ASSISTANT SECRETARY OF DEFENSE
WASHINGTON, D C 20301

HEALTH AFFAIRS

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

JUN 6 1984

UNITED STATES DEPARTMENT OF DEFENSE

Appeal of	)	
	)	
Sponsor:	)	OASD(HA) File 84-10
	)	FINAL DECISION
SSN:	)	

This is the FINAL DECISION of the Assistant Secretary of Defense (Health Affairs) in the CHAMPUS Appeal OASD(HA) Case File 84-10 pursuant to 10 U.S.C. 1071-1089 and DoD 6010.8-R, chapter X. The appealing party is the CHAMPUS beneficiary, a retired member of the United States Air Force. The appeal involves the denial of CHAMPUS cost-sharing of two percutaneous transluminal coronary angioplasties (PTCA) and related services provided December 20-23, 1981, and June 30 through July 3, 1982. The amount in dispute is $2,897.75.

The hearing file of record, the Hearing Officer's Recommended Decision, and the Analysis and Recommendation of the Director, OCHAMPUS, have been reviewed. It is the Hearing Officer's recommendation that CHAMPUS cost-sharing of the two PTCAs be denied. The Hearing Officer found the care was experimental/investigational when performed and was not medically necessary/appropriate medical care.

The Director, OCHAMPUS, concurs with the Hearing Officer's Recommended Decision and recommends its adoption by the Assistant Secretary of Defense (Health Affairs) as the FINAL DECISION provided the Hearing Officer's discussion of the secondary issue of equitable estoppel be modified for consistency with previous FINAL DECISIONS.

The Assistant Secretary of Defense (Health Affairs), after due consideration of the appeal record, adopts and incorporates by reference the Hearing Officer's Recommended Decision, as modified in accordance with the recommendation of the Director, OCHAMPUS, to deny CHAMPUS cost-sharing of the appealing party's two PTCAs and related care based on findings the care was experimental/investigational when performed and was not medically necessary/appropriate medical care.

In my review, I find the Recommended Decision adequately states and analyzes the issues, applicable authorities, and evidence, including authoritative medical opinions, in this appeal. The findings are fully supported by the Recommended Decision and the

appeal record. Additional factual and regulation analysis is not required. The Recommended Decision is acceptable for adoption as the FINAL DECISION by this office with one modification.

The Hearing Officer, in her discussion of erroneous payments, stated that the Federal Government is not bound by the doctrine of equitable estoppel in the absence of affirmative misconduct and that there is no evidence of affirmative misconduct by the fiscal intermediary in this appeal. In numerous FINAL DECISIONS, this office has stated that the Government is not estopped to deny erroneous acts of its agents, including its fiscal intermediaries, in violation of law or regulation. E.g., OASD(HA) File Numbers 84-03, 83-03, 80-15, and 80-10. To the extent the Hearing Officer's decision regarding the doctrine of estoppel is inconsistent with prior decisions of this office, I must reject it. Rejection of the Hearing Officer's discussion of the issue of estoppel does not materially affect the Hearing Officer's Recommended Decision in this case, however, because the Hearing Officer found that the appealing party failed to qualify for relief under the estoppel criteria most favorable to the appealing party.

SUMMARY

In summary, the FINAL DECISION of the Assistant Secretary of Defense (Health Affairs) is to deny CHAMPUS cost-sharing of the two percutaneous transluminal coronary angioplasties and related services provided to the appealing party December 20-23, 1981, and June 30 through July 3, 1982, as this care was experimental/investigational when performed and was not medically necessary/appropriate medical care. The claims and appeal of the beneficiary are, therefore, denied. As CHAMPUS payments were issued by the fiscal intermediary for some of the noncovered and related services, the matter of potential recoupment is referred to the Director, OCHAMPUS, for consideration under the Federal Claims Collection Act. Issuance of this FINAL DECISION completes the administrative appeal process under DoD 6010.8-R, chapter X, and no further administrative appeal is available.

