HEALTH AFFAIRS

THE ASSISTANT SECRETARY OF DEFENSE

WASHINGTON, DC 20301-1200

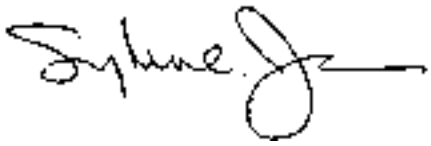
MAR 05 1996

MEMORANDUM FOR:
ASSISTANT SECRETARY OF THE ARMY (M&RA)
ASSISTANT SECRETARY OF THE NAVY (M&RA)
ASSISTANT SECRETARY OF THE AIR FORCE (MRAI&E)

SUBJECT: DoD Participation in Clinical Cancer Trials

Today Dr. Richard Klausner, Director of the National Cancer Institute, and I signed an interagency agreement solidifying our partnership in the fight against cancer. Through this agreement, and a recently expanded cancer demonstration project, our beneficiaries now have many more choices in the treatment of their diseases. Attached is the formal interagency agreement and a copy of the demonstration notice which, together, describe the program. I am also forwarding fact sheets which you may use in publicizing this important initiative.

The success of this program depends on full participation and cooperation at all levels of the organization, especially physicians in our military medical treatment facilities. I expect immediate and wide dissemination by the Surgeons General of the attached information to all MTFs, so our patients can have full access to state-of-the-art cancer therapies.



Stephen C. Joseph, M.D., M.P.H.

HA POLICY 96-033

Attachments:

As Stated

INTERAGENCY AGREEMENT BETWEEN THE DEPARTMENT OF DEFENSE AND NATIONAL CANCER INSTITUTE

FOR PARTNERSHIP IN CLINICAL TRIALS FOR CANCER

INTRODUCTION:

The National Cancer Institute (NCI) sponsors and actively coordinates an extensive clinical trials program for the evaluation of therapy for various types of cancer. The NCI's program includes sponsorship of studies of treatments in single institutions, as well as large, multi-center, randomized trials in cooperative networks. The trials encompass studies of cancers occurring in virtually all anatomical sites and in all stages of disease. The NCI clinical trials program has been the means by which the oncology community has developed most of the formal clinical evidence for the efficacy of the various treatment approaches in clinical cancer.

The Department of Defense (DoD) provides and maintains readiness to provide medical services and support to the Armed Forces during military operations, and to provide health services and support to members of the armed forces, their family members, and to others entitled to DoD medical care. These medical services are provided to approximately 8.3 million beneficiaries through the direct care system, comprised of 120 military hospitals, and through care purchased from civilian providers who are reimbursed by DoD through the Civilian Health and Medical Program of the Uniformed Services (CHAMPUS). The current medical program, called TRICARE, which integrates care in the direct care system with care provided under CHAMPUS, offers beneficiaries health care choices through an enrollment, HMO-like option called TRICARE Prime or through TRICARE Standard, an indemnity-like option. TRICARE Standard beneficiaries may obtain reduced cost-shares on a case-by-case basis, if they choose network providers under TRICARE Extra.

DoD, currently, provides patients an opportunity to participate in clinical trials for cancer either in the direct care system or, in limited circumstances, through civilian providers who are reimbursed through TRICARE/ CHAMPUS. DoD facilities and the NCI have some joint efforts to allow patients to access clinical trials for cancer.

PURPOSE:

The purpose of the interagency agreement is to expand the partnership and allow DoD beneficiaries to participate in various NCI sponsored clinical trials, either through the medical treatment facilities (MTFs) that have been approved to conduct NCI trials or through civilian care reimbursed by DoD. DoD shares public and scientific concern about disappointing cure rates under standard cancer therapies and has an interest and a responsibility to participate in the appropriate evaluation of improved therapeutic approaches for DoD patients. Through this agreement, DoD will have access to clinical research and patients can receive state-of-art care through NCI-sponsored clinical trials throughout the country by participating in the evaluation of emerging new therapies that have significant promise for the successful treatment of cancers.

SCOPE:

1. The DoD participation in the agreement includes only Phase II and Phase III clinical trials for cancer. There are four non-mutually exclusive categories of NCI clinical trials sponsorship. They include trials reviewed and approved by the Cancer Therapy Evaluation Program, NCI Cooperative Group studies, studies that are conducted in clinical and comprehensive Cancer Centers under an NCI-approved protocol review and surveillance mechanism, and NCI Grant studies.

