



ASSISTANT SECRETARY OF DEFENSE

WASHINGTON, D.C. 20301

2 DEC 1980

HEALTH AFFAIRS

FINAL DECISION: Appeal
OASD(HA) Case File 19-79

The Hearing File of Record, the tape of oral testimony presented at the hearing, and the Hearing Officer's RECOMMENDED DECISION (along with the Memorandum of Concurrence from the Director, OCHAMPUS) on OASD(HA) Appeal Case No. 19-79 have been reviewed. The amount in dispute (hospital and physician costs) is \$5,588.00. It was the Hearing Officer's recommendation that the CHAMPUS contractor's initial determination to deny CHAMPUS benefits for the surgical implantation of the penile prosthesis, including the associated hospital expenses incurred during the period 2 May 1977 through 9 May 1977, be upheld. It was his finding that the medical necessity for the procedure had not been established and that the device implanted was a prosthesis, which is excluded by law and under the applicable Army Regulation AR 40-121. The Principal Deputy Assistant Secretary of Defense (Health Affairs) acting as the authorized designee of the Assistant Secretary, concurs with the recommendation and accepts it as the FINAL DECISION.

PRIMARY ISSUE

The primary issue in dispute in this case is whether the elective procedure, surgical implantation of a penile prosthesis, qualifies for CHAMPUS benefits. CHAPTER 55, Title 10, Section 1077 (a)(2)(B), excludes prosthetic devices except artificial limbs and artificial eyes. The applicable implementing regulation in effect at the time the service was rendered contained a provision which identified those services/supplies not authorized and which stated, "Prosthetic devices (other than artificial limbs, artificial eyes)... [are excluded]" (Reference: Army Regulation AR 40-121, Chapter 5, Section 5-4, e.)

The applicable regulation defines medically necessary as, "necessary services or supplies ... essential to the care of the patient or the treatment of the medical or surgical condition." [emphasis added] (Reference: Army Regulation AR 40-121, Chapter 1, Section 1-3, c.) In addition, at the time the surgery was performed, the Department of Defense Appropriations Act for Fiscal Year 1977 precluded the expenditure of CHAMPUS appropriated funds for "...therapy [treatment] or counseling for sexual dysfunctions or sexual inadequacies." (Reference: Public Law 94-419, 90, State 1298, Section 743)

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The appealing party and his attorney submitted statements and presented testimony detailing the issues and factors which, in their view, supported the position that the surgical implantation of the penile prosthesis qualified for benefits under CHAMPUS. 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 generally correct.

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

1. Impotency. The attorney-representative maintained that the fact the appealing party suffered from impotency was well established. He cited this as a bodily malfunction and therefore took exception that there was any question about extending CHAMPUS benefits for the surgical implant of a penile prosthesis to correct the condition. Impotency is the persistent inability in the human male to obtain and maintain an erection sufficient to access orgasm and satisfactory ejaculation during sexual intercourse. There are basically three types of impotence: erectile, the persistent difficulty in obtaining and maintaining an erection; ejaculatory, the failure to ejaculate; and premature ejaculation. Impotency may be total or partial, constant or intermittent. The origin of the disorder is usually psychogenic but may also be organic. In males over 50 years of age, impotency can also be related to the aging process. The Hearing File of Record substantiates that the appealing party sought out a physician because of impotency. Further, although the information available is somewhat anecdotal, it would appear that the type of impotence experienced by the appealing party was erectile in nature, and intermittent at least until a few months before the disputed surgery was performed, at which time it is claimed total impotency occurred. The actual presence of the impotence is, however, a moot point because whether or not the appealing party actually experience this dysfunction was never questioned. Rather, the issues in the case relate to whether or not the implanted device is a prosthesis and whether impotency can be considered a sexual dysfunction or sexual inadequacy. The implant surgery was denied because it was determined that the device was a prosthesis and that impotency was, in fact, a sexual dysfunction. It is therefore difficult to ascertain the attorney-representative's purpose in raising this issue. (References: Army Regulation AR 40-121, Chapter 5, Section 5-4., e.; Public Law 94-419, 90, stat 1298, Section 743).