William Mayer, M.D.

RECOMMENDED DECISION
Claim for CHAMPUS Benefits
Civilian Health and Medical Program of the
Uniformed Services (CHAMPUS)

Appeal of)
) RECOMMENDED DECISION
Social Security Number:)

This is the Recommended Decision of CHAMPUS Hearing Officer Hanna M. Warren in the appeal of , and is authorized pursuant to 10 U.S.C. 1071-1089 and DoD 6010.8-R, Chapter X. The appeal involves the denial of CHAMPUS cost sharing for two percutaneous transluminal coronary angioplasties and related medical care December 20-23, 1981, and June 30th through July 3, 1982. The amount billed CHAMPUS for medical care was $3,613.00. The record indicates that the beneficiary's private health insurance paid $715.25 so the total amount in dispute is $2,897.75.

The hearing file of record has been reviewed. It is the OCHAMPUS position that the formal review determination dated August 26, 1983, denying CHAMPUS cost sharing for the procedures described as percutaneous transluminal coronary angioplasty and related medical care be upheld on the basis that at the time the procedures were performed on the beneficiary percutaneous transluminal coronary angioplasty (PTCA) was considered experimental and/or investigational for the treatment of coronary artery disease, not rendered in accordance with generally accepted professional medical standards and therefore not appropriate medical care under the CHAMPUS Law and Regulation.

The Hearing Officer after due consideration of the record, including the material submitted by the beneficiary by letter dated March 8, 1984, agrees with the Formal Review Decision denying CHAMPUS cost-sharing. The recommended decision of the Hearing Officer is therefore to deny cost-sharing for all medical care provided to the appealing party in connection with the two percutaneous transluminal coronary angioplasties.

The record reveals in Exhibit 1, page 3, that a statement was submitted by - Emory University Clinic for the medical services in connection with the anioplasty on December 21, 1981, and for the procedure on July 1, 1982, which is described as "surgery". Both of these bear a charge of $1,500.00. The other charges are for professional services on December 20th and 23rd, cardiovascular stress test on December 21st and 23rd, and electrocardiograms on December 21st and 23rd. For the second angioplasty the charges were for professional services on June 30th and July 3rd, a cardiovascular stress test on July 2nd and an x-ray on July 30th. The total charge by Emory University Clinic is $3,613.00 (Exhibit 1, page 3). The statement dated December 29, 1982, The explanation of CHAMPUS benefits dated January 17, 1983, (Exhibit 2, page 3) shows that for the December claim of $1,870.00, CHAMPUS allowed $1,868.00, paid $1,401.00, other insurance paid $420.50, and the patient's liability was $467.00. A later explanation dated January 31, 1983, shows that the angioplasty on December 21, 1981, was denied. The explanation of CHAMPUS benefits for the July, 1982 pro-

cedure (Exhibit 2, page 2) again shows the surgery (which was the angioplasty) was allowed as were the additional charges. It shows the surgery was allowed and on a total claim of $1,743.00, CHAMPUS allowed $1,712.90. The patient's cost-share was $429.23, other insurance paid $294.75 and CHAMPUS paid $1,284.00. Mr. letter in response to the Fiscal Intermediary inquiry (Exhibit 4, page 1) says that the name of the surgery was angioplasty, the dates of his hospitalization were June 30th, 1982, through July 3rd, 1982, and the hospital bill was paid by other insurance. Mr. wrote again on February 5, 1983, and pointed out to the Fiscal Intermediary that they had authorized cost-sharing for the angioplasty on July 1, 1982, but not for the same procedure on December 21, 1981. He also inquired as to whether a check for $270.00 was sent directly to Emory University Clinic (Exhibit 5). By letter dated February 17, 1983, (Exhibit 6) the Fiscal Intermediary Mutual of Omaha advised Mr. that the angioplasty on July 1, 1982, had been allowed in error and asked for a refund of $1,125.00. They also advised him that the $275.00 which CHAMPUS had paid for the services in December 1981 had been sent directly to Emory University Clinic. The Fiscal Intermediary by letter dated March 22, 1983, advised Mr. that his claim had been reviewed and that the denial of both angioplasties was being upheld on the basis they were specifically excluded from the CHAMPUS program. This denial was again upheld upon reconsideration. The beneficiary then requested a review by OCHAMPUS and a formal review decision was issued on August 26, 1983 (Exhibit 12). A timely request for hearing was filed (Exhibit 13) and the beneficiary waived his right to appear at the hearing and asked that a decision be made on the record (Exhibit 15). The record is unclear as to what was paid and refunded to the Fiscal Intermediary and I have arrived at the amount in dispute by taking the total charge by Emory University Clinic and subtracting what was paid by the beneficiary's private insurance. I am also assuming from the record that the private insurance paid for charges for both hospitalizations.