2. All medical care and testing required to determine eligibility for an NCI-sponsored clinical trial, including the evaluation for eligibility at the institution conducting the NCI-sponsored study, will be provided or reimbursed by DoD. Preauthorization must be obtained, as described in item 12, before initial evaluation.

3. All medical care required as a result of participation in approved clinical trials; for example, purchasing and administering all approved chemotherapy agents (except for the investigational agent), treatment of complications of care, and diagnostic care; will be provided by MTFs or by civilian providers engaged in the NCI-sponsored studies, who will be reimbursed by DoD following TRICARE/CHAMPUS reimbursement rules. This also includes necessary follow-up care and testing that takes place after the period of active treatment on protocol is completed.

4. All DoD MTFs providing oncology services will be allowed to apply for participation in NCI protocols for both adult and pediatric cancers according to the usual NCI Cooperative Group or other clinical trials participation review process.

5. Any TRICARE/CHAMPUS authorized provider providing oncology services will be allowed to apply for participation in NCI protocols in both adult and pediatric cancers according to the usual NCI Cooperative Group or other clinical trials participation review process.

6. The DoD shall not provide reimbursement for costs associated with any non-treatment research activities associated with participation in clinical trials. These include, but are not limited to: data collection activities, management and analysis of the data, salaries of the research nurses, and the cost of the investigational agents (if used in the protocol). These research costs will not be the responsibility of the patient participating in the clinical trials. DoD shall not provide reimbursement for care rendered in the National Institutes of Health Clinical Center.

7. NCI will provide to MTFs and civilian providers a user-friendly, active information system through the Physician Data Query (PDQ). This system will provide quick access to information on NCI-sponsored clinical trials open to patient accrual throughout the country. The system will identify clinical trials and participating investigators at the nearest or most appropriate medical facility. Information from the PDQ may be accessed on-line via computer or through the 1-800 PDQ Search Service.

8. No TRICARE/CHAMPUS reimbursement will be allowed for participation in clinical trials that are not sponsored by NCI. All NCI sponsored clinical trials will be listed in the PDQ. In the event that a particular clinical protocol is not listed in the PDQ, NCI will provide status information to determine if the protocol has received NCI sponsorship, but has not yet been entered into the PDQ.

9. The NCI shall provide administrative support to coordinate all NCI activities related to this joint effort. DoD

will provide a project officer who will coordinate DoD activities under this agreement.

10. The DoD and the NCI will jointly develop and conduct programs to educate MTFs and civilian providers about this clinical trials initiative and the information systems that are available for referral.

11. The DoD and the NCI will jointly participate in education initiatives to inform the DoD eligible community of the opportunity to participate in NCI-sponsored studies.

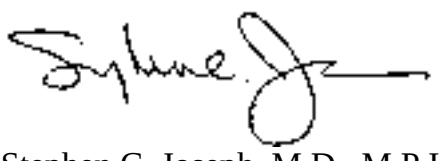
12. DoD will require preauthorization of any patient participation in clinical trials that will be reimbursed by TRICARE/CHAMPUS through verification of the proposed trial in PDQ. DoD will provide a centralized 1-800 number to support this preauthorization requirement. The current number for providers seeking program information and authorization is 1-800-779-3060, Palmetto GBA. DoD plans to decentralize the preauthorization requirements to the managed care support contractors when the managed care support contracts are awarded.

13. All TRICARE/CHAMPUS rules, policies, and regulations continue to apply to the care provided, except as identified in this agreement. This includes, but is not limited to policies on referrals, authorized providers, and managed care requirements.

14. The effective date of participation will be the date of the agreement.

15. This agreement may be terminated at the request of either party. The party desiring termination of the agreement shall provide, in writing, a 90 day advance notice to the other party indicating the intent to terminate the agreement.

16. This joint effort will be conducted for three years from the date of the agreement. An evaluation of the clinical trials partnership will be conducted to determine if continuation of the agreement is justified. Soon after the establishment of this agreement, DoD and NCI will decide on the information to be collected for this evaluation, to include, but not be limited to, utilization and relative costs.



Stephen C. Joseph, M.D., M.P.H.
Assistant Secretary of Defense (Health Affairs)

Richard D. Klausner, M.D.
Director, National Cancer Institute

Office of the Secretary

Cancer Treatment Clinical Trials

AGENCY: Office of the Secretary, DoD.

