ASSISTANT SECRETARY OF DEFENSE

WASHINGTON, D.C. 20301

19 MAR 1981

\LTH AFFAIRS

FINAL DECISION Appeal

Appealing Party

OASD(HA) Case File 21-79

The Hearing File of Record, the tape of the oral testimony presented at the hearing, the Hearing Officer's RECOMMENDED DECISION and the Memorandum of Nonconcurrence from the Director, OCHAMPUS, on OASD(HA) Appeal Case No. 21-79 have been reviewed. The amount in dispute is $2,525.06. (It is noted, however, that the outcome of this appeal also affects an additional amount of $3,789.52 that was paid for services related to the same surgical episode.) It was the Hearing Officer's recommendation that the Contractor's initial determination to deny CHAMPUS benefits for the surgical implantation of a Cerebellar Stimulator and the related anesthesia services performed as a treatment for Cerebral Palsy should be reversed. It was his finding that the surgery was medically necessary for the treatment of the illness and that the procedure was not "experimental" as described in the CHAMPUS Regulation, DoD 6010.8-R.

After due consideration and careful review of the evidence presented, the Principal Deputy Secretary of Defense (Health Affairs) acting as the designee for the Assistant Secretary, does not accept the RECOMMENDED DECISION. It is OASD(HA)'s finding that the Hearing Officer did not reflect proper evaluation of evidence or reasonable interpretation of the applicable regulation, and that the evidence he did cite was totally irrelevent to the substantive matters at issue.

This FINAL DECISION is, therefore, based on the facts contained in the Hearing File of Record and as presented in oral testimony and although this FINAL DECISION also reverses the initial denial, it is not on the basis of the primary (substantive) issue in the case--i.e., whether the disputed surgical procedure is experimental. (The decision, in fact, confirms that the initial denial of CHAMPUS benefits for services/supplies related to the surgical implantation of a Cerebellar Stimulator on the basis it is experimental was correct.) Rather, the reversal of the initial denial is based on a related technical issue.

PRIMARY ISSUE(S) IN DISPUTE

The primary issue in dispute in this case is whether the surgical implantation of a Cerebellar Stimulator and the related anesthesia services rendered as a treatment for Cerebral Palsy constituted care than can be considered as being provided in accordance with accepted professional medical standards or whether it is still investigational (i.e., experimental). Another issue is whether the device itself is still at the investigational stage of development, particularly with respect to this procedure, and whether it had received full marketing approval from the responsible Federal agency.

The applicable regulation in effect at the time the disputed services were rendered defined "Experimental" [in part] as "... medical care that is essentially investigatory or an unproven procedure or treatment regimen ... does not meet the generally accepted standards of usual professional medical practice in the general medical community..." (Reference: CHAMPUS Regulation DoD 6010.8-R, CHAPTER II, Subsection B.67.) The regulation further speaks to experimental services and supplies under the section describing exclusions and limitations, stating "... [excluded are] services and supplies not provided in accordance with accepted professional medical standards; or related to essentially experimental procedures or treatment regimens." (Reference: CHAMPUS Regulation, DoD 6010.8-R, CHAPTER IV, Subsection G.16.)

The issue related to anesthesia service is addressed in the definitions section of the Regulation which states [in part], "Anesthesia services means the administration of an anesthetic agent...in connection with otherwise covered surgery..." [emphasis added] (Reference: CHAMPUS Regulation DoD 6010.8-R, Chapter II, Subsection B.12.) And again in the section on exclusions and limitation, the regulation states, "...[excluded are] services and supplies (including inpatient institutional costs) related to a non-covered condition or treatment..." (Reference: CHAMPUS Regulation DoD 6010.8-R, Chapter IV, Subsection G.69.)

The appealing party and the attending physician submitted statements and/or testimony which, in their view, supported the position that the surgical implantation of the Cerebellar Stimulator device was a recognized, accepted treatment for Cerebral Palsy and was medically necessary. The appealing party also maintained that, in fact, the care was sponsored and recommended by the physicians at the Military Regional Medical Center where he and his family had been receiving their primary medical care. He further asserted that related anesthesia

services should be covered independently of the surgical procedure, whether or not the related surgery was deemed to be experimental. Nonetheless, it is the finding of the Principal Deputy Secretary of Defense (Health Affairs) that the facts presented in this case do not support the appealing party's position.

