Dated: January 8, 1996.
Beverly Fayson,
FAR Secretariat.
[FR Doc. 96–945 Filed 1–23–96; 8:45 am]
BILLING CODE 6820–EP–M

DEPARTMENT OF DEFENSE

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. 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 the 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 CHAMPUS 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 Untied 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 expended 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 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.

Dated: January 19, 1996.

L.M. Bynum,

Alternate OSD Federal Register Liaison Officer, Department of Defense.

[FR Doc. 96–971 Filed 1–23–96; 8:45 am]

BILLING CODE 5000–04–M

Defense Policy Board Advisory Committee; Notice of Advisory Committee Meeting

SUMMARY: The Defense Policy Board Advisory Committee will meet in closed session on 5–6 February 1996 from 0800 until 1700 in the Pentagon, Washington, DC.

The mission of the Defense Policy Board is to provide the Secretary of Defense, Deputy Secretary of Defense and the Under Secretary of Defense for Policy with independent, informed advice and opinion concerning major matters of defense policy. At this meeting the Board will hold classified discussions on national security matters.

In accordance with Section 10(d) of the Federal Advisory Committee Act, Public Law 92–463, as amended [5 U.S.C. App. II, (1982)], it has been determined that this Defense Policy Board meeting concerns matters listed in 5 U.S.C. 552b(c)(1) (1982), and that accordingly this meeting will be closed to the public.

Dated: January 18, 1996.

L.M. Bynum,

Alternate OSD Federal Register Liaison Officer, Department of Defense.

[FR Doc. 96–970 Filed 1–23–96; 8:45 am]

BILLING CODE 5000–04–M

Department of the Army

Armed Forces Epidemiological Board (AFEB)

AGENCY: Office of The Surgeon General.

ACTION: Notice of Open Meeting.

SUMMARY: In accordance with section 10(a)(2) of Public Law 92–463, The Federal Advisory Committee Act, this announces the forthcoming AFEB Meeting. The meeting will be held from 0800–1700, Thursday, February 29, 1996 and 0800–1200, Friday, March 01, 1996. The purpose of the meeting is to discuss infectious disease issues relevant to the Bosnian deployment. The meeting location will be at the Walter Reed Army Institute of Research, Washington, D.C., Building 40, Room 3092. This meeting will be open to the public but limited by space accommodations. Any interested person may attend, appear before or file statements with the committee at the time and in the manner permitted by the committee.

FOR FURTHER INFORMATION CONTACT:

COL Vicky Fogelman, AFEB Executive Secretary, Armed Forces Epidemiological Board, Skyline Six, 5109 Leesburg Pike, Room 667, Falls Church, Virginia 22041–3258, (703) 681–8012/3.

SUPPLEMENTARY INFORMATION: None.

Gregory D. Showalter,

Army Federal Register Liaison Officer.

[FR Doc. 96–913 Filed 1–23–96; 8:45 am]

BILLING CODE 3710–08–M