ISSUES AND FINDING OF FACT

The primary issue in dispute is whether the two percutaneous transluminal coronary angioplasties provided the appealing party were experimental for the treatment of coronary artery disease at the time administered and therefore not rendered in accordance with generally accepted professional medical standards under the CHAMPUS Regulation, DoD 6010.8-R. Secondary issues that will be addressed include whether related medical care is a CHAMPUS benefit and burden of proof.

EXPERIMENTAL MEDICAL CARE

The Civilian Health and Medical Program of the Uniform Services (CHAMPUS) is a health benefits program authorized under law as set forth in Chapter 55, Title 10, United States Code. The Department of Defense Appropriation Act of 1979, Public Law 95-457, in appropriating funds for CHAMPUS prohibited the use of such funds for "...any service or supply which is not medically or psychologically necessary to prevent, diagnose or treat a mental or physical illness, injury, or body malfunction as assessed or diagnosed by a physician, dentist, or clinical psychologist...". This prohibition has consistently appeared in each subsequent Department of Defense Appropriation Act.

The Department of Defense Regulation DoD 6010.8-R was issued under authority of statute to establish policy and procedures for the administration of CHAMPUS. The Regulation describes CHAMPUS benefits in DoD 6010.8-R Chapter IV A.1., as follows:

> "Scope of Benefits: Subject to any and all applicable definitions, conditions, limitations, and/or exclusions specified or enumerated in this Regulation, the CHAMPUS basic program will pay for medically necessary services and supplies required in the diagnosis and treatment of illness or injury, including maternity care. Benefits include specified medical services and supplies provided to eligible beneficiaries from authorized civilian sources such as hospitals, other authorized institutional providers, physicians and other authorized individual professional providers as well as professional ambulance service, prescription drugs, authorized medical supplies and rental of durable equipment".

Medically necessary is defined in the Regulation as "the level of services and supplies (that is, frequency, extent and kind) adequate for the diagnosis and treatment of illness or injury (including maternity care). Medically necessary includes concept of appropriate medical care". In this same chapter of the Regulation appropriate medical care is defined as "a. that medical care where the medical services performed in the treatment of disease or injury...are in keeping with the generally acceptable norm for medical practice in the United States" (DoD 6010.8-R, Chapter II B.14).

Chapter IV of the Regulation in paragraph C provides as follows:

> Exclusions and Limitations: In addition to any definitions, requirements, conditions and/or limitations enumerated and described in other chapters of this Regulation, the following are specifically excluded from the CHAMPUS basic program. (Emphasis theirs).
>
> 15. Not in accordance with accepted standards; experimental. Services and supplies not supplied in accordance with accepted professional medical standards; or related to essentially experimental procedures or treatment regimens.
>
> NOTE: The fact that a physician may prescribe, order, recommend, or approve a service or supply does not, of itself, make it medically necessary or make the charge an allowable expense, even though it is not specifically listed as an exclusion.

Experimental is defined in Chapter II B.68 as "medical care that is essentially investigatory or an unproven procedure or treatment regimen (usually performed under controlled medical legal conditions) which does not meet the generally accepted standards of usual professional medical practice in the general medical community".