ACTION: Notice of Demonstration Project

SUMMARY: This notice is to advise interested parties of a demonstration project in which the DoD will expand a current demonstration for breast cancer treatment clinical trials to include all cancer treatment clinical trials under approved National Institutes of Health, National Cancer Institute (NCI) clinical trials. Participation in these clinical trials will improve access to promising cancer therapies for CHAMPUS eligible beneficiaries when their conditions meet protocol eligibility criteria. DoD financing of these procedures will assist in meeting clinical trial goals and arrival at conclusions regarding the safety and efficacy of emerging therapies in the treatment of cancer. This demonstration project is under the authority of 10 U.S.C., section 1092.

EFFECTIVE DATE: January 1, 1996.

FOR FURTHER INFORMATION CONTACT:

SUPPLEMENTARY INFORMATION:

A. Background

On November 15, 1994, the Department provided notice of a demonstration in the Federal Register (59 FR 58834) which provides CHAMPUS reimbursement for eligible beneficiaries who receive treatment under approved National Cancer Institute trials for high dose chemotherapy with stem cell rescue (HDC/SCR) for breast cancer. The National Cancer Institute (NCI) is a component of the National Institutes of Health (NIH) of the Department of Health and Human Services. The demonstration purpose was to improve beneficiary access to promising new therapies, assist in meeting the National Cancer Institute's clinical trial goals, and arrival at conclusions regarding the safety and efficacy of HDC/SCR in the treatment of breast cancer. The November 15, 1994, notice anticipated the possibility of expanding the demonstration to include other protocol-based clinical investigations which have been NCI approved.

The NCI trials program is the principal means by which the oncology community has developed clinical evidence for the efficacy of various treatment approaches in cancer therapy. Participating institutions include NCI's network of comprehensive and clinical cancer centers, university and community hospitals and practices, and military treatment facilities. Despite this extensive network which includes the nation's premier medical centers, cure rates for most types of cancer remain disappointing, highlighting the significant effort still required for improvement. The principal means by which advances in therapy will be realized is through application of research to victims of cancer. In support of NCI's efforts to further the science of cancer treatment, the Department is expanding its current breast cancer demonstration to include all NCI-sponsored phase II and phase

III clinical trials. This expanded demonstration will enhance current NCI efforts to determine safety and efficacy of promising cancer therapies by expanding the patient population available for entry into clinical trials and stabilizing the referral base for these clinical activities. While this demonstration provides an exception to current CHAMPUS benefit limitations, the Department hypothesizes that this increased access to innovative cancer therapies will occur at a cost comparable to that the Department has experienced in paying for conventional therapies under the standard CHAMPUS program. Results of this demonstration will provide a framework for determining the scope of DoD's continued participation in the NCI's research efforts.

B. Requirements of participation

Participation in this demonstration is limited to Phase II or Phase III clinical trials sponsored by the National Cancer Institute. Sponsorship by the National Cancer Institute is defined as review and approval of clinical trials under the Cancer Therapy Evaluation Program, NCI Cooperative Group studies, NCI Cancer Center studies, or NCI Grant studies. Beneficiaries receiving cancer treatment in a protocol outside one of these four categories are not eligible for participation.

Cancer Therapy Evaluation Program (CTEP). Under this NCI program, all protocols which involve the use of NCI investigational drugs or studies that have any NCI funding and use an investigational agent. CTEP reviews each protocol for completeness, scientific merit, duplication of existing studies, patient safety, and adequacy of regulatory and human subjects protective aspects. Upon final acceptance of the protocol, written approval is sent to the protocol source.

Cooperative Group Studies. NCI Cooperative Groups are composed of academic institutions and cancer treatment centers and practices throughout the United States and abroad which collaborate in NCI-sponsored research by contributing patients to NCI approved group-conducted clinical trials. The groups vary in research focus but share a common purpose of developing and conducting large scale trials in multi-institutional settings.

Cancer Center Studies. The NCI Cancer Centers Program includes NCI-designated institutions which meet NCI criteria as clinical and comprehensive cancer centers. NCI sponsored studies at cancer centers include all protocols that have been approved by an NCI approved institutional peer review and quality control system at the institution, as well as cooperative group, CTEP reviewed studies, and grant studies.

