

## VI.2. Administrative and National Policy Requirements

### 45 CFR Part 74 and Part 92

For more information on the Code of Federal Regulations, see the National Archives and Records Administration at the following Internet address: <http://www.access.gpo.gov/nara/cfr/cfr-table-search.html>.

The following additional requirements apply to this project:

- AR-4 HIV/AIDS Confidentiality Provisions.
- AR-7 Executive Order 12372.
- AR-8 Public Health System Reporting Requirements.
- AR-9 Paperwork Reduction Act Requirements.
- AR-11 Healthy People 2010.
- AR-14 Accounting System Requirements.
- AR-16 Security Clearance Requirement.

Additional information on these requirements can be found on the CDC Web site at the following Internet address: <http://www.cdc.gov/od/pgo/funding/ARs.htm>.

## VII. Agency Contacts

For general questions about this announcement, contact: Technical Information Management Section, CDC Procurement and Grants Office, 2920 Brandywine Road, Atlanta, GA 30341, Telephone: 770-488-2700.

For program technical assistance, contact: Ron Sanders, Program Consultant, National Center for HIV, STD and TB Prevention, Division of HIV AIDS Prevention, 1600 Clifton Road, NE Mail stop E-47, Atlanta, GA 30333, Telephone: 404-639-4678, E-mail: [RLS5@cdc.gov](mailto:RLS5@cdc.gov).

For financial, grants management, or budget assistance, contact: Kang Lee, Grants Management Specialist, CDC Procurement and Grants Office, 2920 Brandywine Road, Atlanta, GA 30341, Telephone: 770-488-2733, E-mail: [kil8@cdc.gov](mailto:kil8@cdc.gov).

Dated: June 28, 2004.

**Alan Kotch,**

*Acting Director, Procurement and Grants Office, Centers for Disease Control and Prevention.*

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**BILLING CODE 4163-18-P**

## DEPARTMENT OF HEALTH AND HUMAN SERVICES

### Centers for Disease Control and Prevention

#### [Program Announcement 05003]

### Tuberculosis Elimination and Laboratory; Notice of Availability of Funds—Amendment

A notice announcing the availability of fiscal year (FY) 2004 funds for Tuberculosis Elimination and Laboratory was published in the **Federal Register** on May 27, 2004, Volume 69, Number 103, pages 30300-30312. The notice is amended as follows: On page 30300, Column 1, "Application Deadline", change deadline date to July 29, 2004. On page 30308, Column 3, "Application Deadline", change deadline date to July 29, 2004.

Dated: June 28, 2004.

**Alan Kotch,**

*Acting Director, Procurement and Grants Office, Centers for Disease Control and Prevention.*

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## DEPARTMENT OF HEALTH AND HUMAN SERVICES

### Food and Drug Administration

### Request for Nominations for Nonvoting Members Representing Industry Interests on Public Advisory Panels or Committees

**AGENCY:** Food and Drug Administration, HHS.

**ACTION:** Notice.

**SUMMARY:** The Food and Drug Administration (FDA) is requesting nominations for nonvoting industry representatives to serve on certain device panels of the Medical Devices Advisory Committee in the Center for Devices and Radiological Health.

FDA has a special interest in ensuring that women, minority groups, individuals with physical disabilities, and small businesses are adequately represented on its advisory committees. Therefore, the agency encourages nominations for appropriately qualified candidates from these groups.

**DATES:** Industry organizations interested in participating in the selection of a nonvoting member to represent industry for vacancies listed in this notice must send a letter to FDA by August 2, 2004, stating their interest in one or more panels. Concurrently, nomination materials for prospective candidates

should be sent to FDA by August 2, 2004. A nominee may either be self-nominated or nominated by an organization to serve as a nonvoting industry representative.

**ADDRESSES:** All letters of interest and nominations should be sent to Kathleen L. Walker, Center for Devices and Radiological Health (HFZ-17), Food and Drug Administration, 2098 Gaither Rd., Rockville, MD 20850, 301-594-1283, ext. 114, e-mail: [KLW@CDRH.FDA.GOV](mailto:KLW@CDRH.FDA.GOV).

**FOR FURTHER INFORMATION CONTACT:** Kathleen L. Walker, Center for Devices and Radiological Health (HFZ-17), Food and Drug Administration, 2098 Gaither Rd., Rockville, MD 20850, 301-594-1283, ext. 114, e-mail: [KLW@CDRH.FDA.GOV](mailto:KLW@CDRH.FDA.GOV).

**SUPPLEMENTARY INFORMATION:** Section 520(f)(3) of the Federal Food, Drug and Cosmetic Act (21 U.S.C. 360j(f)(3)), as amended by the Medical Device Amendments of 1976, provides that each medical device panel include one nonvoting member to represent the interests of the medical device manufacturing industry.

FDA is requesting nominations for nonvoting members representing industry interests for the vacancies listed below:

Medical Device Panels of the Medical Device Advisory Committee	Approximate Date Representative is Needed
Circulatory System Devices Panel	July 1, 2005
Ear, Nose, and Throat Devices Panel	Nov. 1, 2004
Immunology Devices Panel	Mar. 1, 2005
Medical Devices Dispute Resolution Panel	Oct. 1, 2004
Neurological Devices Panel	Dec. 1, 2004
Obstetrics and Gynecology Devices Panel	Feb 1, 2005
Orthopaedic and Rehabilitation Devices Panel	Sept. 1, 2004

## I. Functions

The functions of the medical device panels are listed as follows: (1) Review and evaluate data on the safety and effectiveness of marketed and investigational devices and make recommendations for their regulation; (2) advise the Commissioner of Food

and Drugs regarding recommended classification or reclassification of these devices into one of three regulatory categories; (3) advise on any possible risks to health associated with the use of devices; (4) advise on formulation of product development protocols; (5) review premarket approval applications for medical devices; (6) review guidelines and guidance documents; (7) recommend exemption to certain devices from the application of portions of the Act; (8) advise on the necessity to ban a device; (9) respond to requests from the agency to review and make recommendations on specific issues or problems concerning the safety and effectiveness of devices; and (10) make recommendations on the quality in the design of clinical studies regarding the safety and effectiveness of marketed and investigational devices.