The CHAMPUS policy manual DoD 6010.47-M, Volume 1, Chapter IV, Section 2, p.75972.1 describes percutaneous transluminal coronary angioplasty as a procedure of inserting a balloon catheter into a narrow or occluded artery in order

to canalize and dilate the artery by inflating the balloon. PTCA in the treatment of arteriosclerotic obstruction in the lower extremities, i.e., the ileac, femoral, and popliteal arteries, is a covered procedure but the procedure involving other arteries, including coronary arteries, was considered investigational until December 29, 1982. For services after that date the angioplasty may be covered for treatment of stenotic lesions of a single coronary artery for patients when the likely alternative is coronary bypass surgery and the patients have the following characteristics: intractable angina inadequately controlled with maximal medical therapy, objective evidence of myocardial ischemia and normal ventricular function.

In order to effectively administer world wide programs such as CHAMPUS, policy guidelines are established to interpret the Law and Regulation. These guidelines are constantly being reviewed by OCHAMPUS. This case is an example of the evolution of a new medical procedure. Attachement A to Exhibit 32 is titled "Public Health Service Assessment of Percutaneous Transluminal Coronary Angioplasty for Treatment of Stenotic Lesions of a Single Coronary Artery-1982". This report was issued by the Office of Health Research, Statistics, and Technology (OHRST) which is a division of the Department of Health and Human Services. In describing its assessment activities it states as follows: "OHRST widely publicizes its plans to conduct evaluations so that all with information and viewpoints to contribute may do so. The involvement of other PHS agencies and experts from the private sector in gathering information, performing analysis, reviewing results, and reaching recommendations, provides access to wide experience and expertise and also fosters credibility and acceptance of the conclusions reached. The activities of OHRST are not aimed at affecting the practice of medicine nor does OHRST have regulatory authority on matters pertaining to health insurance coverage. Rather, its goal is to provide the Health Care Financing Administation (HCFA) with the best current evaluations of health care technology, so as to facilitate their policy and decision making processes". It goes on to state that the issues are generally raised by Medicare contactors when they concern new or unusual procedures or policy. A notice is then placed in the Federal Register stating that OHRST is beginning an evaluation; it then collects information, and evaluates it to develop a PHS recommendation. The PHS assessment which resulted from this OHRST study was submitted to Health Care Financing Administration regarding PTCA for treatment of stenotic lesions of the coronary arteries.

PTCA was first used to dilate the coronary artery of a patient suffering from ischemic heart disease in 1977. In 1979 the National Heart, Lung, and Blood Institute (NHLBI) established an international registry to collect baseline information as well as follow-up data on treated patients. A workshop was held in June 1981 to re-evaluate PTCA and data was presented at that time on 1500 patients who had been registered by April 1981 from 73 sites. The report states that the data "supported the technical feasibility and safety of the procedure in experienced hands. Unfortunately because the follow-up data were incomplete and scanty, a meaningful assessment of overall efficacy was not possible". A discussion followed of the complications and success rates reported by different physicians performing the procedure. It states on page 11 that the complications with PTCA appear to be the leading major concern of this procedure and one reviewer of Registry Information concluded that PTCA had been unsuccessful in approximately forty per cent (40%) of the patients. At the time of the report (1982) the position of following professional societies on PTCA is given on page 15. The American College of Physicians found it to be an investigational procedure: "the immediate efficacy and safety of the procedure

is not established". The Cardiovascular Procedures and Cardiovascular Surgery Committees of the American College of Cardiology find that "rather than being considered experimental at this time, the ACC committees describe PTCA as investigative; that is a technique which has progressed to limited human applications, but one which as yet cannot be considered as a standard procedure in clinical medicine". The Society of Thorasic Surgeons finds it to be still in a clinical investigatory stage with its application limited to a small highly selected patient population. The American Roentgen Ray Society concluded in March, 1981, that there was insufficient clinical and experimental data to make a judgment regarding PTCA and that the entire procedure needed further study. The Joint Council for the International Cardiovascular Society and the Society for Vascular Surgery had concerns regarding the safety and clinical effectiveness of the technology and recommended that the federal government conduct a survey. The Society of Cardiovascular Radiology found it experimental only for those lesions involving the left main stem coronary artery and the American Heart Association concluded that the procedure was safe and effective in experienced hands.

