schools which offer graduate programs in behavioral health and mental health practice, and other public or private nonprofit health or educational entities to assist the disadvantaged to enter the graduate from health professions schools. Some programs provide for the repayment of health professions education loans for disadvantaged students.

The following income figures were taken from poverty thresholds published by the U.S. Bureau of the Census, using an index adopted by a Federal Interagency Committee for use in a variety of Federal programs. That index includes multiplication by a factor of 1.3 for adaptation to health professions and nursing programs which support training for disadvantaged individuals or those from disadvantaged backgrounds. The income figures have been updated to reflect increases in the Consumer Price Index through December 31, 1999.

Size of parents' family*	Income level**
1	$11,100
2	14,400
3	17,200
4	22,000
5	26,000
6 or more	29,200

*Includes only dependents listed on Federal income tax forms.

**Rounded to the nearest $100. Adjusted gross income for calendar year 1999.

Dated: May 18, 2000.

Claude Earl Fox,

Administrator.

[FR Doc. 00–12991 Filed 5–23–00; 8:45 am]

BILLING CODE 4160–15–M

DEPARTMENT OF HEALTH AND HUMAN SERVICES

National Institutes of Health

Establishment of Interagency Council on Biomedical Imaging in Oncology in Call for Requests to Present

The National Cancer Institute (NCI), Food and Drug Administration (FDA), and the Health Care Financing Administration (HCFA) are pleased to announce the formation of an Interagency Council on Biomedical Imaging in Oncology. This announcement summarizes the purpose of this newly created Interagency Council, how it will function, the types of advice it will provide, its composition and membership, and the time of the first Council meeting.

Name of Committee: The National Cancer Institute, Food and Drug Administration, and the Health Care, Financing Administration Interagency Council on Biomedical Imaging in Oncology.

Due Date for Request: June 8, 2000.

Contract Person: Ellen G. Feigal, Deputy Director, Division of Cancer Treatment and Diagnosis, National Cancer Institute, 31 Center Drive, Building 31, Room 3A44, Bethesda, MD 20892–2440, Tel; 301 496–6711, Fax: 301 496–0826, E-mail: *ef30d@nih.gov.*

SUPPLEMENTARY INFORMATION:

What Is the Interagency Council?

The Interagency Council is a newly created multi-agency group designed to serve as a sounding board for investigators and manufacturers attempting to take emerging medical imaging technology to market. It consists of a core staff from the FDA, HCFA, and NCI with experience and knowledge concerning the decision-making processes for their agency for medical imaging products. Additional agency staff may be added to the core group on specific matters when needed. The purpose of the Council is to provide multi-agency advice that may help guide imaging technology developers in the fight against cancer. the Council will provide advice on projects or project proposals brought voluntarily by investigators and technology/device developers in industry and academia. It offers a new, multi-agency perspective to the communication with government agencies that is already available to investigators and companies.

Why Does the Nation Need This?

In September, 1999, the NCI and the National Electrical Manufacturer's Association co-sponsored the First NCI-Industry Forum and Workshop on Biomedical Imaging in Oncology. This meeting included senior leadership from industry, FDA, HCFA, NCI, and researchers from academia. We gathered to discuss ways to align investment in imaging technologies with the biomedical opportunities and unmet clinical needs in cancer. Participants asked the NCI to convene meetings between the multiple government agencies and industry to facilitate forward movement of promising technologies into the marketplace. The overall goal is to bring effective technologies into clinical use so that an impact on the public health can be achieved. The summary of the Forum and Workshop and follow-up comments to that conference can be reviewed on http://dino.nci.nih.gov/dctd/forum.

What Will the Interagency Council Do?

The three agencies participating in the Interagency Council all have different roles in the development of medical imaging technologies. NCI has created and is expanding a Biomedical Imaging Program. This effort currently funds innovative device and technology development, small animal imaging, in vivo cellular and molecular imaging centers, and a clinical trails imaging network (ACRIN). FDA is responsible for determining the safety and efficacy of specific products proposed for marketing and for marketing and for monitoring those products while they are on the market. HCFA is responsible, as a Federal health insurance provider, for determining coverage and reimbursement for products and services in the marketplace for their beneficiaries. By participating in the Council, these three agencies will be able to provide coordinated assistance to sponsors as they go through the development and regulatory processes necessary to bring products to market.

The specific roles envisioned by the participants in the Council are as follows:

NCI will provide input on scientific and medical issues, information on the initiatives and research resources available to fund or develop imaging technologies, explain the process for gaining access to such resources, and facilitate future interactions of imaging technology developers with NCI staff or with other NCI-sponsored investigators.

FDA will provide information on the issues that may need to be addressed to establish that a product is safe and effective, explain its existing guidance and procedures, and facilitate future interactions of imaging technology developers with its regulatory staff. How FDA may interact with sponsors is defined in statutes, regulations, and performance goals, and FDA expects that the Council will provide a mechanism to explain to imaging technology developers how to work within existing processes to bring products to market.

HCFA will provide information on its coverage and reimbursement processes, and facilitate future interactions of imaging technology developers with HCFA staff.

The products of the Interagency Council will be:

- Suggestions on the scientific and medical issues related to proposals, and information regarding available resources, potential relevant contacts for investigators within FDA, HCFA, NCI or with other investigators; and
- Written summary of the session, detailing the agenda topic, participants,

and proposed plans or advice given or discussed.