In order to assure that the appealing party and all others concerned fully understand the bases upon which the initial denial is being reaffirmed as correct, each of the points is addressed in this FINAL DECISION.

1. Presence of Cerebral Palsy: Treatment Medically Necessary. The appealing party strongly asserted that his dependent daughter suffered from Cerebral Palsy and that the surgery in question was medically necessary. The Hearing File of Record clearly establishes the presence of Cerebral Palsy, that her condition was related to her premature birth, low birth weight and the possibility of neonatal injury or anoxia. Her motor function was delayed and at an early age spasticity of right upper extremity and lower extremities was noted. Her intellectual capacity was not impaired, however. Previous surgical procedures to correct squinting of the eyes, scissoring of the legs and contraction of the feet were performed. In July 1977 when the disputed surgery was performed, the patient was fifteen years of age and confined to a wheel chair, with only the left upper extremity having any substantial function. The right arm was severely spastic as were both the lower extremities. On the basis of an article which appeared in a popular (non-scientific) magazine, the appealing party sought out the surgery in anticipation that implantation of the Cerebellar Stimulator would improve function by reducing spasticity and his daughter was accepted as a candidate for the surgery. The procedure was not intended to treat the Cerebral Palsy condition itself, only to reduce the spasticity of the muscles associated with the disorder. That the child suffered from Cerebral Palsy with associated severe spastricity was never at issue. Nor was the basis of the CHAMPUS denial related to whether or not it was medically necessary to reduce the spasticity--that obviously was a worthwhile goal. Rather, denial was based on the finding that the surgical procedure itself is experimental--i.e., it is still investigational, unproven as to safety and efficacy. (Reference: CHAMPUS Regulation DoD 6010.8-R, CHAPTER II, Subsection B.67.; Chapter IV, subsection G.16.)

2. General Acceptance of Surgical Procedure in Professional Community: Weight of Evidence. Although the appealing party and the attending physician strongly endorsed the surgical implantation of the Cerebellar Stimulator to control the spasticity associated with Cerebral Palsy, and asserting that it was not experimental, the weight of professional opinion is strongly to the contrary. The Hearing File of Record establishes that those professional groups and Federal agencies having special expertise and/or responsibility for public policy in this area were unanimious in their opinions that the surgical procedure in dispute was still generally investigational and unproven, despite the espousal by certain individual proponent physicians.

- o American Association of Neurological Surgeons. Statements received from the President of this Association confirmed that the procedure (and the device) were at the investigational stage of development and that a conclusion regarding safety and efficacy had not yet been drawn. The neurological specialists did not consider the procedure as standard within their specialty.

- o Department of Health and Human Services (DH&HS). This Federal agency (formerly Dept of Health, Education and Welfare) reported that The National Institutes of Health and The Food and Drug Administration did not currently support the use of Cerebellar Stimulators as being safe and effective in the treatment of spasticity or movement disorders. These agencies did not indicate that the procedure or the device were generally accepted by the medical community or that development was beyond the investigational stage.

- o Health Care Financing Administration (HCFA): Medicare. It was confirmed that Medicare, currently the largest Federal medical benefits program, considers the Cerebellar Stimulator implantation an investigational procedure. Benefits are not provided for this procedure under that Program on the basis that the Social Security Act prohibits expenditures of Medicare funds for experimental services.

- o Subcommittee of Neuroaugmentation Devices of the Joint Materials and Devices Committee. The chairman of this committee reported that implantation of Cerebellar Stimulator devices had not been

proven to be effective and that the committee did not recommend that it be included as a standard procedure in neurological surgery.