2. Penile Implant: Prosthesis. The attorney-representative initially maintained that the penile implant device was not a prosthesis, thus not excluded by law and regulation. He then took the contradictory position that while the implant might be a prosthetic device, costs associated with its surgical implantation still qualified for benefit because of certain circumstances applicable to this case.
- o Penile Implant a Support System. It was claimed that the penile implant represented a medical support system, not a prosthetic device. What was meant by this assertion was not made clear nor was any evidence submitted which defined exactly what a medical support system is or how in this instance it differed from a prosthetic device. In the absence of any supporting documentation, no consideration could be given this to this assertion.
 - o Not a Cosmetic Prosthetic Device. The attending physician, supported by the attorney-representative, claimed that benefits should be extended because a penile implant is "not a cosmetic prosthetic device." We could find nothing in the Hearing File of Record to indicate that the question of whether the penile implant was a "cosmetic" prosthetic device was ever raised. The matter at issue is whether the penile implant device is a prosthesis--cosmetic or otherwise. The law excluding prostheses does not differentiate between a "cosmetic" or "noncosmetic" prosthesis and makes as its only exceptions artificial limbs and eyes. Again, it is unclear why this was raised as it is not relevant to the points at issue in this case.
 - o Penis Qualifies as a Limb. The attorney-representative strongly asserted that even if the penile implant is considered a prosthesis, the penis qualifies as a "limb" and therefore the penile implant should be considered for benefits because it falls within the prosthetic device exception for artificial limbs. The definition of "limb," according to Dorland's Illustrated Medical Dictionary (25th Edition), is "1. one of paired appendages of the body used in locomotion or grasping. In man, an arm or leg with all its component parts..." [emphasis added] Neither the attorney nor the appealing party presented supporting evidence from medical experts, anatomists, or physiologists, nor cited any legal precedents, that would substantiate the position that in the medical and anatomical sense the term "limb" was ever intended to denote the penis. In the absence of evidence to the contrary, it must continue to be the con-

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clusion that the term "limb" used in reference to the human anatomy is understood to mean an arm or a leg and its component parts, and is not a term applied to the penis.

- o Penile Prosthesis: Similar to Hip Replacement. The appealing party's attorney also claimed that the penile implant was no different than a hip replacement--a prosthesis which he understood qualifies for CHAMPUS benefits. The attorney makes a point in that both the penile implant and hip replacement are prostheses. He failed to recognize, however, that the hip is composed of the head of the femur (upper portion of the leg), which is the part generally replaced in hip prosthesis surgery, therefore appropriately falling within the exception to the exclusion on prostheses--i.e., an arm or a leg with all its component parts.

Despite the various assertions made by the appealing party and his attorney, it is our finding that the penile implant is, without any doubt or reservation, a prosthetic device. This question is essentially settled by documentation from the manufacturer which identifies the device as an "Inflatable Penile Prosthesis." Since it has also been determined the penis does not meet the definition of "limb," it is concluded that the penile implant device, as a prosthesis, is excluded from benefits, inasmuch as it is not used to replace an artificial arm or leg or any of its component parts. (Reference: AR 40-121, Chapter 5, Section 5-4.e.)

3. Surgical Insertion of Penile Implant Device: Medically Necessary. It was strongly asserted by the appealing party and the attorney representative that the surgical procedure to insert the penile implant was medically necessary and [it was implied] that notwithstanding any other restrictions or limitations, benefits should be extended for the associated costs.
 - o While it is not questioned that impotency existed, the Hearing File of Record is does not contain definitive evidence as to cause, type or extent. In one statement the appealing party identified the onset of impotency as dating back to 1972. Other information indicates this symptom first occurred as early as 1970. The attending physician indicated, "...he feels his problems started following an automobile accident..." which occurred four years later in August 1976. There was no documentation submitted concerning any residual effect of the accident

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or the type of injuries sustained except the general statement of the attorney that the appealing party suffered a pelvic injury.

