

SUMMARY: Under the provisions of the Paperwork Reduction Act of 1995 (44 U.S.C. Chapter 35), the Federal Acquisition Regulation (FAR) Secretariat has submitted to the Office of Management and Budget (OMB) a request to review and approve an extension of a currently approved information collection requirement concerning Mistake in Bid. A request for public comments concerning this burden estimate was published at 60 FR 53914, October 18, 1995. No public comments were received.

DATES: *Comment Due Date:* February 23, 1996.

ADDRESSES: Comments regarding this burden estimate or any other aspect of this collection of information, including suggestions for reducing this burden, or obtaining a copy of the justification, should be submitted to: FAR Desk Officer, OMB, Room 10102, NEOB, Washington, DC 20503, and a copy to the General Services Administration, FAR Secretariat (MVRS), 18th & F Streets, NW, Room 4037, Washington, DC 20405. Please cite OMB Control No. 9000-0038, Mistake in Bid, in all correspondence.

FOR FURTHER INFORMATION CONTACT: Mr. Ralph De Stefano, Office of Federal Acquisition Policy, GSA (202) 501-1758.

SUPPLEMENTARY INFORMATION:

A. Purpose

When a mistake in bid is discovered by the contracting officer (CO) after bid opening but before award, the CO obtains verification of the bid intended. This verification is needed to establish the bidder's correct bid. If the bidder requests permission to correct the bid, the bidder must submit clear and convincing evidence that a mistake was made. If the bidder requests permission to correct the bid and submits evidence that a mistake was made, the evidence is analyzed by the CO to determine whether or not the bidder should be allowed to correct the bid. The data (evidence) submitted by the bidder is attached to bidder's bid and placed in the contract file along with the CO's determination.

The verification of the correct bid is attached to the original bid and a copy of the verification is attached to the duplicate bid and placed in the contract file.

B. Annual Reporting Burden

Public reporting burden for this collection of information is estimated to average 30 minutes per response, including the time for reviewing instructions, searching existing data

sources, gathering and maintaining the data needed, and completing and reviewing the collection of information.

The annual reporting burden is estimated as follows: Respondents, 4,673; responses per respondent, 1; total annual responses, 4,673; preparation hours per response, .5; and total response burden hours, 2,337.

Obtaining Copies of Justifications

Requester may obtain copies of justification from the General Services Administration, FAR Secretariat (MVRS), Room 4037, Washington, DC 20405, telephone (202) 501-4755. Please cite OMB Control No. 9000-0038, Mistake in Bid, in all correspondence.

Dated: January 18, 1996.

Beverly Fayson,

FAR Secretariat.

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[OMB Control No. 9000-0139]

Request for Public Comments Regarding OMB Clearance Entitled Federal Acquisition and Community Right-to-Know

AGENCIES: Department of Defense (DOD), General Services Administration (GSA), and National Aeronautics and Space Administration (NASA).

ACTION: Notice of request for public comments regarding an extension to an existing OMB clearance received pursuant to the emergency processing provisions of the Paperwork Reduction Act of 1995 (Public Law 104-13) (3000-0139).

SUMMARY: Under the provisions of the Paperwork Reduction Act of 1995 (44 U.S.C. Chapter 35), the Federal Acquisition Regulation (FAR) Secretariat will be submitting to the Office of Management and Budget (OMB) a request to review and approve an extension of a currently approved information collection approved pursuant to the emergency processing provisions of the Paperwork Reduction Act of 1995 (Public Law 104-13). This OMB clearance (9000-0139) currently expires on January 31, 1996.

DATES: *Comment Due Date:* February 23, 1996.

ADDRESSES: Comments regarding this burden estimate or any other aspect of this collection of information, including suggestions for reducing this burden, or obtaining a copy of the justification, should be submitted to FAR Desk Officer, OMB, Room 10102, NEOB, Washington, DC 20503, and a copy to the General Services Administration,

FAR Secretariat, 18th & F Streets, NW., Room 4037, Washington, DC 20405. Please cite OMB Control No. 9000-0139, Federal Acquisition and Community Right-to-Know, in all correspondence.

FOR FURTHER INFORMATION CONTACT: Mr. Ralph De Stefano, Office of Federal Acquisition Policy, GSA (202) 501-1758.

SUPPLEMENTARY INFORMATION:

A. Purpose

The interim rule added FAR Subpart 23.9 and its associated solicitation provision and contract clause which implement the requirements of Executive Order (E.O.) 12969 of August 8, 1995 (60 FR 40989, August 10, 1995), "Federal Acquisition and Community Right-to-Know," and the Environmental Protection Agency's "Guidance Implementing Executive Order 12969; Federal Acquisition; Community Right-to-Know; Toxic Chemical Release Reporting" (60 FR 50738, September 29, 1995). The interim rule requires offerors in competitive acquisitions over \$100,000 (including options) to certify that they will comply with applicable toxic chemical release reporting requirements of the Emergency Planning and Community Right-to-Know Act of 1986 (42 U.S.C. 11001-11050) and the Pollution Prevention Act of 1990 (42 U.S.C. 13101-13109). The rule does not apply to acquisitions of commercial items under FAR Part 12 or contractor facilities located outside the United States. This rule does not apply to subcontractors beyond first-tier.

B. Annual Reporting Burden

Public reporting burden for this collection of information is estimated to average 0.50 minutes per response, including the time for reviewing instructions, searching existing data sources, gathering and maintaining the data needed, and completing and reviewing the collection of information.

The annual reporting burden is estimated as follows: Respondents (includes first-tier subcontractors), 167,487; responses per respondent, 1; total annual responses, 167,487; preparation hours per response, 0.50; and total response burden hours, 83,744.

Obtaining Copies of Justifications

Requester may obtain copies of justifications from the General Services Administration, FAR Secretariat (MVRS), Room 4037, Washington, DC 20405, telephone (202) 501-4755. Please cite OMB Control No. 9000-0139, Federal Acquisition and Community Right-to-Know, in all correspondence.

Dated: January 8, 1996.

Beverly Fayson,
FAR Secretariat.

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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 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