## II. Selection Procedure

Any organization in the medical device manufacturing industry wishing to participate in the selection of a nonvoting member to represent industry on a particular panel should send a letter stating that interest to the FDA contact (see **FOR FURTHER INFORMATION CONTACT**) within 30 days of publication of this notice. Persons who nominate themselves as industry representatives for the panels will not participate in the selection process. It is, therefore, recommended that nominations be made by someone within an organization, trade association, or firm who is willing to participate in the selection process. Within the subsequent 30 days, FDA will send a letter to each organization and a list of all nominees along with their resumes. The letter will state that the interested organizations are responsible for conferring with one another to select a candidate, within 60 days after receiving the letter, to serve as the nonvoting member representing on a particular device panel. If no individual is selected within the 60 days, the Commissioner may select the nonvoting member to represent industry interests.

## III. Application Procedure

Individuals may nominate themselves or an organization representing the medical device industry may nominate one or more individuals to serve as nonvoting industry representatives. A current curriculum vitae (which includes the nominee's business address, telephone number, and e-mail address) and the name of the panel of interest should be sent to the FDA contact person. FDA will forward all nominations to the organizations that

have expressed interest in participating in the selection process for that panel.

This notice is issued under the Federal Advisory Committee Act (5 U.S.C. app. 2) and 21 CFR part 14, relating to advisory committees.

Dated: June 24, 2004.

**William K. Hubbard,**

*Associate Commissioner for Policy and Planning.*

[FR Doc. 04-15012 Filed 7-1-04; 8:45 am]

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## DEPARTMENT OF HEALTH AND HUMAN SERVICES

### Health Resources and Services Administration

#### **CDC/HRSA Advisory Committee on HIV and STD Prevention and Treatment; Ryan White Comprehensive AIDS Resources Emergency (CARE) Act; Reauthorization Workgroup**

**AGENCY:** Health Resources and Services Administration, HHS.

**ACTION:** Notice of opportunity to provide written comments.

**SUMMARY:** On May 15, 2003, the Centers for Disease Control and Prevention (CDC)/Health Resources and Services Administration (HRSA) Advisory Committee on HIV and STD Prevention and Treatment (CHACHSPT) established the Ryan White Comprehensive AIDS Resources Emergency (CARE) Act Reauthorization Workgroup. The workgroup is seeking public input about future HIV/AIDS care program directions pertaining to resource allocation issues related to the third reauthorization of the Ryan White CARE Act. The CHACHSPT will subsequently submit a set of formal recommendations relating to resource allocation issues for reauthorization of the Ryan White CARE Act to the HRSA Administrator and the Secretary of the Department of Health and Human Services.

**DATES:** To be assured of consideration, written comments should be postmarked no later than July 30, 2004.

**ADDRESSES:** Written comments should be sent to the CHACHSPT, c/o HRSA, HIV/AIDS Bureau, Office of Policy and Program Development, Attention: Shelley Gordon, Parklawn Building, Room 7-18, 5600 Fishers Lane, Rockville, Maryland 20857.

**FOR FURTHER INFORMATION CONTACT:** Ms. Shelley Gordon, HRSA, HIV/AIDS Bureau, Office of Policy and Program Development, (301) 443-9684, fax (301) 443-3323, or e-mail: [SGordon@hrsa.gov](mailto:SGordon@hrsa.gov).

**SUPPLEMENTARY INFORMATION:** The purpose of the request for comments is

to obtain public input regarding resource allocation issues related to the Ryan White CARE Act, as amended. Resource allocation issues relate to the CARE Act provisions or statutory requirements which affect the distribution of funds across and within the various components of the CARE Act.

In 2003, the CHACHSPT carefully examined all aspects of the CARE Act and considered testimony from three public meetings held around the country designed to gather suggestions about future program directions in HIV and AIDS care and treatment programs. The CHACHSPT developed recommendations which were adopted by the Committee in November 2003 and formally submitted to the HRSA Administrator and the Secretary of the Department of Health and Human Services in 2004. Since that time, the report on Public Financing and Delivery of HIV Care was released by the Institute of Medicine, and new and ongoing issues about HIV/AIDS resources have been raised by communities and CARE constituents. Therefore, further examination by the CHACHSPT of resource allocation issues is desired.

Written comments should be limited to no more than 10 single-spaced pages (or 20 double-spaced) and should contain the name, address, telephone and fax numbers, and any organizational affiliation of the person(s) providing written comments. Respondents may be contacted by the CHACHSPT Ryan White CARE Act Reauthorization Workgroup to answer questions regarding their submitted comments. We are particularly interested in comments which address the following issues:

1. The use of HIV case reporting and service utilization data to determine eligibility under Title I and funding under Titles I and II of the CARE Act;
2. Changes to the existing Titles I and II hold harmless provisions;
3. Changes in the percentages of the Title I grant awarded by formula and competitively;
4. Changes in the percentages of the Title II AIDS Drug Assistance Program (ADAP) distributed by formula and supplemental awards;
5. Comparability and portability of the ADAP; and
6. Institute of Medicine report on: "Public Financing and Delivery of HIV Care: Securing the Legacy of Ryan White."

(Authority: Pub. L. 92-463 (5 U.S.C., App. 2); 42 U.S.C. 217a, Sec. 222 of the Public Health Service Act)