- o The clinical evidence submitted in the Hearing File of Record indicates the appealing party received Testosterone injections for the impotency condition during the period August-November 1976 and that he reported some positive results. A psychiatric consultation was also obtained but the results were not provided and apparently no specific psychiatric therapy was instituted. The record does indicate, however, that the appealing party has had a long history of psychoneurosis for which, at the time of the surgery, he was under drug management--i.e., daily administration of Mellaril. The Physician's Desk Reference (PDR--33rd Edition) lists as potential side effects of this drug a diminishing of the Libido (sexual desire) and a tendency to suppress ejaculation. The record is silent as to what consideration was given to the appealing party's drug therapy as a cause or contributing factor to his impotency.
- o The appealing party self-referred himself for the implant surgery. The Hearing File of Record is silent as to why he chose to discontinue the medical therapy. The pre-surgery physical examination performed at the university center speculates the impotency was of either psychogenic or post-injury etiology. No evidence was submitted to indicate that further testing was done to determine whether the impotency was psychogenic, physiological, due to the drug therapy--or that the aging process was contributing (he was 58 at the time of surgery). Apparently the test to determine if erections occurred during REM sleep was not performed. This is considered a definitive test to determine whether impotency is of psychogenic or physiological origin. (The fact that the appealing party was capable of at least partial erections and ejaculations would indicate the problem was psychogenic or due to the drug therapy or aging process --since the prosthetic device does not create any natural ability for an erection or ejaculation.)

That such tests were not performed prior to the surgery raises some serious questions as to its appropriateness. To proceed with the implant surgery without first fully assessing the patient and those factors contributing to the impotency create doubts as to the necessity for the procedure.

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Further, it was not essential in order to treat a medical or surgical condition. The surgically implanted prosthesis did not treat the impotency. As indicated by the Hearing Officer, its only purpose was to provide a mechanical means to accomplish sexual intercourse. Notwithstanding these discussions, however, the whole issue of medical necessity is irrelevant because even if it had been found that the surgery could be considered medically necessary treatment, such a determination would be overcome by the specific exclusions related to prosthetic devices and sexual dysfunction. In this instance regardless of claimed medical necessity, the services/supplies in dispute are specifically excluded. (References: Army Regulation AR 40-121, chapter 5, Section 5-4e; Public Law 94-419, 90, Stat 1298, Section 743)

4. Sexual Dysfunction: Surgery not a Therapy. The attorney-representative also asserted that even though impotency might be a sexual dysfunction, he questioned that surgery was excluded because he did not consider it a "therapy." It was his position that the term therapy was commonly used to denote those practices generally associated with mental health not surgery. Dorland's Illustrated Medical Dictionary (25th Edition) refers to therapy as "treatment." In the medical community, the term therapy can be and often is, used as a general term to describe all forms of treatment--i.e., medical, surgical, drug, psychiatric, etc. The attorney-representative did not support his opinion with documentation from language experts nor did he cite any legal decision or precedents which limited the definition of the term "therapy." Therefore, in the absence of substantive evidence to the contrary, it must be concluded that the concept of therapy can and does include surgery. It is further pointed out that the term therapy as it is used in the Defense Appropriations Act for FY 77, has been interpreted to preclude the payment of CHAMPUS benefits for any type of service related to sexual dysfunction or sexual inadequacies. (Reference: Public Law 94-419, 90, Stat 1298, Section 743)
5. Prosthetic Device: Impotency a Sexual Dysfunction. Despite vigorous claims to the contrary on the part of the appealing party and his attorney-representative, it is the finding of the Principal Deputy Assistant Secretary of Defense that the disputed surgery does not qualify for benefits. First, the penile implant device is a prosthesis which is other than an artificial limb or eye, and as such is excluded from benefits by law and implementing regulation. Second, impotency is a sexual dysfunction and thus any type of service associated with such dysfunction, however meritorious

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or successful, is excluded by the Defense Appropriations Act for FY77. (References: Army Regulation AR 40-121, Chapter 5, Section 5-4.e.; Public Law 94-419, 90; stat 1298, Section 743)