The professional association of neurologists and neurosurgeons, as well as the National Institute of Health,[1/] the Department of Health, Education and Welfare, the Food and Drug Administration and the Health Care Financing Administration were in agreement that conclusive evidence as to the safety and efficacy of Cerebellar Stimulator implantation has not yet been presented. Statements submitted by individual physicians in support of the procedure (and the device) generally reported only the results of their personal experiences with the procedure rather than scientificly controlled studies. Evidence of general acceptance within the medical community was not claimed or substantiated. As is evident from this case, CHAMPUS does not unilaterally decide whether a surgical procedure or treatment regimen falls within the definition of "experimental"--rather, there is extensive research and consultation. In reaching its conclusion on the specific surgery and device at issue in this case it is the CHAMPUS position that the support for the procedure coming from physician advocates cannot carry the same weight or credibility as the professional opinions expressed by the leadership of the neurological specialists' professional association or the Federal agencies charged with

---

1/ To assure that there has been no change in the status of this procedure since the time of the Hearing, the National Institutes of Health was contacted immediately preceding the issuance of this FINAL DECISION. It was again confirmed that while there are those individual physicians who espouse the procedure and there is some anecdotal indication that the implantation procedure may be helpful, it is still considered investigational --i.e., it is still unproven as to efficiency and safety. The scientific community has initiated controlled studies, but it will be at least another three years before sufficient scientific data will be available on which to base any conclusions. It is repeatedly pointed out by the scientific community that because this procedure (if eventually accepted) can be expected to be performed to a great extent on children and young adults, safety, particularly in relation to long term use, is of paramount importance.

the responsibility of determining the efficacy and safety of medical procedures and devices. (Reference: CHAMPUS Regulation, DoD 6010.8-R Chapter IV, Subsection G.16.)

3. The Device. The status of the Cerebellar Stimular as a medical device is also at issue. The Cerebellar Stimulator was developed for implantation in brain tissue. As such its use and distribution is controlled under the Medical Devices Amendment enacted by Congress in 1976. The law awarded the responsibility of establishing the safety and efficacy of medical devices to the Food, Drug and Cosmetic Administration. This agency confirmed that as of January 1979 the Cerebellar Stimulator attained Class III status, which means it is still considered to be in the investigational stage of development. Approval for unlimited use will be awarded only after the safety and efficacy had been established. It is concluded, therefore, that the device as well as the procedure must be considered to fall within the CHAMPUS definition of "experimental" and thus excluded from benefits. (Reference: CHAMPUS Regulation DoD 6010.8-R, CHAPTER II, Subsection B.67; IV, Subsection G.16.)

4. Related Anesthesia. The appealing party also maintained that whether or not the surgery itself was determined to be covered, that the anesthesia should be paid. Apparently the basis of his position is that the anesthesia was medically necessary to perform the surgery. This is not the issue, however. The Program did not question the fact that anesthesia is a prerequisite to the performance of surgery. Rather the issue is that the surgery for which the anesthesia was administered was determined to be a noncovered treatment on the basis it falls within the CHAMPUS definition of "experimental." Therefore all related services and supplies including the anesthesia are also excluded. (Reference: CHAMPUS Regulation DoD 6010.8-R, Chapter II, Subsection B.12; Chapter IV, Subsection 6.69.)

SECONDARY ISSUES

The appealing party, while strongly supporting the surgery his daughter received, also directed substantial attention to secondary issues, which he asserted supported special consideration for CHAMPUS to extend benefits in this case.

1. Issuance of Certificate of Nonavailability (CNA): Authorization of CHAMPUS Benefits. It was the position of the appealing party that the issuance of a Certif-

icate of Nonavailability (CNA) was prima facia evidence of his position that the procedure was recommended and sponsored by the Military Regional Medical Center and that therefore CHAMPUS benefits should be paid. Based on the Hearing File of Record and his oral testimony, it is acknowledged that the appealing party sincerely believes this, but it is simply not correct. When a Uniformed Services hospital issues a Nonavailability Statement, it only indicates that the type of inpatient care being requested is not available at that facility at that particular time. It does not guarantee that CHAMPUS benefits will be provided as asserted by the appealing party. A copy of the CNA which was issued in this case was included in the Hearing File of Record. Correct information concerning the CNA is clearly stated in the first section of that document under the heading "ISSUANCE OF THIS STATEMENT MEANS..."