Will the Interagency Council Maintain Confidentiality?

Council meetings will be closed to the public. Information exchanged with the Interagency Council will be held in confidence by the participants, consistent with applicable laws. The NCI, FDA, and HCFA are all agencies in the Department of Health and Human Services, and by law are obligated to protect from disclosure trade secrets and confidential commercial information.

Who Can Present Before the Interagency Council?

Any company or academic investigator developing a device or technology relevant to biomedical imaging in cancer who seeks the perspectives of a multi-agency assessment and discussion may present.

What Is the Process?

The first due date for request is June 8, 2000. The Council will consider additional calls for requests after the initial Interagency Council meeting has taken place on July 20, 2000. The Council expects to meet about four times each year, if it receives enough requests to do so.

The Council may schedule discussion of several similar types of products at a single meeting. Generally, the Council will give preference in scheduling meetings to promising new technologies that are viewed as important new developments in cancer imaging.

Each meeting will be attended by the available core members on the Council. The core members also may invite additional relevant staff within their agency to attend the Council meetings. Logistics for the meeting date, time, and location will be coordinated by the Council coordinator, and communicated to all participants.

Request to Present

The requestor should follow a standardized format that the Council will make available on the Internet or that can also be completed and sent by hard copy. The information that the requestor will need to provide includes:

- Name of investigator, professional title(s) and degree(s) of investigator;
- Name of company and or/institution affiliation;
- What is the question/issue that you want to raise? Do you need/want representatives from the 3 government agencies, e.g., NCI, FDA, and HCFA, present for the presentation and discussion? Will you have data to present?

Submit to: Council Coordinator (same address as listed for contact information).

Reply to Letter of Intent

Within approximately 3 working days of receipt of the letter of request, the Council coordinator will send a letter acknowledging receipt of the request. Within 30 days, and after consultation with Council representatives, the Council coordinator will either invite the requester to a meeting (at the requestor's expense) if it appears that the question or issue would benefit from a multi-agency discussion, or indicate the Council's determination that a meeting will not be provided. A letter of invitation will ask the requestor to provide specific questions or issues they want to discuss with the Council, and, at the discretion of the requestor, relevant background information and data in a packet not to exceed 25 pages.

It if is not thought that a multi-agency discussion is required or desirable, then a letter will be sent to requestor stating the reason why such a meeting request has been denied. If appropriate, the letter may suggest other viable paths the requestor might pursue.

If the Council has already met with requestor before, the Council coordinator will determine if this is a new situation that requires a multi-agency discussion.

All letters will be kept on file with Council at the NCI.

Provision of Background Material

The requestor will submit background materials within two weeks of receipt of the letter from the Council. The Council coordinator will distribute the completed packet to the core members of the Interagency Council, and to the ad hoc members.

During the Session

Each session will last about a half-day, e.g., 3 to 4 hours, to discuss at most 2 or 3 issues. The general format of the session will consist of the requestor presenting their question/issue, and background information including data, when available. This will be a relatively informal discussion that can be interrupted as needed to answer questions, and clarify issues. At the conclusion of each topic, the Council will summarize the main issues and plans or set of actions that might be considered.

Follow-Up After the Session

Within one week after the meeting, the Council coordinator will prepare minutes of the meeting noting the main take-home points of the discussion and the conclusions. It will include the names of all participants in the session, the question or issue being addressed, and the proposed plans or advice given or discussed. The coordinator will obtain review and concurrence in the minutes by each agency participating in the meeting. The minutes will be sent to the person requesting the meeting and to agency representatives within four weeks of the meeting. The Council will keep one copy of the letter, as well as the letter of request and the submitted background information, on file at the NCI.

What the Interagency Council Is Not

The Interagency Council is intended to provide research groups with advice on the spectrum of scientific, regulatory, coverage and reimbursement issues that affect the development of imaging devices or technologies.

The Council's advice does not replace the legislatively mandated roles and functions of the agencies individually. In particular, the Interagency Council does not approve funding of research and development, and does not make or guarantee FDA regulatory, or HCFA coverage or reimbursement decisions.

Request to Present to the Interagency Council

(Suggested format)
Name of investigator: _____
Professional title(s) and degree(s) of investigator: _____
Name of company and/or institution affiliation: _____
Address: _____
_____
City: _____
State: _____
Zip: _____
What is the question/issue that you want to raise: _____
_____
Do you need/want representatives from the three government agencies, e.g., NCI, FDA, and HCFA, present for the presentation and discussion? Yes __ No __
Will you have data to present? Yes __ No __
Will you be presenting confidential commercial or proprietary information? Yes __ No __
Submit applications to: Jaime Quinn, M.P.H. Council Coordinator, National Cancer Institute, 31 Center Drive, Building 31, Room 3A44, Bethesda, MD 20892–2440. Tel: 301–496–6711, Fax: 301–496–0826, Email: *jq14u@nih.gov.*

Dated: May 16, 2000.

Alan Rabson,

Deputy Director, National Cancer Institute, National Institutes of Health.

[FR Doc. 00–13026 Filed 5–23–00; 8:45 am]

BILLING CODE 4140–01–M