SECONDARY ISSUES

The appealing party and his attorney-representative, while strongly supporting the need for the disputed surgery, also directed substantial attention to secondary issues, which it was 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 Attorney-representative that the issuance of a Certificate of Nonavailability (CNA) was prima facie evidence of approval of the penile implant surgery by CHAMPUS. It was his position that if there had been no intent to provide CHAMPUS benefits for the procedure, the CNA should not have been issued and the patient should have been advised that coverage was not available. Although it is acknowledged the appealing party may believe this to be true, it represents a complete misunderstanding of the purpose of issuing a CNA. When a Uniformed Service hospital issues a Nonavailability Statement, it only means 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. Nor does it imply that the requested service will never again be available at the facility. A copy of the CNA which was issued in this case was included in the Hearing File of Record. Correct information concerning the Certificate of Nonavailability is clearly stated in the first section that document under the heading, "ISSUANCE OF THIS STATEMENT MEANS..."
2. CHAMPUS Advisor Misinformation. The appealing Party maintained that the CHAMPUS Advisor at a large Regional Medical Center assured him that CHAMPUS benefits were available for the surgical implantation of a penile prosthetic device. While there is no documentation in the Hearing File of Record to support this claim, such verification becomes a moot point. Every effort is made to train CHAMPUS Advisors so they can provide assistance and accurate information to beneficiaries; however, any interpretations as to whether a specific medical service will be covered under CHAMPUS is not an official decision of the Program. Whether or not CHAMPUS benefits are payable in a specific case cannot be

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ascertained until a fully completed claim is submitted and adjudicated. And while it is truly unfortunate when an advisor provides misleading, incomplete or incorrect information to a beneficiary, such errors are not binding on the Program. The decision in this or any other appeal must be based on the merits of the case, in compliance with the law and applicable regulations.

3. Retired Organization Misinformation. The appealing party also claimed he was assured by a retiree organization that the disputed surgery would be covered. No evidence in the Hearing File of Record supported this statement so it could not be verified. If a retiree organization did, in fact, advise the appealing party that the specific surgery would be covered, that organization erroneously usurped Program prerogatives. It is recognized that such organizations provide useful information to retired members about CHAMPUS (usually based on material provided by the Program). This is considered a valuable service. However, such organizations have no legal status or authority in making benefit determinations.
4. Financial Hardship. It was claimed that had the appealing party known that CHAMPUS would not cost share the implant surgery, he would not have undertaken the disputed procedure. An administrative decision based on financial hardship was requested--i.e., essentially that the appealing party had proceeded with the surgery expecting CHAMPUS to cost share and now that CHAMPUS had denied liability, he had been adversely affected financially. While it is deeply regretted when a Program decision causes financial problems for a beneficiary, financial hardship per se is not a valid basis on which to consider an appeal. There is nothing in the law or regulations which speaks to financial hardship as a consideration in benefit determinations. To assure uniform, unbiased Program decisions, review of appeal cases must be made on the substantive issues as they relate to application of law and regulations.
5. Penile Implant Surgery Available in Direct Care System. The appealing party and his attorney-representative strongly asserted that because the penile implant surgery is done in some Uniformed Service hospitals, that this should automatically make CHAMPUS benefits available when the surgery is performed in the civilian sector.
 - o First, while it is true that penile implant surgery is performed in certain Uniformed Service Hospitals, it is not routinely available. Such surgery is permitted in

the direct care system only for the purpose of maintaining the professional competency of certain specialties. Very specific criteria are used to determine patient-candidates for the surgery. From what is known about the type and probable cause of the impotency experienced by the appealing party (and also his age), it is quite possible he would not have been considered a suitable candidate for the penile implant surgery even if space and professional capability had been available. Further, when the implant surgery is done in a Uniformed Service facility, the patient must pay for the prosthetic device since the same provision of the law which excludes prosthetic devices under CHAMPUS also excludes them from being provided in the direct care system.

- o Second, even if the appealing party had contacted a particular direct care hospital which did have the professional capability to perform the surgery, there is no guarantee he would have been accepted. As a retiree, the appealing party's access to Uniformed Service direct care facilities is, by law, on a space available/professional capability basis. His priority for care is third level--with active duty members first priority and dependents of active duty members having second priority. Primarily due to physician shortages, many Uniformed Service facilities are unable to accept retirees for any kind of care.
- o And lastly, concerning the specific surgery in dispute in this case, the fiscal year 1977 Appropriations Act which limited the use of CHAMPUS funds for any service or supply used in connection with conditions which fall into the category of sexual dysfunction or sexual inadequacy does not apply to services/supplies provided in the direct care system. So even though such surgery is precluded under CHAMPUS no such statutory limitation has been imposed on the direct care system.