The OHRST report concluded that in carefully selected patients experienced cardiologists could obtain a success rate in excess of eighty per cent (80%) with a mortality rate of approximately one per cent (1%). In a memorandum from the Public Health Service to Health Care Financing dated August 5, 1982, it states that although the Public Health Service recognizes that the utility of PTCA has been demonstrated only on a short term basis they do take the position of recommending PTCA "for treatment of stenotic lesions of a single coronary artery limited to the group of patients described above". The Public Health Service recommends re-evaluation of PTCA in two years (Exhibit 32, attachment B). On the basis of this report, Medicare extended coverage for PTCA on November 15, 1982. OCHAMPUS utilized this report to evaluate the efficacy of this treatment and the decision was made to provide CHAMPUS benefits for coronary artery angioplasty provided the patients fell into the select patient group as outlined above, and coverage was extended as of December 29, 1982. The record is unclear as to whether the beneficiary met the requirements even if the PTCA's had been performed after December 29, 1982. The Assistant Medical Director, OCHAMPUS, found the medical records were inadequate for him to conclude the beneficiary had the requisite characteristics (Exhibit 16, Attachment C). Because I have found PTCA was still experimental/investigatory at the time the services were rendered to the beneficiary in this hearing, it is not necessary for me to decide if he would have met the criteria for coverage in December, 1982.

The beneficiary wrote that on August 12, 1981, he had triple coronary artery bypass surgery but in November of that same year his chest pains returned. He had another angiogram and it showed that "one of the bypasses did not graft and that I would have to have another operation to do a single bypass". He was told that a second operation so soon after the first would be dangerous and his physician (Dr. Urquhart) recommended that he go to Emory University Clinic in Atlanta, Georgia, to see Dr. Gruentzig, "the best in the world for angioplasty" and he might avoid a second operation. He did go to Emory University and the first angioplasty was done on December 21, 1981. The beneficiary stated that after the procedure he could walk or run without pain in his chest and returned to work with no problems (Exhibit 7). Four months after this procedure though, the chest pains returned and the beneficiary returned to Emory University Clinic for the second angioplasty which was done July 1, 1982.

The beneficiary's doctor in California, Robert R. Urquhart, M.D., wrote a letter on behalf of the beneficiary on April 6, 1983, (Exhibit 10, page 9). He stated that the original bypass operation on August 12, 1981, was a left internal mammary bypass to the anterior descending and saphenous vein bypasses to both the lateral circumflex and right coronary artery. After the surgery the beneficiary's symptoms returned due to failure of the internal mammary bypass graft to the anterior descending. The angiogram showed: "The reason for his continuing chest pain was a piece of cholesterol in the upstream anterior descending which occluded flow, combined with failure of the internal mammary bypass graft to restore flow". The doctor stated that under those circumstances the patient would have had to have a repeat coronary bypass using the vein instead of the other internal mammary artery with the possibility that this procedure created a higher risk than the intial operation because of adhesions and "because there is always the possibility of damaging the useful vein bypass grafts". Dr. Urquhart considered the better alternative would be an angioplasty of the anterior descending coronary artery and would also be less expensive as the bypass would cost approximately $25,000.00. He stated: "This procedure is effective, safe, and has minimal hospitalization. Success rate equals that of reoperation". He went on to say that when the original surgery was done on the beneficiary in August 1981, "balloon angioplasties were just starting to be done - this is now a new technique and I believe will replace approximately 25% to 30% of all future coronary artery bypass operations". He recommended that the beneficiary go to Dr. Gruentzig in Atlanta, Georgia, whom he considered to be the world's foremost expert on this procedure. "His case was a complex one and I felt the center's new to this technique should not be used".