2. Applying Regulation Retroactively. The appealing party repeatedly complained that the denial of CHAMPUS benefits in this case was made on the basis of a retroactively applied regulation. This is not correct. The applicable regulation (DoD 6010.8-R) was published in the Federal Register on 4 April 1977 and implemented 1 June 1977. The surgery in question was performed on 15 July 1977. While we cannot ascertain the basis of the appealing party's complaint, this objection is essentially moot since the prior regulation contained a similar provision. Therefore, even if this appeal case was reviewed on the basis of that prior regulation, the decision would be the same--a denial on the basis the surgery does not constitute generally accepted practice. (Reference: Army Regulation AR 40-121, Chapter 5, Section 5-2)

3. Length of Time for Initial Determination: Principle of Estoppel. The appealing party also asserted that there was an unreasonable delay in making the initial denial decision which led him to assume the service was covered--implying the principle of estoppel should apply. First, since CHAMPUS is a Federal Program and the principle of estoppel does not apply to actions of the Federal Government, the question is moot. However, it should be noted for the record that even if estoppel had applied, it would not have been operative in this case. The Hearing File of Record indicates the claims for the surgery and anesthesia were promptly submitted by the physicians in August 1977, but to an organization other than the current CHAMPUS Fiscal Intermediary. The record is silent as to whether they were returned to the physician for resubmission or whether the claims were eventually

forwarded on to the proper Fiscal Intermediary. In any event the claims for the surgery and anesthesia were not received by the CHAMPUS Fiscal Intermediary until October, and were referred for medical review almost immediately. The claims for the surgery and related anesthesia were initially denied by the Fiscal Intemediary on 16 January 1978--approximately ninety (90) days after the claims were received. This is not an overly long period of time for a decision in a case that required extensive professional research and medical review before the claims could be entered into the normal processing channel. While it is admittedly unfortunate that the claims were not initially submitted to the proper location, CHAMPUS cannot reasonably be held accountable for the time lost due to this error. As soon as the claims were received by the Fiscal Intermediary, appropriate action was taken to initiate medical review in order that a decision could be made on payment or denial.

4. Claims for Related Services Paid. It was noted by the appealing party that CHAMPUS paid the claims for the hospital stay (related to the surgery in dispute) without question and implied that this obligated the Program to also pay for the surgery. CHAMPUS acknowledged that prior to recognizing that the surgical procedure was one which is still considered investigational, payment was made not only for the related hospital stay, but also for a consultation and a reevaluation X-ray. That an error occurred, however, in no way binds the Program to continue the error; action that is required in such situations is to correct the error--not perpetuate it. Therefore, the fact that other claims related to the surgical episode in question were paid in error does not mandate issuance of an appeal decision favorable to the appealing party. Appeal decisions must be based on the merits of the case, in keeping with the law and applicable regulations, regardless of any prior errors that may have occurred.

5. Length of Time in Appeal. The appealing party complained that the CHAMPUS Administrative Appeals process was a bureaucratic maze. He further commented on the extended period of time that had elasped between the initial denial and the concluding stages of the appeal process. These are legitimate complaints. The Department of Defense is aware of the situation and efforts are being made to bring about improvements. For example, a regulation change is currently being considered that will decrease the number of levels of appeal and speed up the process. It should

be recognized, however, that the formal CHAMPUS Administrative Appeals system is still relatively new. (As a matter of fact this appeal case was one of the early cases to enter the appeal process.) Procedures and staffing requirements are still in the developmental stages. It is also noted that had there been no formal appeal system, the appealing party would not have been afforded an opportunity to present his views at a hearing or to have an appellate review by the Office of the Assistant Secretary of Defense (Health Affairs). While the delays currently in the system are acknowledged, again this does not mandate the issuance of a decision favorable to the appealing party.

6. Financial Hardship. The appealing party requested administrative consideration an the basis of hardship--i.e., essentially that the surgery had been performed with the expectation that CHAMPUS would extend its benefits--and that because CHAMPUS denied liability, he and his family have been adversely affected financially. While it is deeply regretted when a Program decision causes financial problems for a Military family, financial hardship per se is not a valid basis on which to consider an appeal. To assure uniform, unbiased Program decisions, consideration must be made on the substantive issue(s) as they relate to application of law and regulations.