In view of the above, the claim that because the penile implant surgery is done in some Uniformed Service Hospitals CHAMPUS benefits must therefore be extended, has no relevance to the issues under consideration in this appeal.

6. Penile Implant Surgery Available in Veterans Administration Hospitals. It was similarly asserted by the appealing party and his attorney-representative that because the penile implant surgery is performed in Veterans Administration Hospitals that, again, this should automatically make CHAMPUS

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benefits available. The appealing party reported he contacted the VA Hospital nearest him and was advised that while the penile implant surgery was being performed there, due to the fact that the specialist who did the surgery was being re-assigned, no new patients were being accepted. It was further reported that subsequent to the time the appealing party had the implant surgery done in a civilian hospital, the VA Hospital resumed accepting patients because another specialist with the needed professional expertise had arrived on staff. The Veterans Administration medical care system and that of CHAMPUS and the Uniformed Services operate under different laws and have been charged with different missions. What is or is not available or authorized by the Veterans Administration has no bearing on CHAMPUS whatsoever and is totally irrelevant to this CHAMPUS appeal case.

7. 5th Amendment: Equal Protection Under the Law. The Attorney-representative also raised a Constitutional question under the 5th amendment--i.e., denial of equal protection under the law. He claimed that to provide the penile implant procedure at Veteran's Hospitals and in Uniformed Service hospitals but not extend benefits under CHAMPUS amounted to unequal treatment under the law. As stated by the Hearing Officer, a Constitutional question is not within the purview of the CHAMPUS administrative appeals systems.
8. Implant Procedure Resulted in a Cure. The appealing party and his attorney-representative, strongly endorsed the penile implant surgery, claiming it resulted in a cure in that with the use of the prosthetic device he could maintain an erection and accomplish ejaculation. Again, as noted by the Hearing Officer, the penile implant did not effect a cure of a medical condition, rather it assisted in overcoming a sexual dysfunction by mechanical means--but the sexual dysfunction continued. The sole purpose of the surgical procedure was to insert a prosthesis device by which an erection could be mechanically maintained. This is verified from the hospital records which indicate both the pre-surgical and postsurgical diagnoses, as well as the discharge diagnosis, to be the same--i.e., impotency. Notwithstanding the claim that the impotency was cured, whether or not the penile implant procedure was successful is immaterial. Extension of CHAMPUS benefits is not limited to those situations where a regimen is successful or a cure effected. In fact, success is not a consideration in an individual case. In this appeal the primary issues are whether the implant device is a prosthesis and whether impotency can be classified as a sexual dysfunction. It has been determined the

answer is "yes" to both issues, thus the disputed surgery and the penile implant device are specifically excluded by law. Such exclusion takes precedence over any other assertions.

9. Other Similar Cases Paid: Discrimination. The appealing party and his attorney-representative claimed knowledge of other similar cases being paid by CHAMPUS and implied that denial in this instance represented discriminatory action on the part of the Government. Since no details were provided relative to payment of the alleged similar cases, no comments can be made on any specific case. Since the penile implant procedure has always been excluded under the Program, if the appealing party or his attorney have information to provide on any such cases, CHAMPUS will review them to determine if benefits have been paid in error. Notwithstanding the fact that such an error may have occurred, however, it has no bearing on the FINAL DECISION in this case. The Program is not bound by an error that may have been made by one of its employees or those of its agents. The decision in this appeal must be made on its own merits, in compliance with the law and applicable regulations.
10. Lack of Program Information. The appealing party complained that he and his civilian providers of care were not kept fully informed about the exclusion of prosthetic devices. It was his view the Program was obligated to provide such information, and that failure to do so established his entitlement to benefits. First, the penile implant procedure has never been covered under CHAMPUS--i.e., the limitation on prosthetic devices has been in the law since the 1966 amendments (which became known as CHAMPUS) were enacted, and reinforced by implementing regulations. Additionally, Program information materials have routinely listed this exclusion. Program responsibility to provide comprehensive information to beneficiaries and providers is recognized and considerable effort goes into meeting this obligation. In the last analysis, however, it is the beneficiary's responsibility to keep informed concerning the Program's benefits and limitations. As to prostheses, the beneficiary has had over ten years to familize himself with this exclusion. This does not appear to be a valid complaint.
11. Benefits Extended for Related Services. According to the appealing party and his attorney, CHAMPUS extended benefits in the amount of \$54.08 for a consultation and laboratory test related to the surgery. The information in the Hearing File of Record tends to support this claim. Because a copy of the original claim was not available for review, it cannot