The beneficiary also submitted a report dated March 1, 1983, from the office of the Vice President for Health Affairs, Emory University (Exhibit 10, page 11). It is "a brief outline of some of the programs and research projects we are working with at the moment". It discusses their basic cancer and clinical research projects and their attack against coronary artery disease stating:

> "Our cardiologists continue to refine the balloon angioplasty procedure pioneered by Andreas Gruentzig a professor of both medicine (cardiology) and radiology here at the medical school. Ten per cent of the patients who would have been considered in the past for coronary bypass surgery, now undergo the simple operation under a local anesthetic. During the operation, a tiny balloon connected to a hollow tube is passed through a patient's arteries to the site of an accumulation of fatty deposits that threaten to close off the blood flow. When the balloon is positioned at the site of the blockage it is inflated, flattening the blockage against the arterial walls where it is virtually harmless.
>
> The Woodruf Medical Center's cardiology team currently performs as many as six of these procedures every day, more than 1500 to date, making Emory's work the largest effort in balloon angioplasty in the world".

A letter was written on September 8, 1983, by David P. Hall, M.D. who was assistant to Dr. Gruentzig (Exhibit 13, page 2). Dr. Hall stated that on December 21, 1981, when the beneficiary had his first angioplasty that Dr. Gruentzig had been performing them for approximately four (4) years and "had demonstrated

that this particular procedure was a viable alternative to coronary bypass surgery". He stated that it was important to the beneficiary to be able to have an angioplasty as a repeat operative procedure entailed considerably higher risks because of the previous bypass surgery. He reports that the second angioplasty was done in June 1982 "to reopen the artery after an apparent fibrotic response". He continues "these procedures at the time they were performed were not investigational in nature and continue to present themselves as an option for people with significant coronary artery disease. The alternative to these procedures in this patient would be bypass surgery with the above-discussed attendant risk increased because of previous sternotomy, not to mention the cost of such a procedure".

The beneficiary wrote to me on March 8, 1984, (Exhibit 18). He reviewed the letter from Dr. Gruentzig's assistant stating that Dr. Gruentzig had been doing angioplasties for four (4) years by December, 1981, and also the letter from Dr. Urquhart advising that a second bypass would have entailed greater risk. In this letter he states "well I feel in my case it was a proven procedure and very successful because I did not have to return to the hospital for the second time to have another bypass which could have been fatal---While I was in the hospital December 21, 1981, and July 1, 1982, many of the doctors, both civilian and military were being trained to perform this method of angioplasty". In this letter the beneficiary also raises the issue that he was given a non-availability statement stating that this speciality was not available at military hospitals. He makes the argument "I feel that if angioplasty was not authorized, the non-availability statement should have not been given to me and that I should have been informed that this was not a CHAMPUS function".

It is my conclusion that PTCA for coronary artery disease in December 1981 and July 1982 was still an investigational/experimental procedure and thus not rendered in accordance with generally accepted medical standards for medical practice in the United States and excluded from benefit under the CHAMPUS program.

The issue of medical necessity, appropriate care and experimental procedures was discussed in a previous final decision by the Assistant Secretary of Defense (Health Affairs) who held: "I am constrained by regulatory authorities to authorize benefits only for services which are generally accepted in the treatment of disease or illness and are documented by authoritative medical literature and recognized professional opinions" (CASD-HA-0181). The decision goes on to state that the care which was at issue was not medically necessary based upon "lack of medical documentation, authoritative medical literature and recognized professional opinions sufficient to establish a general acceptance and efficacy of the program at the time the care was received. The specific CHAMPUS Regulation bears repeating as appropriate care is defined as where the medical services performed 'are in keeping with the generally acceptable norm for medical practice in the United States'."