7. Obligation to Active Duty Members. The appealing party strongly asserted that the Government is obligated to provide all needed medical care for an active duty family--that if it is not available from a Uniformed Service facility, CHAMPUS benefits should be payable. It is agreed that by law the Government obligation to provide all needed medical care to the active duty member is absolute. Based on the same law, however, this absolute right does not apply to dependents of active duty members. It is unfortunate that many Military sponsors have this misconception. What the law does provide is that after active duty members, their dependents have first priority for medical care at Uniformed Service facilities on a space available/professional capability basis, but this availability is not guaranteed. Where direct care is not available, CHAMPUS benefits are payable, subject to the law and applicable regulations. By statute CHAMPUS was not designed as a full payment Program. It has a deductibles and requires cost sharing; and there are benefit exclusions and limitations, generally patterned after major third party programs. Under the authority granted to the Department of Defense, it has been determined that it is not appro-

priate for Program funds to be expended for surgical procedures or other treatment regimens which are still investigational and have not been proven efficacious or safe. While this policy may adversely impact on an individual beneficiary, there is an overriding Program responsibility to protect all beneficiaries by assuring that funds are used only for safe, appropriate, and generally accepted treatment regimens.

RELATED ISSUE

Supplemental Care Issue: Reversal Decision. The representative claimed that CHAMPUS benefits should be extended for the surgical implantation of the Cerebellar Stimulator because the procedure had been recommended by the physicians as the Military Regional Medical Center where he and his family received their primary care. This appears to be somewhat of an overstatement since the Hearing File of Record indicates that the appealing party learned of the disputed surgical procedure and device from a popular monthly magazine and contacted the Military Regional Medical Center about the possibility of the procedure being performed in that facility. It was not a surgery being performed at the Military facility. The clinical information made available for review indicates the Military physician was actually unfamiliar with the procedure. Nonetheless, a long-distance telephone contact was made with the provider named in the article and an appointment set for the child to be evaluated as a candidate for surgery--i.e., a direct referral to a civilian source of medical care, contrary to Service instructions and despite the fact the Military physician was unfamiliar with the procedure. There is no documentation provided which indicates there was any discussion at the time of the direct referral concerning the fact the procedure might be investigational. Under sworn testimony the sponsor/representative maintained this possibility was never discussed with him. In view of the direct referral, as well as the lack of counseling that the procedure might being experimental, it was the finding of the Principal Deputy Assistant Secretary of Defense (Health Affairs) that this care was properly the responsibility of the referring Military Service, for payment out of its Supplemental funds, not CHAMPUS. The case was therefore referred to that Service, which refused to accept responsibility. Because of the recalcitrance on the part of the responsible Military Department, because of the length of

time since the disputed surgery was performed, and despite the finding that the initial determination to deny CHAMPUS benefits on the basis the procedure was "experimental" was a proper one, a reversal decison is being issued.

SUMMARY

This FINAL DECISION to reverse the initial denial and extend CHAMPUS benefits in this case is no way implies that the initial determination to deny benefits was incorrect under the provisions of the applicable Regulation. In fact, it continues to be the Program's position that the Cerebellar Implantation procedure is experimental. The reversal simply reflects consideration of the special circumstances identified in this case--i.e., direct referral by a military physician.

OCHAMPUS is directed to reimburse the appealing party for the 15 June 1977 surgery and related anesthesia, subject to the application of the reasonable charge determination procedures in effect at that time. Further, the sponsor/respresentative is cautioned that inasmuch as this FINAL DECISION represents an exceptional circumstance, its effect applies only to the specified 1977 services. Batteries or other maintenance, device replacement and/or any other service/supply related to the surgical implantation of a Cerebellar Stimulator subsequent to the initial surgery itself, continues to be excluded.

* * * * * *

Issuance of this FINAL DECISION is the concluding step in the CHAMPUS administrative appeal process.

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