins A, C, D and E, Pantothinic Acid, Magnesium, Calcium, Choline, Inosital, B-15, Zinc, Niacinimide and digestive enzymes. A high protein, low carbohydrate diet was also prescribed. Other medications including Premarin (a hormone, generally used for Menopausal Syndrome), Thyroid, Inderal (generally used for high blood pressure), Valium (a tranquilizer), Meprobamate (also a type of tranquilizer), and eye drops, were also periodically ordered. Essentially the same plan of treatment was continued through the twenty month period

except that the frequency of parental medications was reduced from almost daily at the beginning to approximately weekly in the second year of therapy.

- Adrenal Cortex Extract. The attending phyician and the President of the American Academy of Medical Preventics, a proponent organization for the type of treatment in dispute, claimed that Adrenal Cortex Extract was effective treatment for Hypoadrenocortism and Functional Hypoglycemia. Even if these diagnoses had been clinically established, it is the CHAMPUS position first, that Adrenal Cortex Extract has been found to be of no medical use in the treatment of adrenal insufficiency; and second, that Adrenal Cortex Extract is not an appropriate treatment for any cause of Hypoglycemia. This position is based on the generally accepted views of the medical profession in the United States as substantiated by a 1973 joint statement issued by physicians and scientists associated with the American Diabetis Association, the Endocrine Society and the American Medical Association. No evidence was presented by the appealing party or her attending physician that contradicted these conclusions, nor was information provided that would indicate more current research data is available. Nothwithstanding the support for this therapy expressed by the president of an organization encouraging the use of Adrenal Cortex Extract, the overwhelming weight of professional opinion supports the position that the use of Adrenal Cortex Extract is not considered useful nor appropriate--i.e., it is not in keeping with the norms of medical practice in the United States. (Reference: Army Regulation AR 40-121, Chapter 5, Section 5-2; CHAMPUS Regulation DoD 6010.8-R, CHAPTER II, Subsections, B. 14 and CHAPTER IV, Subsection G.16.)

- Administration of B Vitamin Preparations. The appealing party, supported by written statements from her attending physician, maintained that parental administration of Vitamin B preparations was required to treat the Functional Hypoglycemia, Hypoadrenocortism Psychophysiological Endocrine Reaction and B vitamin deficiency. Again, even if these diagnoses had been clinically established, there was no evidence presented to substantiate the claim that B Vitamin therapy was effective for these conditions. It is the extant opinion of the general medical professional that B Vitamins do not constitute a generally accepted treatment except for B-12 administered in connection with certain Anemias,

certain Gastrointestinal Malabsorption Disorders and certain Neuropathies. No evidence was submitted to indicate any of these conditions was present in the appealing party. However, this discussion is essentially moot since CHAMPUS specifically excludes vitamins (the one exception being B12 administered for the specified certain conditions). Since no contraindicating evidence or information was submitted relative to the efficiency of B Vitamins for Functional Hypoglycemia, Hypoadrenocortism and Psychophysiological Endrocrine Reaction, the initial conclusion that the B Vitamins represented ineffective and inappropriate care continues to be the Program's position. (Reference: Army Regulation AR 40-121, Chapter 5, Section 5-2, CHAMPUS Regulation DoD 6010.8-R CHAPTER II, Subsections, B 14., and CHAPTER IV, Subsection G.16 and G. 63.)