OCHAMPUS determined that percutaneous transluminal coronary angioplasty was an experimental and/or investigational procedure prior to December 29, 1982, more than one year after the beneficiary received the first procedure in this hearing and six months after the second. This was based on extensive review and evaluation of the procedure by OHRST which was published in 1982. There is no medical literature in the record showing the efficacy and general acceptance of PTCA in December 1981 or July 1, 1982, except for the statements of the physicans who treated the beneficiary and even these show this procedure was in a

stage of evolution. Dr. Urquhart in his letter written in April, 1983, states that angioplasty was just starting to be done when the beneficiary first had his surgery, and goes on to describe this as a "new technique" which he thinks will become more useful. He referred the beneficiary from California to Atlanta, Georgia, because he "felt centers new to this technique should not be used". Clearly certain research centers are in the forefront of pioneering new procedures and in those centers the new procedures and treatments are acceptable medical care, but that is not the standard I must apply as Hearing Officer.

The lack of adequate facilities in California would certainly support the position that PTCA was not in keeping with the generally accepted norm for medical practice in the United States nor was it the usual professional medical practice in the general medical community.

Dr. Gruentzig's assistant stated that he had been performing angioplasties for approximately four (4) years and makes the statement that the procedure was "a viable alternative to coronary bypass surgery". There is nothing other than his statement to substantiate this claim. The fact that by 1981 Dr. Gruentzig had been doing angioplasties for four (4) years may be substantiated by the OHRST report (Exhibit 16, Attachment D). This report states that in 1977 Dr. Gruntzig first used PTCA to dilate the coronary arteries stenosis of a patient suffering from ischemic heart disease". It is possible this is the same doctor even though the names are spelled differently.

I have considered the beneficiary's statements regarding the improvement in his health and certainly the procedure appears to have been successful for him, but whether or not PTCA was successful or resulted in a lack of symptoms for this particular patient is not the issue. Payment of CHAMPUS benefits cannot be dependent upon treatment being successful in any individual case. The efficacy of a treatment regimen must be established and be recognized by national professional organizations in the medical profession, not by individual patients. Another final decision by the Assistant Secretary of Defense (Health Affairs), OASD-HA-83-04, states: "The Department of Defense recognizes individual preference for certain services and possible improvements of the patient's condition which may be perceived as a result of such services. However, I am constrained by statutory and regulatory authorities to authorize CHAMPUS benefits only for services which are generally accepted in the treatment of disease or illness and are documented by authoritative medical literature and recognized professional opinion". Benefits are predicated on the regulatory requirements of whether the treatment is still experimental/investigatory at the time it is rendered. The record in this case establishes the investigational and/or experimental nature of PTCA in December 1981, and July 1, 1982, and does not contain evidence satisfactory to overcome the policy adopted by OCHAMPUS.

With limited exceptions not applicable to this appeal CHAMPUS is an "at risk" program. Claims are filed, appropriate information is obtained, and the claim is adjudicated. This is clearly stated in the Nonavailability Statement submitted by the beneficiary (Exhibit 1, page 5). "If you receive medical care from civilian sources and it is determined that all or part of the care is not authorized under the CHAMPUS, THE GOVERNMENT WILL NOT PAY for the unauthorized care. The determination whether medical care you may receive from civilian sources is authorized for payment cannot be made at this time because this determination depends, among other things, upon the care you actually received. Further, no statement regarding your condition or diagnosis made hereon will be

considered in any way determinative as to whether care rendered for such condition is payable under the CHAMPUS". CHAMPUS is a federal statutory benefits program operated pursuant to law and implementing regulations. While private insurance companies are free to contractually extend benefits without reference to enabling legislation I am bound by the CHAMPUS statutory provisions, including various exclusions and limitations in the regulatory interpretation of the provisions. Different companies and governmental entities providing benefits for health care services all have different rules and regulations governing the coverage they provide. The same is true for CHAMPUS and as Hearing Officer I am bound by these specific provisions. What treatment is provided a particular patient is a personal choice between the patient and his doctor but a CHAMPUS claim must be allowed or denied based on the CHAMPUS Law and Regulations. OCHAMPUS has not taken the position, nor do I as hearing officer in making this decision, that the beneficiary should have known that the care would not be reimbursed or that he should not seek medical care of his choice. My decision does not involve whether the actual care itself was properly provided but only whether the charge for the care will be cost shared by CHAMPUS.