NCI Grants. NCI directly supports clinical investigations through a variety of contract and grant mechanisms. All clinical trial protocols are peer reviewed, quality assured and meet all FDA requirements.

The Department, through CHAMPUS, will provide reimbursement for all medical care required as a result of participation in approved clinical trials. This includes purchasing and administering all approved chemotherapy agents (except for the investigational agent), all inpatient and outpatient care, including diagnostic and laboratory services not otherwise reimbursed under an NCI grant program. CHAMPUS will not provide reimbursement for costs of non-treatment research activities associated with the clinical trials. The Department will not provide reimbursement for care rendered in the National Institutes of Health Clinical Center. CHAMPUS beneficiaries seeking treatment in an NCI sponsored clinical trial must receive preauthorization for proposed treatment. All institutional and individual providers must be CHAMPUS authorized providers in order to receive reimbursement under this demonstration. Evidence of NCI sponsorship for a requested protocol will be that it is identified in the NCI comprehensive data base, Physician's Data Query (PDQ), or NCI supplements to that data

base.

C. Caseload, Costs Approximately 11,760 CHAMPUS eligibles are diagnosed with some form of cancer each year, based on age adjusted incidence rates. Recognizing that some individuals participating in Phase III trials would be randomized for conventional treatment as part of a control group, the number of cases receiving treatment under NCI-sponsored Phase II and Phase III clinical trials is roughly estimated to be between 120 and 350. The number may grow as awareness of the expanded demonstration increases the potential pool of patients meeting protocol eligibility requirements, and as new NCI studies are established for a wider variety of cancer treatments.

D. Operation of the Demonstration

The Director, OCHAMPUS will designate a first line determiner (which may be a CHAMPUS contractor) regarding eligibility of specific protocols, specific institutions conducting those protocols and the eligibility of each specific CHAMPUS patient's participation in protocols under the terms of the Demonstration. The Assistant Secretary of Defense (Health Affairs) will designate a Project Officer in the Office of the Deputy Assistant Secretary of Defense for Clinical Services who will provide clinical oversight for the demonstration and resolve any clinical issues that cannot be resolved by the Director, OCHAMPUS, or designee.

Demonstration participation will be available to all CHAMPUS eligible beneficiaries. Active duty members continue to be eligible for direct care system services. OCHAMPUS will contract for and provide day to day oversight of contractor case referral, case coordination, demonstration funds disbursements and maintaining the integrity of those funds, identification of the services that are payable under CHAMPUS and TRICARE, and all related tracking and reporting requirements.

Each patient with cancer would undergo an initial evaluation by his or her physician. After discussing the various treatment options with the patient, if the patient agrees to enter a clinical study, the physician will determine available NCI clinical trials and participating institutions. The physician will then arrange for evaluation of the patient at the selected center. Physicians at the center involved in the clinical trial would make the actual patient selection based upon the clinical criteria for their study.

The contractor(s) would not be involved in clinical issues or in directing patients to a particular institution or a specific clinical trial. The contractor(s) would be the single point of contact for nationwide provider and patient information and claims adjudication and payment.

The HDC/SCR clinical trials for breast cancer demonstration project is hereby terminated as a separate project. It is fully incorporated into this NCI clinical trials demonstration project.

E. Limitations of the Demonstration

This demonstration is limited to protocols which are NCI-sponsored Phase II and Phase III clinical trials. All care reimbursed as part of this demonstration must fall into one of the four NCI sponsorship categories described in this demonstration notice. No CHAMPUS reimbursement will be allowed for participation in clinical trials that are not sponsored by the NCI. All standard CHAMPUS and TRICARE rule, policies, and regulations will continue to apply, except where otherwise noted in this demonstration. Treatment under this demonstration is

exempt from Specialized Treatment Services (STS) Program requirements.

F. Effective Date.

The final terms and conditions of this demonstration were approved by the Assistant Secretary of Defense(Health Affairs) during the first days of January, 1996. We are aware of a number of specific cases in which therapy under NCI sponsored clinical trials was required to begin immediately. We have therefore established an effective date of January 1, 1996, for this demonstration. We are waiving the normal 30-day advance notice in order to accommodate these urgent cases. This demonstration will end December 31, 1996, unless extended by another notice. If, after the year under demonstration there is evidence of significant increases in cost as a result of beneficiary participation in clinical trials for cancer, the Department will re-evaluate the continuation of the demonstration.