- Megavitamin Therapy: Mineral Supplements. The appealing party described her therapy as "Megavitamin" therapy. The physician's clinical notes in the Hearing File of Record do indicate extensive vitamin and mineral preparations were prescribed but there was no comment or description by the attending physican specifying Megavitamin Therapy or that it was a part of the plan of treatment (nor was Megavitamin therapy listed on the claims that were submitted). There was no indication as to why, or for what symptoms, the vitamin and minerals were being prescribed. Anecdotal information indicated the presence of a mental disorder for which the appealing party was evaluated and for which psychotherapy was prescribed. The Megavitamin Therapy may have been related to the mental disorder. Since no clinical information was submitted concerning the mental problem or its treatment, this cannot be verified. However, again this is a moot point. First, the use of oral vitamin therapy is not an issue and second, vitamins and mineral supplements are generally excluded under CHAMPUS. (And because oral vitamin preparations do not require a prescription, they do not qualify as a prescription drug.) Further, Megavitamin Therapy for psychiatric disorders is specifically excluded under CHAMPUS. (Reference: Army Regulation AR 40-121, Chapter 1, Section 5-2 and 5-8d(3); CHAMPUS Regulation DoD 6010.8-R CHAPTER II, Subsections B. 14., and B.103, and CHAPTER IV, Section D., Paragraph 3.f. and Subsections G.1., G.16, G.63 and G.72)

- Diet. The clinical information contained in the Hearing File of Record indicates the attending physician counseled and recommended concerning the appealing party's diet.

Although complete details concerning the recommended diet were not presented, it appears from comments in the clinical notes that the appealing party was advised to follow a high protein, low carbohydrate diet. There was also some evidence that the attending physician recommended avoidance of at least some of the foods to which a positive allergic reaction had been obtained. While treatment of Hypoglycemia is usually dietary, more would have to be known about the specifics of the prescribed diet to determine whether it was appropriate for Hypoglycemia. However, the question is essentially moot since the dietary advise was only incidental to the overall treatment plan. That diet advice was given does not impact on the decision that the treatment regimen which consisted primarily of parental administration of Adrenal Cortex Extract and B Vitamins is considered to be ineffective and inappropriate. (Reference: Army Regulation AR 40-121, Chapter 5, Section 5-2; CHAMPUS Regulation DoD 6010.8-R CHAPTER II, Subsections, B 14. and CHAPTER IV, Subsection G.16.).

- Only Alternative Therapy: Use of Cortisone. The appealing party insisted the only other treatment available to her was Cortisone and that she refused to undergo such therapy. (It is assumed the appealing party was referring to Cortisone as an alternative to Adrenal Cortex Extract for her claimed adrenal insufficiency.) Her stated reason was that as a child, she had eye problems and Cortisone was therefore contraindicated. She further implied that since she refused Cortisone, benefits should be extended for the treatment in dispute as her treatment of choice. This position is not acceptable. First, since her adrenal insufficiency had not been clinically established, it cannot be ascertained what type of treatment, if any, was indicated. Second, even if Hypadrenocortism had been clinically diagnosed, since there is no documentation concerning the childhood eye problem nor any medical opinion that the Cortisone would have presented an undue risk, this argument is a personal one only and has no standing. And finally, even if Cortisone had been found to be the treatment of choice but its use was contraindicated because of potential adverse opthalmic effects, it still would not affect the central issue in this case. The fact that another treatment might be contraindicated does not impact the CHAMPUS position that the treatment that was actually obtained

by the appealing party was inappropriate and not in keeping with the norms for medical practice in the United States. (Reference: Army Regulation AR 40-121, Chapter 5, Section 5-2 and CHAMPUS Regulation DoD 6010.8-R CHAPTER II, Subsection, B.14. and CHAPTER IV, Subsection G.16.).