The argument was made that this was an arbitrary decision as of December 29, 1982. I agree that it is difficult to look at the evolutionary state of this procedure in December, 1981, when subsequent studies, medical literature, and experience have shown it to be generally accepted in the medical community but that is what we must attempt to do since that is when the service was rendered. Even Dr. Urquhart was writing almost 9 months after the beneficiary's last angioplasty and described it as "just starting" in August, 1981, and "now a new technique" in 1983.

I am certain the beneficiary will agree that the CHAMPUS program must be administered in a fair and equitable manner to all participants. To insure this a Regulation has been published pursuant to the provisions of the CHAMPUS Law and this Regulation, which has been extensively discussed in my decision, has certain specific exclusions and criteria for coverage. One of these criteria for coverage is that the services provided must be generally accepted in the medical community and not experimental/investigational. The record in this hearing regarding percutaneous transluminal coronary angioplasty shows that in December, 1981, and July, 1982, evaluations were still being made of this treatment with respected professional societies taking the position it was still investigational. The general acceptance, safety and efficacy of angioplasty for coronary arteries is not supported by medical opinion and authoritative literature contemporaneous with the dates of care.

RELATED MEDICAL CARE

The CHAMPUS regulation in Chapter IV. G. 66. excludes from CHAMPUS cost sharing "all services and supplies (including inpatient institutional costs) related to a noncovered condition or treatment". Under this regulatory provision all related professional services must be denied since I have concluded that PTCA was a noncovered treatment in December, 1981 and July, 1982. A previous final decision (OASD-HA-8346) states: "When a denial of coverage is appealed to OCHAMPUS, the entire episode of care must be taken into consideration. In those instances where there has been a previous cost-sharing of part of the claim, there is the possibility that previously paid claims will also be denied cost-sharing. The appeal process is not limited to segments of a claim; as stated above, it must address the entire episode of care".

The payment by the CHAMPUS Fiscal Intermediary of angioplasty and related medical charges was erroneous. It is unfortunate this erroneous determination was made but the fact that erroneous payments were made (whether or not subsequently identifed and recouped) is not in any way binding upon the program in connection with future benefit payments. The error cannot be used as the basis for making further erroneous payments; to do otherwise would result in perpetrating a mistake instead of correcting it. The federal government is not bound by the equitable doctrine of estoppel in the absence of affirmative misconduct and there is no evidence in the record to indicate affirmative misconduct on the part of the Fiscal Intermediary. The record indicates that no CHAMPUS benefits were paid in connection with the hospitalization of the beneficiary for either procedure. If the Director, OCHAMPUS, determines that hospital charges were paid, they too were paid in error as charges related to a noncovered treatment.

BURDEN OF EVIDENCE

A decision on a CHAMPUS claim on appeal must be based on evidence in the hearing file of record. Under the CHAMPUS regulation the burden is on the appealing party to present whatever evidence he can to overcome this initial adverse decision (Chapter X. 16. (h and i). It is my decision that the beneficiary has not met this burden and the OCHAMPUS denial of benefits is amply supported by evidence in the record.

SUMMARY

In summary, it is the recommended decision of the Hearing Officer that the percutaneous transluminal coronary angioplasties provided to the beneficiary on December 21, 1981, and July 1, 1982, and related medical care in connection therewith be denied CHAMPUS cost-sharing because the care was experiental/investigational at the time rendered for the treatment of lesions of the coronary artery and therefore not appropriate and medically necessary care under the CHAMPUS Law and Regulation.

Hanna M. Warren

HANNA M. WARREN,
Hearing Officer