be determined what diagnosis was shown. Nonetheless, even if it could be verified that an erroneous payment was made, it would have no effect on this FINAL DECISION, which must be based on the case issues, in compliance with the law and applicable regulations. (For the record, since it has been four years since the erroneous payment was apparently made, no effort will be made to investigate the matter or pursue recoupment.)

12. Religious Issue. The appealing party maintained that his right to marry in the Catholic Church was impaired because of his impotency. He claimed that Church doctrine required that a marriage be consummated. The attorney-representative further claimed that by excluding the penile implant procedure from CHAMPUS benefits it was, in fact, denying the appealing party (and other impotent males of the Catholic faith) the right to marry in the religion of his choice. While no evidence of Church law or doctrine was presented that substantiated this contention, the question is moot. CHAMPUS is administered on the basis of its authorizing law and applicable regulations--not on the basis of religious doctrine or tenets. Further, as with the Constitutional issue, the issue of religious rights is not within the purview of the CHAMPUS administrative appeals system. (For the record we find it curious this religious issue was raised despite the fact the Hearing File of Record indicates the appealing party lists himself as divorced.)
13. Incorrect Regulation Cited. At one level of appeal, the current CHAMPUS Regulation (DoD 6010.8-R) was erroneously cited instead of AR 40-121, which was in effect at the time the disputed surgical procedure was performed. Because of this the appealing party and his attorney apparently concluded a regulatory provision was being applied that was effective after the surgery was performed. This mix-up is unfortunate but represents a technical error only. The denial of benefits in this case is based on two laws, one effective 1 October 1966 and the other 1 October 1975. Their provisions applied equally to both the current and prior regulations. And while use of the incorrect regulatory reference was no doubt confusing, it had no impact on the substantive issues in the case.
14. Use of Discretionary Authority. The attorney-representative urged the use of Discretionary Authority to pay for the costs associated with the surgical implantation of the penile prosthesis. The cited provision is under the current regulation. The prior regulation, which was in effect at the time the penile implant surgery took place, contained no Discretionary Authority provision. Even if the current regulation were applicable to this case, the Discretionary

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Authority provision may be applied only under very unusual and limited circumstances. It cannot be applied to any situation that would effect a "class" of beneficiaries either directly or indirectly. Further, the provision specifically precludes waiving any requirement or provision imposed by statute. Since the substantive issues in this case involve specific statutory provisions, Discretionary Authority is not an option.

RELATED ISSUE

Drug Therapy for Impotency: CHAMPUS Benefits Extended. The attorney pointed out the fact that CHAMPUS benefits were extended for the drug therapy which the appealing party received for his impotency. He questioned the rationale in denying the surgery but not the drug therapy. This is a reasonable question. Based on the information in the Hearing File of Record it is our conclusion that the drug therapy was paid in error. The law which precludes the use of CHAMPUS funds in connection with sexual dysfunction and sexual inadequacies does not differentiate between types of therapies--it excludes all such treatment. In view of the period of time that has elapsed, however, recoupment action will not be initiated.

SUMMARY

This FINAL DECISION in no way implies that the appealing party is in anyway restricted from seeking out any type of medical service he choses. It only confirms that the penile implant surgical procedure and the related prosthetic device do not qualify for benefits under the CHAMPUS.

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Our review indicates the appealing party has recieved full due process in his 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)