o Appropriateness of Care: Weight of Evidence. Although the appealing party and her attending physician strongly endorsed the use of Andrenal Cortex Extract and administration of B Vitamin compounds, there is no professional support for this treatment regimen in the general medical community. The Medical Policy Committee of the CHAMPUS Fiscal Intermediary had determined this type of treatment to be ineffective and inappropriate (unrelated to CHAMPUS). The appealing party recorded that when she attempted to obtain the Adrenal Cortex Extract injections from her group practice plan and a Military medical facility, both had refused--again, on the basis it was ineffective and not in keeping with their standards of medical practice. (She noted she was also advised by both that the primary treatment for Hypoglycemia was diet.) The Medical Care Foundation that reviewed the case for CHAMPUS advised that the questioned treatment is not regarded as acceptable medical practice. Physicians and scientists associated with the American Diabetis Association, the Endocrine Society and the American Medical Association in a joint special report stated it was their conclusion that Adrenal Cortex Extract was not of any known medical use, not even in the treatment of Adlenal insufficiency and that this drug is not an appropriate treatment for any cause of Hypoglycemia. Except for the attending physician, the only professional opinion supporting use of the treatment came from the president of a proponent organization dedicated to encouraging the use of Adrenal Cortex Extract, Megavitamin Therapy and other therapies not currently accepted by the general medical community in the United States. The personal opinions contained in statements of the appealing party's neighbors and a state senator were of anecdotal interest, but provided no evidence that can be considered in this case. It is therefore the finding of the Assistant Secretary of Defense (Health Affairs) that despite the appealing party's claim to the contrary, the weight of professional opinion is overwhelmingly in support of the position that the treatment regimen in question is ineffective, inappropriate, and not in keeping with the norms extant in medical practice in the United

States today. (Reference: Army Regulation AR 40-121, Chapter 5, Section 5-2; CHAMPUS Regulation DoD 6010.8-R CHAPTER II, Subsection B.14 and CHAPTER IV, Subsection G.16.)

SECONDARY ISSUES

The appealing party, while strongly supporting the treatment regimen she received, did not direct her primary focus to the substantive issues. Instead she raised several secondary issues which she asserted supported special consideration for CHAMPUS to extend benefits in this case.

1. Unorthodox Treatment: Patient's Right of Choice. First it was claimed by the appealing party that she had a right to choose her treatment even if it was considered to be unorthodox. She further asserted that denial of benefits by CHAMPUS constituted an abridgement of her constitutional rights. This argument is not persuasive. CHAMPUS does not infringe upon the appealing party's right to freely select the practitioner and/or treatment of her choice (assuming the practitioner is acting within the scope of a valid license and the treatment can be legally rendered). The appealing party is herself proof that CHAMPUS does not interfere with this right--she did seek out and receive the treatment of her choice. In administering CHAMPUS, the Department of Defense has the same obligation as those offering direct medical care (as represented in this case by the appealing party's group practice plan and a military medical facility)--i.e., to see that it does not encourage or support treatment modalities that are considered ineffective, unproven, unsafe, and/or not generally recognized as being in accordance with accepted professional medical standards in the United States. That an individual may wish to seek out unorthodox treatment is a personal decision and the appealing party was perfectly within her right to pursue such treatment. However, when an individual makes such a choice they must do so with the understanding that it will also involve personal financing. A public program such as CHAMPUS has a broader obligation--i.e., an overall responsibility to its beneficiaries--which includes providing the maximum protection possible from the standpoint of both professional and fiscal accountability. Permitting its funds to be used to pay for care that is, at best, ineffective or inappropriate, and thus possibly encouraging its proliferation, would not be in the best interest of the beneficiary community the Program serves. However, regardless of the matter at issue in this appeal, it is the Government's

position that because a specific service, supply, or treatment modality is excluded from CHAMPUS does not translate into an infringement of a beneficiary's freedom of choice. The right of freedom of choice is separate and distinct, and in no way related to the benefit elements that may or may not be included in a third party program.

