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HEALTH AFFAIRS

THE ASSISTANT SECRETARY OF DEFENSE

WASHINGTON, DC 20301-1200

NOV 23 1999

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: Policy Memorandum: Expanded Interagency Agreement between the Department of Defense and National Cancer Institute for Partnership in Clinical Trials for Cancer Prevention and Treatment

Dr. Richard Klausner, Director of the National Cancer Institute, and I signed an interagency agreement on June 21, 1999, extending and expanding our Partnership in the fight against cancer. Beginning in 1996, the Department of Defense (DoD) provided patients with an opportunity to participate in Phase II and Phase III National Cancer Institute (NCI) sponsored cancer treatment clinical trials either in the direct care system or through participating civilian providers. The care provided under these trials is reimbursed through a TRICARE/ CHAMPUS demonstration project.

The purpose of this interagency agreement is to expand the Partnership and allow DoD beneficiaries to participate in NCI sponsored clinical trials in cancer prevention in addition to cancer treatment. Through this agreement, DoD will have access to some of the most promising advances in cancer research through NCI sponsored clinical trials throughout the country. Attached are the formal interagency agreement and a copy of the demonstration notice, which, together, describe the program.

The success of this program depends on full participation and cooperation at all levels of the organization, especially physicians in our military treatment facilities. I request that the Surgeons General distribute the attached information to all military treatment facilities, so our patients can have full access to state-of-the-art cancer prevention and management strategies.

Dr. Sue Bailey

Attachments:
As stated

cc:
Surgeon General of the Army
Surgeon General of the Navy
Surgeon General of the Air Force

INTERAGENCY AGREEMENT BETWEEN THE DEPARTMENT OF DEFENSE AND NATIONAL CANCER INSTITUTE FOR PARTNERSHIP IN CLINICAL TRIALS FOR CANCER PREVENTION AND TREATMENT

INTRODUCTION:

The National Cancer Institute (NCI) sponsors and actively coordinates an extensive clinical trials program for the evaluation of prevention, early detection, treatment, and supportive care for various types of cancer. The NCI's program includes sponsorship of studies 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 development. 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 prevention, early detection, and management 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 the full range of health 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.

Beginning in 1996, DoD provided patients with an opportunity to participate in phase II and phase III NCI sponsored cancer treatment clinical trials for cancer either in the direct care system or through civilian providers who are reimbursed through TRICARE/CHAMPUS through a demonstration project.

PURPOSE:

The purpose of this interagency agreement is to expand the partnership and allow DoD beneficiaries to participate in NCI sponsored clinical trials in cancer prevention in addition to cancer treatment. DoD shares public and scientific concern about disappointing cure rates under standard cancer management and has an interest and a responsibility to participate in the appropriate evaluation of improved approaches for DoD patients with and without cancer. Through this agreement, DoD will have access to some of the most promising advances in cancer research through NCI-sponsored clinical trials throughout the country by participating in the evaluation of emerging new strategies that have significant promise for the prevention and successful treatment of cancers.

SCOPE:

1. The DoD participation in the agreement includes only Phase II and Phase III clinical trials for cancer prevention or management of established disease. There are four non-mutually exclusive categories of NCI clinical trials sponsorship. They include trials reviewed and approved by the Cancer Therapy Evaluation Program or, as appropriate, the Division of Cancer Treatment, NCI Cooperative Group studies, studies that are conducted in clinical and comprehensive Cancer Centers under an NCI-approved protocol review monitoring system, 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 chemoprevention agents or chemotherapy agents (except for the investigational agent), cancer screening tests, 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 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 oncology studies 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 an 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.

8. No TRICARE/CHAMPUS reimbursement will be allowed for participation in clinical trials that are not sponsored by NCI. 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.

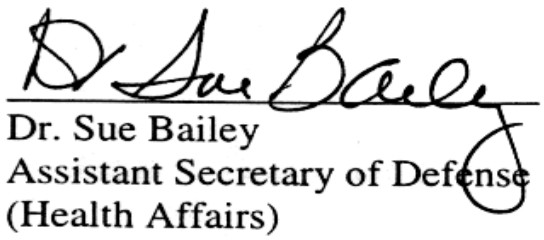
12. DoD will require preauthorization of any patient participation in clinical trials that will be reimbursed by TRICARE/CHAMPUS through verification of the proposed trial in PDQ. DoD will maintain the centralized 1-800 number to support this preauthorization requirement.

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.

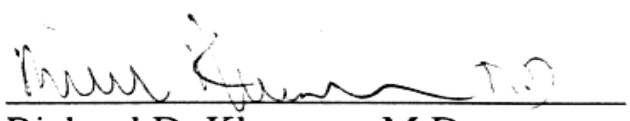
14. The effective date of participation will be the date of the agreement.

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 one additional year from the date of the agreement. An evaluation of the clinical trials partnership will be conducted to determine if this demonstration should become a permanent benefit. Soon after the establishment of this agreement, DoD and NCI will decide on the information to be collected for this evaluation.



Dr. Sue Bailey
Assistant Secretary of Defense
(Health Affairs)



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

Date: June 21, 1999

[Federal Register: June 8, 1999 (Volume 64, Number 109)]
[Notices]
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DEPARTMENT OF DEFENSE

Office of the Secretary

Civilian Health and Medical Program of the Uniformed Services (CHAMPUS)

AGENCY: Office of the Secretary, DoD.

ACTION: Notice of expansion of cancer treatment clinical trials demonstration project.

SUMMARY: This notice is to advise interested parties of an expansion of a demonstration project in which the DoD provides CHAMPUS reimbursement for eligible beneficiaries who receive cancer treatment under approved National Cancer Institute (NCI) clinical trials to include NCI sponsored cancer prevention clinical trials. Participation in these clinical trials will improve TRICARE/CHAMPUS eligible beneficiary access to emerging new therapies that have significant promise for the prevention and successful treatment of cancers. 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 prevention and treatment of cancer. At this time, there is insufficient demonstration data for a full evaluation of costs associated with enrollment in clinical trials. Expanding the current demonstration to provide reimbursement for costs associated with NCI sponsored clinical trials for cancer prevention will augment current patient accruals to clinical trials and allow for data collection in order to perform a comprehensive economic analysis. This demonstration also affects TRICARE, the managed health care program that includes CHAMPUS. This demonstration project, which is under the authority of 10 U.S.C., section 1092, will expire December 31, 1999.

EFFECTIVE DATE: June 21, 1999.

FOR FURTHER INFORMATION CONTACT: Kathy Larkin, Office of the Assistant Secretary of Defense (Health Affairs), TRICARE Management Activity, (703) 681-3628.

SUPPLEMENTARY INFORMATION:

A. Background

On January 24, 1996, the Department provided notice in the Federal Register (61 FR 1899) of an expansion of an existing demonstration for breast cancer treatment clinical trials to include all cancer treatment clinical trials under approved National Cancer Institute (NCI) clinical trials. The demonstration purpose is 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 emerging therapies in the treatment of cancer. The January 24, 1996, notice anticipated the possibility of extending the demonstration. 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 expanded its 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.

In recognition of the successful partnership with the NCI, the current demonstration is being expanded to allow DoD beneficiaries to participate in NCI sponsored clinical trials in cancer prevention in addition to caner treatment. This expansion of the current demonstration will enhance continued 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 prevention therapies will occur at a cost comparable to that which 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.

L.M. Bynum,
Alternate OSD Federal Register Liaison Officer, Department of Defense.
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