2. Success of Treatment Plan. The appealing party, her attending physician, a friend and a state Senator, all generally endorsed the treatment plan in question as highly successful. The appealing party claimed that administration of the adrenal cortex extract and B vitamin resulted in increased daily activity, better functioning and a decrease in symptoms. First, there was no clinical evidence submitted that substantiated the degree of symptoms and/or disfunction being experienced by the appealing party at the time the Adrenal Cortex Extract and B Vitamin therapy was initiated. Nor was there any scientific or clinical evidence submitted that would substantiate increased adrenocortical function, increased glucose tolerance, decreased glucose intolerance, elimination or improvement of an endocrine imbalance or that any vitamin or mineral imbalance had improved. Further, the somewhat limited clinical notes provided by the attending physician indicated the same symptoms persisted throughout the period of treatment. If the intensity of any symptomatology was, in fact, reduced, this could have been due to adherence to a dietary regimen. Or any improvement could have been the result of psychotherapy (in the likely event her mental problems contributed to her symptoms). Or the continued use of Premarim and the tranquilizers may have overcome symptoms associated with a menopausal syndrome. In view of the multiple therapies included in the regimen, it would be difficult to conclude that any one rendered a specific benefit. However, whether or not the treatment in question was or was not successful is moot. Payment of CHAMPUS benefits is not limited to only these situations when a treatment is successful or a cure is effected. In fact, success of treatment is not a consideration in terms of an individual case. Benefits are predicated on an overall "effectiveness" basis--i.e., that a treatment modability is considered effective and appropriate by the general medical community. It was the Program's determination that the treatment at issue in this appeal did not meet these criteria.

3. CHAMPUS: Not a Contact of Insurance. The appealing party maintained that as an insurance program CHAMPUS benefits should be extended on the basis that the treatment (at least

in her judgement) was beneficial. First, while CHAMPUS benefits are structured similarly to those of private health insurance plans, CHAMPUS is not a contract of insurance. Its beneficiaries pay no premiums nor is the Program subject to control of state insurance commissions or insurance contract law. CHAMPUS is a Federal program of medical benefits enacted into law in 1966. The provisions of that law, (CHAPTER 55, Title 10, United States Code) and its regulations promulgated under authority granted by that law, are controlling. The CHAMPUS regulations specifically require that benefits be provided only for those services and supplies which are determined to be medically necessary and appropriate. As stated previously, the CHAMPUS position in this matter does not preclude the appealing party from obtaining whatever care she personally desires. It simply limits the availability of CHAMPUS benefits when such care is determined to be not in accordance with the generally accepted medical practice in the United States.

4. Court Decision. A document was submitted by the appealing party indicating that the Court of the City of New York had ruled in favor of a plaintiff who sought reimbursement for expenses associated with cancer treatment, in particular drugs which were not approved for use in the United States. The decision implies further that a patient has the right to rely on the physician's decision as to what types of treatment are necessary. First, the circumstances and details of the case in litigation are not similar--the court case involved a terminal illness and treatment outside the United States. Second, the patient certainly has the right to rely on his/her physician as a matter of personal choice, but this does not bind CHAMPUS to extend benefits. The current CHAMPUS regulation states, "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." (Reference: CHAMPUS Regulation DoD 6010.8-R, CHAPTER IV, "NOTE" at end of Section G.) However, the matter of the court decision is moot. As properly recognized and stated by the Hearing Office in his RECOMMENDED DECISION, "This is a decision by a municipal court in a contract matter and is neither controlling nor persuasive in this [a CHAMPUS] matter."

SUMMARY

This FINAL DECISION is not meant to imply that the appealing party did not experience symptoms or may not have required treatment. It does confirm the Program's position that the

diagnoses of Psychophysiological Endocrine Reaction, Functional Hypoglycemia, Adrenocortism and Vitamin deficiency were not clinically established. Therefore any treatment related to those diagnoses must be considered medically unnecessary. It further confirms that even if the diagnoses had been clinically established, the parental administration of Adrenal Cortex Extract and B Vitamins represents ineffective and inappropriate care--i.e., care not provided in accordance with accepted professional standards in the United States.

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Our review indicates the appealing party has been afforded full due process in her appeal. Issuance of this FINAL DECISION is the concluding step in the CHAMPUS appeals process. No further administrative appeal is available.

Vernon McKenzie
Principal Deputy Assistant Secretary
of Defense (Health Affairs)